ECOLAB, INC.

National Organic Standards Board
(NOSB)

National List Petition

Acidified Sodium Chlorite Solutions

Petitioner

Ecolab, Inc.
370 N. Wabasha Street
St. Paul, MN 55102-1390

Submitted By

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October 26, 2006

National Organic Standards Board (NOSB)
c/o Mr. Robert Pooler
Agricultural Marketing Specialist
National Organic Program
USDA/AMS/TM/NOP
Room 2510 – So., Ag Stop 0268
P.O. Box 96456
Washington, DC 20090-6456

Federal Express Delivery

Dear Mr. Pooler:

We are pleased to submit to you, on behalf of our client, **Ecolab, Inc**. two (2) copies of our **Petition for Evaluation of the Substance** – ***Acidified Sodium Chlorite (ASC) Solutions for Inclusion On the National List of Substances Allowed in Organic Handling.***

Specifically this petition request is to permit the use of **Acidified Sodium Chlorite (ASC) Solutions** as follows:

- **Category:** *Organic Handling – Processing Aid*
- **NOP Reference**: *205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))"*
- **Section:** *205.605 (b) Synthetics allowed*
- **Annotation**: *For use in wash and/or rinse water according to FDA limitations. For direct food contact and hard food contact surfaces.*

Further, please be advised that this petition will be followed by a second petition for this substance *Acidified Sodium Chlorite (ASC) Solutions* for the use as per the **NOP 205.603 Synthetic Substances Allowed for Use In Organic Livestock Production;** *specifically for use as teat dip and to treat poultry drinking water.* This petition will include some duplicate data and support materials and specific support materials and data relevant to the requested livestock categories.

Since the use of *Acidified Sodium Chlorite (ASC) Solutions* has a long history of safe, functional and effective use, and has been thoroughly researched, tested and documented and approved for use by several domestic and foreign food agencies; we are requesting the NOP-NOSB for an accelerated *TAP Review Process*. Further FDA has confirmed in the letters attached to this petition that ASC meets the Agency's definition of a food contact substance.

To the best of my knowledge, our petition is complete, accurate and meets the petition requirements as published in the *Notice of Guidelines and Call for National List Petitions Federal Register 65:135 (13 July, 2000) P. 43260-43261 and 7CFR 205.607.*

If you have any questions relative to this petition and/or if we can be of further assistance, please contact me.

Thank you.

Very truly yours,

AGRISYSTEMS INTERNATIONAL

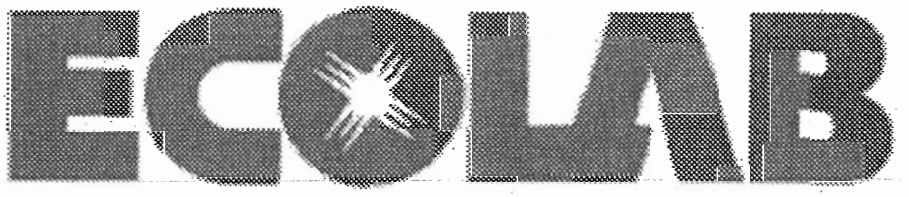
Thomas B. Harding, Jr.
President and
Organic Program Consultant
On behalf of Ecolab, Inc.

ECOLAB, INC.

National Organic Standards Board (NOSB)

National List Petition

Acidified Sodium Chlorite Solutions



Petitioner

Ecolab, Inc.
370 N. Wabasha Street
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Submitted By

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Materials Petition

TO:

National Organic Standards Board (NOSB)
c/o Mr. Robert Pooler
Agricultural Marketing Specialist
USDA/AMS/TM/NOP
Room 2510 – So. Ag Stop 0268
P.O. Box 96456
Washington, D.C. 20090-6456

PETITIONER:

Ecolab Inc.
John G. Wood, Director
Product Registration & Compliance
370 N. Wabasha Street
St. Paul, Minnesota 55102-1390

SUBMITTED FOR PETITIONER BY:

AgriSystems International
Organic Program Consultants
Thomas B. Harding, Jr., President
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Wind Gap, 18091
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Item A

National List Category Being Petitioned

Organic Handling – Processing Aid

Non-agricultural (non organic) substances allowed in or on processed products labeled Organic or Made With Organic (specified ingredients)

Item B

1. **Substance's Common Name:** **Acidified Sodium Chlorite Solutions**

Identification

Chemical Name(s):
Chlorous acid

CAS Number:
7758-19-2 (sodium chlorite)
14998-27-7 (chlorous acid)

Other Names:
ASC
Sanova® SANOVA®

Other Codes:
EINECS 231-836-6
RTECS No. VZ 4800000
UN No. 1496

References Regulatory (Federal, State & International):
FDA food additive clearances at 21 CFR 173. 325 and 178.1010 (Reference 40 CFR 180.940 (EPA).

EPA - Registration Number 1677-219 Sanova Base (25%) (Formerly EPA Reg. No. 45631-22)
Registration Number 1677-335
40 CFR 180.940 – Food Tolerance Exemptions for active and inert ingredients for use in antimicrobial formulations (Food contact surface sanitizing solutions) – Oxychloro species (including chlorine dioxide) generated by acidification of an aqueous solution of sodium chlorite

USDA/FSIS - Directive 7120.1 – Safe and Suitable Ingredients Used in the Production of Meat and Poultry products.
Approval of Sanova for on-line reprocessing of pre-chilled carcasses that are accidentally contaminated with digestive tract contents during slaughter.
(USDA/FSIS letter June 14, 2001). (See Reference 2)

Letter of No Objection **(April 22, 2005)** for use of acidified sodium chlorite solutions as a antimicrobial agent for treatment of post lethality exposed ready to eat deli meats, frankfurters, and other cooked sausages.

EU NO. 853/2004 (EFSA)

2. Manufacturer(s) Name, Address and Telephone:

- **United States**

  Occidental Chemical Corporation
  A Subsidiary of Occidental Petroleum Corp.
  5005 LBJ Freeway
  Dallas, TX 75244-6119

- **Canada:**

  ERCO Worldwide
  A Division of Superior Plus, Inc.
  302 The East Mall, Suite 200
  Toronto, CN Canada M9B 6C7

3. Intended and Current Use(s):

a. **Direct Food Contact** *(Secondary Direct Food Additive)*– Poultry carcass, organs and parts; Red Meat carcass, organs and parts, Seafood (finfish and crustaceans) and Fruits and Vegetables (raw and further processed); processed, comminuted or formed meat product

b. **Indirect Direct Food Contact** – Hard surface food contact sanitization

General Reference:

Sodium chlorite is a precursor in the preparation of *acidified sodium chlorite (ASC)* solutions approved by the *FDA 21 CFR 173.325 as a secondary direct antimicrobial food treatment, USDA/FSIS also approved acidified Sodium Chlorite Solutions as an antimicrobial agent for post lethality exposed ready to eat deli meats, frankfurters and other cooked sausages, and 21 CFR 178.1010 as a sanitizing solution to be safely used on food-processing equipment and utensils and other food-contact articles as specified. The United States Environmental Protection has evaluated the product chemistry, toxicology and efficacy data of acidified sodium chlorite for registration to treat fruits and vegetables and hard surface food contact surfaces. As a result of these robust safety reviews, US EPA has registered Sanova Base (25%) EPA Reg. No. 1677-219 (formerly EPA reg. No. 45631-22) as an antimicrobial agent to reduce the growth of microorganisms that cause spoilage on fruits and vegetables. Also US EPA has registered Sanova 335 EPA Reg. No. 45631-24 as a ready to use hard food contact surface sanitizer. Due to the regulatory jurisdictional shift in the wake of the Food Quality Protection Act (FQPA), the 21 CFR 178.1010 clearance was transferred by EPA to 40 CFR 180.940 providing the appropriate exemption from food tolerance for this material for application to food contact surfaces.. The ownership of both EPA registrations transferred from Alcide Corp. to Ecolab Inc. on April 7, 2005 and August 1, 2006 respectively (see Tab 2).*

(c) The additive is used as an antimicrobial agent in accordance with current industry practice in the processing of red meat, red meat parts, and organs as a component of a spray or in the processing of red meat parts and organs as a component of a dip. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9.

(d) (2) The additive is used as a single application in processing facilities as an antimicrobial agent to reduce pathogenic bacteria due to cross-contamination during the harvesting, handling, heading, evisceration, butchering, storing , holding, packing, or packaging of finfish and crustaceans; or following the filleting of finfish; in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is uysued at levels that result in a sodium chlorite concentration of 1,200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treated seafood shall be cooked prior to consumption. *Reference FDA March 8, 2006.*

(e) The additive is used as an antimicrobial agent on raw agricultural commodities in the preparing, packing, or holding of the food for commercial purposes, consistent with section 201 (q)(1)(B)(i) of the act, and not applied for use under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act, in accordance with current industry standards of good manufacturing practice. Applied as a dip or a spray, the additive is used at levels that result in chlorite concentration of 500 to 1200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treatment of the raw agricultural commodities with acidified sodium chlorite solutions shall be followed by a potable water rinse, or by blanching, cooking, or canning.

(f) The additive is used as an antimicrobial agent on processed, comminuted or formed meat food products (unless precluded by standards of identify in 9 CFR part 319) prior to packaging of the food for commercial purposes, in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations of 500 to 1200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.5 to 2.9.

(g) The additive is used as an antimicrobial agent in the water applied to processed fruits and processed root, tuber, bulb, legume, fruiting (i.e., eggplant, groundcherry, pepino, tomatillo and tomato), and cucurbit vegetables in accordance with current industry standards of good manufacturing practices as a component of a spray or dip solution, provided that such application be followed by a potable water rinse and a 24-hour holding period prior to consumption. However, for processed leafy vegetables (i.e. vegetables other than root, tuber, bulb, legume, fruiting and cucurbit vegetables) and vegetables in the Brassica (Cole) family, application must be by dip treatment only, and must be preceded by a potable water rinse and followed by a potable water rinse and a 24-hour holding period prior to consumption. When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm, in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

In addition, the attached letter dated August 25, 2006 from FDA's Office of Food Additive Safety (Center for Food Safety and Applied Nutrition) states the uses of solutions as described in 21 CFR 173.325 "Acidified sodium chlorite solutions" meet FDA's definition of a "food contact substance" as defined by the Federal, Food, Drug, and Cosmetic Act:

...any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding good if such use is not intended to have any technical effect in such food.

(See Reference 1)

Consistent with FDA's definition, USDA/FSIS has issued letters on ***February 8, 2001*** *and* ***December 31, 2001*** *which state that the treatment of comminuted or formed meat products and red meat products* ***do not result in a lasting functional effect in these finished food products.*** *These letters further state these uses of acidified sodium chlorite solutions are "processing aid" and do not require declaration as ingredients on food processor labels.*

(See Reference 1)

Specific Reference:

21 CFR §173.325 Acidified sodium chlorite solutions

Acidified sodium chlorite solutions may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by mixing an aqueous solution of sodium chlorite (CAS Reg. No. 7758-19-2) with any generally recognized as safe (GRAS) acid.

(b)(1) The additive is used as an antimicrobial agent in poultry processing water in accordance with current industry practice under the following conditions:

(i) As a component of a carcass spray or dip solution prior to immersion of the intact carcass in a prechiller or chiller tank;

(ii) In a prechiller or chiller solution for application to the intact carcass;

(iii) As a component of a spray or dip solution for application to poultry carcass parts; or

(iv) In a prechiller or chiller solution for application to poultry carcass parts.

(2) When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm), in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

(3) When used in a prechiller or chiller solution, the additive is used at levels that result in sodium chlorite concentrations between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.8 to 3.2.

Additional References:

CFR 21 Part 178.1010 Sanitizing Solutions (46)

4. Substance Mode of Action:

- **Handling Processing Aid and Hard Surface Sanitizer**

General Action

Primary mode of action is oxidative. ASC Solutions disinfect by oxidation of the outer cell membrane of vegetative bacterial cells, endospores, yeast, and mold spores. This mechanism of oxidation is by the transfer of electrons, whereas the stronger the oxidizer, the faster electrons are abstracted from the microorganisms and the faster the microorganism is inactivated or killed.

Composition Solutions:

a. *ASC* solutions used under 21 CFR 173.325 secondary food additive regulations are exclusively binery compositions (i.e., composed only of sodium chlorite and GRAS acid).

b. *ASC* solutions used under 40 CFR 180.940 sanitizing solution regulations may include an agent to lower the surface tension of the application medium to enhance effectiveness.

Specific Mode of Action:

The principal germicidal activity of this antimicrobial system derives from chlorous acid ($HClO_2$ [CAS No. 13898-47-0] which forms as a predictable fraction of the total chlorite species (ClO_2) in the solution virtually instantaneously upon the acidification of the sodium chlorite solution.

$$H^+ + ClO_2^- \overset{Ka}{\Leftrightarrow} HClO_2$$

Chlorous acid has a Ka of 1.1×10^{-2} (pKa = 1.96). The degree to which chlorous acid forms will depend on the hydrogen ion concentration (i.e., pH) in the solution and from this constant the relative amount of chlorous acid can be calculated for the pH range of intended application of this acidified chlorite system (~2.3 – 3.2), as follows:

$$\%\, HClO_2 = \frac{1}{1 + 10^{(pH - pKa)}} \times 100\%$$

Sample results from this calculation over the intended treatment pH ranges follow:

pH	%Chlorite as $HClO_2$
2.3	31.4
2.5	22.2
2.6	18.1
2.7	15.0
2.8	12.3
2.9	10.0
3.0	8.5
3.1	7.0
3.2	5.6

The ability to provide sustained antimicrobial activity based on the presence of chlorous acid relies on the presence of reservoirs of chlorite and hydrogen ions in the solution. As the chlorous acid is consumed, through interaction with microorganisms and certain other organic matter in solution, re-equilibration will occur to produce more of the cidal chlorous acid.

The antimicrobial action of acidified sodium chlorite is principally oxidative. ASC oxidizes thiol groups of disulfides, sulfoxides, or disulfoxides (e.g., cysteine, methionine, tyrosine, tryptophan are amino acids which are reactive with ASC solutions).

In addition to the direct chemical attack, ASC solutions also exhibit non-specific attack on other amino acid components of bacterial cell membranes. This leads to alteration of (intact) cell surface potential which leads to electrolyte (K+/Na+ imbalance and, ultimately, to cell death. There is evidence of destruction or impairment of cellular structural organization, interference with energy-yielding metabolism, and interference with biosynthesis and growth of bacterial cells.

5. Source of the substances and description of its manufacturing procedures:

Sodium chlorite the chemical formula ($NaClO_3$) is made by the reduction of chlorine dioxide. Chlorine dioxide (ClO_2) is made from the reduction of sodium chlorate ($NaClO_3$) using sulfuric acid and hydrogen peroxide or sulfuric acid and NaCl (common salt). Sodium chlorate is made by electrolyzing a solution of NaCl.

NaCl+ water + 6 Faradays of electricity → sodium chlorate

$NaClO_3$ + a mineral acid + a reducing agent (H_2O_2 or methyl alcohol or NaCl)

→ chlorine dioxide (ClO_2)

ClO_2 + a reducing agent (H_2O_2 or methyl alcohol or NaCl)

→ sodium chlorite

ASC solutions are made on-site and on-demand by mixing a solution of sodium chlorite with natural citric acid. In a typical large processing facility (poultry, beef or produce), the precursors -25% sodium chlorite and -50% citric acid – are stored in two, separate, 6500-gallon bulk storage tanks. These precursors are pumped by proportionating pumps and a water dilution module to make

In 40 CFR 180.1070 "Sodium chlorite: exemptions from the requirement of a tolerance" sodium chlorite is exempted from the requirement of a tolerance for residues when used in accordance with good agricultural practice as a seed-soak treatment in the growing of the raw agricultural commodities crop group *Brassica* (cole) leafy vegetables and radishes.

NIEHS: Reference the National Toxicology Program.

FDA: The Food and Drug Administration (FDA) concluded that acidified sodium chlorite solutions are safe per *21 CFR 173.325.*

e. International

No CODEX, Canadian, or Mexican maximum residual limits (MRLs) have been established for residues of chlorite or chlorine dioxide in meat, milk, poultry or eggs.

European Food Safety Authority (EFSA) (EU)

Opinion of the AFC Panel related to Treatment of Poultry Carcasses With Chlorine Dioxide, Acidified Sodium Chlorite, Trisodium Phosphate and Peroxyacids. *Adopted December 6, 2005 (Question No. EFSA-Q.2005-0002)*

Summary

The Commission has asked EFSA to update the previous opinion expressed by the Scientific Committee on Veterinary Measures Relating to Public Health (SCVPH) on 14-15 April, 2003 with regard to the toxicological risks to public health from possible reaction products (e.g. semicarbazide) of chlorine dioxide, acidified sodium chlorite, trisodium phosphate and peroxyacids when applied on poultry carcasses.

When examining the possibility for reaction products, no halomethanes have been reported to be formed in treatments with chlorine dioxide in water. No chlorinated organics have been found after treatments of poultry carcasses with acidified sodium chlorite. No detectable effects on the oxidation status of fatty acids in poultry carcasses were reported following treatment with peroxyacids. Furthermore, semicarbazide was not detected (limit of detection of 1 pg/kg) in laboratory tests on poultry carcasses after treatment by immersion with acidified sodium chlorite. The Panel notes that the initial health concerns about semicarbazide are no longer relevant. As set out in previous EFSA opinion, new data showed that semicarbazide is not genotoxic in vivo.

Based on conservative estimates of poultry consumption in European adults, the Panel estimated potential exposure to residues arising from these treatments.

the final use dilution product. In a typical application, the final product is 1000 ppm (0.1%) sodium chlorite, 6000 ppm (0.6%) citric acid, and 99.3% water.

In smaller facilities, the citric acid may be obtained and used as solid citric acid granules.

6. Previous Reviews By State, Federal and International Agencies:

Please Reference Attachment 1

a. Reference: FDA, USDA/FSIS, etc.

b. Drinking Water Treatment:

In connection with the use of chlorine dioxide as potable water disinfectant, the United States Environmental Protection Agency developed an extensive review of the health and ecological effects of chlorine dioxide, and its principal byproducts, chlorite and chlorate. It was initially published in the Federal Register on July 29, 1994 (Vol. 59, Section 145, pp.38668-388829); then updated and published as a report by the US EPA Office of Science and Technology, Office of Water on March 31, 1994 entitled Final Draft Drinking Water Health Criteria Document for Chlorine dioxide, Chlorite and Chlorate. A subsequent revision was published in April 1996 (copy attached) as Chlorine Dioxide, Chlorite and Chlorate.

c. Animal Metabolism, Enforcement Methodology, Storage Stability, and Magnitude of the Residue

The phase IV Review of sodium chlorite (C. Swartz, 2/2/93) waived animal metabolism, analytical methods, storage stability and magnitude of the residue data because "...CBRS has determined that although it is not possible to establish with certainty whether finite residues will be incurred in meat, milk and eggs, there is no reasonable expectation of finite residues significantly above the naturally occurring background levels." (-p.5 of EPA response p. 20 of Bioxy EPA Petition PP 6F4783: Petition, Releasable Correspondence, Memoranda.).

d. EPA/NIEHS/Other Sources

OFPA 6518 (1)(1) STATES, "In establishing the National List or proposed amendments to the National List, the Board shall review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and such other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List."

EPA: The USEPA has conducted significant investigations into the health, environmental and safety aspects of sodium chlorite in regard to its use as a precursor to making chlorine dioxide for drinking water treatment. Because the principal byproduct of chlorine dioxide oxidation/disinfection is the chlorite ion, the EPA considers the toxicology of chlorine dioxide and chlorite ion to be equivalent.

On the basis of available data and taking into account that processing of poultry carcasses (washing, cooking) would take place before consumption, the Panel considers that treatment with trisodium phosphate, acidified sodium chlorite, chlorine dioxide, or peroxyacid solutions, under the described conditions of use, would be of no safety concern.

The Panel notes that spraying of poultry carcasses with antimicrobials, by comparison to dipping and immersion treatments, will reduce the exposure to residues and by-products that might arise.

The Panel stresses that the use of antimicrobial solutions does not replace the need for good hygienic practices during processing of poultry carcasses, particularly during handling, and also stresses the need to replace regularly the water of chiller baths.

EU Municipal Water Source Use

For decades chlorine dioxide has been used by thousands of European municipalities for the treatment of drinking and ASC are used throughout Europe and Asia as a general purpose disinfectant and sterilization.

f. Relevant Support Data:

Please Reference Attachment 1

7. Additional Information EPA, FDA and State Authorities, etc.

Please Reference Attachment 2

- EPA
- FDA
- EFSA Data

8. Chemical Abstract Data and Labeled Products & MSDS Forms:

Please Reference Attachment 3

- **Sodium Chlorite ($NaClO_2$)** **CAS No. 7758-19-2**
- **Chlorous Acid** **CAS No. 14998-27-7**
  (From Acidification of Sodium Chlorite)

- **Other Codes:**

EINECS	231-836-6
RTECS No.	VZ-4800000
UN No.	1496

- **Labeled Products and Material Safety Data Sheets (MSDS)**

- **SANOVA Food Additive Base (25%)**
- **SANOVA BASE (25%)**
- **OXXIUM 203 (Intermediate)**
- **EXSPOR BASE**
- **SANOVA 335**
- **SANOVA Food Additive Activator Concentrate**

9. Substance Physical Properties and Mode of Action:

Please Reference Attachment 4

(a)Chemical Interactions With Other Substances, Used in Organic Production; (b) Toxicity and Environmental Persistence; (c) Environmental Imports From Its Use or Manufacturer (d) Effects On Human Health; (c) Effects On Soil Organisms, Crops or Livestock.

10. Safety Information Including MSDS and Substance Report From NIEHS:

Please Reference Attachment 5

11. Research Information, Substance Reviews and Bibliographies and Citations Which Present Contrasting Positions Presented By the Petitioner:

Please Reference Attachment 6

12. Petition Justification Statement:

Acidified sodium chlorite solutions (ASC) are some of the most effective microbiocides found for the treatment of poultry, red meat and parts, seafoods and the postharvest treatment of fresh and processed fruits and vegetables.

From a *Food Safety* prospective *ASC* has been thoroughly tested and proven effective against some of the most serious and infectious pathogenic and spoilage organisms that threatens the organic food system – i.e. *E.coli, Salmonella, Campylobacter, Listeria and Bacillus* and *Erwinia, Botyritus, Aspergillus, Fusarium* respectively to reference a few.

There are no natural and/or organic materials and/or treatments approved for food handling and postharvest treatment beyond hot water and steam treatments – and these alternatives provide minimal, short term effectiveness in either controlling or reducing these pathogens, fungi, etc.

There are other antimicrobials and sanitizers available, they too are synthetic and most are not on the National List. Further when *ASC* solutions are used per label requirements, only small diluted amounts are used as microbial interventions under a HACCP System which requires constant monitoring and oversight.

ASC does not chlorinate organics and is rather benign environmentally when used and handled as required by *FDA Labeling* and when properly handled fits into a sustainable food production systems approach.

ASC solutions quickly break down into its component parts, all of which are found naturally in the agroecosystem; i.e. *citric acid, salt and water* – therefore having little, if any environmental impact; especially when used in conjunction with a responsible resource re-cycling program. *ASC* does not damage aquatic-life, or form chlorinated hydrocarbons with mutagenic or carcinogenic properties.

Finally the *Petitioner* believes *ASC based solutions* are excellent microbiocides to assist the organic producers and handlers in protecting the *Food Safety* of the organic food production system from unwanted pathogens, through their responsible and effective use. Therefore protecting our natural resources from contamination and provide the consumer with the healthiest and safest organic food products possible!

13. A Commercial Confidential Information Statement:

The information Compiled Herein Is Considered Confidential!

Ecolab Inc.

National List NOSB Petition ASC

List of Attachments

Attachment 1

6. **Previous Reviews By State, Federal & International Agencies**

Attachment 2

7. **Additional Information, EPA, FDA and State Authorities, Etc.**

Attachment 3

8. **Chemical Abstract Data and Labeled Products & MSDS Forms**

Attachment 4

9. **Substance Physical Properties and Mode of Action:**

   (a) Chemical Interactions With Other Substances, Used in Organic Production; (b) Toxicity and Environmental Persistence. (c) Environmental Imports From Its Use or Manufacturer; (d) Effects On Human Health; (e) Effects on Soil Organisms, Crops or Livestock.

Attachment 5

10. **Safety Information Including MSDS & Substance Report NIEHS**

Attachment 6

11. **Research Information, Substance Reviews and Bibliographies and Citations Which Present Contrasting Positions Presented By the Petitioner**

Attachment 1

6. Previous Reviews By State, Federal & International Agencies

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
College Park, MD 20740

August 25, 2006

John Wood
Ecolab, Inc.
370 North Wabash Street
St. Paul, MN 55102

Dear Mr. Wood:

This responds to your inquiry of July 10, 2006, requesting information regarding the regulatory status of certain antimicrobial solutions that are listed in Title 21 Code of Federal Regulations (CFR), Part 173. Specifically, you ask whether the uses of the solutions described in 21 CFR 173.325 *Acidified sodium chlorite solutions*, 21 CFR 173.370 *Peroxyacids* and in paragraph (a)(5) of 21 CFR 173.315 *Chemicals used in the washing or to assist in the peeling of fruits and vegetables* are food-contact substances within the meaning of that term in the Federal Food, Drug, and Cosmetic Act.

The Federal Food, Drug, and Cosmetic act defines a food-contact substance as "*... any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.*"

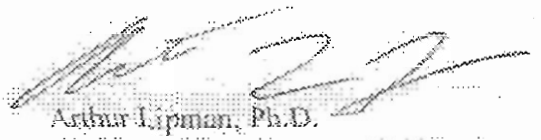
In implementing the food-contact substance notification provisions of the law, the FDA recognized that Congress intended for food additives that exert their technical effect directly in or on the food to be authorized through the traditional food additive petition process. Also, those that do not have any technical effect in the food were intended to be authorized through the newer food-contact substance notification process. However, Title 21 CFR, Part 173, lists many additives that exert a transient technical effect in food during its manufacture, but are either reduced or eliminated from the food such that they do not achieve a technical effect in the food as marketed to consumers. The FDA recognizes food additives that have no ongoing technical effect in the finished food, as marketed to the consumer, as food-contact substances that may be authorized through the food-contact notification process.

Therefore, the uses of additives listed in 21 CFR Part 173, are considered to be food-contact substance uses, including those listed in 21 CFR 173.325 *Acidified sodium chlorite solutions*, 21 CFR 173.370 *Peroxyacids* and in paragraph (a)(5) of 21 CFR 173.315 *Chemicals used in the washing or to assist in the peeling of fruits and vegetables*.

provided that they exert no ongoing technical effect in the finished food as marketed to the consumer.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,



Arthur Lipman, Ph.D.
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

United States Department of Agriculture | Food Safety and Inspection Service | Office of Policy and Program Development | Washington, D.C. 20250/3700

APR 22 2005

Mr. John G. Wood
Director, Product Registration and Compliance
Ecolab, Inc.
370 N. Wabasha Street
St. Paul, MN

Dear Mr. Wood:

This letter is in response to your letter dated March 10, 2005 and a follow up to our meeting of March 3, 2005 in which you requested a letter of no objection from FSIS for the use of Sanova (acidified sodium chlorite) as a post-lethality treatment on ready-to-eat (RTE) meat and poultry products including all deli meats, frankfurters, and cooked sausages applied prior to packaging the food for commercial purposes, and in accordance with current industry standards of good manufacturing practices.

Acidified sodium chlorite is approved as secondary direct food additive in Title 21 of the Code of Federal Regulations (CFR), Section 173.325 as an antimicrobial agent on processed, comminuted, or formed meat food products prior to packaging the food for commercial purposes, and in accordance with current industry standards of good manufacturing practices. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations of 500 to 1200 ppm, in combination with any GRAS acid at levels to achieve a pH of 2.5 to 2.9.

Subsequent to the approval of acidified sodium chlorite as a secondary direct additive, the Food Safety and Inspection Service (FSIS) clarified that acidified sodium chlorite may be used to treat processed comminuted or formed meat products with standards of identity in 9 CFR Part 319. Similarly, FSIS has no objection to the use of acidified sodium chlorite to treat processed, comminuted, or formed poultry products including those with a standard of identity in 9 CFR, Part 381.

FSIS *does not require* a letter of no objection from the Agency for the use of antimicrobial agents as treatments for post lethality exposed RTE products as described in 9 CFR, Part 430. It is an establishments responsibility to use any antimicrobial agent that has been found to be safe and suitable, if they choose to formulate or treat their products with antimicrobial agents (e.g., for compliance with Alternative 1 or Alternative 2 as described in 9 CFR 430.4). In regard to acidified sodium chlorite, it has been shown to reduce pathogenic microorganisms and is currently approved for use as an antimicrobial agent on processed, comminuted, and formed meat and poultry products (e.g., frankfurters, deli meats, etc.). These approved uses are also currently listed in FSIS Directive 7120.1., Amendment 3, titled, "Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products." Therefore, the Agency does not object to the use of acidified sodium chlorite as an antimicrobial agent for the treatment of post lethality exposed RTE products, e.g., deli meats, frankfurters, and other cooked sausages.

If we can be of further assistance, please contact Mr. Jeff Canavan, Food Technologist, or me at Area Code (202) 205-0279.

Sincerely,

Robert C. Post, Ph.D., Director
Labeling and Consumer Protection Staff

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

March 8, 2006

John G. Wood
Director, Product Registration & Compliance
Ecolab, Inc.
370 N. Wabasha Street
St. Paul, MN 55102-1390

Dear Mr. Wood:

This responds to your electronic mail inquiry dated January 24, 2006, requesting advice from FDA on how best to proceed with a request to broaden the conditions of use for those acidified sodium chlorite solutions (ASC) described in Title 21 Code of Federal Regulations (CFR) 173.325, and in particular the use conditions described in §173.325, paragraph (d)(2). Specifically, your letter states that Ecolab intends to seek approval to broaden the use level limitation of acidified sodium chlorite solutions to allow a range of 500-1200 parts per million (ppm) for finfish only. You state that Ecolab has generated new data that demonstrates that 500 ppm acidified sodium chlorite solutions are effective antimicrobials when applied to rainbow trout, and ask several questions relating to data requirements for a possible Food Contact Notification submission.

When it is necessary for FDA to establish a tolerance limitation (i.e. a maximum use level) in order to assure that the proposed use of a food additive will be safe, FDA must set the maximum use level at the lowest level that is needed to accomplish the intended technical effect even when higher levels of use may be shown to be safe (see FFDCA, Sec. 409(c)(4)). Furthermore, if the data before the FDA fails to establish that the use of the additive results in any technical effect, then the minimum level required to accomplish no effect at all is zero, and FDA can not establish a regulation providing for the proposed use. Consequently, the technical effect data in a food additive petition or Food Contact Notification is used to establish the maximum use level that is safe and will not result in unnecessary exposure to the additive.

Title 21 CFR 173.325, paragraph (d)(2) provides for the use of acidified sodium chlorite solutions identified therein at levels that result in a sodium chlorite concentration of 1200 ppm on finfish and crustaceans. Further, Title 21 CFR 172.5 *General Provisions for Direct Food Additives* states, in paragraph (a)(1), that good manufacturing practice shall be defined to include the following restriction: The quantity of the substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritive, or other technical effect in food. By 21 CFR 172.5(a)(1), if a manufacturer can achieve his intended technical effect with an ASC solution having a sodium chlorite concentration less than 1200 ppm, then he should employ the lower use level.

In order to provide manufacturers the flexibility to comply simultaneously with both of these regulations, it is important to specify no minimum level of use in § 173.325. It is therefore unnecessary to submit a Food Contact Notification to provide for the use of acidified sodium chlorite solutions at levels of 500 ppm on finfish because, 21 CFR 173.325(d)(2) already provides for the use of such solutions at levels below 1200 ppm on both finfish and crustaceans.

If you have any further questions on this matter, please do not hesitate to contact us, 301 436 1205.

Sincerely,

Mark A. Hepp
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

United States Department of Agriculture | Food Safety and Inspection Service | Office of Policy, Program Development and Evaluation | Washington, D.C. 20250/3700

DEC 3 1 2001

Mr. Robert G. Hibbert
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005-3096

Dear Mr. Hibbert:

I am responding to your letter of November 26, 2001, requesting clarification concerning the acceptability of acidified sodium chlorite on all processed, comminuted, or formed meat food products; specifically those products covered by standards of identity or composition in Title 9 of the Code of Federal Regulations (CFR), Part 319.

According to 21 CFR, Section 173.325, acidified sodium chlorite may be used as an antimicrobial agent on processed, comminuted, or formed meat food products (unless precluded by standards of identity in 9 CFR Part 319) prior to packaging the food for commercial purposes, in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations of 500 to 1200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.5 to 2.9.

On July 10, 2001, you submitted a letter to the Food Safety and Inspection Service (FSIS) requesting permission to use acidified sodium chlorite on cooked comminuted sausages with standards of identity in 9 CFR, Section 319.180. At that time, we re-evaluated the previously submitted data and concluded that the data show that acidified sodium chlorite, when applied to comminuted meat products, complies with the Food and Drug Administration's definition of a processing aid (found in their labeling regulations 21 CFR, Section 101.100 (a) (3)). There was no lasting functional effect and treated product did not exhibit delayed discoloration, extended shelf life, or abnormal spoilage. Also, no detectable oxychlorine residues were detected in the treated product. Consequently, on October 17, 2001, we issued a letter to you indicating that acidified sodium chlorite may be used, under the conditions specified in 21 CFR, 173.325 (f), as an antimicrobial agent to treat cooked comminuted sausages that are defined by standards of identity in 9 CFR, 319.180.

FDA is responsible for determining the safety of food ingredients and additives as well as prescribing safe conditions of use. However, while FDA has the responsibility for determining the safety of food ingredients and additives, FSIS retains, under the Federal Meat Inspection Act, the authority to determine that new ingredients and additives are suitable for use in meat products.

Suitability relates to the effectiveness of the additive to perform the intended technical effect, and the assurance that the conditions of use will not result in an adulterated product or one

that misleads consumers. Normally, to determine suitability, data must be submitted that establish the lowest level necessary to achieve the intended technical effect for each specific food product category in which the additive is to be used.

While we note that the Agency does not have any data substantiating the suitability of the use of acidified sodium chlorite on processed, formed meat food products, the Agency has determined that, in this instance, the data that were submitted for processed, comminuted meat food products can be extrapolated to apply to processed, formed meat food products. Chlorous acid, which is formed in aqueous solution, is an unstable material and is oxidatively consumed through interaction with microorganisms and organic matter. Therefore, whether the processed meat food product is comminuted or formed, the acidified sodium chlorite treatment should not have any lasting effect on the product, and no oxychlorine residuals should be present at the time of consumption of the meat food product. Furthermore, since the FDA regulation (21 CFR 173.325) would allow for the use of acidified sodium chlorite to treat non-standardized processed, comminuted, or formed meat food products, and this treatment will not have any impact on standards of identity or composition for processed, comminuted, or formed meat food products, the Agency is not requesting that separate data be submitted to establish suitability with standardized processed, formed meat food products.

We would not have any objection to the use of acidified sodium chlorite, in accordance with the conditions specified in 21 CFR, 173.325 (f), as an antimicrobial agent to treat processed, comminuted, or formed meat food products with standards of identity in 9 CFR, Part 319. There are no labeling issues in regard to the treated products because approval of the use of acidified sodium chlorite is that of a secondary direct additive.

If we can be of further assistance, please do not hesitate to contact Mr. Bill Jones or me at Area Code (202) 205-0279.

Sincerely,

for Robert C. Post, Ph.D., Director
Labeling and Consumer Protection Staff

United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

OCT 17 2001

Mr. Robert G. Hibbert
McDermott, Will & Emery
600 13th Street, N.W.
Washington, DC 20005-3096

Dear Mr. Hibbert:

I am responding to your letters of July 10, 2001, to Mr. Thomas J. Billy, Administrator, and September 13, 2001, to me written on behalf of your client, Alcide Corporation, regarding the use of their product, acidified sodium chlorite on cooked comminuted sausages with standards of identity in Title 9 of the Code of Federal Regulations (CFR), Section 319.180. You are seeking clarification of the Agency's position on approving a new use for this substance that was conveyed in a letter to you dated June 27, 2001, from Dr. Robert C. Post, Director, Labeling and Consumer Protection Staff (LCPS). Dr. Post indicated that the consideration of the new use of acidified sodium chlorite would require an amendment to the Federal meat inspection regulations because of the need to amend food standards. You have also had a meeting with me and Mr. Philip Derfler, Deputy Administrator, Office of Policy, Program Development, and Evaluation, on this matter.

As we have discussed, the standards of identity listed in 9 CFR, Part 319, prescribe content and preparation requirements for various meat products. It has been the long-standing position of this Agency that ingredients not expressly permitted by a standard of identity cannot be used in that product until the standard of identity has been amended to permit use of the ingredients. This policy has been applied to all direct food additives.

We have considered your assertion that the Agency could allow the use of acidified sodium chlorite on standardized cooked meat sausages because the use is similar to that of a processing aid. We evaluated the information that you provided from representatives of the American Meat Institute Foundation and Kansas State University which listed several examples of Food and Drug Administration (FDA) approved additives that you contend are being used as processing aids in meat and poultry products with standards of identity and that are not labeled.

We have re-evaluated the previously submitted data and we have concluded that the data show that acidified sodium chlorite, when applied to comminuted products, complies with the FDA's definition of a processing aid (21 CFR, Section 101.100 (a) (3)). Furthermore, the data show that there was no lasting functional effect, and that treated product does not exhibit delayed discoloration, extended shelf life, or abnormal spoilage. Also, no detectable oxychlorine residues were detected in the treated product. After reviewing the data, the Food Safety and Inspection Service has determined that acidified sodium chlorite may be used, under the conditions specified in 21 CFR, 173.325 (f), as an antimicrobial agent to treat cooked comminuted sausages that are defined by standards of identity in 9 CFR, 319.180. There are no labeling issues in regard to the treated product.

We have also considered your request to allow the new use of these antimicrobials on an interim basis according to the tenets of 9 CFR, 303.1(h). With regard to the application of

9 CFR , 303.1(h), in order to waive the standards of identity regulations, the Administrator needs to be reacting to a public health emergency or be permitting experimentation so that new procedures, equipment, or processing techniques may be tested to facilitate definite improvements. We do not see either of these criteria being met in this instance.

We understand the limitations posed by the Agency's approach to allowing new ingredients in additional categories of standardized meat products, especially where ingredients such as antimicrobials are concerned. Therefore, we have decided to pursue the development of a direct final rule to adopt, as soon as possible, changes to standards of identity in the Federal meat (and poultry) inspection regulations that would permit the use of *any* safe and suitable antimicrobial and other defined classes of ingredients. Thus, the situation such as the one you have appealed will not occur in the future because case-by-case rulemaking on individual ingredients would be unnecessary.

Sincerely,

Margaret O"K. Glavin
Associate Administrator

United States Department of Agriculture

Food Safety and Inspection Service

Office of Policy, Program Development and Evaluation

Washington, D.C. 20250/3700

JUN 14 2001

Mr. Robert G. Hibbert
McDermott, Will & Emery
600 13th Street, N.W.
Washington, DC 20005-3096

Dear Mr. Hibbert:

I am responding to your letter of May 4, 2001, submitted on behalf of your client, Alcide Corporation, requesting clarification on the current regulatory status of Alcide's Sanova system in Federally inspected poultry processing establishments. The Sanova system uses acidified sodium chlorite as an antimicrobial agent.

Acidified sodium chlorite may be used as an antimicrobial agent in poultry processing water under the conditions prescribed in Title 21 of the Code of Federal Regulations (CFR), Section 173.325. That regulation states that acidified sodium chlorite may be used: (1) as a component of a carcass spray or dip solution prior to immersion of the intact carcass in a prechiller or chiller tank; (2) in a prechiller or chiller solution for application to the intact carcass; (3) as a component of a spray or dip solution for application to poultry carcass parts; (4) in a prechiller or chiller solution for application to poultry carcass parts; and (5) as a component of a post-chill carcass spray or dip solution when applied to poultry meat, organs, or related parts or trim. When used in a spray or dip solution, sodium chlorite concentrations must be between 500 and 1200 ppm, in combination with any Generally Recognized as Safe (GRAS) acid at a level sufficient to achieve a solution pH of 2.3 to 2.9. When used in a prechiller or chiller solution, the sodium chlorite concentrations must be between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.8 to 3.2.

On December 1, 2000, the Food Safety and Inspection Service (FSIS) published in the Federal Register, a proposed rule entitled "Performance Standards for On-line Antimicrobial Reprocessing of Pre-Chill Poultry Carcasses." The proposed change will allow, on a voluntary basis, the on-line reprocessing of pre-chilled carcasses that are accidentally contaminated with digestive tract contents during slaughter. The treated carcasses must meet pre-chill performance standards for *Salmonella* and *E. coli* that are significantly lower than the existing criteria for verifying process control for *E. coli* and the pathogen reduction performance standards for *Salmonella* for chilled poultry. Establishments doing on-line antimicrobial reprocessing will need to do so in accordance with the Hazard Analysis and Critical Control Points system requirements in Title 9 CFR, Part 417.

Alcide Corporation was one of several companies that, over the past few years, have been doing in-plant testing to generate data on the effectiveness of their antimicrobial systems. In fact, in November 1999, Alcide submitted a petition to FSIS requesting that the Agency conduct rulemaking to approve the use of its Sanova continuous on-line processing system using acidified sodium chlorite as the antimicrobial treatment.

In the Proposed Rule published in the Federal Register on December 1, 2000, FSIS stated that, because the Agency has decided to go forward with this rulemaking, it has granted the Alcide petition, in part, except for the company's request to use non-quantitative performance standards. The Agency is requesting comments on Alcide's method of collecting data based on degrees of reduction of bacteria (i.e., there was an average reduction by 27.27 percent of the prevalence of *Salmonella* on the treated samples) versus a quantitative method based upon absolute levels of reduction (i.e., less than 0.5 percent of the treated samples were positive for *Salmonella*). In the interim, while the Agency continues with the rulemaking process, Alcide's Sanova system may continue to be used for on-line reprocessing of pre-chilled carcasses that are accidentally contaminated with digestive tract contents during slaughter. This would also apply to foreign meat and poultry processing establishments exporting products to the United States because they are required, by law, to be operating under a system that is equivalent to that for domestic meat and poultry establishments.

Finally, any carcasses treated with the Sanova system and found to retain water will need to disclose that fact in their labeling in accordance with the Final Rule on "Retained Water in Raw Meat and Poultry Products; Poultry Chilling Requirements" that was published on January 9, 2001, in the Federal Register.

If we can be of further assistance, please contact Mr. Bill Jones or me at Area Code (202) 205-0279.

Sincerely,

Robert C. Post, Ph.D., Director
Labeling and Consumer Protection Staff

Department of Agriculture
and Inspection Service
Washington, D.C. 20250

FEB – 8 2001

Mr. Robert G. Hibbert
McDermott, Will & Emery
600 13th Street, N.W.
Washington, D.C. 20005-3096

Dear Mr. Hibbert:

This is in response to issues raised in your letter of December 18, 2001. We can confirm that, consistent with the January 12, 2001, Federal Register Notice of the Food and Drug Administration and the letter of February 11, 2001, from Charles Edwards, we do not object to the use of acidified sodium chlorite on red meat products.

As you are aware, the labeling issues were more complex and have been discussed with you by the Office of Policy, Program Development and Evaluation staff. From those conversations and the data you recently sent me that were enclosed with your letter of February 5, 2001, we understand that acidified sodium chlorite does not have a functional effect in finished products made with raw materials treated with the Sanova system. Essentially, the data show that finished products made with treated materials will not exhibit delayed discoloration, extended shelf life, or abnormal spoilage as compared to finished products made with untreated raw materials. Therefore, labeling is not required.

Another aspect of the labeling issue arises from the possibility of moisture retention and the requirements of our regulation on retained water. We have reviewed the materials you submitted and have no objection to the protocol used to collect data demonstrating that labeling would not be required.

This should address any issues that might surround the use of this treatment system by inspected establishments. We appreciate the efforts of your client in expanding the available technologies that can be used in meat processing.

Sincerely,

Philip S. Derfler
Deputy Administrator
Office of Policy, Program Development
and Evaluation

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250-3759

JAN - 7 1999

Dr. G. Kere Kemp
ExecutiveVice President
Alcide Corporation
8561 154th Avenue NE
Redmond, WA 98052

Dear Dr. Kemp:

This letter is in response to your request for approval of the Sanova system as an antimicrobial treatment. We have considered your request as a petition to amend 9 CFR 381.147(f)(4) to permit the use of acidified sodium chlorite as an antimicrobial agent. The Food Safety and Inspection Service (FSIS) has completed the technical review of your application and supporting data, including data from FSIS approved inplant testing. FSIS has determined that the acidified sodium chlorite in a system using Sanova International equipment is effective in reducing microbial levels on raw poultry carcasses when applied as a spray or dip solution.

The Food and Drug Administration (FDA) concluded (Federal Register Vol. 61, pages 17828-17829) that an acidified sodium chlorite solution is safe and will have the intended effect of reducing microbial contamination on poultry. FDA consulted with FSIS scientists when making this determination.

Based on these determinations, FSIS is proceeding with rulemaking proposing to add acidifie sodium chlorite solution to the poultry product inspection regulations, 9 CFR 381.147(f)(4) as an antimicrobial agent to reduce microbial levels on raw poultry carcasses. FSIS also grants interim approval for use of acidified sodium chlorite solution as a processing aid for the purpose of reducing microbial levels on raw poultry carcasses when used as a spray or dip in accordance with the conditions prescribed in § 173.325 (21 CFR Part 173).

Sincerely,

Thomas J. Billy
Administrator

Access to Additional Support Data

FSIS:

- Food Safety and Inspection Service New Technology Information Table [http://www.fsis.usda.gov/regulations/New_Technology_Table/index.asp]

- Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products; 7120.1 (Amend 8); 7/3/06 [www.fsis.usda.gov/OPPDE/rdad/FSIS Directives/7120.1_Amend_8.pdf]

FDA-CFSAN:

- Inventory of Effective Premarket Notifications for Food Contact Substances [http://www.mindfully.org/Food/2005/Food-Contact-Substances-FDA15feb05.htm]

EPA:

- List A: Antimicrobial Products Registered with the EPA as Sterilizers January 4, 2006 [http://www.epa.gov/oppad001/list_a_sterilizer.pdf]

- Registration Eligibility Decisions; Notice of Availability – Chlorine Dioxide [http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/06-7959.pdf]

- Chemical Profile for SODIUM CHLORITE (CAS Number: 7758-19-2) [http://www.scorecard.org/chemical-profiles/summary.tcl?edf_substance_id=7758-19-2)

- U.S. EPA PC Code: 020502

- CA DPR Chem Code:2148

Special Note:

- **Rather than overload the *TAP Reviewers and/or the NOSB* we have elected to provide the above data access list for your convenience and specific data selection.**

Dr. G. Kere Kemp
Executive Vice President
Chief Scientific Officer
Alcide Corporation
8561 154th Avenue NE
Redmond, Washington 98052

FEB 11 2000

Dear Dr. Kemp:

We have received your information and request to apply the recent publication (dated 12/23/99) of the final rule "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products" to approving the use of acidified sodium chlorite on red meat products.

As you noted, the December 23 revision of the regulation permits food ingredients that have been approved by FDA for use in the production of meat and poultry products to be used without separate approval by the Food Safety and Inspection Service (FSIS), subject to certain limitations. Based on this final rule, we have no objection to the use of acidified sodium chlorite on red meat products, including carcasses, parts, and organs, in federally inspected establishments provided it complies with established regulatory guidelines including EPA, FDA, and OSHA.

Sincerely,

Charles R. Edwards

Charles R. Edwards
Director
Labeling, Product, and Technology Standards Division
Office of Policy, Program Development, and Evaluation

Department of Agriculture
and Inspection Service
Washington, D.C. 20250

AUG 9 2000

Mr. Robert G. Hibbert
Attorney at Law
Counsel to Alcide Corporation
McDermott, Will & Emery
600 - 13th Street, N.W.
Washington, D.C. 20005-3096

Dear Mr. Hibbert:

This is in response to your March 22, 2000, letter on behalf of your client, the Alcide Corporation, requesting that the Food Safety and Inspection Service (FSIS) amend its tables of approved food ingredients codified in Title 9 of the Code of Federal Regulations, section 424.21 (9 CFR 424.21) to include currently acceptable uses for acidified sodium chlorite in meat and poultry products. We apologize for the delay in responding.

On December 23, 1999, FSIS published in the *Federal Register* a final rule, entitled "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry products." This final rule streamlined the process for approving the use of food ingredients and sources of radiation in meat and poultry products by providing for the simultaneous review, by the Food and Drug Administration (FDA) and FSIS of requests for the use of food ingredients and sources of radiation in meat and poultry products.

Except in very limited circumstances, FDA will now list in its regulations, Title 21 Code of Federal Regulations (21 CFR), food ingredients and sources of radiation that are safe to use in the production of meat and poultry products. FSIS will limit substance-specific rulemaking under the authority of the Federal Meat Inspection Act and the Poultry Products Inspection Act to those necessary to establish specific prohibitions or limitations on the use of a food ingredient or source of radiation in meat or poultry products. FSIS rulemaking may be necessary where a standard of identity or composition prohibits or limits the use of an ingredient, or when the ingredient is not expected to be in the product.

In the final rule, FSIS consolidated various existing regulations on food ingredients and sources of radiation into a single new part (9 CFR Part 424) applicable to both meat and poultry establishments. This included combining the separate listings of food ingredients approved for use in meat and poultry products into a single table (9 CFR 424.21(c)) and eliminating

unnecessary differences in the listings. FSIS also indicated that it intended to review its listings in 9 CFR and eliminate those listings that duplicate FDA's listings in 21 CFR. FSIS has already started this process of eliminating duplicate listings from 9 CFR by removing the listings for approved sources of radiation for use on meat and poultry from the combined chart. Ionizing radiation for the treatment of food, including meat and poultry products, is currently listed in 21 CFR, Section 179.26.

Acidified sodium chlorite is currently listed in 21 CFR 173.325 for various uses in meat and poultry products. The listings in 21 CFR are consistent with the new procedures established under the recently published final rule. Also, since FSIS is in the process of removing duplicate listings from its regulations, we do not plan to add to Title 9 regulations for the use of a substance in meat and poultry products, when that use is already reflected in 21 CFR.

FSIS intends to maintain a comprehensive listing, possibly in its directive system, of substances authorized for use in the production of meat and poultry products. As such, FSIS will no longer add any more listings to the table of approved substances for use in meat and poultry products, which is in 9 CFR 424.21(c). In fact, FSIS is exploring the possibility of transferring this table to 21 CFR.

We hope this information is helpful. If we can be of further assistance, please let us know.

Sincerely,

Philip S. Derfler
Deputy Administrator
Office of Policy, Program Development
and Evaluation

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250-3759

JAN - 7 1999

Dr. G. Kere Kemp
ExecutiveVice President
Alcide Corporation
8561 154th Avenue NE
Redmond, WA 98052

Dear Dr. Kemp:

This letter is in response to your request for approval of the Sanova system as an antimicrobial treatment. We have considered your request as a petition to amend 9 CFR 381.147(f)(4) to permit the use of acidified sodium chlorite as an antimicrobial agent. The Food Safety and Inspection Service (FSIS) has completed the technical review of your application and supporting data, including data from FSIS approved inplant testing. FSIS has determined that the acidified sodium chlorite in a system using Sanova International equipment is effective in reducing microbial levels on raw poultry carcasses when applied as a spray or dip solution.

The Food and Drug Administration (FDA) concluded (Federal Register Vol. 61, pages 17828-17829) that an acidified sodium chlorite solution is safe and will have the intended effect of reducing microbial contamination on poultry. FDA consulted with FSIS scientists when making this determination.

Based on these determinations, FSIS is proceeding with rulemaking proposing to add acidified sodium chlorite solution to the poultry product inspection regulations, 9 CFR 381.147(f)(4) as an antimicrobial agent to reduce microbial levels on raw poultry carcasses. FSIS also grants interim approval for use of acidified sodium chlorite solution as a processing aid for the purpose of reducing microbial levels on raw poultry carcasses when used as a spray or dip in accordance with the conditions prescribed in § 173.325 (21 CFR Part 173).

Sincerely,

Thomas J. Billy
Administrator

Health Protection Branch

Direction générale de la protection de la santé
Bureau of Chemical Safety
Food Directorate
Banting Building
Address Locator:2201B1
Ottawa, Ontario
K1A 0L2

September 27, 1999

Our File:FS97010601

Dr. G. Kere Kemp
Vice President Clinical Research
Alcide Corporation
8561 154th Avenue NE
Redmond, WA

Dear Dr. Kemp:

This is in reference to your request for the use of acidified sodium chlorite acid antimicrobial solutions in poultry processing waters.

Based on the information submitted, we would have no objection to the use of chlorous acid (50-266 ppm) generated by the acidification of sodium chlorite at pH 2.5-2.9 in the poultry process water used prior to the poultry being immersed in pre-chiller or chiller tanks provided the ingredients are of food-grade quality.

We trust this is satisfactory.

Yours truly,

Karl Cavlovic

Karl Cavlovic
Additives and Contaminants Section
Chemical Health Hazard
Assessment Division

cc: G. Thiessen
Canadian Food Inspection Agency

Canada

Access to Additional Support Data

FSIS:

- Food Safety and Inspection Service New Technology Information Table [http://www.fsis.usda.gov/regulations/New_Technology_Table/index.asp]

- Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products; 7120.1 (Amend 8); 7/3/06 [www.fsis.usda.gov/OPPDE/rdad/FSIS Directives/7120.1_Amend_8.pdf]

FDA-CFSAN:

- Inventory of Effective Premarket Notifications for Food Contact Substances [http://www.mindfully.org/Food/2005/Food-Contact-Substances-FDA15feb05.htm]

EPA:

- List A: Antimicrobial Products Registered with the EPA as Sterilizers January 4, 2006 [http://www.epa.gov/oppad001/list_a_sterilizer.pdf]

- Registration Eligibility Decisions; Notice of Availability – Chlorine Dioxide [http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/06-7959.pdf]

- Chemical Profile for SODIUM CHLORITE (CAS Number: 7758-19-2) [http://www.scorecard.org/chemical-profiles/summary.tcl?edf_substance_id=7758-19-2)

- U.S. EPA PC Code: 020502

- CA DPR Chem Code:2148

Special Note:

- **Rather than overload the *TAP Reviewers and/or the NOSB* we have elected to provide the above data access list for your convenience and specific data selection.**

List of Various ASC Evaluations Conducted and Support Data (Available Upon Request from Petitioner)

#1	Section 1	Letter re: Commercial Plant Evaluation of Acidified Sodium Chlorite
#2	Section 2	Pilot Evaluation of Acidified Sodium Chlorite (practice for broiler slaughter
#3	Section 3	6.0 Experimental Designs – Tables
#4	Section 4	In-Vivo Efficacy Evaluation of Acidified----------Solutions – Part II
#5	Section 5	In-Vivo Efficacy Evaluation of Acidified----------Solutions – Part III
		##########
#1	Section 6	In-Vivo Efficacy Evaluation of Acidified----------Solutions – Part IV
#2	Section 7	In-Vivo Efficacy Evaluation of Acidified - Solutions – Part V
#3	Section 8	6.0 Experimental Designs – Tables (Different from above)
#4	Section 9	In-Vivo Efficacy Evaluation of Acidified----------Solutions –Part VI
#5	Section 10	6.0 Experimental Designs – Tables (Different from above)
#6	Section 11	In-Vivo Efficacy Evaluation of Acidified----------Solutions – Part VII
		##########
#7	Section 12	450(c) Poultry Antimicrobial Final Report 01/96
#8	Section 13	Food Additive Petition – 9/9/94 – Original
#1	Section 14	Identity and Technical Properties of Food Additive
#2	Section 15	Exhibit 1 – Raw Material Specification Sheets; sodium chlorite, lactic acid, phosphoric acid; malic acid
#3	Section 16	Supportive Data and Use Levels
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		##########
#1	Section 18	Appendix I – Potentiometric Titration of Oxychlorines
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#5	Section 22	Reference 2 – Extraction of Mutagens from Chlorinated Poultry Chiller Water

#1	Section 23	Reference 4 – A Kinetic Study of the Reaction of Aqueous Chlorine and Chlorine Dioxide with Amino Acids, Peptides and Proteins
#2	Section 24	Reference 6 – Chlorine Dioxide, Chemistry and Environmental Impact of Oxychlorine Compounds
#3	Section 25	Reference 8 – Chlorine Dioxide; Drinking Water Issues
#4	Section 26	Reference 10 – not available
#5	Section 27	Reference 12 – See Appendix I
		##########
#1	Section 28	Identity and Technical Properties of Food Additive
#2	Section 29	Amount, Purpose, Directions and Labelling of the Food Additive
#3	Section 30	Analytical Methods for Oxychlorine Species and Chlorinated and Oxidized Organic Matter on Poultry Tissue
#4	Section 31	Tolerance Consideration and Proposed Regulation
#5	Section 32	Environmental Assessment
#6	Section 33	Appendix II – Oxyhalide Analysis by HPLC Ion Analysis
#7	Section 34	Millennium Results – Sample Information
#8	Section 35	Appendix V – Characterization of Poultry Carcasses
#9	Section 36	Reference I – The Chemistry of Chlorine Dioxide
#10	Section 37	Reference 3 – Effect of Exposure of Meat & Poultry to Chlorinated Water on the Retention of Chlorinated Compounds and water
		##########
#1	Section 38	Reference 5 – Reactions of Aqueous Chlorine Dioxide
#2	Section 39	Reference 7 – Halogenated Byproduct Formation
#3	Section 40	Reference 9 –Subpart Z–Toxic and Hazardous Substances–Air Contaminants
#4	Section 41	Reference 11 – Use of Chlorine Compounds in the Food Industry
#5	Section 42	Reference 13 – Chlorine Dioxide: Drinking Water Issues

NOTE

Chlorine Dioxide, Chlorite and Chlorate
Drinking Water Health Advisory
Office of Water
U.S. Environmental Protection Agency

This health advisory (HA) for chlorine dioxide, chlorite and chlorate is being issued as an interim draft. This HA has been peer reviewed by external reviewers. As stated in the introduction of the HA, this HA serves as informal technical guidance to assist Federal, State and local officials responsible for protecting public health when emergency spill or contamination occur. The HA should not be construed as legally enforceable Federal standards. Consequently, this HA does not establish or affect legal rights or obligations and it does not represent final Agency action on the issues addressed.

This health advisory is consistent with the health risk assessment conducted to support the proposed drinking water criteria for chlorine dioxide, chlorite and chlorate[1]. Both the criteria document and health advisory have been externally peer reviewed, and the proposed drinking water criteria and health advisory may be subject to change as new information becomes available. The Chlorine Dioxide Panel of the Chemical Manufacturers Association is conducting a two-generation reproductive study on chlorite, which is expected to be completed in 1996. EPA will conduct a 90-day and two-year chronic study of sodium chlorate in drinking water using rats and mice. In finalizing the proposed drinking water criteria on chlorine dioxide, chlorite and chlorate, EPA will evaluate these studies and any other new studies that may become available, and determine if any changes to the proposed criteria are warranted. EPA will also amend the HA, if necessary, to reflect any changes based on the evaluation.

U.S. EPA. 1994. U.S. Environmental Protection Agency. National Primary Drinking Water Regulations; Disinfectants and Disinfection Byproducts; Proposed Rule. Fed. Reg. 59 (145):38668-38829. July 29.

U.S. Environmental Protection Agency. 1994. Final Draft Drinking Water Health Criteria Document for Chlorine dioxide, Chlorite and Chlorate. Office of Science and Technology, Office of Water. March 31, 1994.

April 1996

CHLORINE DIOXIDE, CHLORITE AND CHLORATE

Drinking Water Health Advisory
Office of Water
U. S. Environmental Protection Agency

I. INTRODUCTION

The Health Advisory (HA) Program, sponsored by the Office of Water (OW), provides information on the health effects, analytical methodology and treatment technology that would be useful in dealing with the contamination of drinking water. Health Advisories describe nonregulatory concentrations of drinking water contaminants at which adverse health effects would not be anticipated to occur over specific exposure durations. Health Advisories contain a margin of safety to protect sensitive members of the population.

Health Advisories serve as informal technical guidance to assist Federal, State, and local officials responsible for protecting public health when emergency spills or contamination situations occur. They are not to be construed as legally enforceable Federal standards. The HAs are subject to change as new information becomes available.

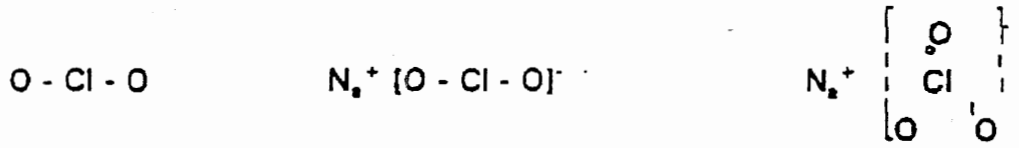
Health Advisories are developed for one-day, ten-day, longer-term (approximately 7 years, or 10 percent of an individual's lifetime), and lifetime exposures based on data describing noncarcinogenic endpoints of toxicity. For those substances that are known or probable human carcinogens, according to the Agency classification scheme (Group A or B), Lifetime HAs are not recommended. The chemical concentration values for Group A or B carcinogens are correlated with carcinogenic risk estimates by employing a cancer potency (unit risk) value together with assumptions for lifelong exposure and the consumption of drinking water. The cancer unit risk is usually derived from the linearized multistage model with 95 percent upper confidence limits. This provides a low-dose estimate of cancer risk to humans that is considered unlikely to pose a carcinogenic risk in excess of the stated values. Excess cancer risk estimates may also be calculated using the one-hit, Weibull, logit or probit models. There is no current understanding of the biological mechanisms involved in cancer to suggest that any one of these models is able to predict risk more accurately than another. Because each model is based on differing assumptions, the estimates that are derived can differ by several orders of magnitude.

II. GENERAL INFORMATION AND PROPERTIES

The main focus of this Health Advisory is the possible health risks associated with the use of chlorine dioxide (ClO_2) as a drinking water disinfectant. Chlorine dioxide is transformed into chlorite (ClO_2^-) and chlorate (ClO_3^-) following its entry into water. Therefore, human exposures to chlorite and chlorate are likely to occur as a result of contact with chlorine dioxide-treated water.

CAS No. Chlorine dioxide: 10049-04-4
Chlorite: 7758-19-2 (sodium salt)
Chlorate: 7775-09-0 (sodium salt)

Structural Formula



Chlorine Dioxide Sodium Chlorite Sodium Chlorate

Synonyms (NIOSH, 1983; Windholz, 1976)

- Chlorine dioxide: Chlorine oxide, Chlorine peroxide, Dioxide 50, Chloroperoxyl.
- Sodium chlorite: No synonyms located.
- Sodium chlorate: Atlacide, Chlorax, Oxycil, Shed-A-Leaf, VAL-Drop.

Uses (Meister, 1986; NAS, 1987; Windholz, 1976)

- Chlorine dioxide: Disinfection and odor/taste control of water; bleaching of cellulose, paper-pulp, flour and oils; cleaning and detanning of leather.
- Sodium chlorite: On site production of chlorine dioxide; bleaching agent in production of paper, textiles and straw products; manufacture of waxes, shellacs and varnishes.
- Sodium chlorate: Preparation of ClO_2; manufacture of dyes, matches, explosives and weed killers; tanning and finishing leather. Chlorates have been used as defoliants (Meister, 1986).

Properties (Windholz, 1976)

	Chlorine Dioxide	Sodium Chlorite	Sodium Chlorate
Chemical Formula	ClO_2	$NaClO_2$	$NaClO_3$
Molecular Weight	67.5	90.5 67.5 (chlorite ion)	106.5 83.5 (chlorate ion)
Physical State	Gas (yellow-red)	Crystalline	Crystalline
Boiling Point (°C)	10	--	Decomposes
Melting Point (°C)	-59.5	(180-200 decomp.)	248
Density (at 0°C)(g/cm^3)	1.63 (liq.)	2.46	2.49
Vapor Pressure (25°C)	--	Negligible	--
Specific Gravity	--	--	--
Water Solubility (g/L)	67 (25°C)	390 (17°C)	790 (0°C)
Log Octanol/Water Partition Coefficient (log K_{ow})	--	--	--
Taste Threshold (Water), mg/L	0.4	--	--
Odor Threshold (Water), mg/L	0.4	--	--
Conversion Factor (ppm air to mg/m^3)	1 ppm = 2.8 mg/m^3 1 mg/m^3 = 0.36 ppm		

Occurrence

- Chlorine dioxide (ClO_2) does not occur in nature. Chlorine dioxide is added to drinking water as a disinfectant and for odor/taste control. It is effective in this application due to its oxidative activity. Due to shipping/handling considerations, ClO_2 is usually generated at the point-of-use from various chlorine sources (NAS, 1987). It has been estimated that approximately 10% of surface water plants and 1% of ground water plants, serving more than 10,000 people, currently use chlorine dioxide for disinfection in the United States (USEPA, 1992a). It is assumed that none of the plants serving fewer than 10,000 people use chlorine dioxide.

- Chlorite appears in drinking water as a result of using chlorine dioxide for disinfection. Masschelein (1989 in Bull and Kopfler,1991) reported that 40-60% of chlorine dioxide used in water disinfection is converted to chlorite in finished water while Gordon et al. (1990) reported that 70% of chlorine dioxide used in water disinfection is converted to chlorite in finished water. . Chlorite concentrations were found to range from 15-

740 ug/L with a mean of 317 ug/L in five finished water samples from plants using chlorine dioxide (Bolyard et al., 1993). Bull and Kopfler (1991) reported the results of a pilot plant study in which source water from the Ohio River was dosed with 1600 ug/L of chlorine dioxide with resulting chlorite concentrations between 300-500 ug/L.

- Chlorate is used in a wide variety of manufacturing processes (NAS, 1987; Bolyard et al., 1993) and can be found in source water at low concentrations. It can also be formed as a result of chlorine dioxide application and can result from using hypochlorite solution and gaseous chlorine for disinfection. In source waters, chlorate concentrations in nine systems ranged from 10-81 ug/L with a mean of 25 ug/L (Bolyard et al., 1993) and ranged from less than 10-884 ug/L with a median value of less than 10 ug/L at 111 sites (Gordon et al. 1995). In four systems using chlorine dioxide, chlorate concentrations in finished water ranged from 21-330 ug/L with a mean of 200 ug/L (Bolyard et al. 1993). In systems using hypochlorite solutions, chlorate concentrations in finished water samples from 111 systems ranged from less than 10-9180 ug/L with a median value of 161 ug/L (Gordon et al, 1995) and ranged from 11-660 ug/L with a mean of 162 ug/L from fifteen systems (Bolyard et al. 1993). In four systems using gaseous chlorine, chlorate concentrations from the terminal point in the distribution system ranged from less than 10-47 ug/L with a mean of 20 ug/L (Bolyard et al, 1993).

- No information was found in the available literature regarding the occurrence of chlorine dioxide, chlorite or chlorate in air or food. However, EPA currently believes that drinking water accounts for the preponderance of exposure to these compounds, and has proposed a relative source contribution (RSC) of 80% (the maximum allowable) for drinking water (U.S. EPA, 1994a).

Environmental Fate

- Chlorine dioxide is an irritating, toxic, greenish yellow gas produced by the reaction of chlorite ions with hydrochloric acid or chlorine gas (Faust and Aly, 1983). It is an unstable compound, being sensitive to temperature, pressure and light. It can form an explosive mixture with air at concentrations greater than 4 percent (NAS, 1987). It is used as both a disinfectant and an oxidizing agent in the treatment of potable water (Faust and Aly, 1983).

- Chlorine dioxide is a more effective disinfectant than chlorine at alkaline pHs. Faust and Aly (1983) reported that chlorine is a slightly more effective microbiocide against Escherichia coli than chlorine dioxide at pH

6.5, but at pH 8.5 chlorine dioxide is twenty times more effective than chlorine.

- Chlorine dioxide is often used for the oxidation of organic materials which cause taste and odor problems in potable water (Faust and Aly, 1983). It also oxidizes iron and manganese to their insoluble oxidation states and thus facilitates the removal of these metals from potable water (NAS, 1987). When chlorine dioxide is the oxidant or disinfectant in water treatment, instead of chlorine, trihalomethane formation is diminished (Thompson, 1988). Chlorine dioxide also does not react with ammonia or organic nitrogen compounds to form chloramines as does chlorine (Faust and Aly, 1983).

- Chlorine dioxide treated water contains chlorine dioxide, chlorate and chlorite ions. Chlorite ion is believed to be the major product of chlorine dioxide reduction (Faust and Aly, 1983). Normally about 40 to 70 percent of the applied chlorine dioxide will be rapidly converted to chlorite ions (Aieta and Ber, 1986; Bull and Kopfler, 1991). Since chlorite ions degrade very slowly to chloride, the chlorite ion levels in treated water are relatively stable (Werdehoff and Singer 1987). The formation of chlorate ions occurs at much lower levels than chlorite ions (Faust and Aly, 1983). Chlorate ion formation is increased in acidic solutions and with exposure to sunlight (Condie, 1986).

III. PHARMACOKINETICS

Absorption

- One half of a ClO_2 dose (1.5 mg/kg) orally administered in water to rats was absorbed from the gastrointestinal (GI) tract within 11 minutes (Abdel-Rahman, 1985).

- Much of an ingested quantity of ClO_2 is probably changed chemically prior to absorption since Bercz et al. (1982) found that monkey saliva caused a 70 percent disappearance of ClO_2 within 1 minute following mixing in a test vessel.

- Abdel-Rahman et al. Conducted several studies on the pharmacokinetics of ClO_2 (1980a,b, 1982). Radiolabeled $^{36}ClO_2$ was administered orally to small groups of young white male rats at doses of approximately 1.5 m/kg. ClO_2 was rapidly absorbed from the GI tract with a peak plasma level of 7 μg/mL reached at 1 hour post-dosing. The rate constant for absorption of ^{36}Cl into plasma under these conditions was 3.77 $\pm$ 0.24/hour, and the half-life ($T_{1/2}$) for absorption of ^{36}Cl into plasma was

0.18 ± 0.01 hours. Approximately 31% of the initial does of the radiolabel was excreted in the urine and 10% in the feces within 72 hours of administration. Although only 43% of the total initial dose was excreted through urinary and fecal routes, the total recovery of the radiolabel from the organs, skin and carcass and excretion was 95% at 72 hours. When 100 mg/L ClO_2 in drinking water was administered to rats for 15 days followed by a single oral dose of 3 ml of 300 mg/L $^{36}ClO_2$, ^{36}Cl plasma levels peaked at 2 hours. The absorption rate constant for this group was 3.16 ± 0.42/hour, corresponding to a $T_{1/2}$ of 0.22 ± 0.03 hours. A comparison of the multiple-dose study and single-dose treatments showed that there was no significant difference between the rates of absorption.

- Abdel-Rahman et al. (1982, 1984a) administered 0.15 mg/kg (0.17 μCi) $^{36}ClO_2^-$ in 3 mL of a 10-mg/L solution of ClO_2^- orally to male Sprague-Dawley rats. The peak ^{36}Cl plasma level (470 ng/mL) was reached at two hours post-dosing. Label was absorbed from the intestine into plasma with a rate constant of 0.198 ± 0.06/hour and an absorption $T_{1/2}$ of 3.5 ± 1.06 hours. Approximately 34.5% of the radiolabel was excreted in the urine, and 4.8% was recovered in the tissues within 72 hours of administration. 4.8% of the initial radiolabel dose was recovered in the tissues (Abdel-Rahman,1982). In another report (Abdel-Rahman, 1984a), the tissue distribution of the radiolabel were listed as radiolabel per gram of tissue but the total weights of the tissues were not provided. Therefore, the total recovery of the radiolabel could not be calculated.

- Abdel-Rahman et al. (1982, 1984a) administered 0.065 mg/kg (0.85 μCi) $^{36}ClO_3^-$ in 3 mL of a 5-mg/L solution of ClO_3^- orally to male Sprague-Dawley rats. A peak plasma level (185 ng/mL) was reached after 30 minutes, with a rate constant for absorption from the intestine into plasma of 0.399 ± 0.151/hour, and an absorption $T_{1/2}$ of 1.74 ± 0.66 hours. Approximately 40% of the radiolabel was excreted in the urine, and 5% was recovered in the tissues within 72 hours. 5% of the initial radiolabel dose was recovered in tissues within 72 hours (Abdel-Rahamn, 1982). In another report (Abdel-Rahman, 1984a), the tissue distribution of the radiolabel were listed as radiolabel per gram of tissue but the total weights of the tissues were not provided. Therefore, the total recovery of the radiolabel could not be calculated.

Distribution

- Following oral administration of ^{36}Cl-radiolabeled ClO_2 in water to rats, 10% of the Cl tracer was recovered within 72 hours in nine major organs

(Abdel-Rahman, 1985). No particular organ appeared to selectively concentrate Cl tracer following ClO_2 exposure.

- Abdel-Rahman et al. (1980b, 1982, 1984a) administered 1.5 mg/kg (0.7 μCi) $^{36}ClO_2$ in 3 mL of a 100-mg/L solution of chloriteorally to male Wistar rats. About 4.5% of the administered radioactivity was recovered in the tissues. Each tissue contained less than 1% of the initial dose (0.16% to 0.81%), with the highest levels found in the kidney, followed by lung, plasma, stomach, ileum, liver, duodenum, spleen and bone marrow.

- Abdel-Rahman et al. (1982, 1984a) administered 0.15 mg/kg (0.17 μCi) $^{36}ClO_2^-$ in 3 mL of a 10-mg/L solution of ClO_2^- orally to male Sprague-Dawley rats. About 4.8% of the dosed radioactivity was recovered in the tissues. Each tissue contained less than 1% of the administered radioactivity (0.09% to 0.64%), with the highest levels found in the plasma, followed by stomach, testes, skin, lung, duodenum, kidney, carcass, spleen, ileum, bone marrow and liver.

- Abdel-Rahman et al. (1980b, 1982, 1984a) administered 0.065 mg/kg (0.85 μCi) $^{36}ClO_3^-$ in 3 mL of a 5-mg/L solution of ClO_3^- orally to male Sprague-Dawley rats. About 5% of the dosed radioactivity was recovered in the tissues. Each tissue contained less than 1% of the administered radioactivity (0.15% to 0.68%), with the highest levels found in the plasma, followed by stomach, lungs, testes, kidney, skin, duodenum, spleen, ileum, carcass, liver and bone marrow.

Metabolism

- ClO_2 is rapidly altered following ingestion (via oral gavage) by monkeys (Bercz et al., 1982). This was demonstrated by a combination of observing disappearance of both ClO_2 in salivary solution and residual oxidizing equivalents in stomach fluid.

- The majority of an orally administered dose of ClO_2 was reduced to Cl^- in rats (lesser amounts appeared as ClO_2^- and ClO_3^-) as shown by results from urinary assays (Abdel-Rahman et al., 1980a, 1980b).

- Urine assays indicated that ClO_2^- administered to rats was transformed primarily to Cl^- with lesser amounts appearing as unchanged ClO_2^- (Abdel-Rahman et al., 1984). Volatile Cl substances such as Cl_2 were not found to be metabolites in this experiment.

- ClO_3^- administered to rats appeared primarily in the form of Cl^- in the urine with lesser amounts appearing as ClO_3^- and ClO_2^- (Abdel-Rahman et al., 1984).

Excretion

- After 72 hours of orally dosing rats with radiolabeled ClO_2, 30% of the initial dose of the radiotracer was excreted in urine and 10% in feces. (Abdel-Rahman et al., 1982).

- Plasma radiolabeled ^{36}Cl, derived from radiolabeled ClO_2 orally administered to rats, had a clearance half-life of 44 hours (Abdel-Rahman et al., 1980a).

- Abdel-Rahman et al. (1980a, b, 1982) administered 1.5 mg/kg (0.7 μCi) $^{36}ClO_2$ in 3 mL of a 100-mg/L solution of ClO_2 orally to male Wistar rats. After 72 hours, 30.81% of the administered radioactivity had been excreted in the urine and 10.1% in the feces (Abdel-Rahman et al., 1982). Urinary ^{36}Cl excretion was the greatest at 24 and 48 hours after the administration of ClO_2. The following metabolites (expressed as percentage of initial dose) were found in the urine: Cl^- (26.93%), ClO_2 (3.46%) and ClO_3^- (0.73%). ^{36}Cl was not detected in expired air.

- Abdel-Rahman et al. (1982, 1984a) administered 0.15 mg/kg (0:17 μCi) $^{36}ClO_2^-$ in 3 mL of a 10-mg/L solution of ClO_2^- orally to male Sprague-Dawley rats. After 72 hours, 34.51% of the administered radioactivity had been excreted in the urine and 4.75% in the feces. The following metabolites (expressed as percentage of initial dose) were found in the urine: Cl^- (31.55%), ClO_2^- (6%). ClO_3^- was not detected in the urine nor ^{36}Cl in expired air.

- Abdel-Rahman et al. (1982, 1984a) administered 0.065 mg/kg (0.85 μCi) $^{36}ClO_3^-$ in 3 mL of a 5 mg/L solution of ClO_3^- orally to male Sprague-Dawley rats. After 72 hours of dosing, 40.14% of the administered radioactivity was excreted in the urine and 3.14% in the feces. The following metabolites (expressed as percentage of initial dose) were found in the urine: Cl^- (20.5%), ClO_2^- (3.95%) and ClO_3^- (8.2% to 13.2%). ^{36}Cl was not detected in expired air. ClO_3^- elimination from the body has an initial rapid phase ($T_{1/2}$ = 6 hours) during which substantial amounts of unchanged ClO_3^- are excreted in the rat urine. A second, slower phase ($T_{1/2}$ = 37 hours) corresponds to the elimination rates for Cl^- and ClO_2^- seen in studies specific to these substances.

IV. HEALTH EFFECTS

Humans

Short-term Exposure

Chlorine Dioxide

- In a Phase I rising dose tolerance investigation, Lubbers et al., (1981) administered six increasing doses of ClO_2 to each of 10 human male volunteers. Doses of 0.1, 1.0, 5.0, 10.0, 18.0 and 24.0 mg/L ClO_2 in one liter of drinking water were ingested with a 2-day observation period between doses. Serum chemistry, blood count and urinalysis parameters were monitored. A treatment-related change in group mean values of serum uric acid was observed. However, the authors concluded that no detrimental physiologic effect occurred. The highest dose tested, 24 mg/L (0.34 mg/kg/day for a 70-kg adult) can be identified as a single-dose no-observed-adverse-effect level (NOAEL).

Chlorite

- Lubbers et al. (1981) performed a Phase I rising dose tolerance investigation of ClO_2^- (as sodium chlorite) utilizing 10 human male volunteers. Single doses of 0.01, 0.1, 0.5, 1.0, 1.8 and 2.4 mg/L ClO_2^- in one liter of drinking water were ingested by each subject. Changes in group mean values for serum urea nitrogen, creatinine and urea nitrogen/creatine ration were observed. The authors concluded that no adverse physiologic effect occurred; therefore, the highest dose tested, 2.4 mg/L (0.034 mg/kg/day), can be identified as a single-dose NOAEL.

Chlorate

- Because of its use as a weed killer, a relatively large number of chlorate poisonings have occurred (NAS, 1987). Common effects that have been reported include methemoglobin (MetHb), cyanosis, anuria, abdominal pain and renal failure, while jaundice, hemoglobinuria, convulsions, anemia, monocytic erythrophage-cytosis, intravascular coagulation, elevated blood urea, methemalbumin, oliguria, renal tubular necrosis and erythrocyte abnormalities also have been observed (Bloxham et al., 1979; Helliwell and Nunn, 1979; Jackson et al., 1961; Lee et al., 1970; Motin et al., 1970; O'Grady and Jarecsni, 1971; Stavrou et al., 1978; Steffen and Seitz, 1981; Timperman and Maes, 1966; Vakili, 1977; Yoshida et al., 1977).

0.036 mg/kg/day of ClO_2 (for a 70-kg adult), can be considered a NOAEL.

Chlorite

- Lubbers et al. (1981) studied 10 human male volunteers who ingested 0.5 L/day of water containing 5 mg/L of ClO_2^- (2.5 mg/day of ClO_2^-) for 12 weeks followed by an 8 week observation period. Assuming that an adult male human weights 70 kg, this dose is equivalent to 0.036 mg/kg/day. Treatment with ClO_2^- was associated with a change in group mean corpuscular hemoglobin (MCH); however, since a trend in MCH change over time was not demonstrated, the authors were reluctant to attach physiological significance to the observation. Three glucose-6-phosphate dehydrogenese-deficient subjects were also administered the above treatment. Although the small number of subjects limited statistical reliability, the data suggest changes with time in serum albumin/globulin ratios, MetHb, serum thyroxine (T_4) and mean corpuscular hemoglobin concentration as a result of the ClO_2^- exposure. The frequent blood monitoring in these studies allowed the authors to conclude that no adverse physiological effects were seen in these studies and thus a NOAEL of 0.036 mg/kg/day was identified.

Chlorate

- Ten human male volunteers ingested 2.5 mg/day of ClO_3^- (0.036 mg/kg/day) for 12 weeks in a Phase II clinical evaluation (Lubbers et al., 1982). Treatment was associated with a change in group mean serum urea nitrogen and mean corpuscular hemoglobin. The authors did not associated physiological significance with these observations. The exposure of 0.036 mg/kg/day was considered a NOAEL for 12 weeks of exposure in humans.

Animals

Short-term Exposure

Chlorine Dioxide

- No lethality data regarding the oral ingestion of chlorine dioxide were located. However, Haller and Northgraves (1995) exposed six guinea pigs to chlorine dioxide by inhalation for various brief periods of time. Animals exposed to 150 ppm (420 mg/m^3) for 5 or 15 minutes survived, but a 44 minute exposure to the same level was lethal.

Based on standard equivalency factors (U.S. EPA, 1986) for the guinea pig (body weight = 0.84 kg, inhalation rate = 0.4 m^3/day), these doses approximate 0.7, 2.1 and 6.1 mg/kg at a rate of 0.139 mg/kg/minute. Higher dose levels were reported to be more rapidly lethal, although one animal developed a resistance to higher doses if preconditioned by gradually increasing lower doses.

- Moore and Calabrese (1980, 1981) investigated the effect of ClO_2 on a number of hematologic parameters in A/J and C57L/J mice. Animals (sexes not reported) were supplied with water containing ClO_2 at a concentration of 100 mg/L for a period of 30 days. Assuming a water consumption rate of 190 mL/kg/day (U.S. EPA, 1986a), this corresponds to a dose of approximately 19 mg ClO_2/kg/day. Glucose-6-phosphate dehydrogenase (G6PD) activity, red blood cells, hematocrit, white blood cells, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, reticulocyte levels and osmotic fragility were measured. No significant effects of ClO_2 exposure on any parameter were detected. There were no differences in either strain's response to ClO_2, even though levels of G6PD activity were lower in C57L/J mice (a deficiency of glucose-6-phosphate dehydrogenase is known to increase the hemolytic susceptibility of humans to oxidizing agents). This study identified a NOAEL of 19 mg ClO_2/kg/day, the only dose tested.

- In a rising dose protocol study, Bercz et al. (1982) exposed 12 African Green monkeys to water containing ClO_2 at concentrations of 0, 30, 100 or 200 mg/L, corresponding to measured doses of 0, 3.5, 9.5 and 11 mg/kg/day. Each dose was maintained for 30 to 60 days. The high dose study was terminated after one week due to low water consumption (poor palatability) and dehydration of the animals, which also displayed erythema and ulceration of the oral mucosa. A slight suppression of thyroid function (decreased serum levels of thyroxine, or T_4) was observed in monkeys receiving the 9.5 mg/kg/day dose. No other hematological or clinical chemistry effects were noted. No effects were seen at the 3.5 mg/kg/day dose level, which is thus considered a NOAEL. This study was limited because exposed monkeys served as their own controls and had been used for previous experiments.

- Harrington et al. (1986) treated six female monkeys for 8 weeks with drinking water containing 100 mg/L of ClO_2. This corresponded to an average measured dose of about 4.6 mg/kg/day. A suppression of thyroid function (decreased serum T_4 levels) was observed after

4 weeks of treatment, but circulating T_4 levels rebounded to above normal after 8 weeks of treatment.

- Harrington et al. (1986) also administered drinking water containing 0, 100 and 200 mg/L to ClO_2 to male rats (12 animals/dose). Assuming that a rat drinks 140 mL water/kg/day (U.S. EPA, 1994), the exposures are equivalent to 0, 14 and 28 mg/kg/day. A dose-dependent suppression of thyroid function (decreased T_4 levels) was observed after 8 weeks of treatment and no rebound of T_4 levels was observed. The exposure level of 100 mg/L, equivalent to a dose of approximately 14 mg/kg/day, is considered a lowest-observed-adverse-effect level (LOAEL) in rats.

Chlorite

- Single dose studies in rats demonstrated an LD_{50} of 105 mg/kg (Musil-et al., 1964) or 136 mg/kg (Sperling, 1959) for ClO_2^- administered as the sodium salt.

- Quail were more resistant than rats to the toxic effects of ClO_2^- with an LD_{50} of 493 mg/kg in quail (Fletcher, 1973).

- Heffernan et al. (1979) investigated the ability of ClO_2^- to produce methemoglobinemia in cats. Single oral doses of 20 mg ClO_2^-/kg, administered to three cats as compressed milk-sugar tablets, produced methemoglobin concentrations of 10% to 30% in one to two hours, and a single oral dose of 64 mg ClO_2^-/kg administered to one cat produced over 40% methemoglobinemia in less than one hour. Methemoglobin levels declined to 50% of peak values after an additional three to four hours. This study identified a LOAEL of 20 mg ClO_2^-/kg/day, the lowest dose tested using multiple cats.

- Moore and Calabrese (1980) exposed A/J and C57L/J mice (11 to 23 animals of each species per dose) to 0, 1, 10 or 100 mg/L of $NaClO_2$ in drinking water for 30 days. Assuming water consumption of about 0.19 L/kg/day (U.S. EPA, 1986a), these correspond to doses of approximately 0, 0.14, 1.4 or 14 mg ClO_2^-/kg/day. Of 11 hematological parameters studied, statistically significant ($P<0.05$) increased in both strains were observed at the highest dose (100 mg/L) for mean corpuscular volume, osmotic fragility and G6PD activity. Lower doses (1 or 10 mg/L) were without apparent effect. This study identified a NOAEL of 10 mg ClO_2^-/L (1.4 mg/kg/day) and a LOAEL 100 mg ClO_2^-/L (14 mg/kg/day).

- Bercz et al. (1982) exposed African Green Monkeys to chlorite in drinking water using an exponential rising-dose protocol which each animal served as its own control. Sequential exposure concentrations were 25, 50, 100, 200 and 400 mg/L, with each exposure period lasting 30 to 60 days. Because of the unusual protocol, the incompleteness of weight and water consumption data, and the possibility that water consumption may have significantly declined at higher exposure levels, these concentrations cannot confidently be converted to average daily dosages (mg/kg/day). However, the authors reported that decreases in serum T_4 levels were not observed, even at doses up to approximately 60/mg/day. Although dose-dependent anemia and methemoglobinemia were reported, neither a NOAEL or a LOAEL can be established because of the protocol and reporting limitations described above.

- In experiments with adult male mixed-breed cats, Heffernan et al. (1979) reported that exposure to drinking water containing 500 mg of ClO_2^-/L (7 mg/kg/day, authors' determination) produced a 20% to 30% decrease in packed cell volume and hemoglobin concentrations within two weeks. Increasing the concentration of ClO_2^- in the drinking water to 1,000 mg/L exacerbated this effect, but no significant elevation in methemoglobin levels was observed (data not reported). Both packed cell volume and hemoglobin concentration returned to near normal three weeks after exposure ceased. Measurement of the half-life of ^{51}Cr-labeled erythrocytes in cats (four per dose level) treated with 10, 100, 250 or 500 mg $NaClO_2$/L of drinking water (0.6, 3, 6 or 7 mg/kg/day as determined by the authors; a reflection of reduced water consumption at elevated doses) revealed a dose-related increase in the turnover of red blood cells, which was statistically significant ($P<0.02$) at levels of 100 mg/L (3 mg/kg/day) or above. The red blood cell half-life was reduced to 6.02 to 6.72 days for the 3 to 7 mg/kg/day groups, compared to 8.53 days for the control group. The authors concluded from this study that the primary effect of ClO_2^- was destruction of red blood cells rather than oxidation of hemoglobin. A NOEL of 0.6 mg/kg/day and a LOEL of 3 mg/kg/day were determined on the basis of red blood cell survival.

Sodium Chlorate

- An acute oral dosing study in dogs demonstrated lethality at levels of $NaClO_3$ as low as 600 mg/kg ClO_3^- (Sheahan et al. 1971).

- Heywood et al. (1972) reported that doses of 200 to 326 mg/kg/day of $NaClO_3$ (157 to 256 mg ClO_3^-/kg/day) administered repeatedly by

stomach tube (as 50 mL of 6% solution) to eight dogs over a five-day period decreased packed cell volume, hemoglobin and red blood cells. A consistent increase in plasma urea concentration was also observed, suggesting some compromise of renal function. Two animals that received 308 or 326 mg/kg $NaClO_3$ displayed loss of appetite and body weight and had blood in their urine or feces. One died after four days of exposure. Five of eight animals displayed tissue pathology indicative of hemolysis such as Kupffer cells containing brown pigment, and hematological values relating to the red blood cells were reduced in all animals. The highest methemoglobin level was seen in the animal which died, but methemoglobinemia was not correlated with changes in the other monitored hematological parameters. This study identified doses of 157 mg ClO_3^-/kg/day or higher as a effect level, but did not clearly identify either a NOAEL or LOAEL.

- Bercz et al. (1982) exposed African Green Monkeys to chlorate in drinking water using an exponential rising-dose protocol which each animal served as its own control. Sequential exposure concentrations were 25, 50, 100, 200 and 400 mg/L, with each exposure period lasting 30 to 60 days. Because of the unusual protocol, the incompleteness of weight and water consumption data, and the possibility that water consumption may have significantly declined at higher exposure levels, these concentrations cannot confidently be converted to average daily dosages (mg/kg/day). However, the authors reported that decreases in serum T_4 levels were not observed, even at doses up to approximately 60/mg/day. Although slight dose-dependent anemia and methemoglobinemia were reported, they were not considered significant by the authors. Neither a NOAEL or a LOAEL can be established because of the protocol and reporting limitations described above.

Dermal/Ocular Effects

- ClO_2 gas is known to be irritating to the eyes and mucous membranes (Windholz, 1976).

- Ophthalmoscopic examinations were conducted as part of a 3-month study in beagle dogs administered $NaClO_3$ (Bio/dynamics, Inc., 1987a). Dogs were orally doses with 0, 10, 60 or 360 mg/kg/day of ClO_3^-. No treatment-related ophthalmoscopic effects were observed.

- No information was found in the available literature regarding the dermal/ocular effects of either sodium chlorite or sodium chlorate.

Long-term Exposure

Chlorine Dioxide

- Groups of Sprague-Dawley rats (10/sex) were administered chlorine dioxide in drinking water for 90 days at concentrations of 0, 25, 50, 100 or 200 mg/L (Daniel et al. 1990). As indicated by the authors, these concentrations correspond to doses of 0, 2, 4, 6 or 12 mg/kg/day ClO_2 for males, and 0, 2, 5, 8 or 15 mg/kg/day for females. Following exposure, clinical signs, survival, body weight and food and water consumption were monitored. Hematological and clinical chemistry parameters were evaluated, and gross and histopathological examination were performed. Hematological parameters were comparable to controls throughout the duration of the study. A significant increase in the incidence of nasal lesions (goblet cell hyperplasia and inflammation of nasal turbinates) was found at all ClO_2 dose levels. However, these lesions may well have been the result of direct contact with chlorine dioxide solution, rather than ingestion of drinking water containing chlorine dioxide. Furthermore, the toxicological significance of these findings is uncertain, as they have not been reported in other reviewed studies and may possibly be a dosing artifact.

- Revis et al. (1986) exposed male Carneau pigeons on calcium-deficient diets to drinking water containing 0, 2 or 15 ppm ClO_2 (0, 0.07 or 0.5 mg/kg/day based on an assumed water consumption of 25 mg/day and a body weight of 0.75 kg) for 3 months. Birds were subdivided into groups that contained normal-fat or fat-supplemented diets (containing 10% lard and 0.5% cholesterol). Studies on birds fed a normal diet were not performed. After 90 days, high-dose ClO_2 pigeons fed normal-fat or high-fat diet supplements displayed some evidence of enhanced serum cholesterol, low density lipoprotein cholesterol and aortic plaque size, and depressed thyroid activity. A LOAEL of 2 ppm is suggested by the data. However, the data lacked consistency, dose-responsiveness, and adequate dietary controls, which compromises establishing reliable NOAEL/LOAEL levels for purposes of extrapolation to humans.

- Haag (1949) administered ClO_2 in drinking water to rats at concentrations of 0, 0.5, 1, 5, 10 and 100 ppm for 2 years. The study indicated that administration of ClO_2 in drinking water at concentrations of 100 mg/L for 2 years resulted in substantially decreased survival of both male and female albino rats. Combining data for both sexes (7/sex/dose), mean life span was reduced from

approximately 85 weeks in control animals to about 58 weeks in animals supplied water containing 100 mg ClO_2/L. This concentration equates to a time-weighted average dose of 12.5 mg/kg/day based on body weight and water consumption data. The survival of animals consuming water containing 10 mg ClO_2/L (1.3 mg/kg/day) or below was not significantly affected. Histopathologic studies were also performed on representative animals from each dose group, but no correlation was observed between treatment and any pathological finding. This study identifies a NOAEL of 1.3 mg/kg/day and a LOAEL (based on decreased survival) of 13 mg/kg/day.

- The role of ClO_2 in the production of methemoglobinemia and hemolytic anemia was investigated by Abdel-Rehman et al. (1980a), Couri and Abdel-Rahman (1980) and Abdel-Rahman et al. (1984c). Male Swiss-Webster mice and/or Sprague-Dawley rats were supplied with drinking water containing 1, 10, 100 or 1,000 mg ClO_2/L for up to one year. Assuming water consumption of 0.14 L/kg/day by the rats and 0.19 L/kg/day by the mice (U.S. EPA, 1986a), the first three concentrations provided doses of approximately 0.14, 1.4 or 14 mg ClO_2/kg/day for rats and 0.19, 1.9 or 19 mg ClO_2/kg/day for mice. The highest concentration (1,000 mg/L) may produce a substantial decrease in water consumption, and thus a dependable estimate of the dose by unit body weight is not possible. A number of hematological parameters were measured at 2, 4, 6, 7, 9 or 12 months of exposure, including red blood cell counts, osmotic fragility, hematocrit, and levels of the following: hemoglobin, glutathione reductase, glutathione peroxidase, catalase, glutathione and methemoglobin. For most parameters, some differences relative to controls were observed. However, there was not consistent relationship with dose, and effects were not observed consistently throughout the period of exposure. Although the authors identified some of these changes as being statistically significant based on multiple T-test analyses, at least 5% of all measurements in a large multi-variable data set of this sort will appear to be statistically different from controls, even in the absence of a treatment-related effect. The most consistent finding with ClO_2 treatment was an increase in catalase activity, which occurred at 1,000 mg/L in both species, and at 10 and 100 mg/L in mice. A dose-dependent increase in resistance of red blood cells to hemolysis in hypotonic media as also observed in rats at levels of 10 to 100 mg of ClO_2/L at nine months, with a somewhat smaller response observed at 1,000 mg/L. These studies are not considered suitable for derivation of a reliable NOAEL or LOAEL because the reported effects are of uncertain biological and statistical significance.

Chlorite

- Revis et al. (1986) exposed male Carneau pigeons to 0, 2 or 15 ppm (0, 0.07 or 0.5 mg/kg/day based on an assumed water consumption of 25 mg/day and a body weight of 0.75 kg) ClO_2^- in drinking water for 3 months. The birds were maintained on low-calcium diets with half of the birds being maintained on an atherogenic diet (see discussion under chlorine dioxide). Studies on birds fed a normal diet were not performed. After 90 days, monitoring for thyroid hormones (triiodothyronine [T_3] and thyroxine [T_4]), aortic plaques, blood cholesterol and lipoproteins was performed. The authors reported enhanced serum cholesterol and low density lipoproteins as well as increased aortic plaque size in the high dose group, but not in the low dose group. Because few statistically significant changes and no clear dose-response patterns were observed, this study suggests a NOAEL of 15 ppm (0.5 mg/kg/day) for pigeons that is of uncertain value for extrapolation to humans. This lack of effect on aortic plaque size was also demonstrated in a similar study by Penn et al. (1990), wherein pigeons were exposed to chlorinated water.

- In a series of studies, Heffernan et al. (1979) exposed rats to 0, 10, 50, 100, 250, 500 mg/L of ClO_2^- in drinking water (equivalent to 0, 1, 5, 10, 25 or 50 mg/kg/day) for 30 to 90 days. Hematological parameters were monitored, and the three highest concentrations, 100, 250 and 500 mg/L ClO_2^-, produced transient anemia. At 90 days, RBC glutathione levels were 40% below controls in the 100 mg/L group (10 mg/kg/day) with at least a 20% reduction in the 50 mg/L (5 mg/kg/day) rats. This effect was evident after only 30 days, with corresponding reductions of 31% and 15%. The study identifies a NOAEL of 1 mg/kg and a LOAEL of 5 mg/kg/day based on reduced RBC glutathione levels.

- Ridgway (1992) exposed rats (15/sex/group) to 10, 25 or 80 mg/kg/day $NaClO_2$ (8, 19 or 60 mg ClO_2^-/kg/day) by oral gavage for 13 weeks. No ocular effects or changes in body weight gain or food consumption were noted. Salivation either immediately before dosing or at dosing was observed from the third week of exposure in all high-dose animals and periodically in two mid-dose males. Hypoactivity and pale extremities were observed in the high-dose animals. Treatment-related mortality was seen in three males (attributed to anemia for 2 males) and one female at the high dose after 10 weeks of exposure. Significant hematological changes that were evident in males and/or females in the high-dose groups included decreased RBC count (83 to 92% of control), hemoglobin (81 to 89%

of control) and packed cell volume (90% of control), and increased mean cell volume (MCV) and mean cell hemoglobin (MCH) 107 to 109% of control. Morphological changes were evident in RBCs at 60 mg/kg/day, and increased neutrophil and decreased lymphocyte counts were reported in males at the 19 and 60 mg/kg/day doses. Red blood cell glutathione levels were not measured in the study. The hematological effects reported at these levels appeared to be negligible and compensatory mechanisms probably existed. Relative spleen weights were elevated significantly in mid- and high-dose females and high-dose males. Relative adrenal weights were also significantly increased in high-dose animals and mid-dose females, whereas, absolute adrenal weights were significantly elevated only in females (all dose levels). Squamous epithelial hyperplasia with hyperkeratosis, ulceration, chronic inflammation and edema were observed in the nonglandular stomach of several high-dose animals. Minimal hyperkeratosis and ulceration with moderate chronic inflammation were observed in the stomach of two 19-(mg/kg)/day males. Therefore, a chlorite NOAEL of 8 mg/kg/day and a LOAEL of 19 mg/kg/day were determined, based primarily on increased spleen and adrenal weights (in females) and histopathological changes in the gastric mucosa.

- Haag (1949) examined the effects of $NaClO_2$ (0, 1, 2, 4, 8, 100 or 1,000 mg/L) in the drinking water of albino rats (7 animals/sex/group) on survival and postmortem pathology in a 2 year study. There was no clear indication that any concentration of $NaClO_2$ up to 1,000 mg/L significantly affected the lifespan of the animals. No effects were observed in animals exposed to 8 mg/L (0.7 mg/kg/day, based on measured consumption) or less. Animals exposed to 100 or 1,000 mg/L (9.3 or 81 mg ClO_2^-/kg/day) exhibited treatment-related renal pathology, characterized by distention of the glomerular capsule and appearance in the renal tubules of a pale pinkish staining material. These effects were also observed in a group of animals that had been administered sodium chlorite at a concentration equimolar to 1,000 mg $NaClO_2$/L. The author concluded the renal pathology was a nonspecific salt effect. The NOAEL for this study is 0.7 mg/kg/day.

- Couri and Abdel-Rahman (1980) and Abdel-Rahman et al. (1984b) reported that exposure of rats to water containing ClO_2^- at concentrations of 100 mg/L (14 mg/kg/day based on water consumption of 0.14 L/kg/day [U.S. EPA,1986a) for 6 to 12 months decreased red blood cell glutathione concentrations substantially. These authors also observed a somewhat smaller decrease in the levels of glutathione at 10 mg ClO_2^-/L (1.4 mg/kg/day) at six months,

but not at 12 months of treatment. Abdel-Rahman et al. (1984b) also examined the effects of $NaClO_2$ in drinking water (10 or 100 mg $NaClO_2$/L) on red blood cells, but found no clear effect. Significant decreases in the osmotic fragility of erythrocytes taken from rats subjected to 100 mg $NaClO_2$/L (14 mg/kg/day) were observed after two, seven and nine months of treatment (effect was not significant at four months), and in animals exposed to 10 mg $NaClO_2$/L (1.4 mg/kg/day) after seven and nine months. As discussed earlier, neither the statistical nor the biological significance of these observations was clear.

Chlorate

- Bio/dynamics, Inc. (1987a) exposed beagle dogs (4/sex/dose) by gavage to ClO_3^- at doses of 0, 7.8, 47 or 282 mg/kg/day for 3 months. These was no significant effect at any dose level on body weight, food consumption, clinical chemistry, organ weights, gross necropsy or tissue histopathology. Hematological changes were limited to a slight elevation in methemoglobin levels in high dose animals, but this appeared to be within normal limits and was not judged to be treatment-related. This study identifies a NOAEL of 282 mg/kg/day in dogs.

- Bio/dynamics, Inc. (1987b) exposed Sprague-Dawley rats (14/sex/dose) by gavage to doses of 0, 7.8, 78 or 784 mg/kg/day of ClO_3^- for up to 3 months. No treatment-related effects were observed for mortality, physical appearance or behavior, body weight, food consumption, clinical chemistry, gross necropsy or organ histopathology. At the high dose, hematological changes indicative of anemia included decreases in erythrocyte count, hemoglobin concentration and percent hematocrit. This study identifies a NOAEL of 78 mg/kg/day and a LOAEL of 784 mg/kg/day in rats.

- Abdel-Rahman et al. (1980a) exposed male Sprague-Dawley rats to drinking water containing 10 or 100 mg/L (1.4 or 14 mg/kg/day based on a water consumption rate of 0.19 L/kg/day [U.S. EPA ,1986a) of ClO_3^- for 4 months and reported decreases in the glutathione content of red blood cells (observed at two months, but not at four months of exposure), an apparent increased resistance of the erythrocytes to hemolysis in hypotonic solution at the high dose group and some distortions of the erythrocyte membrane. Similar inconsistent results were reported by Couri and Abdel-Rahman (1980) in rats exposed to these same concentrations of $NaClO_3$ for 6 to 12 months. Abdel-Rahman et al. (1984b) reported that the apparent decrease in osmotic

fragility of the red cells became progressively more marked as ClO_3^- exposure was extended beyond a few months. After nine months of exposure to ClO_3^- concentrations of 10 mg/L (1.4 mg/kg/day), hemoglobin concentrations, hematocrit and red blood cell counts were statistically lower than controls, and these effects were more pronounced at 100 mg/L (14 mg/kg/day). This study suggested that the LOAEL for ClO_3^- was probably between 1 and 10 mg/kg/day, but the data were not adequate to form a firm conclusion.

Reproductive Effects

Chlorine Dioxide

- Female rats were exposed to 0, 1, 10 or 100 ppm ClO_2 in drinking water (equivalent to 0, 0.1, 1.0 or 10 mg/kg/day based upon a EPA consumption rates [1986a]) for 2.5 months before mating and throughout gestation (Suh et al., 1983). At the highest dose (10 mg/kg/day), there was a slight inhibition in the number of implants and live births per pregnancy. No effects were observed at 1.0 mg/kg/day, which is identified as the NOAEL. The LOAEL was thus 10 mg/kg/day.

- Carlton et al. (1991) dosed male and female Long-Evans rats by oral gavage with 0, 2.5, 5.0 or 10 mg/kg/day of ClO_2 in deionized water. Males were doses for 56 days prior to mating. Females were dosed for 14 days prior to mating, during the 10-day mating period, and throughout gestation and lactation (73 days total). Sperm concentration, motility, velocity and morphology were determined in males; fertility rate and gestation time were determined in females. Reproductive organ weights were determined in both sexes. No toxicity or adverse effects on reproductive parameters were observed in parental animals. Litter size, pup viability, pup weight and weight gain were not affected. Vaginal weight was decreased in weanlings of high-dose dams. T_4 levels were significantly decreased in adult males exposed to 10 mg/kg/day, while they were significantly increased in male pups exposed to 10 mg/kg/day on postnatal day 17. However, these thyroid hormone changes were not dose-related, and no alterations were seen in T_3 levels in male adults or pups. A NOAEL of 10 mg/kg/day (highest dose tested) was identified; however, a LOAEL was not achieved.

- Meier et al. (1985) studied the ability of ClO_2 to induce spermhead abnormalities in male B6C3F1 mice. Animals were dosed by gavage

with 3.2, 8 or 16 mg ClO_2/kg/day for five days. Mice were examined for spermhead abnormalities at one, three and five weeks after the last dose so that effects on all stages of spermatogenesis could be examined. No effects of ClO_2 treatment on spermhead abnormalities was observed at any dose tested. This study identified a NOAEL of 16 mg ClO_2/kg/day, but did not identify a LOAEL.

- The effect of chlorine dioxide on DNA synthesis in the testicular tissue of male Sprague-Dawley rats was investigated after 3 weeks (Suh et al., 1984) or 3 months (Abdel-Rahman et al., 1984b) of exposure in drinking water to 0, 10 or 100 mg/L. Based on EPA consumption rates (U.S. EPA,1986a), these approximate doses of 0, 1.0 or 10 mg/kg/day. Based on reduced incorporation of ^{3}H-thymidine into testicular DNA, these studies indicated a NOAEL and a LOAEL of 1.0 and 10 mg/kg/day, respectively, after a 3-week exposure to chlorine dioxide, and LOAEL of 1.0 mg/kg/day when exposure was extended to 3 months. The biological consequences of this effect, however, are not clear.

Chlorite

- Moore and Calabrese (1982) treated female A/J mice (10/group) with distilled water or 100 ppm $NaClO_2$ in drinking water (equivalent 10 mg ClO_2^-/kg/day, based on assumed water consumption of 100 mL/kg/day) from day 1 of gestation through lactation. Conception rates were reduced 17% compared to controls. The body weights of pups at weaning were reduced in treated mice relative to controls, demonstrating that 10 mg/ ClO_2^-/kg/day is the LOAEL for this study.

- Carlton and Smith (1987, 1985) conducted three experiments in which Long-Evans rats (12 males or 24 females/dose/experiment) were exposed to drinking water sodium chlorite concentrations of 0, 1, 10, 100 or 500 ppm (equivalent to 0, 0.075, 0.75, 7.5, or 27 10 mg ClO_2^-/kg/day based on EPA consumption rates [U.S. EPA, 1986a]) and a 28% decrease in water consumption at the 500 ppm concentration that was reported by the authors). Experiment-one males were exposed to 0, 1, 10, 100 ppm sodium chlorite for 56 days prior to breeding, plus 10 days during breeding. Experiment-two males were exposed for 72 to 76 days to 0,10, 500 ppm sodium chlorite, while subsequent experiment-three males were exposed to 0, 10, 100 ppm sodium chlorite. In experiment one, females were exposed to 0, 1, 10, 100 ppm sodium chlorite for 14 days prior to breeding, 10 days during breeding, and throughout gestation and

lactation until pups were weaned on post-parturition day 21. Collectively, these experiments indicated abnormal sperm morphologies, as well as reduced sperm direct progressive movement and velocity, at the 100 and 500 ppm doses. Based on these abnormal sperm parameters, a NOAEL and a LOAEL of 0.75 (10ppm dose) and 7.5 (100 ppm) mg/kg/day, respectively, were established. Although conception rates, lengths of gestation, maternal body weight gains, histological appearance of reproductive tracts and litter sizes were not affected by chlorite exposure, a fertility rate that was only 67% of the control value was observed in female rats exposed to the low dose but not at the high dose precluded establishing a reliable NOAEL for female reproductive parameters. Thyroid hormone levels were measured on postnatal days 17, 21 and 40 in rat pups exposed to 0 or 7.5 mg/kg/d. A NOAEL of 0.75 mg/kg/d and a LOAEL of 7.5 mg/kg/d was determined based on decreased T3 and T4 levels in rat pups.

- The effect of chlorite on DNA synthesis in the testicular tissue (as well as kidneys and small intestines) of male Sprague-Dawley rats was investigated after 3 weeks (Suh et al., 1984) or 3 months (Abdel-Rahman et al., 1984b) of exposure in drinking water to 0, 10 or 100 mg/L (equivalent to 0, 1 or 10 mg/ClO_2^-/kg/day using EPA consumption rates). Based on reduced incorporation of ^{3}H-thymidine into testicular and liver DNA in the high dose group, these studies indicated a NOAEL and a LOAEL of 1.0 and 10 mg/kg/day, respectively, after a 3-week exposure to chlorine dioxide, and LOAEL of 1.0 mg/kg/day when exposure was extended to 3 months. The biological consequences of this effect, however, are not clear.

- Couri et al (1982) reported that very high levels of ClO_2^- administered in drinking water (20,000 ppm, equivalent to 159 mg/kg/d) to pregnant rats resulted in fetal resorptions, sometimes of entire litters. Resorptions were not observed when dose was reduced to 5,000 ppm (122 mg/kg/d). The authors point out this effect may have been due to anoxia induced by the hemolytic effects of chlorite. This study did not identify a NOAEL or useful LOAEL value.

- Meier et al. (1985) administered $NaClO_2$ by gavage to male B6C3F1 mice at doses of 8, 20 or 40 mg ClO_2^-/kg (10/dose group) for five consecutive days. Sperm were taken at one, three and five weeks after the last treatment for evaluation. There were no increased incidences of spermhead abnormalities at any time period or at any dose. This study identified a NOAEL of 40 mg ClO_2^-/kg/day, but did not identify a LOAEL.

(3 mg/kg/day), which was considered a NOAEL. The corresponding LOAEL was 14 mg/kg/day.

- In a second experiment, rat pups were exposed directly (by gavage) to 14 mg ClO_2/kg (equivalent to the dose received by a pregnant dam drinking water containing 100 mg ClO_2/L) on days 5 to 20 of postnatal age (Orme et al., 1985). In this case, a larger depression of serum T_4 levels was observed, and a somewhat greater and more consistent delay in the development of exploratory and locomotor activity resulted at days 18 and 19 postpartum ($p < 0.05$). Pup body weight gain was also reduced ($p < 0.05$). Serum T_3 levels increased slightly, but this was not statistically significant. Based on decreased pup development and decreased thyroid hormone levels, this study identifies a NOAEL of 3 mg/kg/day and a LOAEL of 14 mg/kg/day.

- Taylor and Pfohl (1985) found that cell number (measured by total DNA content) was significantly depressed at 21 days of age in the cerebellum of rat pups (N = 12) born to dams supplied from two weeks prior to mating through lactation with water containing 100 mg ClO_2/L (about 14 mg/kg/day to the dam). Rat pups which were dosed directly by gavage with 14 mg/kg/day had depressed cell numbers in both the cerebellum and forebrain at 11 days of postnatal age, and displayed decreased voluntary running-wheel activity at 50 to 60 days of postnatal age (despite the fact the ClO_2 treatments were terminated at 20 days of age). These data suggest that ClO_2 is capable of influencing brain development in neonatal rats, and this study identifies a LOAEL of 14 mg/kg/day. No other doses were tested in this study.

- Toth et al. (1990) evaluated the developmental neurotoxic potential of chlorine dioxide (14 mg/kg/day) administered directly to Long-Evans rat pups by oral intubation during postnatal days 1 to 20. One male and one female pup per litter were sacrificed on postnatal days 11, 21 and 35. Body weights were 3 to 5% lower than the control values at each time. Relative weights of the cerebellum, forebrain and olfactory bulbs in treated rats were significantly increased on day 35. Forebrain cell proliferation was decreased on postnatal day 35, and there were decreased in forebrain weight and protein content on postnatal days 21 and 35. Cell proliferation in the cerebellum and olfactory bulbs was generally comparable to untreated controls, as were migration and aggregation of neuronal cells in the cerebral cortex. Histopathological examinations of the forebrain, cerebellum and brain stem did not reveal any gross lesions (although there was a decrease in dendritic spines in the Krieg's area 18 of the brain). Also, there

were no significant changes in the serum levels of the thyroid hormones T_4 and T_3. This study identified a LOAEL for chlorine dioxide of 14 mg/kg/day (the only dose tested).

- Mobley et al. (1990) exposed female Sprague-Dawley rats (12/group) to drinking water containing 0 or 100 ppm chlorine dioxide from 10 days prior to breeding with untreated males until the pups were sacrificed at 35 to 42 days post-conception (total exposure of 9 weeks). Based upon an assumed water consumption rate of 0.14 L/kg/day (U.S. EPA, 1986), doses were approximately 0 or 14 mg/kg/day. However, the concentration of chlorine dioxide in water bottles reportedly deteriorated about 8% over the 24-hour period between changes in fresh solutions. At birth, the total weight of treated litters was significantly less ($P \leq 0.05$) than controls. Exploratory activity was depressed in the treated pups ($P \leq 0.05$) during the 36 to 39 day, but not the 39 to 41 day, post-conception interval. No significant changes in serum total T_3 or T_4 levels were observed, however, mean T_3 uptake values were significantly depressed ($P \pm 0.05$) at 37 and 38 days post-conception. A LOAEL of 14 mg/kg/day was determined for this study based on depressed exploratory behavior in rat pups.

Chlorite

- Moore and Calabrese (1982) found that treatment of maternal mice with 100 ppm ClO_2^- in drinking water (22 mg/kg/day, based on authors' data) through gestation and lactation resulted in pups with decreased body weights (14% below controls) and growth rates at weaning. This study identifies a LOAEL for development effects of 22 mg ClO_2^-/kg/day the only dose tested.

- Suh et al. (1983) examined fetuses from maternal rats exposed to ClO_2^- via drinking water at levels of 0, 1 or 10 mg/L (approximately 0, 0.10 or 1.0 mg/kg/day). No statistically significant, compound-related skeletal or soft tissue anomalies were observed. A NOAEL of 1.0 mg/kg/day was thus established.

- Mobley et al. (1990) exposed female rats (12/group) for 9 weeks to drinking water containing 0, 20 and 40 ppm chlorite (as sodium chlorite) (0, 3 and 8 mg ClO_2^-/kg/day), beginning 10 days prior to breeding with untreated males until the pups were sacrificed at 35 to 42 days post-conception. Exploratory activity was depressed ($P \leq 0.05$) in pups from the 3 mg/kg/day group on 36 and 37 days post-conception, but not on days 38 to 40 post-conception, and in pups

from the 6 mg/kg/day dose group at 36 through 39 days post-conception. Exploratory activity was comparable among treated and control groups on days 39 to 41 post-conception. No significant differences in serum total triiodothyronine (T_3) or thyroxine (T_4) were seen between control and treated pups. A significant increase ($P \leq 0.05$) in free T_4 occurred in the 6 mg/kg/day pups when compared with controls. A developmental LOAEL of 3 mg ClO_2^-/kg/day was identified for this study based on the neurobehavioral effect (depressed exploratory behavior) in rat pups.

- Groups of female New Zealand white rabbits (16 to 17/dose) were administered sodium chlorite in the drinking water continuously at concentrations of 0, 200, 600 and 1,200 ppm (daily mean intake of 0, 10, 26 and 39 mg ClO_2^-/kg/day) from gestation days 7 to 20 (Irvine 1990). Maternal clinical signs and body weights along with food and water consumption were monitored. Gross necropsy was performed and mean numbers of corpora lutea, implantations and live fetuses were also evaluated. Fetal weights were determined. External, visceral and skeletal examinations were performed. This study identified a NOEL of 10 mg ClO_2^-/kg/day and a LOEL of 26 mg ClO_2^-/kg/day for maternal (decreased fecal output, food consumption and water intake) and developmental (decreased fetal weight and skeletal retardation [delayed ossification]) toxicity.

Chlorate

- Bio/dynamics, Inc. (1987c) administered $NaClO_3$ to pregnant CD rats by gavage at doses of 0, 10, 100 or 1,000 mg/kg/day (equivalent ot 0, 7.8, 78 or 784 mg ClO_3^-/kg/d) on days 6 to 15 of gestation. There were no maternal deaths in treated animals, and no treatment-related effects were evident in maternal body weight gain, food consumption, physical observations, number of implantations or gross necropsy. Examination of fetuses on day 20 revealed no effects on fetal weight or sex ratio, and no treatment-related effects on external, visceral or skeletal abnormalities were detected. This study identifies a developmental NOAEL of 1,000 mg/kg/day (equivalent to 784 mg ClO_3^-/kg/d) in rats.

- Suh et al. (1983) supplied groups of eight or nine female Sprague-Dawley pregnant rats with water containing 1 or 10 mg ClO_3^-/L for 10 weeks prior to breeding, during breeding and throughout gestation. On day 20, animals were sacrificed and fetuses were examined. The reported incidence of skeletal abnormalities (incomplete or bipartite

sternebrae, missing sternebrae, extra or rudimentary ribs, extra vertebrae or incomplete ossification) was 31% in the control group, 52% in the 1 mg/L (0.10 mg ClO_3^-/kg/day) group and 55% in the 10 mg/L (1.0 mg/kg/day) group. Because of the limited numbers of animals used, these differences were not statistically significant. One animal at 10 mg ClO_3^-/L was found to have a soft tissue anomaly (hydronephrosis). This study identified a NOAEL of 1.0 mg ClO_3^-/kg/day, but did not identify a LOAEL.

Mutagenicity

Chlorine Dioxide

- Miller et al. (1986) evaluated the mutagenic potential of concentrates prepared from drinking water treated with chlorine dioxide. The authors reported that samples concentrated 400-fold by reverse osmosis produced no mutagenic response in Salmonella strains TA98 or TA100, either in the presence or the absence of a metabolic activation system. Samples concentrated 4,000-fold by macroreticular resin were mutagenic only for the TA98 Salmonella strain (without metabolic activation).

- No chromosomal abnormalities were seen in mouse bone marrow cells following 5 days of gavage dosing at a level of 16 mg ClO_2/kg/day using the micronucleus test and cytogenetics assay (Meier et al., 1985).

- Male mice were evaluated for sperm-head abnormalities following ClO_2 gavage exposures up to 16 mg/kg/day for 5 days (Meier et al., 1985). No compound-related effects were seen at this dose level.

Chlorite

- No chromosomal abnormalities were seen in mouse bone marrow cells following 5 days of gavage dosing at a level of 40 mg chlorate using the micronucleus and cytogenetics assay (Meier et al., 1985).

- Hayashi et al. (1988) conducted a micronucleus test in which male ddY mice (6/dosage group) were given a single dose of ClO_2^- by gavage at 37.5, 75, 150 or 300 mg/kg then sacrificed 18 hours later. The results were considered negative by the authors, although there was a significant increase in micronuclei ($p<0.01$) above historical

controls at 150 mg ClO_2^-/kg. Therefore, the results of this study are considered equivocal.

Chlorate

- May (1989a, 1989b) demonstrated that sodium chlorate was not mutagenic to Salmonella typhimurium strains TA98, TA100, TA1535, TA1537 or TA1538 at concentrations of 0, 50, 158, 500, 1,580 or 5,000 μg/plate, with or without S9 metabolic activation, but did cause dose-dependent primary DNA damage in strains of Escherichia coli at doses ranging from 100 to 10,000 μg/mL.

- Sodium chlorate at concentrations of 100 to 10,000 μg/mL did not induce unscheduled DNA synthesis (UDS, an indicator of DNA damage) in culture HeLa S3 cells (Seeberg, 1989).

- Hodson-Walker (1989) reported that sodium chlorate was not demonstrably mutagenic, with or without S9 metabolic activation, in culture Chinese hamster V79 lung cells at concentrations of 8 to 5,000 μg/mL.

- Mackay (1989) assessed the in vivo clastogenic potential (micronucleus production) of sodium chlorate in male and female CD-1 derived bone marrow erythrocytes. Frequencies of micronucleated polychromatic erythrocytes (MPEs) were examined after administration of 0, 200, 1,000 or 5,000 mg/kg sodium chlorate (0, 157, 785 or 3,925 mg/kg ClO_3^-) to male and female mice. The results from harvests at 24-, 48- or 72-hours postexposure did not provide any evidence of increased MPE formation.

- No chromosomal abnormalities were seen in mouse bone marrow cells following 5 days of gavage dosing at a level of 40 mg chlorate using the micronucleus and cytogenetics assay (Meier et al., 1985).

Carcinogenicity

Chlorine dioxide

- Miller et al. (1986) reported that studies designed to assess carcinogenic potential were performed on chlorine dioxide treated water concentrates (4,000 x). The tests which included the lung adenoma assay, the SENCAR mouse initiation-promotion assay and the rat liver foci test indicated a lack of carcinogenic potential for ClO_2-treated water.

- Robinson et al. (1986) studied the effects of dermal exposure to ClO_2 on skin hyperplasia in mice. In the first experiment, groups of five dorsally shaved female SENCAR mice (six to seven weeks of age) were immersed (except for their heads) in aqueous solutions of ClO_2 (1, 10, 100, 300 or 1,000 mg/L) for a 10-minute period on each of four days, and were sacrificed on the fifth day. Skin thickness as the interfollicular epidermis (IFE) was measured by light microscopy using an eyepiece micrometer. Treatment of 1,000 mg/L resulted in increased IFE ($P<0.05$), but no significant increase in cell count per millimeter skin section ($P<0.05$) in the 1,000 and 300 mg ClO_2/L groups. In a second study, 40 mice were immersed once for 10 minutes in a solution containing 1,000 mg ClO_2/L, and groups of 5 were sacrificed on day 1, 2, 3, 4, 5, 8, 10 or 12 after exposure. There was a slight but statistically significant ($P<0.05$) increase of IFE which was apparent within 24 hours and persisted over the 12-day period. The highest IFE values were observed on days 10 and 12 after treatment. The authors concluded that even short-term dermal exposure to high doses of ClO_2 is capable of inducing hyperplastic responses in the mouse skin.

Chlorite or Chlorate

- A long-term (85 weeks) study in which B6C3F1 mice and F344 rats received sodium chlorite in drinking water was reported by Kurokawa et al. (1986). At doses ranging from 18 to 41 mg/kg/day of $NaClO_2$ (equivalent to 13 to 31 mg/kg/day of ClO_2^-), there was no significant increase in tumors in treated versus control rats. Treated male mice exhibited increased ($p<0.05$) incidence of lung and liver tumors although several factors make the study inconclusive: (1) the tumor rates were within historical ranges for control mice, (2) the increases in the liver tumors did not display a dose-response pattern (3) the significant increases were seen only for benign tumors.

- Yokose et al. (1987) reported on the carcinogenic potential of sodium chlorite in B6C3F1 mice of both sexes provided with drinking water containing 0%, 0.025% or 0.05% (0, 250 or 500 ppm) for 80 weeks. Assuming mice drink 0.0057 L/day and that the average body weight is 0.03 kg, these doses correspond to 0, 48 or 95 mg $NaClO_2$/kg/day (0, 36 or 71 mg ClO_2^-/kg/day). The incidences of tumors of the spleen, Harderian gland, subcutis, pituitary, thyroid and ovary were comparable to control levels. The incidences of malignant lymphoma/leukemia in the high dose female group (1/50, 2%) was lower than in controls (7/47, 15%). Although pulmonary adenomas in

the high dose males (5/43, 12%) were higher than control levels (0%), the increases were not dose related. The authors concluded that they study provides no clear evidence of carcinogenic potential of sodium chlorite.

- Kurokawa et al. (1984) tested ClO_2^- for its ability to act as a skin tumor promoter or a complete carcinogen. In the complete carcinogen test, 0.2 mL of a 20 mg $NaClO_2$/mL solution (100 mg/kg per application) in acetone was applied to the shaved backs of 20 female SENCAR mice twice weekly for 51 weeks. No tumors were detected as a result of this exposure. In the test as a tumor promoter, a single initiating dose of 20 μmol of dimethylbenzanthracene (DMBA) was applied to the skin, followed by the 51-week application of $NaClO_2$ as described above. Tumors were observed in six of the 20 mice (30%). No tumors were observed in 20 mice that received DMBA followed by acetone treatments for 51 weeks. Five of the animals (25%) were diagnosed to have squamous cell carcinomas.

- No specific long-term carcinogenicity studies for ClO_2 or ClO_3^- were found in the literature. However, the Haag (1949) study reported under long-term exposure, did not find any tumors in rats following 2-year exposures to ClO_2 or ClO_3^- in drinking water.

V. QUANTIFICATION OF TOXICOLOGICAL EFFECTS

Health Advisories (HAs) are generally determined for one-day, ten-day, longer-term and lifetime exposures if adequate data are available that identify a sensitive noncarcinogenic end point of toxicity. The HAs for noncarcinogenic toxicants are derived using the following formula:

$$HA = \frac{(NOAEL \text{ or } LOAEL) \times (BW)}{(UF)(\_\_\_ L/day)} = \_\_\_ \text{ mg/l (rounded to } \_\_\_ \text{ ug/l)}$$

where:

NOAEL or LOAEL = No- or Lowest-Observed-Adverse-Effect-Level in mg/kg bw/day.

BW = assumed body weight of a child (10 kg) or an adult (70 kg).

UF = uncertainty factor (generally 10, 100, 1,000 or 10,000), in accordance with EPA or NAS/OW guidelines.

L/day = assumed daily water consumption of a child (1 L/day) or an adult (2 L/day).

A. Chlorine Dioxide

One-day Health Advisory

In determining the One-day HA for chlorine dioxide, the lifetime health advisory of 300 μg/L, calculated below, is recommended for use as a conservative estimate for a 1-day exposure. This is because the Lifetime HA is derived from acute developmental effects that in theory could be produced by even a single exposure at the appropriate developmental stage.

It is worth noting that use of the one-day clinical study in humans by Lubbers et al. (1981), which failed to detect any adverse effects on hematological, serum chemistry or urinalysis parameters, would result in essentially the same One-day HA value. The One-day HA for the 10-kg child is calculated as follows:

$$\text{One-day HA} = \frac{(0.34 \text{ mg/kg/day})(10 \text{ kg})}{(10)(1 \text{ L/day})} = 0.34 \text{ mg/L (rounded to 300 } \mu\text{g/L)}$$

where:

0.34 mg/kg/day = NOAEL, based on the one-day clinical study by Lubbers, 1981

10 kg = assumed weight of child.

10 = uncertainty factor; chosen in accordance with EPA or NAS/OW guidelines for use with a NOAEL from a study in humans.

1 L/day = assumed daily water consumption of a child.

Ten-day Health Advisory for Chlorine Dioxide

In determining the Ten-day HA for chlorine dioxide, the lifetime health advisory of 300 μg/L, calculated below, is recommended for use as a conservative estimate for a 10-day exposure. This is because the Lifetime HA is derived from acute developmental effects that in theory could be produced by even a single exposure at the appropriate developmental stage.

Longer-term Health Advisory for Chlorine Dioxide

In determining the Longer-term HA for chlorine dioxide, the lifetime health advisory of 300 μg/L, calculated below, is recommended for use as a conservative estimate for a Longer-term exposure. This is because the Lifetime HA is derived from acute developmental effects that in theory could be produced by even a single exposure at the appropriate developmental stage.

Lifetime Health Advisory

The Lifetime HA represents that portion of an individual's total exposure that is attributed to drinking water and is considered protective of noncarcinogenic adverse health effects over a lifetime exposure. The Lifetime HA is derived in a three-step process. In step 1, one determines the Reference Dose (RfD), formerly called the Acceptable Daily Intake (ADI). The RfD is an estimate of a daily exposure to the human population that is likely to be without appreciable risk of deleterious effects over a lifetime, and is derived from the NOAEL (or LOAEL), identified from a chronic (or subchronic) study, divided by an uncertainty factor(s). From the RfD, a Drinking Water Equivalent Level (DWEL) can be determined (Step 2). A DWEL is a medium-specific (i.e., drinking water) lifetime exposure level, assuming 100% exposure from that medium, at which adverse, noncarcinogenic health effects would not be expected to occur. The DWEL is derived from the multiplication of the RfD by the assumed body weight of an adult and divided by the assumed daily water consumption of an adult. The Lifetime HA is determined in Step 3 by factoring in other sources of exposure, the relative source contribution (RSC). The RSC from drinking water is based on actual exposure data or, if data are not available, a value of 20% is assumed.

If the contaminant is classified as a known, probable or possible carcinogen, according to the Agency's classification scheme of carcinogenic potential (U.S. EPA, 1986b), then caution must be exercised in making a decision on how to deal with possible lifetime exposure to this substance. For human (A) or probable human (B) carcinogens, a Lifetime HA is not recommended. For possible human carcinogens (C), an additional 10-fold safety factor is used to calculate the Lifetime HA. The risk manager must balance this assessment of carcinogenic potential and the quality of the data against the likelihood of occurrence and significance of health effects related to noncarcinogenic end points of toxicity. To assist the risk manager in this process, drinking water concentrations associated with estimated excess lifetime cancer risks over the range of 1 in 10,000 to 1 in 1,000,000 for the 70-kg adult drinking 2 L of water/day are provided in the Evaluation of Carcinogenic Potential section.

The studies by Orme et al. (1985), Taylor and Pfohl (1985) and Toth et al. (1990) have been selected to serve as the basis for the calculation of the Lifetime

HA value for ClO_2. It should be noted that for the most part effects produced by this oxidant are short term in nature. The Orme et al. (1985) study identified a NOAEL of 3 mg/kg/day, based on delayed neurobehavioral effects in rat pups exposed in utero until the end of the lactation period (total of 10 weeks). The LOAEL identified in the study by Orme et al. (1985) is supported by the study by Taylor and Pfohl (1985) where rat pups treated prenatally and during postnatal days 5 to 20 with 14 mg ClO_2/kg/day exhibited depressed number of cells in the cerebellum and forebrain and a decrease in voluntary running wheel activity. Toth et al. (1990) observed decreased forebrain weight and protein content in rats treated postnatally by gavage with 14 mg/kg/day of ClO_2. The critical effects were also seen by Mobley et al. (1990) who reported decreased exploratory behavior in rat pups exposed to 14 mg ClO_2/kg/day in utero and postnatally.

Step 1: Determination of Reference Dose (RfD)

$$RfD = \frac{(3\ mg/kg/day)}{(300)} = 0.01\ mg/kg/day$$

where:

3.0 mg/kg/day = NOAEL, based on absence of effects on neurological development in rat pups born to dams exposed during gestation and lactation (Orme et al. 1985).

300 = Uncertainty factor; this uncertainty factor was chosen in accordance with EPA or NAS/OW guidelines in which a NOAEL from an animal developmental-effects study is employed (factor of 100), and in which a modifying factor of 3 is employed based on the absence of a 2-generation reproduction study.

Step 2: Determination of the Drinking Water Equivalent Level (DWEL)

$$DWEL = \frac{(0.01\ mg/kg/day)\ (70\ kg)}{(2\ L/day)} = 0.35\ mg/L$$

where:

0.01 mg/kg/day = RfD

70 kg = assumed body weight of an adult.

2 L/day = assumed daily water consumption of an adult

Step 3: Determination of Lifetime HA

In determining the Lifetime HA, the DWEL is modified by a relative source contribution factor of 80% because most chlorine dioxide exposure is likely to come from a drinking water source.

Lifetime HA = (0.35 mg/L) (80%) = .28 mg/L (rounded to 300 μg/L)

where:

0.35 mg/L = DWEL

80% = assumed relative source contribution for drinking water disinfection by-product.

Evaluation of Carcinogenic Potential

- Evidence of carcinogenicity has not been observed for ClO_2, ClO_2^- or ClO_3^-.
- The carcinogenic potential of ClO_2 has not yet been evaluated by the EPA. Applying the criteria described in EPA's guidelines for assessment of carcinogenic risk (U.S. EPA, 1986b), ClO_2 may be classified in Group D: not classifiable. This category is for agents with inadequate animal evidence of carcinogenicity.
- IARC has not evaluated the carcinogenicity of ClO_2.

B. Chlorite

One-day Health Advisory for Chlorite

In determining the One-day HA for chlorite, the lifetime health advisory of 80 μg/L, calculated below, is recommended for use as a conservative estimate for a 1-day exposure. This is because the Lifetime HA is derived from acute developmental effects that in theory could be produced by even a single exposure at the appropriate developmental stage.

Ten-day Health Advisory for Chlorite

In determining the Ten-day HA for chlorite, the lifetime health advisory of 80 μg/L, calculated below, is recommended for use as a conservative estimate for a 10-day exposure. This is because the Lifetime HA is derived from acute developmental effects that in theory could be produced by even a single exposure at the appropriate developmental stage.

Longer-term Health Advisory for Chlorite

In determining the Longer-term HA for chlorite, the lifetime health advisory of 80 μg/L, calculated below, is recommended for use as a conservative estimate for a Longer-term exposure. This is because the Lifetime HA is derived from acute developmental effects that in theory could be produced by even a single exposure at the appropriate developmental stage.

Lifetime Health Advisory for Chlorite

The Lifetime HA represents that portion of an individual's total exposure that is attributed to drinking water and is considered protective of noncarcinogenic adverse health effects over a lifetime exposure. The Lifetime HA is derived in a three-step process. Step 1 determines the Reference Dose (RfD), formerly called the Acceptable Daily Intake (ADI). The RfD is an estimate of a daily exposure to the human population that is likely to be without appreciable risk of deleterious effects over a lifetime, and is derived from the NOAEL (or LOAEL), identified from a chronic (or subchronic) study, divided by an uncertainty factor(s). From the RfD, a Drinking Water Equivalent Level (DWEL) can be determined (Step 2). A DWEL is a medium-specific (i.e., drinking water) lifetime exposure level, assuming 100% exposure from that medium, at which adverse, noncarcinogenic health effects would not be expected to occur. The DWEL is derived from the multiplication of the RfD by the assumed body weight of an adult and divided by the assumed daily water consumption of an adult. The Lifetime HA is determined in Step 3 by factoring in other sources of exposure, the relative source contribution (RSC). The RSC from drinking water is based on actual exposure data or, if data are not available, a value of 20% is assumed.

If the contaminant is classified as a known, probable or possible carcinogen, according to the Agency's classification scheme of carcinogenic potential (U.S. EPA, 1986b), then caution must be exercised in making a decision on how to deal with possible lifetime exposure to this substance. For human (A) or probable human (B) carcinogens, a Lifetime HA is not recommended. For possible human carcinogens (C), an additional 10-fold safety factor is used to calculate the Lifetime HA. The risk manager must balance this assessment of carcinogenic potential and the quality of the data against the likelihood of occurrence and significance of health effects related to noncarcinogenic end points of toxicity. To assist the risk manager in this process, drinking water concentrations associated

with estimated excess lifetime cancer risks over the range of 1 in 10,000 to 1 in 1,000,000 for the 70-kg adult drinking 2 L of water/day are provided in the Evaluation of Carcinogenic Potential section.

The subchronic study of Mobley et al. (1990) was selected as the basis of the Lifetime HA. For the most part, effects resulting from exposure to this oxidant are acute in nature. Mobley et al. (1990) identified a LOAEL of 3 mg/kg/day chlorite based on neurobehavioral effects (depressed exploratory activity) in rat pups. This critical effect is support by similar behavioral changes, as well as brain and histopathology, observed with chlorine dioxide exposure (Mobley et al., 1990; Orme et al., 1985; Taylor and Pfohl, 1985; Toth et al., 1990).

Step 1: Determination of the Reference Dose (RfD)

$$RfD = \frac{(3.0\ mg/kg/day)}{(1{,}000)} = 0.003\ mg/kg/day$$

where:

3.0 mg/kg/day = LOAEL, based on neurobehavioral effect (depression of exploration behavior) in rat pups exposed to chlorite in drinking water for 9 weeks (Mobley et al., 1990).

1,000 = Uncertainty factor; this uncertainty factor was chosen in accordance with EPA or NAS/OW guidelines in which an uncertainty factor of 10 each were applied to extrapolate from rats to humans and to protect sensitive human subpopulations. An uncertainty factor of 3 was also applied to the use of a LOAEL because the critical effect was minimal. An additional uncertainty factor of 3 was given for database deficiency (lack of a multigenerational reproductive study).

Step 2: Determination of the Drinking Water Equivalent Level (DWEL)

$$DWEL = \frac{(0.003\ mg/kg/day)\ (70\ kg)}{2\ L/day} = 0.105\ mg/L\ (\text{rounded to } 100\ \mu g/L)$$

where:

0.003 mg/kg/day = RfD

70 kg = assumed body weight of an adult.

2 L/day = assumed water consumption by 70-kg adult

Step 3: Determination of the Lifetime Health Advisory

In determining the Lifetime HA, the DWEL is modified by a relative source contribution factor of 80% because most chlorine dioxide exposure is likely to come from a drinking water source.

Lifetime HA = (0.100 mg/L) (80%) = .080 mg/L (or 80 μg/L)

where:

0.100 mg/L	=	DWEL
80%	=	assumed relative source contribution for drinking water disinfection by-product.

Evaluation of Carcinogenic Potential of Chlorite

- IARC has not evaluated the carcinogenic potential of chlorite.
- The carcinogenic potential of chlorite has not yet been evaluated by the EPA. Applying the criteria described in EPA's guidelines for assessment of carcinogenic risk (U.S. EPA, 1986b), chlorite may be classified in Group D: not classifiable. This category is for agents with inadequate animal evidence of carcinogenicity.

C. Chlorate

No health advisory values are provided because no suitable studies were located for development of all HA values and additional studies are required to assess the health effects of chlorate. EPA will conduct a 90-day subchronic and two-year chronic study of sodium chlorate in drinking water using rats and mice. EPA will review the results of these studies and consider them for development of a health advisory as appropriate.

A NOAEL of 0.036 mg/kg/d (the only dose tested) was identified in the Lubbers et al. (1982) human clinical study . In this study, ten human volunteers ingested 2.5 mg/day of ClO_3^- in drinking water (equivalent to 0.036 mg/kg/d) for twelve weeks and were monitored for a battery of parameters on serum chemistry, blood count, urinalysis, physical examination and some special tests. The EPA

Science Advisory Board (1992b) recommended that an interim health advisory be established using the Lubbers study with an uncertainty factor of one (since the effect is acute and some human subjects were glucose-6-dehydrogenase deficient and therefore represented a sensitive subpopulation). However, EPA believes that the use of an uncertainty factor of one is not adequately protective because the clinical study on chlorate exposure did not include glucose-6-phosphate dehydrogenase deficient human subjects. Moreover, it should be noted that the identified NOAEL of 0.036 mg/kg/d was the only dose tested. Therefore, one cannot determine whether humans can tolerate a higher dose without any adverse health consequences. The use of the Lubbers study with appropriate uncertainty factors to account for use of a subchronic study and protection of the sensitive individuals will likely result in a lifetime health advisory level less than the chlorate concentrations found in finished water.

Animal studies on longer-term chlorate exposure have been also conducted. In studies conducted by Bio/dynamics (1987a, b), NOAELs of 78 and 282 mg ClO_3^-/kg/d in rats and dogs, respectively, were identified following a three-month-exposure to chlorate by gavage. The NOAELS identified from these animal studies are considerably higher than the NOAEL from the Lubbers (1982) clinical human study. However, doses that are lethal to humans (200 mg/kg/d) are only 2-fold greater than the rat NOAEL level or close to the dog NOAEL. In addition, there is no information available to characterize the potential human toxicity between the doses of 0.036 mg/kg/d, the human NOAEL, and 200 mg/kg/d, the apparent human lethal dose.

Evaluation of Carcinogenic Potential for Chlorate

IARC has not evaluated the carcinogenic potential of chlorate.

The weight of evidence that chlorate is a carcinogen has not yet been evaluated by the EPA. Applying the criteria described in EPA's guidelines for assessment of carcinogenic risk (USEPA, 1986b), chlorate may be classified in Group D: not classifiable. This category is for agents with inadequate animal evidence of carcinogenicity.

VI. OTHER CRITERIA, GUIDANCE AND STANDARDS

Proposed limits for the use of ClO_2 in water treatment are based primarily upon assessment of hazards of residual ClO_2^-. The Norwegian Health Authority has recommended the total absence of residual ClO_2^- in drinking water, based on the possible threat to infants who have decreased ability to reduce methemoglobin (Michael et al., 1981). Similarly, in West Germany the applied dose of ClO_2 is officially limited to 0.3 mg/L to prevent possible adverse health effects (Michael et al., 1981; NAS, 1980). The U.S. Environmental Protection Agency has

recommended that when ClO_2 is used in water treatment, the total residual oxidant level (ClO_2 + ClO_2^- + ClO_3^-) should not exceed 1 mg/L (USEPA, 1979).

Suggested-No-Adverse-Response-Levels (SNARLs) for chronic exposure to chlorine dioxide were developed by NAS (1987) based on study results in Orme et al. (1985). In this study a NOAEL for neurobehavioral effects and serum chemistry alterations was determined. The SNARL for adult exposure to chlorine dioxide is 0.21 mg/L and 0.06 mg/L for a child.

The SNARLs for exposure to chlorite and chlorate developed by NAS (1987) are 0.024 mg/L for an adult and 0.007 mg/L for a child, based upon the study by Lubbers et al. (1981) in which a NOAEL for hematological effects was determined. It was noted that an observed-effect level was not determined in this study. Based on this consideration, a threshold for hematological effects in humans cannot be determined.

The recommended threshold limit value (TLV) for inhalation exposure to ClO_2 is 0.1 ppm for 8 hours with a 0.3 ppm ceiling (15 minute exposure) (ACGIH, 1980).

The OSHA standard for ClO_2 in occupational settings is 0.1 ppm TWA.

VII. ANALYTICAL METHODS

For measuring chlorine dioxide residuals, EPA recommends using the Amperometric Method I (SM 4500-ClO_2 C), the DPD method (SM 4500-ClO_2 D), and the Amperometric Method II (SM 4500-ClO_2 E). Additional information on these methods, including their precision and accuracy can be found in "Standard Methods for the Examination of Water and Wastewater", 19th Edition, American Public Health Association, American Water Works Association, and Water Environment Federation, 1995 (APHA, 1995). For chlorite and chlorate ion, EPA recommends using Method 300.0, Determination of Inorganic Anions by Ion Chromatography. For more information on this method, refer to the manual "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA/600/R/93/100, August 1993 (USEPA, 1993). Amperometric methods for chlorite and chlorate can also be used for process control, but the results should be periodically checked against ion chromatographic analysis to determine accuracy.

VIII. TREATMENT TECHNOLOGIES

Chlorite can be removed with treatment by GAC adsorption, however, the GAC usage rates necessary to achieve effective removal of chlorite is not well

defined and GAC appears to be expensive (U.S. EPA 1992c). Recent research indicates that sulfur may not be adequate for chlorite removal in real treatment conditions (Gordon et al. 1990). . While work is underway on how to reduce chlorite residuals at the treatment plant, e.g., using ferrous ion (Griese et al. 1992), additional work is required to determine the best removal technology. At this time, the best means for reducing chlorite levels is to control the use of chlorine dioxide. The proper generation of chlorine dioxide will minimize the amount of chlorate ion produced. For chlorate, there is limited information available on the most effective treatment, but of the various treatments available (e.g., GAC adsorption, diffused aeration), only membrane filtration appears to provide moderate removal of chlorate ion.

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Bioxy EPA Petition PP 6F4783: Petition, Releasable Correspondence, Memoranda

conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether chlorine dioxide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that chlorine dioxide has a common mechanism of toxicity with other substances.

DETERMINATION OF SAFETY FOR U.S. POPULATION, INFANTS AND CHILDREN

Because sodium chlorite and chlorine dioxide are not expected to accumulate in meat, milk, poultry, or eggs, exposure of infants and children will not result from the proposed use. The most likely source of human expqsure to chlorite or chlorine dioxide is through consumption of drinking water. The OW is currently in the process of regulating chlorite and chlorine dioxide.

OTHER CONSIDERATIONS

Product Chemistry

1. Product chemistry data for Aquatize have been previously reviewed by RD (A.Skapars, 10/22/96, D230356).

Animal Metabolism, Enforcement Methodology, Storage Stability, and Magnitude of the Residue

2. The Phase IV Review of sodium chlorite (C.Swartz, 2/2/93) **waived animal metabolism, analytical method, storage stability, and magnitude of the residue data** because, "... CBRS has determined that although it is not possible to establish with certainty whether finite residues will be incurred in meat, milk, and eggs, there is no reasonable expectation of finite residues significantly above the naturally occurring background levels."

International Residue Limits

3. No CODEX, Canadian, or Mexican MRLs have been established for residues of chlorite or chlorine dioxide in meat, milk, poultry or eggs.

SUPPLEMENTAL INFORMATION

Residue Chemistry

Residues of sodium chlorite or chlorine dioxide are not expected in livestock. A 1987 National Research Council report entitled "Drinking Water and Health: Disinfectants and Disinfectant By-Products, Volume 7" (National Academy Press) discussed available tissue distribution data of ^{36}Cl-labeled chlorite and chlorate following administration of either chlorite at 10 mg/L or chlorate at 5 mg/L. The NRC report concluded that, "[available data] suggests that neither [sodium] chlorite nor chlorate bioaccumulates" (page 101).

In aqueous solution, sodium chlorite converts to chlorine dioxide, which is then consumed during the reduction of bacterial activity. The extent and rate of consumption will be determined by bacterial load and reaction with any minerals or other contaminants present in the livestock drinking water. The petitioners noted that livestock drinking water is generally obtained from wells, and thus usually high in minerals and slightly acidic.

The maximal proposed use pattern, 1 part Aquatize per 2,000 parts water (0.05% Aquatize) results in 18 ppm sodium chlorite in livestock drinking water. Because sodium chlorite and chlorine dioxide are highly reactive with bacteria and other contaminants present in water, they would be expected to be rapidly consumed during the reduction of bacterial contamination.

Attachments: Chlorine Dioxide, Chlorite, and Chlorate Drinking Water Health Advisory, Office of Water, USEPA

cc with Attachments: PIRAT, Caswell File, TOX
RDI:PIRAT:5/19/97

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Attachment 2

7. Additional Information, EPA, FDA and State Authorities, Etc.

7.) Information regarding EPA, FDA and state registrations, if any

EPA

Sodium chlorite is listed in 40 CFR PART 180 – Tolerances and exemptions from tolerances for pesticide chemicals in food – Subpart D – Exemptions from Tolerances

> 40 CFR 180.1070 Sodium chlorite; exemption from the requirement of a tolerance.
>
> Sodium chlorite is exempted from the requirement of a tolerance for residues when used in accordance with good agricultural practice as a seed-soak treatment in the growing of the raw agricultural commodities crop group Brassica (cole) leafy vegetables and radishes. [50 FR 51856, Dec. 20, 1985]

Sodium chlorate is exempt from the requirements for a tolerance when used as a defoliant, desiccant, or fungicide on various raw agricultural commodities in accordance with good agricultural practice (40 CFR 180.1020).

Chlorine gas is exempted from the requirements of a tolerance when used preharvest or post harvest in solution on all raw agricultural commodities (40 CFR 180.1095).

Calcium hypochlorite is exempted from the requirements of a tolerance when used preharvest or post harvest in a solution on all RACs and in or on grapes when used as a fumigant by means of a chlorine generator pad (40 CFR 180.1054).

SANOVA® Base (25%) is registered by the EPA. EPA Registration Number: 45631-22.

FDA

Sodium chlorite is Generally Recognized as Safe (GRAS) when used at levels of 215—250 ppm as a slimicide in the manufacture of paper and paperboard that contacts food (21 CFR 186.175).

The first food processing aid approval of ASC (acidified sodium chlorite) solutions—pre-chill dip or spray on chicken carcasses—was published in the Federal Register in 1996 [61 FR 17829, April 23, 1996]. In that publication, the FDA concluded that acidified sodium chlorite solutions are

"safe and will have the intended effect of reducing microbial contamination on poultry". ASC solutions were first used commercially in a poultry processing plant on the Delmarva Peninsula (Delaware, Maryland, Virginia) in 1998.

Up to March 30, 2000, the FDA had approved applications of acidified sodium chlorite (21 CFR) as follows:

> **§ 173.325 Acidified sodium chlorite solutions.**
> Acidified sodium chlorite solutions may be safely used in accordance with the following prescribed conditions:
> (a) The additive is produced by mixing an aqueous solution of sodium chlorite (CAS Reg. No. 7758-19-2) with any generally recognized as safe (GRAS) acid.
> (b)(1) The additive is used as an antimicrobial agent in poultry processing water in accordance with current industry practice under the following conditions:
> (i)As a component of a carcass spray or dip solution prior to immersion of the intact carcass in a prechiller or chiller tank;
> (ii) In a prechiller or chiller solution for application to the intact carcass;
> (iii) As a component of a spray or dip solution for application to poultry carcass parts; or
> (iv) In a prechiller or chiller solution for application to poultry carcass parts.
> (2) When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm), in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.
> (3) When used in a prechiller or chiller solution, the additive is used at levels that result in sodium chlorite concentrations between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution of pH of 2.8 to 3.2.
> (c) The additive is used as an antimicrobial agent in accordance with current industry practice in the processing of red meat, red meat parts, and organs as a component of a spray or in the processing of red meat parts and organs as a component of a dip. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9.
> (d)The additive is used as an antimicrobial agent in water and ice that are used to rinse, wash, thaw, transport, or store seafood in accordance with current industry standards of good manufacturing practice. The additive is produced by mixing an aqueous solution of sodium chlorite with any GRAS acid to achieve a pH in the range of 2.5 to 2.9 and diluting this solution with water to achieve an actual use concentration of 40 to 50 parts per million (ppm) sodium chlorite. Any seafood that is intended to be consumed raw shall be subjected to a potable water rinse prior to consumption.
> (e) The additive is used as an antimicrobial agent on raw agricultural commodities in the preparing, packing, or holding of the food for

commercial purposes, consistent with section 201(q)(1)(B)(i) of the act, and not applied for use under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act, in accordance with current industry standards of good manufacturing practice. Applied as a dip or a spray, the additive is used at levels that result in chlorite concentrations of 500 to 1200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treatment of the raw agricultural commodities with acidified sodium chlorite solutions shall be followed by a potable water rinse, or by blanching, cooking, or canning.

(f) The concentration of sodium chlorite is determined by a method entitled "Determination of Sodium Chlorite: 50 ppm to 1500 ppm Concentration," September 13, 1995, developed by Alcide Corp., Redmond, WA, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC 20204–0001, or the Office of the Federal Register, 800 North Capitol St. NW., Suite 700, Washington, DC.

[61 FR 17829, Apr. 23, 1996, as amended at 63 FR 11119, Mar. 6, 1998; 64 FR 44123, Aug. 13, 1999; 64 FR 49982, Sept. 15, 1999; 65 FR 1776, Jan. 12, 2000; 65 FR 16312, Mar. 28, 2000]

Subsequent approvals have been granted as follows:

22921--22922 Federal Register / Vol. 66, No. 88 / Monday, May 7, 2001 / Rules and Regulations

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(b)(1) * * *

(v) As a component of a post-chill carcass spray or dip solution when applied to poultry meat, organs, or related parts or trim.

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31840--31841 Federal Register / Vol. 66, No. 114 / Wednesday, June 13, 2001 / Rules and Regulations

§ 173.325 Acidified sodium chlorite solutions.

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(f) The additive is used as an antimicrobial agent on processed, comminuted or formed meat food products (unless precluded by standards of identity in 9 CFR part 319) prior to packaging of the food for commercial purposes, in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations of 500 to 1200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.5 to 2.9.

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15719—15720 Federal Register / Vol. 67, No. 64 / Wednesday, April 3, 2002 / Rules and Regulations

§ 173.325 Acidified sodium chlorite solutions.

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(g) The additive is used as an antimicrobial agent in the water applied to processed fruits and processed root, tuber, bulb, legume, fruiting

(i.e. eggplant, groundcherry, pepino, pepper, tomatillo, and tomato) and cucurbit vegetables in accordance with current industry standards of good manufacturing practices, as a component of a spray or dip solution, provided that such application be followed by a potable water rinse and a 24-hour holding period prior to consumption. However, for processed leafy vegetables (i.e. vegetables other than root, tuber, bulb, legume, fruiting, and cucurbit vegetables) and vegetables in the Brassica [Cole] family, application must be by dip treatment only, and must be preceded by a potable water rinse and followed by a potable water rinse and a 24-hour holding period prior to consumption. When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm, in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

78303 – 78305 Federal Register/Vol. 69, No. 250/ Thursday December 30, 2004 December/Rules and Regulations

§ 173.325 Acidified sodium chlorite solutions

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(d)

(2) The additive is used as a single application in processing facilities as an antimicrobial agent to reduce pathogenic bacteria due to cross contamination during the harvesting, handling, heading evisceration, butchering, storing, holding, packing, or packaging of finfish and crustaceans; or following the filleting of finfish; in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is used at levels that result in a sodium chlorite concentration of 1,200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treated seafood shall be cooked prior to consumption.

Health Canada (Bureau of Chemical Safety)

Acidified sodium chlorite solutions are approved for poultry processing waters from pH 2.5 to 2.9 wherein the concentrations of chlorous acid range from 50 – 266 ppm. *(Health Canada Bureau of Chemical Safety letter of 9/27/99).* (Note: At a pH of 2.5, a 1200 ppm solution of sodium chlorite has a dissociation of 22.2% giving a chlorous acid level of 266 ppm chlorous acid. At a pH of 2.9, a 500 ppm solution of sodium chlorite produces 10.0% chlorous acid, or 50 ppm chlorous acid.

Section 7: Support Documents

EPA

Brennis, Robert S., Notice of Pesticide Registration-SANOVA Base (25%) and approved label, September 19, 2001

Emily H. Mitchell, Notice of Pesticide Registration – SANOVA approved label January 19, 2006.

Office of Regulatory Affairs Inspectional References: Investigations Operation Manual, Appendix A-Food Additive Status List-1, 14 pages. Entry on Acidified sodium chlorite solutions (p.5) http://www.fda.gov/ora/inspect_ref/iom/APPENDICES/appaA1.html:

FDA

21 CFR 186.1750 Sodium chlorite. 547. (approval as a slimicide in the manufacture of paper and paperboard that contact food.)

Federal Register, Vol. 61 No. 79, Tuesday, April 23, 1996, 17828—17829.

Federal Register, Vol. 61, No. 120, Thursday, June 20, 1996, 31395—31397.

Federal Register, Vol. 63, No. 44, Friday, March 6, 1998, 11118—11119.

Federal Register, Vol. 63, No. 138, Monday, July 20, 1998, 38746—38747.

Federal Register, Vol. 64, No. 95, Tuesday, May 18, 1999, 26841.

Federal Register, Vol. 64, No. 156, Friday, August 13, 1999, 44122—44123.

Federal Register, Vol. 64, No. 178, Wednesday, September 15, 1999, 49981—49982

Federal Register, Vol. 65, No. 8, Wednesday, January 12, 2000, 1776.

Federal Register, Vol. 65 No. 60, Tuesday, March 28, 2000, 16312.

Federal Register, Vol. 66, No. 88, Monday, May 7, 2001, 22921-22922.

Federal Register, Vol. 66, No. 114, Wednesday, June 13, 2001, 31840-31841

Federal Register, Vol. 67, No. 64, Wednesday, April 3, 2002, 15719-15720.

Federal Register, Vol. 69, No. 250, December 30, 2004, 78303-78305.

21 CFR 173.325 Acidified sodium chlorite solutions. 133-134. (Current up through amendment 65 FR 16312, March 28, 2000).

Health Canada

Cavolic, Karl, Health Canada: Letter to Dr. G. Kere Kemp, September 27, 1999.

Kemp, Kere; Alcide Corporation memo, October 4, 1999

USDA/FSIS

Billy, Thomas J., Letter to Kere Kemp, January 7, 1999. Approval on raw poultry carcasses as a dip or spray.

Edwards, Charles R., Letter to Kere Kemp, February 11, 2000. FSIS has no objection use of acidified sodium chlorite on red meat products, including carcasses, parts, and organs.

Derfler, Philip S., Letter to Robert G. Hibbert, August 9, 2000. FSIS concurrence with FDA approvals currently listed in 21 CFR 173.325 for various uses in meat and poultry products.

Derfler, Philip. S., Letter to Robert G. Hibbert, February 8, 2001. USDA does not require labeling re moisture retention in acidified sodium chlorite on red meat products.

Post, Robert C., Letter to Robert G. Hibbert, June 14, 2001. Allowance of Alcide SANOVA system (acidified sodium chlorite) to be used for on-line reprocessing of pre-chilled carcasses.

Glavin, Margaret, Letter to Robert G. Hibbert, October 17, 2001. Acidified sodium chlorite may be used as an antimicrobial agents to treated cooked comminuted sausages. There are no labeling issues in regard to the treated to the product.

Post, Robert C., Letter to Robert G. Hibbert, December 31, 2001. "There was no lasting function effect and treated product did not exhibit delayed discoloration, reduced shelf life, or abnormal. Also, no detectable oxychlorine residues were detected in the treated product." Approval for acidified sodium chlorite on cooked comminuted sausages.

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (H7510C)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA Reg. Number: 45631-22

Date of Issuance: SEP 19 2001

Term of Issuance:

NOTICE OF PESTICIDE:

__x__ Registration

_____ Reregistration

(under FIFRA, as amended)

Name of Pesticide Product: SANOVA BASE (25%)

Name and Address of Registrant (include ZIP Code):

Alcide Corporation
8651 154th Avenue, NE
Redmond, WA 98052

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

   a. Revise the EPA Registration Number to read, "EPA Registration Number "45631-22".

Signature of Approving Official:
Robert S. Brennis, PM 32
Regulatory Management Branch II
Antimicrobial Division (7510C)

Date: SEP 19 2001

b. Add container disposal language to read "Triple rinse container. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incinerate if allowed to do so by State and Local Authorities. If burning, stay out of smoke.

3. The Confidential Statement of Formula, dated 6/4/01 is acceptable.

4. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Enclosure

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

DANGER. Highly corrosive. May be fatal if swallowed. Do not get in eyes, on skin, or clothing. Do not get on bare hands. Wear goggles or face shield and neoprene gloves and use only thoroughly clean, dry utensils when handling. Irritating to nose and throat. Avoid breathing fumes. Remove and wash contaminated clothing to avoid fire.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

CHEMICAL HAZARDS

Dry sodium chlorite is a strong oxidizing agent. This product becomes a fire or explosive hazard if allowed to dry. Mix only into water. Contamination may start a chemical reaction with generation of heat, liberation of hazardous gases (chlorine dioxide is a poisonous, explosive gas), and possible fire and explosion. Do not contaminate with garbage, dirt, organic matter, household products, chemicals, soap products, paint products, solvents, acids, vinegar, beverages, oils, pine oil, dirty rags, or any other foreign matter.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

SEP 19 2001

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 45631-22

SANOVA® BASE (25%)

ACTIVE INGREDIENT:	Wt. %
Sodium Chlorite*	25.0%
INERT INGREDIENTS:	75.0%
Total:	100.00%

*AVAILABLE CHLORINE 39%
Contains 2.58 lbs. of Sodium Chlorite Per Gallon at 70 °F

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with plenty of water for at least 15 minutes. Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing and shoes. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment.

IF SWALLOWED: Call poison control center immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Alcide Corporation
8561 154th Avenue NE
Redmond, WA 98052-3557

EPA Reg No. 45631-XX
EPA Est.

_____ Gals. Net (_____)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For use in the generation of acidified sodium chlorite in a food processing facility to eliminate the growth of microorganisms that cause spoilage on fruits and vegetables. To be used in conjunction with the SANOVA® Activator and the SANOVA® Food Quality System.

This product may also be used on red meat and poultry, in accordance with 21 C.F.R. § 173.325.

Consult the product technical bulletin for specific application instructions. Your Alcide representative can guide you in the installation and operation of the SANOVA® Food Quality System.

User is responsible for compliance with applicable Federal, State, and local laws regarding proper use and disposal of the waste generated.

STORAGE AND DISPOSAL

STORAGE: Do not contaminate water, food or feed by storage or disposal. Keep product in tightly closed container when not in use. Do not drop, roll or skid drum. Keep upright. Always replace cover. Store in a cool, dry well-ventilated area away from heat or open flame.

In case of contamination or decomposition, do not reseal container. If possible, isolate container in open and well ventilated area. Flood with large volumes of water. If fire occurs, extinguish fire by applying large quantities of water. Any unopened drums near the fire should be cooled by spraying with water.

PESTICIDE DISPOSAL: Pesticide wastes are hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 7, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MS. JOY A. SALVERDA
ECOLAB INC.
370 WABASHA ST. ECOLAB CENTER
ST PAUL, MN 55102

Dear Ms. Salverda:

Subject: Transfer of Pesticide Registrations and Data From Company Number 45631 to Company Number 1677

Pursuant to your request in your letter and transfer agreement of November 18, 2004 and subsequent information received on March 29, 2005, we have approved the transfer of the following registrations and data from ALCIDE CORP, company number 45631 to ECOLAB INC., company number 1677.

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Reg. No.	New EPA Reg. No.
ALCIDE EXSPOR 4:1:1 - BASE	45631-3	1677-216
ALCIDE BRAND LD 10:1.1 BASE	45631-15	1677-217
SD-2	45631-19	1677-218
SANOVA BASE (25%)	45631-22	1677-219
SANOVA GPD CONCENTRATE	45631-23	1677-220

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS & DOMESTIC ANIMALS

DANGER. Highly corrosive. May be fatal if swallowed. Do not get in eyes, on skin, or clothing. Do not get on bare hands. Wear goggles or face shield and neoprene gloves and use only thoroughly clean, dry utensils when handling. Irritating to nose and throat. Avoid breathing fumes. Remove and wash contaminated clothing to avoid fire.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

CHEMICAL HAZARDS

Dry sodium chlorite is a strong oxidizing agent. This product becomes a fire or explosive hazard if allowed to dry. Mix only into water. Contamination may start a chemical reaction with generation of heat, liberation of hazardous gases (chlorine dioxide is a poisonous, explosive gas), and possible fire and explosion. Do not contaminate with garbage, dirt, organic matter, household products, chemicals, soap products, paint products, solvents, acids, vinegar, beverages, oils, pine oil, dirty rags, or any other foreign matter.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

SEP 19 2001

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 45631-22

SANOVA® ASE (25%)

ACTIVE INGREDIENT:	Wt. %
Sodium Chlorite*	25.0%
INERT INGREDIENTS:	75.0%
Total:	100.00%

*AVAILABLE CHLORINE 39%
Contains 2.58 lbs. of Sodium Chlorite Per Gallon at 70 °F

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with plenty of water for at least 15 minutes. Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing and shoes. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment.

IF SWALLOWED: Call poison control center immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Alcide Corporation
8561 154th Avenue NE
Redmond, WA 98052-3557

EPA Reg No. 45631-XX
EPA Est.

_____ Gals. Net (_____)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For use in the generation of acidified sodium chlorite in a food processing facility to eliminate the growth of microorganisms that cause spoilage on fruits and vegetables. To be used in conjunction with the SANOVA® Activator and the SANOVA® Food Quality System.

This product may also be used on red meat and poultry, in accordance with 21 C.F.R. § 173.325.

Consult the product technical bulletin for specific application instructions. Your Alcide representative can guide you in the installation and operation of the SANOVA® Food Quality System.

User is responsible for compliance with applicable Federal, State, and local laws regarding proper use and disposal of the waste generated.

STORAGE AND DISPOSAL

STORAGE: Do not contaminate water, food or feed by storage or disposal. Keep product in tightly closed container when not in use. Do not drop, roll or skid drum. Keep upright. Always replace cover. Store in a cool, dry well-ventilated area away from heat or open flame.

In case of contamination or decomposition, do not reseal container. If possible, isolate container in open and well ventilated area. Flood with large volumes of water. If fire occurs, extinguish fire by applying large quantities of water. Any unopened drums near the fire should be cooled by spraying with water.

PESTICIDE DISPOSAL: Pesticide wastes are hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 7, 2005

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MS. JOY A. SALVERDA
ECOLAB INC.
370 WABASHA ST. ECOLAB CENTER
ST PAUL, MN 55102

Dear Ms. Salverda:

Subject: Transfer of Pesticide Registrations and Data From Company Number 45631 to Company Number 1677

Pursuant to your request in your letter and transfer agreement of November 18, 2004 and subsequent information received on March 29, 2005, we have approved the transfer of the following registrations and data from ALCIDE CORP, company number 45631 to ECOLAB INC., company number 1677.

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Reg. No.	New EPA Reg. No.
ALCIDE EXSPOR 4:1:1 - BASE	45631-3	1677-216
ALCIDE BRAND LD 10:1.1 BASE	45631-15	1677-217
SD-2	45631-19	1677-218
SANOVA BASE (25%)	45631-22	1677-219
SANOVA GPD CONCENTRATE	45631-23	1677-220

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or

package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated November 18, 2004 and subsequent information received on March 29, 2005 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date ECOLAB INC. will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Evelyn Alston at (703) 305-5058.

Sincerely,

Kathryn S. Bouvé

Kathryn S. Bouvé, Chief
Information Services Branch
Information Resources & Services Div. (7504C)

cc: JOHN RICHARDS
ALCIDE CORP
8561 154TH AVE NE
REDMOND, WA 98052

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

EPA Reg. Number: **45631-24**

Date of Issuance: JAN 19 2006

Term of Issuance: Conditional

Name of Pesticide Product: Sanova Base 335

NOTICE OF PESTICIDE:

___ Reregistration
_X_ Registration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Alcide Corporation
8561 154th Avenue, NE
Redmond, WA 98052

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

   a. Revise the EPA Registration Number to read, "EPA Reg. No.45631-24"

   b. The temperature of effectiveness "20°C or Room Temperature" must be added to the label under Directions For Use section.

Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Wanda J. [illegible]

for Emily H. Mitchell, Product Manager - Team 32
Regulatory Management Branch II - Antimicrobials Division

Date: JAN 19 2006

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

If in Eyes:
Hold eye open and rinse slowly and gently with water for at least 15-20 minutes. Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on Skin or Clothing:
Take off contaminated clothing and shoes. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If Inhaled:
Move person to fresh air. If person is not breathing, call 911, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

If Swallowed:
Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

WARRANTY LIMITATION AND DISCLAIMER
ALL EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE OR OTHERWISE ARE EXPRESSLY EXCLUDED. THERE ARE NO WARRANTIES THAT EXTEND BEYOND THE DESCRIPTION OF THE FACE HEREOF. In the event this product or its performance shall not conform with the description on the face hereof, Manufacturers sole obligation shall be to refund the Purchaser the purchase price hereof, or to replace this unit of product with a conforming unit at Sellers option. Purchaser agrees that such refund or replacement shall be Purchasers sole remedy for claims arising out of the purchase or use of this product. Before using this product, user shall determine the suitability of the product for its intended purpose and user assumes all risk and liability in connection therewith. User shall be responsible for its compliance with all federal, state, and local laws and regulations regarding the product and its use, storage, handling, and disposal.

ACCEPTED
with COMMENTS
EPA Letter Dated:
JAN 19 2006
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide,
EPA Reg. No. 45631-4

SANOVA® 335

Ready-to-Use Surface Sanitizer
For use in Commercial Food Processing and Food Preparation Areas

SANOVA® 335 is a ready-to-use spray that is an effective sanitizer against *Listeria monocytogenes* on hard, non-porous surfaces. *SANOVA® 335* may be safely applied to hard, non-porous food-contact surfaces, including plastics and stainless steel.

PART A BOTTLE CONTAINS:

ACTIVE INGREDIENT:	
Sodium chlorite	0.067%
OTHER INGREDIENTS:	99.933%
TOTAL	100.000%

WHEN PARTS A AND B ARE MIXED 1:1, PRODUCT CONTAINS:

ACTIVE INGREDIENT:	
Sodium Chlorite	0.034%
OTHER INGREDIENTS:	99.966%
TOTAL	100.000%

The active ingredient (sodium chlorite at 335 ppm) has an antimicrobial activity equivalent to ≥200 ppm available chlorine, as required for pesticides used for sanitization of food-contact surfaces.

LOT No.: _____

EPA Reg. No. 45631-
EPA Est. No. 035-347-CA-001

Manufactured for:
Alcide Corporation
8561 154th Avenue NE
Redmond, WA 98052-3557

Net Weight: 22 Fluid Ounces (650 mL)

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

Harmful if swallowed, absorbed through skin or inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing spray mist. Wash hands before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Sprayer Assembly
The solutions in each bottle of the twin-pack set are pre-diluted and ready for dispensing through the Trigger Spray Handle. Remove the screw caps on bottles containing Part A and Part B and place the Trigger Spray Handle on the bottle openings. Make sure the locking levers on the Handle are in the "OFF" position, as indicated on the shoulder of each bottle. Place the Handle on the twin-pack bottles, so that only one Part A and one Part B bottle are attached. When the Handle is completely seated, move the lock-levers to the "ON" position, as shown on the shoulder of each bottle. Proceed to dispense as instructed.

Application Instructions
The ideal spray action is to pull or squeeze the handle fully and then to release it or to let it go completely, so that it returns freely to the original or open position. A short pumping action should not be used.

Clean gross filth from surfaces before applying *SANOVA® 335*. Spray on surfaces to be sanitized until saturated. Allow to soak for one minute, then drain excess solution.

STORAGE & DISPOSAL
Pesticide Storage: Store in original containers in cool, dark, dry place. Keep containers upright.
Container Disposal: Triple rinse empty containers with water and offer for recycling or discard in trash. Do not reuse containers.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 1, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MS. JOY SALVERDA
ECOLAB INC.
370 WABASHA ST. ECOLAB CENTER
ST PAUL, MN 55102

Dear Ms. Salverda:

Subject: Transfer of Pesticide Registration and Data From Company Number **45631** to Company Number **1677**

Pursuant to your request in your letter and transfer agreement of February 17, 2006 and subsequent information received dated July 18, 2006, we have approved the transfer of the following registration and data from **ALCIDE CORP**, company number **45631** to **ECOLAB INC.**, company number **1677.**

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Reg. No.	New EPA Reg. No.
SANOVA 335	45631-24	1677-222

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form

"Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated February 17, 2006 and subsequent information received dated July 18, 2006 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date **ECOLAB INC.** will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Evelyn Alston at (703) 305-5058.

Sincerely,

Kathryn S. Bouvé

Kathryn S. Bouvé, Chief
Information Services Branch
Information Technology & Resource Management Div. (7504P)

cc: MR. JOHN RICHARDS
ALCIDE CORP
8561 154TH AVE NE
REDMOND, WA 98052

APPENDIX A - FOOD ADDITIVE STATUS LIST - 1

FOREWORD

This Food Additives Status List is intended to include all foods and drugs use named in regulations promulgated under Sections 401 (Food Standards), 409 (Food Additives) and 512 (Animal Drugs) of the Food, Drug and Cosmetic Act except for the following:

1. Indirect food additives, 21 CFR Parts 174, 175, 176, 177 & Part 178. (except sanitizing agents for food processing equipment are included - 178.1010)

2. Synthetic flavoring substances, 21 CFR 172.515.

3. Color additives, 21 CFR Parts 70, 71, 73, 74, 80 & 82 (For Color Additives Status List (CASL), see IOM Appendix A)

The additives and animal drugs are listed alphabetically. The number of each regulation in which the additive or drug is mentioned is also given.

Substances, which are banned (BAN) or illegal (ILL), are underlined.

Within the space available, tolerances and permitted uses or restrictions are given for each additive or drug for feed use. For complete details, refer to the regulations in the Code of Federal Regulations (CFR), Title 21 or Title 40. The CFR is available from the Superintendent of Documents and is revised annually. New regulations and revisions are published in current issues of the FEDERAL REGISTER as promulgated.

This status list is intended to include all regulated food additives and drugs for feed use (with exceptions noted above). Page revisions are issued periodically to update the list.

NOTE: This exhibit is provided only as a guide in determining whether a manufacturer may be using food additives properly. Attempts have been made to ensure that the list is as complete as possible as it relates to the listing of substances in the CFR. However, it is possible that mistakes or omissions could have occurred. Additionally, there may be cases where the agency has offered interpretations concerning specific provisions of the regulations. For example, in the case of boiler water additives or other minor ingredients, processing aids, or indirect additives, FDA has not objected, in certain cases, to the substitution of ammonium, calcium, magnesium, potassium, or sodium salts for each other when only one is listed in a regulation. Finally, the list is updated only on an annual basis and may not reflect the latest information.

Additionally, certain trade groups, such as the Flavor Extract Manufacturers Association have established expert panels to evaluate the GRAS status of their products. Many of these GRAS substances do not appear in the CFR. Thus, care should be taken before advising a firm that a use of a particular food additive is prohibited or otherwise limited. If there are any doubts or if a particular situation is unclear, you or your supervisor should consult with the CFSAN, Office of Pre-Market Approval/Division of Product Policy (HFS-205) at (202) 418-3090 or the Division of Petition Control (HFS-215) at (202) 418-3070.

Please send corrections or additions to the list, or your suggestions for improvement in content, format, etc., to the Food and Drug Administration, Division of Emergency and Investigational Operations (HFC-130), 5600 Fishers Lane, Rockville, Maryland 20857.

ABBREVIATIONS USED

Type (kind, effect or use of additive)

AC	Anticaking agent
AF	Antifoaming (or defoaming) agent
AOX	Antioxidant BC Boiler compound
BL	Bleaching agent or flour-maturing agent
B&N	Buffer and neutralizing agent
CTG	Component or coating for fruits & vegetables
DS	Dietary supplement
EMUL	Emulsifier
ENZ	Enzyme
ESO	Essential oil and/or oleoresin (solvent free)
FEED	substances under the Food Additives Amendment added directly to feed
FLAV	Natural flavoring agent
FL/ADJ	Substance used in conjunction with flavors
FUM	Fumigant
FUNG	Fungicide
HERB	Herbicide
HOR	Hormone
INH	Inhibitor
MISC	Miscellaneous
NAT	Natural substances and extractives
NNS	Non-nutritive sweetener
NUTR	Nutrient
NUTRS	Nutritive Sweetener
PEST	Pesticide other than fumigant

PRES	Chemical preservative
SANI	Sanitizing agent for food processing equipment
SDA	Solubilizing and dispersing agent
SEQ	Sequestrant
SOLV	Solvent
SP	Spices, other natural seasonings & flavorings
SP/ADJ	Spray adjuvant
STAB	Stabilizer
SY/FL	Synthetic flavor
VET	Veterinary drug, which may leave residue in edible tissues of animals

Status

BAN	Substances banned prior to the Food Additives Amendment (FAA) because
FS	Substance permitted as optional ingredient in a standardized food
GRAS	Generally recognized as safe. Substances in this category are by defin SEC. 201(s) of the FD&C Act, not food additives. Most GRAS sub quantitative restrictions as to use, although their use must c practices. Some GRAS substances, such as sodium benzoate, do h limit for use in foods.
GRAS/FS	Substances generally recognized as safe in foods but limited in standa the standard provides for its use.
ILL	Substances used or proposed for use as direct additives in foods witho under the FAA. Their use is illegal.
PD	Substance for which a petition has been filed but denied because of la Substances in this category are illegal and may not be used in
PS	Substance for which prior sanction has been granted by FDA for specifi number of substances in this category not listed herein becaus published in the FEDERAL REGISTER.
REG	Food additive for which a petition has been filed and a regulation iss
REG/FS	Food additive regulated under the FAA and included in a specific food standard

Other

&	and
amt	amount
art	artificially
avg	average
ca	about, approximately
calc	calculated
CFR	Code of Federal Regulations
cnd	canned
cond	conditions
comb.	w/ in combination with; combined with
comp	component
ctg	coating for fruits, vegetables, tablets
do	Same CFR reference as appears earlier in paragraph
dr	dried
F.R.	Federal Register
g	gram(s)
GMP	In accordance with good manufacturing practices; or sufficient for pur not greater than required
incl	including
mfr	manufacture
mg	milligram(s)
min	mineral
ml	milliliter
nonstdzd	nonstandardized
Part	Refers to Part number under Title 21 CFR
pdt	product
pdtn	production
pest	pesticide
pkg	packaging
ppm	parts per million
prepns	preparations
res	residue
sp	diet special dietary
suppl	supplement
sw	sweetened
tabs	tablets
temp	temporary
veg	vegetable(s)
w/	with
w/o	without
wt	weight
X-ref	cross reference
<	less than
<	less than or equal to
>	greater than
>	greater than or equal to
+	plus

A

Acacia (gum arabic) - STAB, GRAS/FS, See Reg Part 135, Frozen Desserts; Part 169, Food Dressings and Flavorings; Part 169.179, Vanilla Pwd - 184.1330

Acephate (O,S-dimethyl acetylphospheramidothioate & O,S - dimethyl phosphoramidothioate) - PEST, REG, 8 ppm - In cottonseed meal resulting from application to growing crops - 40 CFR 186.100; 4 ppm - Residues in cottonseed hulls and soybean meal resulting from application to growing crop - 40 CFR 186.100

Acesulfam potassium - NNS, REG, See Regulation - 172.800

Acetic acid - B&N/FEED, GRAS/FS, Part 133, Cheese; Part 582.1005, In animal feed practices; 184.1005, 172.814

Acetic anhydride - MISC, REG, In modifying food starch - 172.892

Acetone - SOLV, REG, 30 ppm - As residual solvent in spice oleoresins 173.210

Acetone peroxides - BL, REG/FS, GMP, Part 137, Cereal Flours -172.802

Acetyl-(p-nitrophenyl)-sulfanilamide - FEED, REG, See: Sulfanitran

N-Acetyl-L-Methionine (free, hydrated, or anhydrous, or sodium or potassium salts) - NUTR, REG, In foods, except infant foods and foods containing added nitrites/nitrates - 172.372

Acetylated monoglycerides - EMUL, REG, GMP, Used in food, food processing, food pkg or food stg equipment - 172.828

Acidified sodium chlorite solutions - REG, Used as an antimicrobial agent in a carcass spray or dip solution for poultry processing at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9. Used in a prechiller or chiller tank in poultry processing at levels that result in sodium chlorite concentrations between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.8 to 3.2. Used as an antimicrobial agent in a spray or dip solution for processing of red meat, red meat parts, and organs at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9. Used as an antimicrobial agent in water and ice to rinse, wash, thaw, transport, or store seafood at sodium chlorite concentrations between 40 and 50 ppm, in combination with any GRAS acid levels sufficient to achieve a solution pH 2.5 to 2.9, provided that any seafood that is intended to be consumed raw is subjected to a potable water rinse prior to consumption. Used as an antimicrobial agent in a spray or dip solution on raw agricultural commodities at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm, in combination with any GRAS acid levels sufficient to achieve a solution pH 2.3 to 2.9, provided that treatment of the raw agricultural commodities is followed by a potable water rinse, or by blanching, cooking, or canning - 173.325

Acifluoren, Sodium - HERB, REG, 0.02 ppm - Residues in Cattle & Sheep kidney and liver - 40 CFR 180.383; Residues in goats, hogs and poultry meat, fat and by-products - do; Residues in milk & eggs - do; 0.1 ppm - As residues in/on rice grain, rice straw, soybean, peanut hulls - do

Aconitic acid (equisetic acid, citridic acid, achilleic acid) - SY/FL, GRAS/FS - 184.1007

Acrolein - MISC, REG, In modifying food starch - 172.892

Acrylamide -acrylic acid resin - MISC, REG, < 5 ppm by wt of juice - Used in clarifying beet sugar or cane sugar juice and liquor or corn starch hydrolyzate - 173.5; < 10 ppm by wt of liquor or hydrolyzate; FEED, REG, GMP, As a thickener & suspending agent in non-medicated aqueous suspensions intended for addition to animal feeds - 573.120

Acrylamide-Sodium Acrylate Resin - MISC, REG, 173.5, Boiler Water Additive - 173.310, 172.710 - Adjuvants for pesticide use dilutions

Acrylic Acid 12-acrylamido-2,2-propionic sulfonic acid copolymer - BC, REG, GMP, Boiler water - 173.310

Adjuvants for pesticides use dilutions - ADG/PEST, REG, Surfactants and adjuvants added to pesticide use dilutions to growing crops - 172.710

Adipic acid - B&N/FEED, GRAS, GMP, In animal feed practices - 582.1005 - FLV, GRAS - 184.1009

Adipic anhydride - MISC, REG, In modifying food starch - 172.892

Agar-agar - MISC, GRAS/FS, GRAS - 184.1115 - 0.8% - In baked goods and baking mixes; 2.0% - In confections & frostings; 1.2% - In soft candy; 0.25% - In all other candy; Part 135, Frozen Desserts; Part 150 Art Swt Jelly & Preserves

Aklomide (2-chloro-4-nitro-benzamide) - FEED, REG, 4.5 ppm - In liver & muscles of uncooked edible tissue - 556.30; 3 ppm - In skin w/fat of chickens - 556.30 - Use 558.35

Alachlor - REG, Residues in or on agricultural commodities - 180.249

DL-Alanine - FL/ADJ, REG, 1% of pickling spice - As a flavor enhancer for sweeteners in pickling mix - 172.540

L-Alanine - NUTR, REG - 172.320

Albendazole - VET, REG, Use in cattle as suspension - 520.45a; Use in cattle as paste - 520.45b; 0.2 ppm - As residue in uncooked edible cattle tissue - 556.34 (aminosulfone metabolite); 0.6 ppm - As residue in uncooked edible cattle muscles - 556.34; 1.2 ppm - As residue in uncooked edible cattle liver - do; 1.8 ppm - As residue in uncooked edible cattle kidney - do; 2.4 ppm - As residue in uncooked edible cattle fat - do

Alcohol, Denatured Formula 23A - MISC, REG - 73.1 - Diluent in color additve mixtures for coloring shell eggs

Alcohol, SDA-3A - MISC, REG - 73.1 - Diluent in color additive for marking food

Alcohols/Phosphate Esters of Same Mixture - MISC, REG - 173.315, May be used at a level not to exceed 0.2 percent in lye-peeling solution to assist in the lye peeling of fruit and vegetables.

Aldicarb - PEST, REG - 0.6 ppm - Citrus pulp, dried, present as a result of pesticide application to growing crops - 40 CFR 186.150 - 0.3 ppm - Cottonseed hulls, present as a result of pesticide application to growing crop - 40 CFR 186.150 - 0.5 ppm - Bran Sorghum - 40 CFR 186.150

Alfafa, Extract - GRAS - 182.20

Alfalfa herb and seed - SP/ESO, GRAS - 182.10

Algae, brown (kelp), or red - NAT, GRAS, REG –

184.1120, 184.1121 and 172.365

Alginic Acid and Salts -

Ammonium alginate - MISC, REG, Boiler Water Additive -173.310

Calcium alginate - GRAS - 184.1187

Potassium alginate - GRAS - 184.1610

Sodium alginate - GRAS, REG - 184.1724, Boiler Water Additive - 173.310

Alginic acid - GRAS, 184.1011

Algin - STAB, GRAS/FS, Part 133, Cheeses; Part 135, Frozen Desserts; Part 150 Jellies and Preserves;

Alkanomide produced by condensation of coconut oil fatty acids and diethanolamine - MISC, REG,

< 0.2% by wt application rate - In delinting of cottonseeds - 173.322

n-Alkyl (C12-C18) benzyldimethyl-ammonium chloride cpds, av mol wt 351-380 - SANI, REG, < 200ppm or 150-400 ppm - Of active quaternary compound in the sanitizing solution - 178.1010

n-Alkyl (C12-C14) dimethylethylbenzyl ammonium chloride - SANI, REG, 200 ppm - Of active quaternary compound in the sanitizing solution - 178.1010

-alkyl--hydroxy-poly(oxyethylene) - MISC, REG, < 3 ppm in the flume water - In flume water for washing sugar beets prior to slicing operations - 173.315; < 0.3% by wt application rate - In delinting of cottonseeds - 173.322

Alkylene Oxide Adducts of Alkyl Alcohols - MISC, REG, <0.2% in lye peeling - Assist in lye peeling of fruits and vegetables - 173.315

Allspice - SP/ESO, GRAS - 182.10 and 182.20

Allspice oil and oleoresin - ESO, GRAS - 182.20

Almond, bitter - ESO, GRAS, Free from prussic acid - 182.20

Aloe - FL/ADJ, REG, GMP, Used only in conjunction w/flavors - 172.510

Alpha-amylase -ENZ, REG, used to modify food starch -172.892

Alpha-galactosidase from Morteirella vinaceae var raffinoseutilizer - ENZ, REG, No residue in finished product - Used in the production of sugar (sucrose) from sugar beets and increase sucrose yield in molasses - 173.145

(Alpha RS,2R)-fluvalinate{(RS)-alpha-cyano-3-phenoxy benzyl (R)-2 [2-chloro-4- trifluoromethyl) anilino] -3-methylbutonate - INSECT, REG, 0.1 ppm - As residue in/on cottonseed; In eggs & milk - 40 CFR 180.427; 0.05 ppm - As residue in the meat by-products and fat of cattle, goats, hogs, poultry & sheep - 40 CFR 180.427; 1.0 ppm - As residue in cottonseed oil - 40 CFR 186.3200; 0.3 ppm - As residue in/on cottonseed hulls - 40 CFR 186.3200; 0.01 ppm - As residues in eggs and milk - 40 CFR 180.427; 0.01 ppm - As residues in fat, meat, meat by-products of cattle, goats, hogs, poultry, sheep - 40 CFR 180.427; 0.3 ppm - As residues in/on cottonseed hulls - 40 CFR 186.3400; 1.0 ppm - As residues in/on cottonseed oil (crude & refined) - do; 0.01 ppm - As residues in milk & eggs - 40 CFR 180.427; 0.01 ppm - As residues in fat, meat, meat by-products of cattle, goats, hogs, poultry and sheep - do

Althea flowers or root (marshmallow root) - FL/ADJ, REG, GMP - Used only in conjunction w/flavors - 172.510

Aluminum ammonium sulfate - B&N, GRAS - 182.1127

Aluminum calcium silicate - AC, GRAS/FS - 182.2122 - < 2% by wt - Table salt; Part 169.179, Vanilla Powder

Aluminum nicotinate - DS, REG, As a source of niacin in foods for special dietary use - 172.310

Aluminum phosphide (phosphine) - FUM, REG, <0.01 ppm as phosphine - From use as fumigant - 40 CFR 185.200; <0.1 ppm as phosphine - Maximum residue on animal feeds - 40 CFR 186.200

Aluminum potassium sulfate - B&N, GRAS

Aluminum salts of fatty acids - MISC, REG, GMP - Binder, emul, and AC agent - 172.863

Aluminum sodium sulfate - B&N, GRAS

Aluminum stearate - AF, REG, X-ref - Defoaming agent comp - 173.340 (Used in processing beet sugar & yeast)

Aluminum sulfate - MISC, GRAS, Part 582 - Animal feed; REG, <2.0% in combo. w/<2.0% of 1-octenyl succinic anhydride - In modifying food starch - 172.892; FEED,GMP/GRAS - 582.1125

Ambergris - MISC, GRAS

Ambrette (seed) - SP/ESO, GRAS - 182.10 and 182.20

4-Amino-6-(1,1-dimethyl-ethyl)-3-(Methylthio)-1,2,4-Triazin-5(4H)-one - HERB, REG, 3 ppm - In processed potatoes (including potato chips) resulting from application of the herbicide on the raw agricultural commodity - 40 CFR 185.250; 3 ppm - Residues in animal feed using wheat - 40 CFR 185.250; 2 ppm - Residues in animal feed using tomato pomace - 40 CFR 185.250; 0.3 ppm - Residues in animal feed using sugarcane molasses - 40 CFR 185.250; 0.5 ppm - Residues in animal feed using sugarcane bagasse - 40 CFR 185.250

p-Aminobenzoic acid - MISC, GRAS, <30 mg per day

Aminopeptidase from Lactococcus lactis - MISC, GRAS - To make cheddar cheese and protein hydrolysates - 184, 1985

Amitraz - PEST, REG, 7 ppm - As a residue in citrus pulp for use in animal feeds - 40 CFR 185.250; 0.03 ppm - As residues in milk - 40 CFR 180.287; 0.05 ppm - As residues in meat of cattle - do; 0.1 ppm - As residues in fat of cattle and hogs - do; 0.2 ppm - As residues in kidney and liver of hogs - do; 0.3 ppm - As residues in meat by-products of cattle and hogs - do; 0.03 ppm - As residues in milkfat - do

Ammoniated cottonseed meal - FEED, REG, <20% of total ration - In feed of ruminants as source of protein and non-protein nitrogen - 573.140; <10% of total ration for laying chickens - In feed of chickens as source of protein and non-protein nitrogen (573.140)

Ammoniated glycyrrhizin, licorice, or glycyrrhiza - MISC, FS, GMP, See Licorice

Ammoniated rice hulls - FEED, REG, <20 % of total ration - In feed of beef cattle as source of crude fiber and sole source of non-protein nitrogen - 573.160

Ammonium alginate - STAB, GRAS; BC, REG, GMP - In boiler water - 173.310

Ammonium bicarbonate - B&N, GRAS/FS, Part 163, Cacao Pdts; Part 582 - Animal feeds - 184.1135

Ammonium carbonate - B&N, GRAS/FS, Part 163, Cacao Pdts; Part 582 - Animal feeds - 184.1137

Ammonium caseinate - MISC, FS, Part 136, Bakery Products

Ammonium chloride - MISC, FS/GRAS, Part 136, Bakery Pdts - 184.1138

Ammonium hydroxide - B&N, GRAS/FS, Part 163, Cacao Pdts; Part 582 - Animal feeds - 184.1137, 184.1139

Ammonium persulfate - MISC, REG, <0.075% - Modifier for food starch - 172.892; <0.05% sulfur dioxide

Ammonium phosphate (mono- and dibasic) - B&N, GRAS/FS, Part 136, Bakery Pdts; Part 582 - Animal feeds - 184.1139, 184.1141, 184.1141a, 184.1141b

Ammonium saccharin - NNS, See Saccharin

Ammonium sulfate - MISC, GRAS, GMP - 184.1143

Amoxicillin - VET, REG, 0.01 ppm - In uncooked edible tissues of cattle - 556.38; In milk - 556.38; Use: As Powder & Bolus

Ampicillin - VET, REG, 0.01 ppm neg residues - In uncooked edible tissues of cattle & swine; In milk - 556.40;

Amprolium (1-(4-amino-2-n-propyl-5-pyrimldinylmethyl)-2- picolinium chloride hydrochloride) alone or comb/w other drugs and antibiotics - FEED/VET, REG, 1 ppm - In uncooked liver and kidneys of chickens, turkeys, and pheasants as a residue - 556.50; 0.5 ppm - In uncooked muscle meat of chickens, turkeys, calves, pheasants as a residue - 556.50; 8 ppm - In egg yolks as a residue - 556.50; 4 ppm - In whole eggs as a residue - 556.50; 2 ppm - In uncooked fat of edible tissues of calves - 556.60; Use in drinking water - 520.100; REG - Coccidiostats for feed uses, See 558.55, 558.58, 558.60, 558.62, 558.76, 558.78, 558.128, 558.248, 558.274, 558.460, 558.530

Amylase from Aspercillgus Oryzae - ENZ, REG - 137.105, 137.155, 137.160, 137.165, 137.170, 137.175, 137.180, 137.185, 137.200, 137.205

-Amylase - ENZ, REG, Used to modify food starch - 172.892

Amyloglucosidase Enzyme Product - ENZ, REG, <0.1% by Wt. of gelatinized starch - 173.110 - Degrading gelatinized starch into constituent sugars, in the production of distilled spirits & vinegar

Amyris - FL/ADJ, REG, GMP, Used in conjunction w/flavors - 172.510

Angelica (root, stem, seed) - SP/ESO, GRAS - 182.10 and 182.20

Angola weed - FL/ADJ, REG, GMP, In alcoholic bev only - 172.510

Angostura (cusparia bark) - ESO/SP, GRAS - 182.10 and 182.20

Anhydrous ammonia - FEED, REG, > 16% but < 17% ammonia in feed premix - Source of crude fiber & non-protein nitrogen - 573.180

Animal protein hydrolysate, cond - FEED, REG, Source of animal protein - 573.200

Anise, Star Anise - SP/ESO, GRAS

Anoxomer - AOX, REG, 5000 ppm - 172.105

Antibiotics for growth promotion and feed efficiency - FEED, REG, See Bacitracin Methylene Disalicylate; See Bacitracin Zinc, Bambermycins, Chlortetracycline, Erythromycin thiocyanate, Lincomycin, Monensin, Oleandomycin, Oxytetracycline, Tylosin, Virginiamycin

Anthracite Coal, Sulfonated - MISC, REG - 173.25 - Ion Exchange Resins, Meeting requirements of ASTM method D388-38, Class 1, Group 2

Apramycin - REG, 0.1 ppm - In uncooked muscle of swine - 556.52; 0.3 ppm - In swine liver - do; 0.4 ppm - In kidney & fat of swine - do; Use: Drinking water - 520.110

Apricot kernel (persic oil) - NAT, GRAS

Arabinogalactan - EMUL, REG, GMP, In essential oils, non-nutritive sweeteners, flavor bases, non-standardized dressings, and pudding mixes - 172.610; MISC, REG, GMP, Comp of microcapsules for flavoring oils - 172.230

Arginine (l form only) - NUTR/DS, REG - 172.320

Arnica flower extract - FL/ADJ, REG, GMP, In alcoholic beverages only - 172.510

Arsanilic acid - FEED, REG, (See Arsenic) In poultry feed - 558.55; 558.58; 558.62; 558.248; 558.680

Arsenic - FEED, REG, 2 ppm - As residue in liver & kidney of swine - 556.60; 2 ppm - As residue in edible bypdts of chickens & turkeys - do; 0.5 ppm - As residue in muscle meat of chickens & turkeys, in eggs, & in muscle meat and by-products (other than kidney & liver) of swine - do

Artemisia - FL/ADJ, REG, GMP, Finished food thujone free - 172.510

Artichoke leaves - FL/ADJ, REG, GMP, In alcoholic beverages only - 172.510

Asafoetida - ESO, GRAS - 182.20

Ascorbic acid - PRES, GRAS, GMP - 182.3013; DS, GRAS, GMP - 182.5013; NUTR, GRAS, GMP - 182.8013; MISC, GRAS/FS, Part 137, Cereal Flours; 150.141, 150.161, Art Sw Jellies & Preserves; 155.200 - Canned Mushrooms & Artichokes

Ascorbyl palmitate - PRES, Status under review, contact CFSAN.

Asparagine (l-form) - NUTR/DS, REG - 172.320

Aspartame - NUTRS, REG, GMP, Sweetening agent, sugar substitute uses stated in - 172.804. Sugar substitute tablets, breakfast cereals, chewing gum, dry bases for beverages, instant coffee and tea beverages, gelatins, puddings, fillings, and dairy product analog toppings, ready-to-serve nonalcoholic flavored beverages, tea beverages, fruit juice based drinks where food standards permit such use, fruit flavored drinks and ades, imitation fruit flavored drinks and ades, frozen stick-type confections and novelties, breath mints, hard and soft candy, refrigerated ready-to-serve gelatins, puddings, and fillings, fruit wine beverages with EtOH <7%, yogurt-type products where aspratame is added after pasteurization and culturing, refrigerated flavored milk beverages, frozen desserts, frostings, toppings, fillings, glazes and icings for precooled baked goods, frozen, ready-to-thaw-and-eat cheesecakes, fruit and fruit toppings, frozen dairy and nondairy frostings, toppings, and fillings, fruit spreads, fruit toppings, and fruit syrups, malt beverages with <7% EtOH and containing fruit juice, baked goods and baking mixes 0.5 wt.-% of ready-to bake products or of finished formulation and prior to baking.

Aspartic acid (l-form) - NUTR/DS, REG - 172.320

Aspergillus Niger - MISC, REG, For Fermentation Production of Citric Acid - 173.280

Aspergillus oryzae, prepns from Avermectin B and delta 8,9 geometric isomer - ENZ, /FS, Part 136, Bakery Products; INSECT, REG, 0.1 ppm - As residues in/on dried citrus pulp - 40 CFR 186.300; 0.005 ppm - As residue in cottonseed - 40 CFR 449; 40 CFR 180.449

Avermectin Bi - REG, 0.10 ppm - As residues in/or on dried citrus pulp - 40 CFR 186.300; 0.07 ppm - As residues in or on Tomato pomace - do; 0.02 ppm - As residues in meat and meat by-products of cattle - 40 CFR 180.449; 0.005 ppm - As residues in/on cottonseed - 40 CFR 180.449; 0.005 ppm - As residues in milk - do;

Azaperone - VET, REG, Use: Swine (Injection) - 522.150

Azodicarbonamide - BL, REG/FS, 45 ppm in flour - Part 137, Cereal Flours & 172.806

B

Bacitracin, manganese bacitracin, zinc bacitracin, Bacitracin methylene disalicylate - FEED/VET,

REG, 0.5 ppm (neg res) - As residue in meat and meat by-products of cattle, poultry, pheasants, quail, and swine and in milk & eggs - 556.70; For feed use see 558.55, 558.58, 558.62, 558.76, 558.78, 558.274, 558.430, 558.460, 558.530, 558.680;

Bacteria (harmless, lactic acid producing; propionic acid producing) - MISC, FS, Part 133, Cheeses; Part 166, Margarine

Bacterial Catalase - See Catalase, Bacterial

Bakers Yeast Protein (Saccharomyces Cerevisiae) - NUTR, REG, <10,000 organisms/gm by APC - In foods as Nutrient supplement, 172.325; <10 yeast and mold/gm in final product

Bakers Yeast Glycan - EMUL/STAB, REG, <10,000 organisms/gm by APC - 169.150, Salad Dressings; 172.898 as emulsifier; <10 yeast & molds/gm - Thickener, stabilizer or texturizer; < 5% - In salad dressings, 172.898; GMP, In frozen dessert analogs, sour cream analogs, cheese spread analogs, and in cheese- flavored and sour cream-flavored snack dips - 172.898

Balm (lemon balm) - SP/ESO, GRAS - 182.10 and 182.20

Balsam of Peru - ESO, GRAS - 182.20

Bambermycins - FEED, REG, For feed uses in chickens, turkeys, & swine - 558.95

Basil - ESO, GRAS - 182.20

Basil (bush and sweet) - SP, GRAS - 182.10

Bay, Bay leaves - SP/ESO, GRAS - 182.10 and 182.20

Bay, (Myrcia Oil) - ESO, GRAS - 182.20

Beeswax (bleached, white wax) - MISC, GRAS

Beeswax (yellow wax) - MISC, GRAS - 184.1973

Beeswax, white (cire d'abeille) - FL/ADJ, REG, GMP, In conjunction with flavors - 172.510

Benomyl - FUNG, REG, 70 ppm - In dried apple pomace resulting from application to apples as a residue - 40 CFR 186.350; 125 ppm - In dried grape pomace and raisin waste resulting from application to growing grapes as a residue - 40 CFR 186.350; 50 ppm - In raisins resulting from application to growing grapes as a residue - 40 CFR 186.350; 50 ppm - In dried citrus pulp when present therein as a result of application to the raw agricultural citrus fruits as a residue - 40 CFR 186.350; 50 ppm - In concentrated tomato products resulting from application to growing crop as a residue; In rice hulls resulting from application to raw agricultural rice - 40 CFR 186.350; Animal feed - 582.1155; Pesticide Tolerances - 180.294

Bensulfuron methyl ester - HERB, REG, 0.02 ppm - As residue in/on rice - 40 CFR 180.445; 0.05 ppm - As residue in/on rice straw - do

Bentazon - FEED, REG, 4 ppm - In or on mint hay resulting from application to growing mint - 40 CFR 186.400; HERB, REG, 4 ppm - As residue in mint hay - 40 CFR 186.400; 0.05 ppm - As residues in/on corn grain, sorghum fodder, grain and soybeans - 40 CFR 180.355; 0.2 ppm - As residues in/on sorghum forage - do; 3 ppm - As residues in/on corn fodder or forage, soybean forage - do

Bentonite - MISC, GRAS, GMP, Except in feeds cont buquinolate

Benzathine cloxacillin - VET, REG, 0.02 ppm - As residues in milk - 556.115; Use: Infusion - 526.363

Benzene - MISC, REG, 1.0 ppm - In modified hop extract for beer - 172.560

Benzoic Acid - PRES, GRAS, 0.1%

Benzoin Resin - FL/ADJ, REG, GMP, In conjunction with flavors - 172.510, 73.1

Benzophenone

Benzoyl Peroxide - BL, FS, Part 137, Cereal Flours; Part 133 for milk to be used in certain cheeses

Bergamot (bergamot orange) - ESO, GRAS - 182.20

Beta-carotene - NUTR, GRAS, GMP, Use: Direct human food ingredient - 184.1245

BHA (butylated hydroxyanisole) - AOX/FS, GRAS, 0.02% - Of fat or oil content, incl essential (volatile) oil, of food, incl oleomargarine - Part 166, Margarine; AOX, REG, 10 ppm, alone or w/BHT - In potato granules - 172.110; 32 ppm - In mixed diced, glaceed fruits - 172.110; 50 ppm, alone or w/BHT - In dry breakfast cereals, sweet potato flakes, dehydr potato flakes or shreds - 172.110; 90 ppm in mix or <2 ppm in prep food - In dry mixes for beverages and desserts - 172.110; 200 ppm alone or w/BHT - In emulsion stabilizers for shortenings; 0.1% - In active dry yeast - 172.110; AOX, REG,0.1% alone or w/BHT and/or propyl gallate - In chewing gum base - 172.615; AOX, REG, 0.1% of defoamer - For proc. beet sugar & yeast - 173.340; AOX, REG, 0.5% of essential volatile oil - For use in flavoring substances - 172.515; AOX, REG, In mastitis form, for dairy cattle - 526.820

BHT (butylated hydroxytoluene) - AOX, GRAS, 0.02% - Of fat or oil content, incl essential oil, of food, incl oleomargarine Part 166 - Margarine; FS, 33 ppm in rice - In enriched parboiled rice - Part 137.350; FS, <0.02% in oleomargarine - In any animal fat ingredient permitted in oleomargarine not to exceed 0.02% by wt of such animal fat content, Part 166 - Margarine; AOX, REG, 10 ppm alone or w/BHA - In potato granules - 172.115; 50 ppm alone or w/BHA - In dry breakfast cereals, sweet potato flakes, dehydr potato flakes or shreds - 172.115; 200 ppm alone or w/BHA - In emul stab for shortenings - 172.115; REG, 0.1% alone or w/BHA and/or propyl gallate - In chewing gum base - 172.615; REG, 0.1% of defoamer - For proc. beet sugar & yeast - 173.340; REG, In mastitis form, for dairy cattle - 526.820

Bicarbonate of soda - B&N, GRAS/FS - 137.270, Self-rising Cornmeal

Bifenthrin - PEST, REG, 0.02 ppm - As residues in milk - 40 CFR 180.442; 0.10 ppm - As residues in fat, meat, and meat by-products of cattle, goats, hogs, and sheep - do; 0.50 ppm - As residues in/on cottonseed - do

Bile salts & Ox Bile Extract - SDA, GRAS - 184.4560

Bioflavonoids, citrus - DS, ILL, Any claim for special dietary use renders the food misbranded (VitaSafe case)

Biotin - NUTR/DS, GRAS, GMP - 182.5159; 182.8159

3,6-Bis(2-chlorophenyl)-1,2,4,5 tetrazine - PEST, REG, 20 ppm - In Apple Pomace as a result of application to apples; 40 CFR 186.425

1,1-Bis(p-chlorophenyl)-2,2,2,-trichloroethanol - PEST, REG, 45 ppm - In dried teas as a result of application to growing tea crop - 40 CFR 185.375

Bitter almond - ESO, GRAS, Free of prussic acid - 182.20

Biuret, feed grade - NUTR, REG, GMP, In feed for ruminants except those producing milk for human consumption - 573.220

Blackberry bark extract - FL/ADJ, REG, In conjunction w/flavors only - 172.510

Boiler water additives - Ammonium alginate, cobalt sulfate, lignosulfonic acid, monobutyl ether of polyoxyethylene glycol or potassium tripolyphosphate, sodium carboxymethylcellulose, sodium glucoheptonate, sodium humate, sodium metasilicate, sodium metabisulfite, polyoxpropylene glycol, polyoxyethylene glycol, potassium carbonate, sodium acetate, sodium alginate, sodium aluminate, sodium carbonate, sodium hexametaphosphate, sodium hydroxide, sodium lignosulfonate, sodium nitrate, sodium phosphate (mono-, di-, tri-), sodium polyacrylate, sodium polymethacrylate, sodium silicate, sodium sulfate, sodium sulfite (neutral or alkaline), sodium tripolyphosphate, tannin (incl quebracho extract), tetrasodium EDTA, tetrasodium pyrophosphate, 1-hydroxyethylidene-1, 1-diphosphonic acid and its sodium & potassium salt - BC, REG, GMP, In steam contacting food - 173.310

Hydrazine - BC, REG, In steam contacting food

Acrylamide-sodium acrylate resin - BC, REG, 0.05% of acrylamide monomer - In steam contacting food

Cyclohexylamine or Morpholine - BC, REG, <10 ppm - In steam contacting food except milk and milk products

Octadecylamine - BC, REG, <3 ppm - In steam contacting food except milk and milk productsDiethylaminoethenol - BC, REG, 15 ppm - In steam contacting food except milk and milk products

Trisodium nitrilotriacetate - BC, REG, <5 ppm in feed water - In steam contacting food except milk and milk products

Polymaleic acid and/or its sodium salt - BC, REG, Total < 1 ppm in feed water - In steam contacting food

Sorbitol anhydride esters (a mixture of sorbitan monostearate, polyoxyethylene (20) sorbitan mono stearate (polysorbate 60) and polyoxyethylene (20) sorbitan monolaurate (polysorbate 20) – BC, REG, Each component ≤ 15 ppm in steam contacting food

Bois de rose - ESO, GRAS - 182.20

Boldus leaves - FL/ADJ, REG, In alcoholic beverages only - 172.510

Borax - MISC, ILL, No petition filed, Illegal for use in foods incl. wax ctg for fruits and vegetables. MID permits use in export meats.

Boron - MISC, REG, <310 ppm - In modified hop extract from sodium borohydride - 172.560

Boronia flowers - FL/ADJ, REG, GMP, In conjunction w/flavors only - 172.510

Bromelin or Bromelain (spelling optional) - MISC, MIA, To soften tissue of meats; ENZ, REG, As an enzyme preparation (optional ingredient) in bakery products - 136

Bromides, inorganic - FUM, REG, X-ref - Inorganic bromides

Brominated vegetable oil - STAB, INTERM/REG, <15 ppm - In fruit flavored beverages where not precluded by a standard - 180.30

Bryonia root - FLA/ADJ, REG, GMP, In alcoholic beverages only - 172.510

Bucha leaves oil - FL/ADJ, REG, GMP, In conjunction w/flavors only - 172.510

Buckbeen leaves - FL/ADJ, REG, GMP, In alcoholic beverages only - 172.510

Buquinolate - FEED, REG, 0.4 ppm - In liver, kidney & skin of chickens - 556.90; 0.1 ppm - Residue in muscle of chickens - do; 0.5 ppm - Residues in uncooked yolk of eggs - do; 0.2 ppm - Residues in uncooked whole eggs - do; Feed use in chickens, see 558.62, 558.530 & 558.105

Butadiene styrene rubber - MISC, REG, In chewing gum base - 172.615

Butane, n-butane, iso-butane - MISC, GRAS - 184.1165

Butoxy monoether of mixed (ethylene-propylene) polyalkylene glycol - SANI, REG, GMP, Adequate drainage - 178.1010

n-Butoxypolyoxyethylene polyoxypropylene glycol - AF, REG, GMP, X-ref - Defoaming agent component (used in processing beet sugar) - 173.340

Butter Starter distillate - FLAV, FL/ADJ, GRAS, GMP - 184.1848

Butyl acetate

Butyl Alcohol - MISC, REG - 73.1, 172.560 - Modified hop extract

sec-Butylamine - FUNG, REG, 90 ppm - Residues in citrus molasses or dried citrus pulp for cattle feed - 40 CFR 186.450

1,3-Butylene glycol - SOLV, REG, GMP, In nat & syn flavoring substances except where standards preclude use - 173.220, 573.225. Used in the manufacture of sausage casings as a formulation aid and processing aid - 172.712.

Tert-Butylhydroquinone (TBHQ) - AOX, REG - 172.185, 0.02% of fat or oil content, incl essential (volatile) oil, of food

2(p-tert-Butylphenoxy) cyclohexyl 2-propynyl sulfite - PEST, REG, See Propargite

Butyl rubber - MISC, REG, Component of chewing gum base - 172.615

Butyl stearate - AF, REG, X-ref - Defoaming agent component (used in proc. beet sugar & yeast) - 173.340

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this section, or from those listed in part 181 of this chapter, do not exist or have been waived.

[51 FR 16830, May 7, 1986]

§ 186.1673 Pulp.

(a) Pulp is the soft, spongy pith inside the stem of a plant such as wood, straw, sugarcane, or other natural plant sources.

(b) The ingredient is used or intended for use as a constituent of food packaging containers.

(c) The ingredient is used in paper and paperboard made by conventional paper-making processes at levels not to exceed good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 186.1750 Sodium chlorite.

(a) Sodium chlorite ($NaCLO_2$, CAS Reg. No. 7758-19-2) exists as slightly hygroscopic white crystals or flakes. It is manufactured by passing chlorine dioxide into a solution of sodium hydroxide and hydrogen peroxide.

(b) the ingredient is used at levels from 125 to 250 parts per million as a slimicide in the manufacture of paper and paperboard that contact food.

[45 FR 16470, Mar. 14, 1980]

§ 186.1756 Sodium formate.

(a) Sodium formate ($CHNaO_2$, CAS Reg. No. 141-53-7) is the sodium salt of formic acid. It is produced by the reaction of carbon monoxide with sodium hydroxide.

(b) The ingredient is used as a constituent of paper and paperboard used for food packaging.

(c) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(d) Prior sanctions for sodium formate different from the uses established in this section do not exist or have been waived.

[45 FR 22915, Apr. 4, 1980]

§ 186.1770 Sodium oleate.

(a) Sodium oleate ($C_{18}H_{33}O_2Na$, CAS Reg. No. 143-19-1) is the sodium salt of oleic acid (*cis*-9-octadecenoic acid). It exists as a white to yellowish powder with a slight tallow-like odor. Commercially, sodium oleate is made by mixing and heating flaked sodium hydroxide and oleic acid.

(b) In accordance with § 186.1(b)(1), the ingredient is used as a constituent of paper and paperboard for food packaging and as a component of lubricants with incidental food contact in accordance with § 178.3570 of this chapter, with no limitation other than current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 39372, Oct. 28, 1986]

§ 186.1771 Sodium palmitate.

(a) Sodium palmitate ($C_{16}H_{31}O_2Na$, CAS Reg. No. 408-35-5) is the sodium salt of palmitic acid (hexadecanoic acid). It exists as a white to yellow powder. Commercially, sodium palmitate is made by mixing and heating flaked sodium hydroxide and palmitic acid.

(b) In accordance with § 186.1(b)(1), the ingredient is used as a constituent of paper and paperboard for food packaging with no limitation other than current good manufacturing practice.

(c) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[51 FR 39372, Oct. 28, 1986]

§ 186.1797 Sodium sulfate.

(a) Sodium sulfate (Na_2SO_4, CAS Reg. No. 7757-82-6), also known as Glauber's salt, occurs naturally and exists as colorless crystals or as a fine, white crystalline powder. It is prepared by the neutralization of sulfuric acid with sodium hydroxide.

(b) The ingredient is used as a constituent of paper and paperboard used for food packaging, and cotton and cotton fabric used for dry food packaging.

(c) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 186.1(b)(1).

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[45 FR 6086, Jan. 25, 1980]

Substances	Limitations
alpha-Alkyl-*omega*-hydroxypoly-(oxyethylene) produced by condensation of a linear primary alcohol containing an average chain length of 10 carbons with poly(oxyethylene) having an average of 5 ethylene oxide units.	May be used at an application rate not to exceed 0.3 percent by weight of cottonseeds to enhance delinting of cottonseeds intended for the production of cottonseed oil. Byproducts including lint, hulls, and meal may be used in animal feed.
An alkanomide produced by condensation of coconut oil fatty acids and diethanolamine, CAS Reg. No. 068603–42–9.	May be used at an application rate not to exceed 0.2 percent by weight of cottonseeds to enhance delinting of cottonseeds intended for the production of cottonseed oil. Byproducts including lint, hulls, and meal may be used in animal feed.

[47 FR 8346, Feb. 26, 1982]

§ 173.325 Acidified sodium chlorite solutions.

Acidified sodium chlorite solutions may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by mixing an aqueous solution of sodium chlorite (CAS Reg. No. 7758–19–2) with any generally recognized as safe (GRAS) acid.

(b)(1) The additive is used as an antimicrobial agent in poultry processing water in accordance with current industry practice under the following conditions:

(i) As a component of a carcass spray or dip solution prior to immersion of the intact carcass in a prechiller or chiller tank;

(ii) In a prechiller or chiller solution for application to the intact carcass;

(iii) As a component of a spray or dip solution for application to poultry carcass parts; or

(iv) In a prechiller or chiller solution for application to poultry carcass parts.

(2) When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm), in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

(3) When used in a prechiller or chiller solution, the additive is used at levels that result in sodium chlorite concentrations between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.8 to 3.2.

(c) The additive is used as an antimicrobial agent in accordance with current industry practice in the processing of red meat, red meat parts, and organs as a component of a spray or in the processing of red meat parts and organs as a component of a dip. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9.

(d) The additive is used as an antimicrobial agent in water and ice that are used to rinse, wash, thaw, transport, or store seafood in accordance with current industry standards of good manufacturing practice. The additive is produced by mixing an aqueous solution of sodium chlorite with any GRAS acid to achieve a pH in the range of 2.5 to 2.9 and diluting this solution with water to achieve an actual use concentration of 40 to 50 parts per million (ppm) sodium chlorite. Any seafood that is intended to be consumed raw shall be subjected to a potable water rinse prior to consumption.

(e) The additive is used as an antimicrobial agent on raw agricultural commodities in the preparing, packing, or holding of the food for commercial purposes, consistent with section 201(q)(1)(B)(i) of the act, and not applied for use under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act, in accordance with current industry standards of good manufacturing practice. Applied as a dip or a spray, the additive is used at levels that result in chlorite concentrations of 500 to 1200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treatment of the raw agricultural commodities with acidified sodium chlorite solutions shall be followed by a potable water rinse, or by blanching, cooking, or canning.

(f) The concentration of sodium chlorite is determined by a method entitled "Determination of Sodium Chlorite: 50 ppm to 1500 ppm Concentration," September 13, 1995, developed by Alcide

Corp., Redmond, WA, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC 20204–0001, or the Office of the Federal Register, 800 North Capitol St. NW., Suite 700, Washington, DC.

[61 FR 17829, Apr. 23, 1996, as amended at 63 FR 11119, Mar. 6, 1998; 64 FR 44123, Aug. 13, 1999; 64 FR 49982, Sept. 15, 1999; 65 FR 1776, Jan. 12, 2000; 65 FR 16312, Mar. 28, 2000]

§ 173.340 Defoaming agents.

Defoaming agents may be safely used in processing foods, in accordance with the following conditions:

(a) They consist of one or more of the following:

(1) Substances generally recognized by qualified experts as safe in food or covered by prior sanctions for the use prescribed by this section.

(2) Substances listed in this paragraph (a)(2) of this section, subject to any limitations imposed:

Substances	Limitations
Dimethylpolysiloxane (substantially free from hydrolyzable chloride and alkoxy groups; no more than 18 percent loss in weight after heating 4 hours at 200°C; viscosity 300 to 1,050 centistokes at 25 °C; refractive index 1.400–1.404 at 25°C).	10 parts per million in food, or at such level in a concentrated food that when prepared as directed on the labels, the food in its ready-for-consumption state will have not more than 10 parts per million except as follows: Zero in milk; 110 parts per million in dry gelatin dessert mixes labeled for use whereby no more than 16 parts per million is present in the ready-to-serve dessert; 250 parts per million in salt labeled for cooking purposes, whereby no more than 10 parts per million is present in the cooked food.
Formaldehyde	As a preservative in defoaming agents containing dimethylpolysiloxane, in an amount not exceeding 1.0 percent of the dimethylpolysiloxane content.
α-Hydro-*omega*-hydroxy-poly (oxyethylene)/poly(oxypropylene) (minimum 15 moles)/poly(oxyethylene) block copolymer (CAS Reg. No. 9003–11–6) as defined in § 172.808(a)(3) of this chapter.	For use as prescribed in § 172.808(b)(3) of this chapter.
Polyacrylic acid, sodium salt	As a stabilizer and thickener in defoaming agents containing dimethylpolysiloxane in an amount reasonably required to accomplish the intended effect.
Polyethylene glycol	As defined in § 172.820 of this chapter.
Polyoxyethylene 40 monostearate	As defined in U.S.P. XVI.
Polysorbate 60	As defined in § 172.836 of this chapter.
Polysorbate 65	As defined in § 172.838 of this chapter.
Propylene glycol alginate	As defined in § 172.858 of this chapter.
Silicon dioxide	As defined in § 172.480 of this chapter.
Sorbitan monostearate	As defined in § 172.842 of this chapter.
White mineral oil: Conforming with § 172.878 of this chapter	As a component of defoaming agents for use in wash water for sliced potatoes at a level not to exceed 0.008 percent of the wash water.

(3) Substances listed in this paragraph (a)(3), provided they are components of defoaming agents limited to use in processing beet sugar and yeast, and subject to any limitations imposed:

Substances	Limitations
Aluminum stearate	As defined in § 172.863 of this chapter.
Butyl stearate.	
BHA	As an antioxidant, not to exceed 0.1 percent by weight of defoamer.
BHT	Do.
Calcium stearate	As defined in § 172.863 of this chapter.
Fatty acids	As defined in § 172.860 of this chapter.
Formaldehyde	As a preservative.
Hydroxylated lecithin	As defined in § 172.814 of this chapter.
Isopropyl alcohol.	
Magnesium stearate	As defined in § 172.863 of this chapter.
Mineral oil: Conforming with § 172.878 of this chapter	Not more than 150 p.p.m. in yeast, measured as hydrocarbons.

aviation gatherings. Instructions and the appropriate address for submitting written comments were disseminated to the approximately 360 pilots at those gatherings who expressed an interest in this rulemaking. Verbal comments from those gatherings were noted. In general, most pilots of aircraft equipped with electrical systems expressed agreement with the rule. There was a suggestion that a control tower may be necessary at Pearson. However, others felt a control tower was neither needed nor wanted. In fact, the activity level at Pearson does not approach the level established by the FAA to support a control tower. Some expressed concern that traffic at Pearson would be delayed for PDX traffic either by denying access to the Class D airspace for aircraft arriving at Pearson, or by requiring aircraft departing Pearson Field to hold on the ground until separation from PDX traffic could be achieved. Separation services are not provided for aircraft operating under visual flight rules in Class D airspace. Air Traffic will not be controlling the flow of aircraft arriving at or departing from Pearson.

The Rule

This amendment to part 71 of Federal Aviation Regulations establishes Class D airspace at Pearson Field, Vancouver, Washington. The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

ANM WA D Vancouver, WA
Vancouver, Pearson Field, WA
(lat. 45°37′14″N, long. 122°39′23″W)
Portland International Airport, OR
(lat. 45°35′19″N, long 122°35′51″W)

That airspace extending upward from the surface to but not including 1,100 feet MSL in an area bounded by a line beginning at the point where the 019° bearing from Pearson Field intersects the 5-mile arc from Portland International Airport extending southeast to a point 1½ miles east of Pearson Field on the extended centerline of Runway 8/26, and thence south to the north shore of the Columbia River, thence west via the north shore of the Columbia River to the 5-mile arc from Portland International Airport and thence clockwise via the 5-mile arc to point of beginning. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Seattle, Washington, on April 8, 1996.

Richard E. Prang,

Acting Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 96–9992 Filed 4–22–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 94F–0358]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified solutions of sodium chlorite in poultry processing water. This action is in response to a petition filed by Alcide Corp.

DATES: Effective April 23, 1996; written objections and requests for a hearing by May 23, 1996. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications listed in new § 173.325, effective April 23, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of November 1, 1994 (59 FR 54609), FDA announced that a food additive petition (FAP 4A4433) had been filed by Alcide Corp., Inc., 8561 154th Ave. NE., Redmond, WA 98052, proposing that the food additive regulations be amended to provide for the safe use of acidified solutions of sodium chlorite/chlorous acid in poultry processing water.

FDA has evaluated data in the petition and other relevant material and has consulted with scientists in the Food Safety and Inspection Service in the U.S. Department of Agriculture concerning the technological and practical aspects of the proposed use of acidified solutions of sodium chlorite. The agency concludes that the proposed use of the additive is safe and will have the intended technical effect of reducing microbial contamination on poultry. The agency also concludes that the regulation approving the additive should be entitled "acidified sodium chlorite solutions." Acidification of sodium chlorite results in partial conversion of chlorite to chlorous acid. Also, in the notice of filing, FDA announced that the petition proposed to allow the use of any of the following acids to prepare acidified sodium chlorite solutions: Phosphoric acid, citric acid, hydrochloric acid, lactic acid, malic acid, or sulfuric acid. These acids are all generally recognized as safe (GRAS) acids. The agency has concluded that the use of any GRAS acid is appropriate, and is codifying this conclusion in the regulation. Therefore, 21 CFR part 173 is amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to

approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing for this petition FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before May 23, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. New § 173.325 is added to subpart D to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

Acidified sodium chlorite solutions may be safely used in accordance with the following prescribed conditions:

(a) The additive is produced by mixing an aqueous solution of sodium chlorite (CAS Reg. No. 7758–19–2) with any generally recognized as safe (GRAS) acid.

(b) The additive is used as an antimicrobial agent in poultry processing water as a component of a carcass spray or dip solution prior to immersion of the carcass in a prechiller or chiller tank, or in a prechiller or chiller solution in accordance with current industry practice for use of poultry processing water.

(1) When used in a carcass spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9. The concentration of sodium chlorite is determined by a method entitled "Determination of Sodium Chlorite: 50 ppm to 1500 ppm Concentration," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(2) When used in a prechiller or chiller tank, the additive is used at levels that result in sodium chlorite concentrations between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.8 to 3.2. The concentration of sodium chlorite is determined by a method entitled "Determination of Sodium Chlorite: 50 ppm to 1500 ppm Concentration," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this method is listed in paragraph (b)(1) of this section.

Dated: April 11, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–9783 Filed 4–22–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 529

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor for an approved abbreviated new animal drug application (ANADA) from Macleod Pharmaceuticals, Inc., to Anthony Products Co.

EFFECTIVE DATE: April 23, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525, has informed FDA that it has transferred the ownership of, and all rights and interests in, approved ANADA 200–115 (Gentamicin Sulfate) to Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006. Accordingly, FDA is amending the regulations in 21 CFR 529.1044a to reflect the change of sponsor.

List of Subjects in 21 CFR Part 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR part 529 continues to read as follows:

dispensing with notice and public procedure thereon as unnecessary. For the same reason, good cause exists for dispensing with the requirement for a delayed effective date, under 5 U.S.C. 553 (a)(2) and (d)(3). Also, for the same reason, it is certified that the amendments will not have a significant economic impact on a substantial number of small entities. Accordingly, the amendments are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 or 604.

This document does not meet the criteria for a "significant regulatory action" as specified in Executive Order 12866.

Drafting Information

The principal author of this document was Janet L. Johnson, Regulations Branch. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 10

Caribbean Basin initiative, Customs duties and inspection, Exports, Reporting and recordkeeping requirements.

Amendment to the Regulations

For the reasons set forth in the preamble, Part 10 of the Customs Regulations (19 CFR Part 10) is amended as set forth below.

PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE, ETC.

1. The general authority citation for Part 10 continues to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1321, 1481, 1498, 1508, 1623, 3314;

* * * * *

§ 10.62 [Amended]

2. Section 10.62(c)(2) is amended by removing the reference "Customs Form 7506" and by adding "Customs Form 7501" in its place.

George J. Weise,

Commissioner of Customs.

Approved: May 30, 1996.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 96–15750 Filed 6–19–96; 8:45 am]

BILLING CODE 4820–02–P

RAILROAD RETIREMENT BOARD

20 CFR Part 209

RIN 3220–AB16

Railroad Employers' Reports and Responsibilities

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board (Board) hereby amends its regulations to add sections to permit employers to dispose of payroll records after five years, and for the utilization of payroll records to credit service under the Railroad Retirement Act in the case of employers that have ceased operations. These amendments will alleviate needless record retention and ease reporting requirements for employers that have permanently ceased operations.

EFFECTIVE DATE: June 20, 1996.

ADDRESSES: Secretary to the Board, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611.

FOR FURTHER INFORMATION CONTACT: Thomas W. Sadler, Assistant General Counsel, Railroad Retirement Board, 844 Rush Street, Chicago, Illinois 60611, (312) 751–4513, TDD (312) 751–4701.

SUPPLEMENTARY INFORMATION: Employer reports are used to establish employee compensation and service records. These reports are based on payroll records. The Board's rules and procedures regarding the authorization of disposal of these records and the utilization of payroll records of employers who have abandoned service in lieu of employer reports are presently contained in Board Orders, which are not readily available to the public. Accordingly, the Board adopts regulations specifying that railroad employers may dispose of payroll records more than five years old where there is no dispute pending as to the compensation reported for the periods covered by those records. The Board also to amends its regulations to provide that the Board will accept payroll records in lieu of prescribed reports if there is no official of the employer available to prepare and certify to the accuracy of such reports and if the tax liability involved has been discharged.

On February 15, 1996, the Board published this rule as a proposed rule (61 FR 5970) inviting comments on or before April 15, 1996. No comments were received. No changes have been made to the proposed rule. The Board, with the concurrence of the Office of Management and Budget, has determined that this is not a significant regulatory action under Executive Order 12866; therefore, no regulatory impact analysis is required. There are no information collections associated with this rule.

List of Subjects in 20 CFR Part 209

Railroad employees, Railroad retirement, Railroads.

For the reasons set out in the preamble, title 20, chapter II, part 209 of the Code of Federal Regulations is amended as follows:

PART 209—RAILROAD EMPLOYERS' REPORTS AND RESPONSIBILITIES

1. The authority citation for part 209 continues to read as follows:

Authority: 45 U.S.C. 231f.

2. Part 209 is amended by adding §§ 209.16 and 209.17 to read as follows:

§ 209.16 Disposal of payroll records.

Employers may dispose of payroll records for periods subsequent to 1936, *provided that* the payroll records are more than five years old and that there is no dispute pending pertaining to the compensation reported for the period of those records.

§ 209.17 Use of payroll records as returns of compensation.

Payroll records of employers which have permanently ceased operations may be accepted in lieu of prescribed reports *provided that* there is no official of the employer available to prepare and certify to the accuracy of such reports and, *provided further that* any employer and employee tax liability incurred under the Railroad Retirement Tax Act has been discharged.

Dated: June 11, 1996.

By Authority of the Board.

For the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 96–15705 Filed 6–19–96; 8:45 am]

BILLING CODE 7905–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 92F–0339]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of an aqueous solution of chlorine dioxide and related oxychloro species, generated by acidification of an aqueous solution of sodium chlorite with a solution of sodium gluconate, citric acid, phosphoric acid, and sodium mono- and didodecylphenoxybenzenedisulfonate, as a sanitizing solution to be used on food-processing equipment and utensils, including dairy-processing equipment. This action responds to a petition filed by Rio Linda Chemical Co.

DATES: Effective June 20, 1996 written objections and requests for a hearing by July 22, 1996. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a publication listed in § 178.1010 (21 CFR 178.1010), effective June 20, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of September 22, 1992 (57 FR 43741), FDA announced that a food additive petition (FAP 2B4334) had been filed by Rio Linda Chemical Co., c/o 1414 Fenwick Lane, Silver Spring, MD 20910. The petition proposed that the food additive regulations be amended in § 178.1010 *Sanitizing solutions* (21 CFR 178.1010) to provide for the safe use of an aqueous solution of chlorine dioxide and related oxychloro species, generated by acidification of an aqueous solution of sodium chlorite with sodium gluconate, citric acid, phosphoric acid, and sodium alkylphenoxybenzenedisulfonate, as a sanitizing solution to be used on food-contact surfaces, food-processing equipment, and utensils. Based on information in the food additive petition, FDA has determined that a more specific and therefore more appropriate name for the form of sodium alkylphenoxybenzenedisulfonate used to generate the subject sanitizing solution is sodium mono- and didodecylphenoxybenzenedisulfonate. This more specific name will be used throughout the remainder of this document.

I. Safety and Functional Effect of Petitioned Use of the Additive

Sanitizing solutions are mixtures of chemicals that function together to sanitize food-contact surfaces and are regulated as such. Each listed component in a sanitizing solution has a functional effect, and the agency evaluates the data submitted in support of the efficacy of the entire sanitizing solution. The subject sanitizing solution is an aqueous solution of chlorine dioxide and related oxychloro species, generated by acidification of an aqueous solution of sodium chlorite with a solution of sodium gluconate, citric acid, phosphoric acid, and sodium mono- and didodecylphenoxybenzenedisulfonate. The functions of these components, and the basis for FDA's determination of the safety of these components in the subject sanitizer, are described below.

A. Chlorine Dioxide

Chlorine dioxide functions as an antimicrobial agent in the subject sanitizing solution. Chlorine dioxide is regulated for use in sanitizing solutions under § 178.1010(b)(34) and is regulated for use as an antimicrobial agent in water used in poultry processing under 21 CFR 173.69. On the basis of the data submitted in support of the already-regulated uses of chlorine dioxide, the data contained in the food additive petition submitted in support of this sanitizing solution, and studies in the scientific literature, FDA finds that the use of chlorine dioxide in the subject sanitizing solution is safe (Ref. 1).

B. Sodium Gluconate

Sodium gluconate functions as a sequestering agent in the subject sanitizing solution. Sodium gluconate is listed as GRAS for use in food as a sequestering agent under 21 CFR 182.6757. In addition, FDA regulations permit the addition to a sanitizing solution of any substance that is GRAS for use in food (§ 178.1010(b)). On the basis of the data supporting the GRAS status of sodium gluconate, FDA finds that the use of sodium gluconate in the subject sanitizing solution is safe (Ref. 1).

C. Citric Acid

Citric acid functions as a sequestering agent in the subject sanitizing solution. Citric acid is affirmed as GRAS for use in food under 21 CFR 184.1033. In addition, as stated in the previous paragraph, FDA regulations permit the addition to a sanitizing solution of any substance that is GRAS for use in food. On the basis of the data supporting the GRAS status of citric acid, FDA finds that the use of citric acid in the subject sanitizing solution is safe (Ref. 1).

D. Phosphoric Acid

Phosphoric acid functions as an activator in the subject sanitizing solution. Phosphoric acid is listed as GRAS for use in food under 21 CFR 182.1073. In addition, FDA regulations permit the addition to a sanitizing solution of any substance that is GRAS for use in food. On the basis of the data supporting the GRAS status of phosphoric acid, FDA finds that the use of phosphoric acid in the subject sanitizing solution is safe (Ref. 1).

E. Sodium Mono- and Didodecylphenoxybenzenedisulfonate

Sodium mono- and didodecylphenoxybenzenedisulfonate functions as a surfactant in the subject sanitizing solution. Sodium mono- and didodecylphenoxybenzenedisulfonate is regulated for use as an emulsifier and surface active agent in the manufacture of food-contact materials under the listing for sodium mono- and dialkylphenoxybenzenedisulfonate in 21 CFR 178.3400(c). On the basis of the data submitted in support of the already-regulated use of sodium mono- and didodecylphenoxybenzenedisulfonate and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of sodium mono- and didodecylphenoxybenzenedisulfonate in the subject sanitizing solution is safe (Ref. 1).

F. Conclusion on Safety

As discussed above, FDA has evaluated data on the antimicrobial efficacy of the entire sanitizing solution and data in the petition and other relevant materials on the safety of each of the components of the sanitizing solution. On the basis of this evaluation, the agency concludes that these data and materials establish the safety and efficacy of the additive for use as a sanitizing solution on food-processing equipment and utensils including dairy-processing equipment, and that the regulations should be amended in § 178.1010 as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not

available for public disclosure before making the documents available for inspection.

II. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum entitled "FOAM ADD 10—A terminal no-rinse sanitizer—Manufactured by Rio Linda Chemical Corp.," dated June 10, 1994.

IV. Filing of Objections

Any person who will be adversely affected by this regulation may at any time on or before July 22, 1996 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.1010 is amended by adding new paragraphs (b)(46) and (c)(40) to read as follows:

§ 178.1010 Sanitizing solutions.

* * * * *

(b) * * *

(46) An aqueous solution of chlorine dioxide and related oxychloro species generated by acidification of an aqueous solution of sodium chlorite with a solution of sodium gluconate, citric acid, phosphoric acid, and sodium mono- and didodecylphenoxybenzenedisulfonate. In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

* * * * *

(c) * * *

(40) The solution identified in paragraph (b)(46) of this section shall provide, when ready for use, at least 100 parts per million and not more than 200 parts per million of chlorine dioxide as determined by the method developed by Bio-cide International, Inc., entitled, "Iodometric Method for the Determination of Available Chlorine Dioxide (50–250 ppm Available ClO_2)," dated June 11, 1987, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this method are available from the Division of Petition Control, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC; at least 380 parts per million and not more than 760 parts per million of sodium gluconate; and at least 960 parts per million and not more than 1,920 parts per million of sodium mono- and didodecylphenoxybenzenedisulfonate. Other components listed under paragraph (b)(46) of this section shall be used in the minimum amount necessary to produce the intended effect.

* * * * *

Dated: June 7, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–15726 Filed 6–19–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 520

Oral Dosage Form New Animal Drugs; Neomycin Sulfate Oral Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Rhone Merieux, Inc. The ANADA provides for the use of a generic neomycin sulfate oral solution in drinking water or in milk for cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis.

EFFECTIVE DATE: June 20, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Rhone Merieux, Inc., 7101 College Blvd., Overland Park, KS 66210, filed ANADA 200–153, which provides for the use of neomycin sulfate oral solution in drinking water or in milk of cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis (bacterial scours) caused by *Escherichia coli* susceptible to neomycin. ANADA 200–153 is approved as a generic copy of The Upjohn Co.'s NADA 11–035. The ANADA is approved as of May 8, 1996, and the regulations are amended in 21 CFR 520.1485(b) and (d)(3) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21

Note 3: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD 94-077-016(B)R1 and AD 94-076-036(B)R1, both dated December 4, 1996.

Issued in Fort Worth, Texas, on February 26, 1998.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 98-5733 Filed 3-5-98; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98-ANE-92]

Amendment to Class E Airspace; Laconia, NH; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; correction.

SUMMARY: This action corrects a charting error in the description of revised Class E airspace at Laconia, NH (KLCI) published in the **Federal Register** on February 20, 1998 (63 FR 8563) and intended to provide adequate controlled airspace for those aircraft using the new GPS RWY 26 standard instrument approach procedure to Laconia Municipal Airport.

DATES: Effective 0901 UTC, April 23, 1998.

Comments for inclusion in the Rules Docket must be received on or before March 23, 1998.

ADDRESSES: Send comments on the rule to: Manager, Airspace Branch ANE-520, Federal Aviation Administration, Docket No. 98-ANE-92, 12 New England Executive Park, Burlington, MA 01803-5299; telephone (781) 238-7520; fax (781) 238-7596. Comments may also be sent electronically via the internet to the following address: "9 ne airspacefaa.dot.gov". Comments sent electronically must indicate Docket 98-ANE-92 in the subject line.

The official docket file may be examined in the Office of the Regional Counsel, New England Region, ANE-7, Room 401, 12 New England Executive Park, Burlington, MA 01803-5299; telephone (781) 238-7050; fax (781) 238-7055.

An informal docket may also be examined during normal business hours in the Air Traffic Division, Room 408, by contacting the Acting Manager, Airspace Branch at the first address listed above.

FOR FURTHER INFORMATION CONTACT:

David T. Bayley, ANE-520.3, 12 New England Executive Park, Burlington, MA 01803-5299; telephone (781) 238-7523; fax (781) 238-7596.

SUPPLEMENTARY INFORMATION: On February 20, 1998, the FAA published in the **Federal Register** a direct final rule revising the Class E airspace at Laconia, NH (KLCI) to provide for adequate controlled airspace for those aircraft using the new GPS RWY 26 standard instrument approach procedure to Laconia Municipal Airport (63 FR 8563). Since publication of that direct final rule, the FAA has been advised of a charting error in the description of the Class E airspace at Laconia. This action corrects that error.

Correction to the Direct Final Rule

Accordingly, pursuant to the authority delegated to me, the amendment to Class E airspace at Laconia, NH as published in the **Federal Register** on February 20, 1998 (63 FR 8563), **Federal Register** document 98-4314; and the description in FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1 are corrected as follows:

§ 71.1 [Corrected]

On page 8564, column 3, 9th and 10th lines, correct the words "Belknap NDP 249° bearing" to read "Belknap NDB 249°/069° bearings".

Issued in Burlington, MA, on February 26, 1998.

Bill Peacock,

Manager, Air Traffic Division, New England Region.

[FR Doc. 98-5693 Filed 3-5-98; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 97F-0038]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified solutions of sodium chlorite as an antimicrobial agent in the processing of red meat. This action is in response to a petition filed by Alcide Corp.

DATES: This regulation is effective March 6, 1998; written objections and requests for a hearing by April 6, 1998. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in § 173.325(d) (21 CFR 173.325(d)), effective March 6, 1998.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 5, 1997 (62 FR 5428), FDA announced that a food additive petition (FAP 7A4532) had been filed by Alcide Corp., Inc., 8561 154th Ave. NE., Redmond, WA 98052, proposing that the food additive regulations be amended to provide for the safe use of acidified sodium chlorite solutions for red meat disinfection in processing plants. In its evaluation of the petition, the agency has concluded that red meat is not disinfected, but that the microbial contamination of the meat is reduced. Therefore, the agency is approving this additive as an antimicrobial agent in red meat processing.

FDA has evaluated data in the petition and other relevant material. The agency has also consulted with scientists from the Food Safety and Inspection Service, U. S. Department of Agriculture, concerning the technological and practical aspects of the proposed use of acidified sodium chlorite solutions. Based upon this information and consultation, the agency concludes that the proposed use of the additive is safe, and the additive will have the intended technical effect of reducing microbial contamination on red meat. Therefore, § 173.325 is being amended as set forth below. Additionally, the agency is revising § 173.325 to eliminate redundancy. This revision is strictly editorial and is not a substantive change in the regulation.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person

listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before April 6, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.325 is amended by revising paragraph (b) and adding paragraphs (c) and (d) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(b) The additive is used as an antimicrobial agent in poultry processing water as a component of a carcass spray or dip solution prior to immersion of the carcass in a prechiller or chiller tank, or in a prechiller or chiller solution in accordance with current industry practice for use of poultry process water.

(1) When used in a carcass spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9.

(2) When used in a prechiller or chiller tank, the additive is used at levels that result in sodium chlorite concentrations between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.8 to 3.2.

(c) The additive is used as an antimicrobial agent in the processing of red meat as a component of a carcass spray in accordance with current industry practice. In the carcass spray, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm) in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9.

(d) The concentration of sodium chlorite is determined by a method entitled "Determination of Sodium Chlorite: 50 ppm to 1500 ppm Concentration," September 13, 1995, developed by Alcide Corp., Redmond, WA, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC 20204–0001, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

Dated: February 27, 1998

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–5073 Filed 3–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 60

[AG Order No. 2144–98]

Authorization of Federal Law Enforcement Officers to Request the Issuance of a Search Warrant

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: Rule 41(h) of the Federal Rules of Criminal Procedure authorizes the Attorney General to designate categories of federal law enforcement officers who may request the issuance of search warrants. This rule adds the Office of Inspector General of the United States Postal Service to the list of agencies having federal law enforcement officers authorized to request the issuance of search warrants pursuant to Rule 41(h).

EFFECTIVE DATE: March 6, 1998.

FOR FURTHER INFORMATION CONTACT: Frederick D. Hess, Director, or Donald B. Nicholson, Attorney, Office of Enforcement Operations, Criminal Division, Department of Justice, Washington, D.C. 20530 (202–305–4023) (not a toll-free number).

SUPPLEMENTARY INFORMATION: Previous authorizations by the Attorney General under Rule 41(h) were made by Order No. 510–73 (38 FR 7244, March 19, 1973), as amended by Order No. 521–73 (38 FR 18389, July 10, 1973), Order No. 826–79 (44 FR 21785, April 12, 1979), Order No. 844–79 (44 FR 46459, August 8, 1979), Order No. 960–81 (46 FR 52360, October 27, 1981), Order No. 987–82 (47 FR 39161, September 7, 1982), Order No. 1005–83 (48 FR 11450, March 18, 1983), Order No. 1026–83 (48 FR 37376, August 18, 1983), Order No. 1137–86 (51 FR 22282, June 19, 1986), Order No. 1143–86 (51 FR 26878, July 28, 1986), Order No. 1188–87 (52 FR 19137, May 21, 1987), Order No. 1327–89 (54 FR 9430, March 7, 1989), Order No. 1344–89 (54 FR 20123, May 10, 1989), and Order No. 2000–95 (60 FR 62733, December 7, 1995).

label shall also clearly and conspicuously disclose, either in close proximity to that asterisk or elsewhere on the label, the following statement:

*[The encircled "E"] means this bulb meets Federal minimum efficiency standards.

(i) If the statement is not disclosed on the principal display panel, the asterisk shall be followed by the following statement:

See [Back,Top, Side] panel for details.

(ii) For purposes of this paragraph (e), the encircled capital letter "E" shall be clearly and conspicuously disclosed in color-contrasting ink on the label of any covered product that is a general service fluorescent lamp and will be deemed "conspicuous," in terms of size, if it appears in typeface at least as large as either the manufacturer's name or logo or another logo disclosed on the label, such as the "UL" or "ETL" logos, whichever is larger.

(3)(i) A manufacturer or private labeler who distributes general service fluorescent lamps, compact fluorescent lamps, or general service incandescent lamps (including incandescent reflector lamps) without labels attached to the lamps or without labels on individual retail-sale packaging for one or more lamps may meet the disclosure requirements of paragraphs (e)(1) and (e)(2) of this section by making the required disclosures, in the manner and form required by those paragraphs, on the bulk shipping cartons that are to be used to display the lamps for retail sale.

(ii) Instead of labeling any covered product that is a general service fluorescent lamp with the encircled "E" and with the statement described in paragraph (e)(2) of this section, a manufacturer or private labeler who would not otherwise put a label on such a lamp may meet the disclosure requirements of that paragraph by permanently marking the lamp clearly and conspicuously with the encircled "E".

* * * * *

By direction of the Commission, Commissioner Thompson dissenting.

Donald S. Clark,

Secretary.

[FR Doc. 98-19212 Filed 7-17-98; 8:45 am]

BILLING CODE 6750-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 94F-0040]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of chlorine dioxide as an antimicrobial agent in water used to wash certain fruits and vegetables. This action is in response to a petition filed by the National Food Processors Association.

DATES: The regulation is effective July 20, 1998; written objections and requests for a hearing by August 19, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 24, 1994 (59 FR 13970), FDA announced that a food additive petition (FAP 4A4415) had been filed by the National Food Processors Association, 1401 New York Ave. NW., Washington, DC 20005. The petition proposed that the food additive regulations be amended to provide for the safe use of chlorine dioxide to disinfect waters in contact with fresh fruits and vegetables intended for human consumption. In its evaluation of the petition, the agency has concluded that the water is not disinfected, but the microbial contamination of the water is reduced.

An antimicrobial added to water used to wash fruits and vegetables may be subject to regulation as a food additive under section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348), or may be subject to regulation as a pesticide chemical under section 408 of the act (21 U.S.C. 346a), depending upon the status of the fruit or vegetable which is washed with the antimicrobial solution. FDA regulates antimicrobials added to water used in food and for food processing.[1] An antimicrobial substance added to water used to wash fruits and vegetables that are not raw agricultural commodities[2] is an antimicrobial "used in food and for food processing." EPA regulates, as pesticides under FIFRA (7 U.S.C. 136(u)) and as pesticide chemicals under section 201(q) of the act, antimicrobial substances directed against microbes in water used to wash raw agricultural commodities.

The petition proposed the use of chlorine dioxide in water for contact with fresh fruits and vegetables, regardless of whether such fruits and vegetables are raw agricultural commodities or processed food. This proposed use would include uses subject to EPA regulatory authority, as well as FDA jurisdiction. Because FDA can act only to approve those uses subject to its jurisdiction, the approval set out in this final rule is limited to the use of chlorine dioxide in water used to wash fruits and vegetables that are not raw agricultural commodities. Any person who wishes to request an approval for the use of chlorine dioxide in water used to wash raw agricultural commodities should consult with EPA to ascertain whether a FIFRA pesticide registration and a section 408 of the act tolerance or exemption from the requirement for such tolerance would be required by EPA.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of chlorine dioxide to reduce the microbial contamination of water used to wash fruits and vegetables, other than raw agricultural commodities, is safe and that the additive will achieve its intended technical effect. FDA has also considered the safety of chlorine dioxide breakdown products, i.e., chlorite and chlorate, and concludes

[1] This is consistent with the memorandum of understanding (MOU) between FDA and the Environmental Protection Agency (EPA) on the jurisdiction over substances in drinking water (44 FR 42775, July 20, 1979). Moreover, an antimicrobial that is added to water used in food and for food processing is an antimicrobial that is used in or on a "processed food." The use of an antimicrobial in or on processed food is subject to FDA's regulatory authority as a food additive under section 409 of the act. Such use is not a pesticide use because pests that are in or on processed food are excepted from the definition of fungus in 7 U.S.C. 136(k) and from the definition of pest in 40 CFR 152.5. Therefore, such an antimicrobial is neither a "pesticide" under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136(u)) nor a "pesticide chemical" under section 201(q) of the act (21 U.S.C. 321(q)).

[2] Such nonraw agricultural commodities include, for example, those that are cut, peeled, sliced, chopped, ground, irradiated, or cooked.

that residues of these compounds would be removed from the treated produce if the treatment with chlorine dioxide is followed by a potable water rinse or by blanching, cooking or canning. Therefore, the agency is including in the regulation the requirement that treatment of fruits and vegetables with chlorine dioxide shall be followed by a potable water rinse or by blanching, cooking or canning. Based on the agency's conclusions concerning this proposed use, the regulations in 21 CFR 173.300 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice. The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before August 19, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collections of information. Therefore, clearance of the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.300 is amended by revising paragraph (b) to read as follows:

§ 173.300 Chlorine dioxide.

* * * * *

(b)(1) The additive may be used as an antimicrobial agent in water used in poultry processing in an amount not to exceed 3 parts per million (ppm) residual chlorine dioxide as determined by Method 4500–ClO_2 E, referenced in paragraph (a) of this section, or an equivalent method.

(2) The additive may be used as an antimicrobial agent in water used to wash fruits and vegetables that are not raw agricultural commodities in an amount not to exceed 3 ppm residual chlorine dioxide as determined by Method 4500–ClO_2 E, referenced in paragraph (a) of this section, or an equivalent method. Treatment of the fruits and vegetables with chlorine dioxide shall be followed by a potable water rinse or by blanching, cooking, or canning.

Dated: July 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–19314 Filed 7–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 97F–0405]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of aluminum borate as an antistatic agent and/or antifogging agent for olefin polymers intended for use as packaging materials in contact with food. This action is in response to a petition filed by Shikoku Chemical Corp.

DATES: The regulation is effective July 20, 1998; written objections and requests for a hearing by August 19, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 25, 1997 (62 FR 50387), FDA announced that a food additive petition (FAP 7B4559) had been filed by Shikoku Chemical Corp., c/o SRS International Corp., suite 1000, 1625 K St. NW., Washington, DC 20006–1604. The petition proposed to amend the food additive regulations in § 178.3130 *Antistatic and/or antifogging agents in food-packaging materials* (21 CFR 178.3130) to provide for the safe use of aluminum borate as an antistatic and/or antifogging agent for olefin polymers complying with 21 CFR 177.1520(c) as packaging materials intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 178.3130 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the

France, AD No. T98–551–039(A), dated December 31, 1998.

Issued in Fort Worth, Texas, on May 10, 1999.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 99–12416 Filed 5–17–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 98F–0342]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified solutions of sodium chlorite as an antimicrobial agent in poultry processing. This action is in response to a petition filed by Alcide Corp.

DATES: This regulation is effective May 18, 1999. Submit written objections and requests for a hearing by June 17, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 4, 1998 (63 FR 30498), FDA announced that a food additive petition (FMY 8A4591) had been filed by Alcide Corp., 8561 154th Ave. NE., Redmond, WA 98052. The petition proposed to amend the food additive regulation in § 173.325 (21 CFR 173.325) to provide for a lower pH in the use of acidified sodium chlorite solutions as an antimicrobial agent in poultry processing.

FDA has evaluated data in the petition and other relevant material. The agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and, therefore, (3) the regulation in § 173.325 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before June 17, 1999, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.325 is amended by revising paragraph (b)(1) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(b) * * *

(1) When used in a carcass spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.3 to 2.9.

* * * * *

Dated: May 10, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–12391 Filed 5–17–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 98F–0824]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of anthra(2,1,9-def:6,5,10-d'e'f')diisoquinoline-1,3,8,10 (2H,9H)-tetrone (C.I. Pigment Violet 29) as a colorant for polymers intended for use in contact with food. This action is in response to a petition filed by BASF Corp.

DATES: Effective May 18, 1999; written objections and requests for a hearing by June 17, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–

particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.886 is amended by revising paragraph (c)(2) to read as follows:

§ 172.886 Petroleum wax.

* * * * *

(c) * * *

(2) Poly(alkylacrylate) (CAS Reg. No. 27029–57–8), made from long chain (C_{16}–C_{22}) alcohols and acrylic acid, or poly(alkylmethacrylate) (CAS Reg. No. 179529–36–3), made from long chain (C_{18}–C_{22}) methacrylate esters, having:

(i) A number average molecular weight between 40,000 and 100,000;

(ii) A weight average molecular weight (MW_w) to number average molecular weight (MW_n) ratio (MW_w/MW_n) of not less than 3; and

(iii) Unreacted alkylacrylate or alkylmethacrylate monomer content not in excess of 14 percent, as determined by a method entitled "Method for Determining Weight-Average and Number-Average Molecular Weight and for Determining Alkylacrylate Monomer Content of Poly(alkylacrylate) used as Processing Aid in Manufacture of Petroleum Wax," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. Petroleum wax shall contain not more than 1,050 parts per million of poly(alkylacrylate) or poly(alkylmethacrylate) residues as determined by a method entitled "Method for Determining Residual Level of Poly(alkylacrylate) in Petroleum Wax," which is incorporated by reference. Copies are available from the addresses cited in this paragraph.

* * * * *

Dated: August 5, 1999.

Janice F. Oliver,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–20889 Filed 8–12–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 98F–0014]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified solutions of sodium chlorite as an antimicrobial agent in processing water and ice intended for use in contact with seafood. This action is in response to a petition filed by Bio-Cide International, Inc.

DATES: The regulation is effective August 13, 1999; written objections and requests for a hearing by September 13, 1999. The Director of the Office of the **Federal Register** approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in § 173.325(e) (21 CFR 173.325(e)), effective August 13, 1999.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 26, 1998 (63 FR 3749), FDA announced that a food additive petition (FAP 8A4568) had been filed by Bio-Cide International, Inc., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in 21 CFR part 173 to provide for the safe use of acidified sodium chlorite solutions in processing water and ice intended for use in contact with seafood. In its evaluation of the petition, the agency has concluded that the microbial population of the water and ice is reduced, as long as a residual level of available acidified solution of sodium chlorite is maintained.

Under the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA) (Public Law 105–324), the use of an acidified solution of sodium chlorite used as an antimicrobial agent in water and ice that are used to rinse, wash, thaw, transport, or store seafood is subject to regulation by FDA as a food additive. Such solutions are to be used "in water that comes in contact with the food in the preparing, packing, or holding of the food for commercial purposes," and therefore, such use is exempt from the definition of the term "pesticide chemical" (21 U.S.C. 321(q)(1)(B)(i)). Moreover, as stated in the "Legal and Policy Interpretation of the Jurisdiction Under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of Certain Antimicrobial Substances" (63 FR 54532 at 54541, October 9, 1998), FDA discussed, in the context of its jurisdiction over antimicrobial substances, what constitutes "processing" of seafood, which interpretation is unchanged by ARTCA. FDA stated that fish that is harvested is "processed." Consequently, activities done postharvest to seafood, such as handling, storing, preparing, heading, eviscerating, shucking, or holding, would be activities done to "processed food," not raw agricultural

commodities. Therefore, under ARTCA, fish processing operations and commercial fishing vessels would not be considered a "field" or a "treatment facility where raw agricultural commodities are the only food treated" (21 U.S.C. 321(q)(1)(B)(i)), and thus, an antimicrobial applied to water to which seafood is added at such locations would not be subject to regulation as a "pesticide chemical," but instead would be subject to regulation as a "food additive" under the Federal Food, Drug, and Cosmetic Act (the act).

Although the use of an acidified solution of sodium chlorite as an antimicrobial agent in water and ice that are used to rinse, wash, thaw, transport, or store seafood is regulated under section 409 of the act (21 U.S.C. 348) as a food additive, this intended use may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, manufacturers intending to market acidified solutions of sodium chlorite for such use should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive to reduce the microbial contamination of water and ice that are used to rinse, wash, thaw, transport, or store seafood is safe, will achieve its intended technical effect, and therefore, that the regulation in § 173.325 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may, at any time on or before September 13, 1999, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in the brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.325 is amended by redesignating paragraph (d) as paragraph (e), and by adding new paragraph (d) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(d) The additive is used as an antimicrobial agent in water and ice that are used to rinse, wash, thaw, transport, or store seafood in accordance with current industry standards of good manufacturing practice. The additive is produced by mixing an aqueous solution of sodium chlorite with any GRAS acid to achieve a pH in the range of 2.5 to 2.9 and diluting this solution with water to achieve an actual use concentration of 40 to 50 parts per million (ppm) sodium chlorite. Any seafood that is intended to be consumed raw shall be subjected to a potable water rinse prior to consumption.

* * * * *

Dated: August 5, 1999.

Janice F. Oliver,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–20890 Filed 8–12–99; 8:45 am]

BILLING CODE 4160–01–F

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

Reinstatement of Exchange Visitors Who Fail To Maintain Valid Program Status

AGENCY: United States Information Agency.

ACTION: Interim Final Rule with request for comments.

SUMMARY: This is an Interim Final Rule with request for comments being made by the United States Information Agency (hereinafter "the Agency"). The rule will amend the Agency's Exchange Visitor Program regulations regarding reinstatement of J–1 exchange visitors to valid program status. This Interim Final Rule supersedes the Agency's Statement of Policy which was published in the **Federal Register** on April 24, 1997.

EFFECTIVE DATE: This Interim Final Rule is effective on August 13, 1999. Comments regarding this rulemaking will be accepted until September 13, 1999.

ADDRESSES: United States Information Agency, Office of the General Counsel, 301 Fourth Street, SW, Room 700, Washington, DC 20547–0001.

FOR FURTHER INFORMATION CONTACT: Lorie J. Nierenberg, Office of the General Counsel, United States Informaiton Agency, 301 Fourth Street, SW, Washington, DC 20547; telephone (202) 619–6084.

Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 6: The subject of this AD is addressed in French airworthiness directive 98–153–088(B), dated April 8, 1998.

(f) This amendment becomes effective on September 30, 1999.

Issued in Renton, Washington, on September 2, 1999.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–23470 Filed 9–14–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99–ASO–16]

Removal of Class E Airspace; Arlington, TN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects an error in the geographic coordinates of a final rule that was published in the **Federal Register** on August 24, 1999, (64 FR 46116), Airspace Docket No. 99–ASO–16.

EFFECTIVE DATE: 0901 UTC, November 4, 1999.

FOR FURTHER INFORMATION CONTACT: Nancy B. Shelton, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5627.

SUPPLEMENTARY INFORMATION:

History

Federal Regiser Docket DOCID: fr24au99–4, Airspace Docket NO. 99–ASO–16, published on August 24, 1999, (64 FR46116), revoked Class E airspace at Arlington Municipal Airport, Arlington, TN. Errors were discovered in the geographic coordinates of the Memphis NAS/Millington Municipal Airport, Millington, TN. This action corrects those errors.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the geographic coordinates for the Memphis NAS/Millington Municipal Airport for the Class E airspace at, Millington, TN, as published in the **Federal Register** on August 24, 1999, (64 FR46116), (**Federal** Register Document DOCID: fr24au99–4; page 46116), are corrected as follows:

§ 71.71 [Corrected]

* * * * *

ASO TN E Memphis NAS/Millington, TN [Corrected]

By removing "Lat. 35°21'20" N, long. 89°40'22" W and substituting "Lat. 35°21'24", long. 89°52'13" W".

* * * * *

Issued in College Park, Georgia, on September 1, 1999.

Nancy B. Shelton,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 99–23939 Filed 9–14–99; 8:45 am]

BILLING CODE 4910–13–M]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 121

Operating Requirements: Domestic, Flag, and Supplemental Operations

CFR Correction

In Title 14 of the Code of Federal Regulations, parts 60 to 139, revised as of Jan. 1, 1999, page 433, § 121.339 is corrected by inserting the words "beyond the rated capacity" between the words "capacity" and "of" in the last sentence in paragraph (a)(2).

[FR Doc. 99–55531 Filed 9–14–99; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 99F–0299]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on raw agricultural commodities (RAC's). This action is in response to a petition filed by Alcide Corp.

DATES: This regulation is effective September 15, 1999; written objections and requests for a hearing by October 15, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 3, 1999 (64 FR 10302), FDA announced that a food additive petition (FAP 9A4648) had been filed by Alcide Corp., 8561 154th Ave. NE., Redmond, WA 98052. The petition proposed to amend the food additive regulation in § 173.325 to provide for the safe use of aqueous solutions of acidified sodium chlorite as an antimicrobial agent on RAC's.

The petitioner is proposing to limit the use of this additive to RAC's in preparing, packing, or holding of such commodities for commercial purposes, consistent with section 201(q)(1)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(q)(1)(B)(i)), as amended by the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA) (Public Law 105–324). The petitioner is not proposing that the additive be intended for use for any application under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act, which use would be subject to regulation by the Environmental Protection Agency (EPA) as a pesticide chemical. The proposed use of the additive is to reduce the microbial contamination on RAC's. Under ARTCA, the use of acidified sodium chlorite solutions as an antimicrobial agent on RAC's in preparing, packing, or holding of such RAC's for commercial purposes, consistent with section 201(q)(1)(B)(i) of the act, and not otherwise included within the definition of "pesticide chemical" under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III), is subject to regulation by FDA as a food additive.

Although this use of acidified sodium chloride solutions as an antimicrobial agent on raw agricultural commodities is regulated under section 409 of the act (21 U.S.C. 348) as a food additive, the intended use may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, manufacturers intending to market acidified sodium chlorite solutions for such use should contact the EPA to determine whether this use requires a pesticide registration under FIFRA.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and, therefore, that the regulation in § 173.325 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before October 15, 1999, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.325 is amended by redesignating paragraph (e) as paragraph (f) and by adding new paragraph (e) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(e) The additive is used as an antimicrobial agent on raw agricultural commodities in the preparing, packing, or holding of the food for commercial purposes, consistent with section 201(q)(1)(B)(i) of the act, and not applied for use under section 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III) of the act, in accordance with current industry standards of good manufacturing practice. Applied as a dip or a spray, the additive is used at levels that result in chlorite concentrations of 500 to 1200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treatment of the raw agricultural commodities with acidified sodium chlorite solutions shall be followed by a potable water rinse, or by blanching, cooking, or canning.

* * * * *

Dated: September 8, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-23969 Filed 9-14-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF JUSTICE

21 CFR Part 1308

[DEA-182F]

Schedules of Controlled Substances: Placement of Zaleplon Into Schedule IV

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance, zaleplon, including its salts, into Schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, importation and exportation of zaleplon and products containing zaleplon.

EFFECTIVE DATE: September 15, 1999.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION: Zaleplon is a central nervous system (CNS) depressant that will be marketed under the trade name SONATA™ for the short-term treatment of insomnia.

On March 31, 1999, the Assistant Secretary for Health and Surgeon General, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA letter recommending that zaleplon, and its salts, be placed into Schedule IV of the CSA (21 U.S.C. 801 *et seq.*). Enclosed with the March 31, 1999, letter was a document prepared by the Food and Drug Administration (FDA) entitled "Basis for the Recommendation for Control of Zaleplon in Schedule IV of the Controlled Substances Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider [21 U.S.C. 811 (b)].

The correspondence from the Assistant Secretary for Health and Surgeon General to the DEA dated March 31, 1999, confirmed that FDA had determined that the New Drug Application (NDA) for zaleplon was "approvable" and had issued an approvable letter to the NDA sponsor on January 6, 1999. According to the March 31, 1999, letter from DHHS, "upon full approval of the NDA, zaleplon will have a currently accepted medical use in treatment in the United States."

After a review of the available data, including the DHHS recommendation,

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 99F–2907]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on red meat parts and organs. This action is in response to a petition filed by Alcide Corp.

DATES: This rule is effective January 12, 2000; written objections and requests for a hearing by February 11, 2000.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 30, 1999 (64 FR 47193), FDA announced that a food additive petition (FAP 9A4692) had been filed by Alcide Corp., 8561 154th Ave. NE., Redmond, WA 98052. The petition proposed to amend the food additive regulation in 21 CFR 173.325 (§ 173.325) to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on red meat parts and organs.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulation in § 173.325 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before February 11, 2000, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.325 is amended by revising paragraph (c) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(c) The additive is used as an antimicrobial agent in accordance with current industry practice in the processing of red meat, red meat parts, and organs as a component of a spray or in the processing of red meat parts and organs as a component of a dip. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.5 to 2.9.

* * * * *

Dated: December 30, 1999.

Janice F. Oliver,

Deputy Director for Operations, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–691 Filed 1–11–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 314

[Docket No. 94N–0449]

RIN 0910–AA78

New Drug Applications; Drug Master Files

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its regulation governing drug master files (DMF's). FDA is removing the provision for submitting Type I DMF's and will no longer permit information submitted in a Type I DMF to be incorporated by reference in investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), or amendments or supplements to any of

Issued in Renton, Washington, on March 22, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–7614 Filed 3–27–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 99F–5523]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on poultry carcass parts. This action is in response to a petition filed by Alcide Corp.

DATES: This rule is effective March 28, 2000. Submit written objections and requests for a hearing by April 27, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 6, 2000 (65 FR 782), FDA announced that a food additive petition (FAP 0A4705) had been filed by Alcide Corp., 8561 154th Ave. NE., Redmond, WA 98052. The petition proposed to amend the food additive regulation in § 173.325 (21 CFR 173.325) to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on poultry carcass parts.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and, therefore, (3) the regulation in § 173.325 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by April 27, 2000. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.325 is amended by revising paragraph (b) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(b)(1) The additive is used as an antimicrobial agent in poultry processing water in accordance with current industry practice under the following conditions:

(i) As a component of a carcass spray or dip solution prior to immersion of the intact carcass in a prechiller or chiller tank;

(ii) In a prechiller or chiller solution for application to the intact carcass;

(iii) As a component of a spray or dip solution for application to poultry carcass parts; or

(iv) In a prechiller or chiller solution for application to poultry carcass parts.

(2) When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm), in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

(3) When used in a prechiller or chiller solution, the additive is used at levels that result in sodium chlorite concentrations between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.8 to 3.2.

* * * * *

Dated: March 20, 2000.

L. Robert Lake

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–7536 Filed 3–27–00; 8:45 am]

BILLING CODE 4160–01–F

those standards require implementation or application of a specific technology or technical specification. Under the Electronic Signatures Act, such performance standards must: (1) Serve an important governmental objective; and (2) be substantially related to the achievement of that objective.[44] Even if the electronic storage requirements of Rule 17a–4(f) must be evaluated under Section 104(b)(3)(A) of the Electronic Signatures Act, they serve an important governmental objective and are substantially related to achieving that objective.

1. The Electronic Storage Requirements of Rule 17a–4(f) Serve an Important Governmental Interest

Section 17(a)(1) of the Exchange Act authorizes the Commission to issue rules requiring broker-dealers to make and keep for prescribed periods, and furnish copies thereof, such records as necessary or appropriate in the public interest, for the protection of investors or otherwise in furtherance of the purposes of the Exchange Act.[45] This grant of authority recognizes the importance of broker-dealer recordkeeping to the Commission's regulatory function and investor protection objective. Rule 17a–4, adopted by the Commission pursuant to this authority, sets forth the requirements for keeping and furnishing broker-dealer records. In so doing, the rule serves the important governmental interest of assisting adequate supervision of broker-dealers by the Commission and the SROs. During the debate on the Electronic Signatures Act, the importance of accurate recordkeeping in regulated industries was noted. To quote a statement by Senators Hollings, Wyden and Sarbanes, "bank and other financial regulators need to require that records be retained in order that their examiners can insure the safety and soundness of the institutions and compliance with all relevant regulatory requirements."[46]

Investor protection depends on the examination process, which, in turn, relies on the records that broker-dealers are required to make and maintain. The electronic storage requirements of Rule 17a–4(f) are designed to ensure that broker-dealers will meet their obligation under Section 17(a)(1) and Rule 17a–4 to promptly furnish legible, true and complete copies of such records as are requested by the Commission or its representatives. This is crucial to the Commission's mandate to protect investors. Accordingly, the Commission's regulatory function is undermined to the extent that these records are inaccurate, retained in a non-accessible manner, or capable of alteration. The Commission's enforcement record against unscrupulous broker-dealers that have changed or destroyed records demonstrates how such conduct can harm investors and the public interest.[47]

2. The Electronic Storage Requirements of Rule 17a–4(f) Are Substantially Related to the Important Governmental Interest

The electronic storage requirements are designed to ensure that the Commission can promptly obtain legible, true, and complete records. Because the Commission relies on this ability to fulfill its responsibilities, the requirements are substantially related to the Commission's regulatory function. The Commission, in the release adopting the electronic storage requirements of Rule 17a–4, noted the "importance for recordkeeping of ready access, reliability, and permanence of records."[48] Therefore, the release made clear that the electronic storage requirements were intended as "safeguards against data erasure" and to "facilitate full access to the records during examinations."[49] As noted by Senator Leahy, the Electronic Signatures Act specifically authorizes agencies "to set performance standards to assure the accuracy, integrity, and accessibility of records that are required to be retained."[50] Statements of Senators Hollings, Wyden and Sarbanes, and of Representative Dingell indicate that the intent behind this section of the Electronic Signatures Act was to allow agencies to have standards designed to, among other things, prevent companies from retaining materials in an easily alterable form.[51] The electronic storage requirements of Rule 17a–4(f), such as WORM, are designed for this purpose.

IV. Conclusion

For the foregoing reasons, we find that the electronic storage requirements of Rule 17a–4(f) meet, and are consistent with, the requirements of the Electronic Signatures Act.

List of Subjects in 17 CFR Part 241

Securities.

Amendments to the Code of Federal Regulations

For the reasons set forth in the preamble, the Commission is amending title 17, chapter II of the Code of Federal Regulations as set forth below:

PART 241—INTERPRETATIVE RELEASES RELATING TO THE SECURITIES EXCHANGE ACT OF 1934 AND GENERAL RULES AND REGULATIONS THEREUNDER

1. Part 241 is amended by adding Release No. 34–44238 and the release date of May 1, 2001 to the list of interpretive releases.

Dated: May 1, 2001.
By the Commission.
Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 01–11333 Filed 5–4–01; 8:45 am]
BILLING CODE 8010–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 00F–1487]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified sodium chlorite solutions as a component of a post-chill carcass spray or dip when applied to poultry meat, organs, or related parts or trim. This action is in response to a petition filed by Alcide Corp.

DATES: This rule is effective May 7, 2001. Submit written objections and requests for a hearing by June 6, 2001.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, Washington, DC 20204–0001, 202–418–3074.

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[44] *Id.*

[45] 15 U.S.C. 78o(a)(1).

[46] 146 Cong. Rec. S5230 (daily ed. June 14, 2000) (statement of Sens. Hollings, Wyden, and Sarbanes).

[47] *See e.g., In the Matter of Del Mar Financial Services, Inc., et al.*, Exchange Act Release No. 42421 (Feb. 14, 2000); *In the Matter of A.S. Goldmen & Co., Inc., et al.*, Exchange Act Release No. 41601 (July 7, 1999).

[48] Adopting Release, 62 FR at 6470.

[49] *Id.*

[50] 146 Cong. Rec. S5221 (daily ed. June 15, 2000) (statement of Sen. Leahy).

[51] *See* 146 Cong. Rec. S5230 (daily ed. June 15, 2000) (statement of Sens. Hollings, Wyden and Sarbanes); 146 Cong. Rec. H4353 (daily ed. June 14, 2000) (statement of Rep. Dingell).

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 11, 2000 (65 FR 54855), FDA announced that a food additive petition (FAP 0A4722) had been filed by Alcide Corp., 8561 154th Ave., NE., Redmond, WA 98052. The petition proposed to amend the food additive regulations in § 173.325 *Acidified sodium chlorite solution* (21 CFR 173.325) to provide for the safe use of acidified sodium chlorite solutions as a component of a post-chill carcass spray or dip when applied to poultry meat, organs, or related parts or trim.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and, therefore, that the regulation in § 173.325 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by June 6, 2001. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.325 is amended by removing "or" at the end of paragraph (b)(1)(iii), removing the period at the end of paragraph (b)(1)(iv) and adding "; or" in its place, and adding paragraph (b)(1)(v) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(b)(1) * * *

(v) As a component of a post-chill carcass spray or dip solution when applied to poultry meat, organs, or related parts or trim.

* * * * *

Dated: April 27, 2001.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 01–11330 Filed 5–4–01; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[Region II Docket No. 45–216; FRL–6924–3]

Approval and Promulgation of Implementation Plans; New York; Motor Vehicle Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency is announcing the approval of a State Implementation Plan revision submitted by New York. This revision consists of New York's demonstration of the effectiveness of the enhanced motor vehicle inspection and maintenance (I/M) program decentralized testing network which satisfies the requirements of section 348 of the National Highway Systems Designation Act (NHSDA). In addition, EPA is approving New York's test method, NYTEST, and its effectiveness in relation to the IM240 test method and the regulations implementing the program. The intended effect of this action is to fully approve New York's enhanced I/M program, a requirement of the Clean Air Act.

EFFECTIVE DATE: This rule will be effective June 6, 2001.

ADDRESSES: Copies of the State submittals are available at the following addresses for inspection during normal business hours: Environmental Protection Agency, Region II Office, Air Programs Branch, 290 Broadway, 25th Floor, New York, New York 10007–1866; New York State Department of Environmental Conservation, Division of Air Resources, 50 Wolf Road, Albany, New York 12233; and Environmental Protection Agency, Air and Radiation Docket and Information Center, Air Docket (6102), 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Judy-Ann Mitchell, Air Programs Branch, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10278, (212) 637–4249.

SUPPLEMENTARY INFORMATION:

I. Background

On October 2, 2000 (65 FR 58698), EPA published a notice of proposed rulemaking for the State of New York. The notice proposed approval of revisions to the State Implementation Plan (SIP) for New York's enhanced inspection and maintenance (I/M)

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

Subpart A—Organization and Program Management

1. The authority citation for Part 200, Subpart A, continues to read, in part, as follows:

Authority: 15 U.S.C. 77s, 78d–1, 78d–2, 78w, 78*ll*(d), 78mm, 79t, 77sss, 80a–37, 80b–11, unless otherwise noted.

* * * * *

2. Section 200.30–3 is amended by adding paragraph (a)(73) to read as follows:

§ 200.30–3 Delegation of authority to Director of Division of Market Regulation.

* * * * *

(a) * * *

(73) Pursuant to section 6(a) of the Act, 15 U.S.C. 78f(a), and Rule 6a–1 thereunder, 17 CFR 240.6a–1:

(i) To publish a notice of filing of an application for registration as a national securities exchange, or for exemption from registration based on limited volume; and

(ii) To publish amendments to an application for registration as a national securities exchange, or for exemption from registration based on limited volume.

* * * * *

Dated: June 7, 2001.

By the Commission.

Jonathan G. Katz,

Secretary.

[FR Doc. 01–14830 Filed 6–12–01; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 00F–1488]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on processed, comminuted or formed meat food products (unless precluded by United States Department of Agriculture's standards of identity) prior to packaging of the food for commercial purposes in accordance with current industry standards of good manufacturing practice. This action is in response to a petition filed by Alcide Corp.

DATES: This rule is effective June 13, 2001. Submit written objections and requests for a hearing by July 13, 2001.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, Washington, DC 20204–0001, 202–418–3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 11, 2000 (65 FR 54855), FDA announced that a food additive petition (FAP 0A4724) had been filed by Alcide Corp., 8561 154th Ave. NE., Redmond, WA 98052. The petition proposed to amend the food additive regulations in § 173.325 *Acidified sodium chlorite solutions* (21 CFR 173.325) to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on processed, comminuted, or formed meat food products prior to packaging of the food.

FDA has evaluated data in the petition and other relevant material. FDA is approving the use of acidified sodium chlorite solutions on processed, comminuted or formed meat food products, unless such use is precluded by standards of identity in 9 CFR part 319, prior to packaging of the food for commercial purposes. For example, this acidified sodium chlorite solution is not permitted to be added to ground beef under 9 CFR 319.15. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulation in § 173.325 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by July 13, 2001. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.325 is amended by redesignating paragraph (f) as paragraph (g) and by adding new paragraph (f) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(f) The additive is used as an antimicrobial agent on processed, comminuted or formed meat food products (unless precluded by standards of identity in 9 CFR part 319) prior to packaging of the food for commercial purposes, in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is used at levels that result in sodium chlorite concentrations of 500 to 1200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.5 to 2.9.

* * * * *

Dated: June 5, 2001.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 01–14811 Filed 6–12–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09–01–036]

RIN 2115–AA97

Safety Zone—Ottawa River, Toledo, Ohio

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Ottawa River, Toledo, Ohio. This zone restricts the entry of vessels into the area designated for the June 23, 2001, Summerfest fireworks display. This temporary safety zone is necessary to protect spectators and vessels from the hazards associated with fireworks displays.

DATES: This rule is effective from 6:30 p.m. until 11 p.m. on June 23, 2001.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD09–01–036] and are available for inspection or copying at U.S. Coast Guard Marine Safety Office Toledo, 420 Madison Ave, Suite 700, Toledo, Ohio, 43604 between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LT Herb Oertli, Chief of Port Operations, Marine Safety Office, 420 Madison Ave, Suite 700, Toledo, Ohio 43604; (419) 418–6050.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM, and, under 5 U.S.C. 553(d)(3), good cause exists for making this rule it effective less than 30 days after publication in the **Federal Register**. The Coast Guard had insufficient advance notice to publish an NPRM followed by a temporary final rule. Publication of a notice of proposed rulemaking and delay of effective date would be contrary to the public interest because immediate action is necessary to prevent possible loss of life, injury, or damage to property.

Background and Purpose

This temporary rule is necessary to ensure the safety of spectators and vessels during the setup, loading and launching of a fireworks display in conjunction with the City of Toledo's Summerfest Fireworks. The fireworks display will occur between 6:30 p.m. and 11 p.m. on June 23rd.

This safety zone will encompass all waters and the adjacent shoreline of the Ottawa River, Toledo, Ohio, bounded by the arc of a circle with a 560-foot radius with its center in approximate position 41° 43.21 N, 083° 28.46 W. The fireworks will be launched off the southeast end of the Summit Street Bridge. The Captain of the Port Toledo or his designated on scene representative have the authority to terminate the event.

All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on scene patrol personnel. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Chicago or his designated on scene representative. The Captain of the Port or his designated on scene representative may be contacted via VHF Channel 16.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that order. It is not "significant" under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This finding is based on the historical lack of vessel traffic during this time of year.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: this rule will be in effect for only a few hours for one event and vessel traffic can pass safely around the safety zone.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Marine Safety Office Toledo (see **ADDRESSES**).

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business

To prevent failure of a main landing gear (MLG) actuator to fully extend and retract, which could prevent proper engagement of the downlock mechanism and result in collapse of the MLG during landing, accomplish the following:

Inspections

(a) Do the inspections in paragraphs (a)(1) and (a)(2) of this AD, according to Galaxy (Israel Aircraft Industries) Alert Service Bulletin GALAXY–32A–125, Revision 1, dated February 4, 2002.

(1) Within 3 days after the effective date of this AD, do a general visual inspection of the left and right MLG actuators for leakage of hydraulic fluid. Repeat this inspection before each flight, until paragraph (c) of this AD is accomplished.

Note 2: For the purposes of this AD, a general visual inspection is defined as: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight, and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

(2) Within 15 flight cycles after the effective date of this AD, do a one-time detailed inspection of the left and right MLG actuators for internal abrasions or scratches.

Note 3: For the purposes of this AD, a detailed inspection is defined as: "An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required."

Replacement

(b) If leakage of hydraulic fluid or an internal abrasion or scratch outside the limits specified in Galaxy (Israel Aircraft Industries) Alert Service Bulletin GALAXY–32A–125, Revision 1, dated February 4, 2002, is found on either MLG actuator during any inspection required by paragraph (a) of this AD: Before further flight, replace the discrepant MLG actuator with a new, improved actuator, or with a new or serviceable actuator that has been inspected for and is without internal abrasions or scratches, according to the service bulletin. Replacement of the existing MLG actuator with a new, improved actuator ends the repetitive inspections of that actuator.

Optional Terminating Action

(c) Replacement of the existing left and right MLG actuators with new, improved actuators having part number 4AS2521010–507 (left side) or –508 (right side), as applicable, according to Galaxy (Israel Aircraft Industries) Alert Service Bulletin GALAXY–32A–125, Revision 1, dated February 4, 2002, ends the repetitive inspections required by paragraph (a)(1) of this AD.

Spares

(d) As of the effective date of this AD, no person may install an MLG actuator with part number 4AS2521010–505 (left side) or –506 (right side) on any airplane, unless it has been inspected according to paragraph (a)(2) of this AD and found to be without any internal abrasion or scratch outside the limits specified in Galaxy (Israel Aircraft Industries) Alert Service Bulletin GALAXY–32A–125, Revision 1, dated February 4, 2002.

Alternative Methods of Compliance

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(f) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(g) The actions shall be done in accordance with Galaxy (Israel Aircraft Industries) Alert Service Bulletin GALAXY–32A–125, Revision 1, dated February 4, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D25, Savannah, Georgia 31402. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 5: The subject of this AD is addressed in Israeli emergency airworthiness directive 32–02–01–24, dated February 13, 2002.

Effective Date

(h) This amendment becomes effective on April 18, 2002.

Issued in Renton, Washington, on March 25, 2002.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–7750 Filed 4–2–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 01F–0233]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent in water applied to processed fruits and vegetables. This action is in response to a petition filed by Alcide Corp.

DATES: This rule is effective April 3, 2002. Submit written objections and requests for a hearing by May 3, 2002.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 23, 2001 (66 FR 28525), FDA announced that a food additive petition (FAP 1A4729) had been filed by Alcide Corp., 8561 154th Ave., NE., Redmond, WA 98052. The petition proposed to amend the food additive regulations in § 173.325 *Acidified sodium chlorite solution* (21 CFR 173.325) to provide for the safe use of aqueous solutions of acidified sodium chlorite as an antimicrobial agent in processing waters applied to processed fruits and vegetables.

FDA is using the term "processed" consistent with the meaning of that term set forth in FDA's Antimicrobial Food Additives—Guidance (64 FR 40612, July 27, 1999) (the 1999 guidance). The 1999 guidance describes FDA's interpretation of its jurisdiction over antimicrobial substances subsequent to the enactment of the Food Quality Protection Act of 1996 and the Antimicrobial Regulation Technical Corrections Act of 1998. The 1999 guidance is consistent with the Environmental Protection Agency's

(EPA's) and FDA's joint legal and policy interpretation of "processed food" (63 FR 54532, October 9, 1998). According to the 1999 guidance, processed fruits and vegetables include those that are ground, chopped, sliced, cut or peeled, and do not include fruits and vegetables that simply have leaves, stems, or husks removed. This food additive use of acidified sodium chlorite is for use in water to which processed fruits and vegetables are added (e.g., to which fruits and vegetables that have been ground, chopped, sliced, cut, or peeled are added) in order to mitigate microbiological organisms on the processed fruits and vegetables.

Also, as discussed in the 1999 guidance, antimicrobial substances used to mitigate microbiological organisms on processed food, by adding such substances to water to which processed food is added, are subject to regulation as food additives. The petitioned use of acidified sodium chlorite as an antimicrobial agent in "processing waters" is intended to mitigate microbiological organisms only on the processed fruits and vegetables that are added to the water. Thus, the petitioned use is subject to regulation by FDA as a food additive. To the extent that a manufacturer wants to use acidified sodium chlorite in water to mitigate microbiological organisms in the water itself or to include mitigation of microbiological organisms in the water in addition to those on the processed fruits and vegetables that are added to the water, the manufacturer would need to petition FDA for that food additive use, which is outside the scope of this rule. In addition, the manufacturer would need to consult with EPA to determine whether a pesticide registration would be required for such use.

FDA is requiring, as part of this regulation, that the use of the additive be followed by a potable water rinse and a 24-hour holding period to ensure that there are no detectable residue levels from the use of the additive on the treated processed fruits and vegetables.

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulation in § 173.325 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has considered carefully the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be affected adversely by this regulation may file with the Dockets Management Branch (address above) written objections by May 3, 2002. Each objection shall be numbered separately, and each numbered objection shall specify with particularity the provisions of the regulation to which the objection is made and the grounds for the objection. Each numbered objection for which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in the brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.325 is amended by redesignating paragraph (g) as paragraph (h) and by adding a new paragraph (g) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(g) The additive is used as an antimicrobial agent in the water applied to processed fruits and processed root, tuber, bulb, legume, fruiting (i.e., eggplant, groundcherry, pepino, pepper, tomatillo, and tomato), and cucurbit vegetables in accordance with current industry standards of good manufacturing practices, as a component of a spray or dip solution, provided that such application be followed by a potable water rinse and a 24-hour holding period prior to consumption. However, for processed leafy vegetables (i.e., vegetables other than root, tuber, bulb, legume, fruiting, and cucurbit vegetables) and vegetables in the Brassica [Cole] family, application must be by dip treatment only, and must be preceded by a potable water rinse and followed by a potable water rinse and a 24-hour holding period prior to consumption. When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm, in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

* * * * *

Dated: February 28, 2002.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 02–7969 Filed 4–2–02; 8:45 am]

BILLING CODE 4160–01–S

Airplane Flight Manual (AFM) Revision

(f) Within 72 hours after the effective date of the AD: Revise the Limitations Section of the EMBRAER ERJ 170 AFM by inserting a copy of EMBRAER Operational Bulletin 170–011/04, Revision 1, dated December 23, 2004, into the AFM.

Network Interface Card (NIC) Test

(g) Within 30 days after the effective date of this AD, or before or concurrently with doing the software installation required by paragraph (h) of this AD, whichever occurs first: Do a test to determine proper operation of the NIC communications in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 170–31–0003, dated December 23, 2004. If any failure is detected, before further flight, repair the airplane in accordance with a method approved by either the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate; or the Departmento de Aviacao Civil (DAC) (or its delegated agent).

Software Installation

(h) Within 40 days or 300 flight hours after the effective date of this AD, whichever occurs first: Install the software version of the PRIMUS EPIC system identified as "load 15.3" or higher, in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 170–31–0002, dated December 23, 2004. After installation of this software, remove the AFM revision required by paragraph (f) of this AD.

Submission of Test Results Not Required

(i) Although EMBRAER Service Bulletin 170–31–0003 specifies to submit certain information to the airplane manufacturer, this AD does not include that requirement.

Alternative Methods of Compliance (AMOCs)

(j) The Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Related Information

(k) Brazilian emergency airworthiness directive 2004–12–04, effective December 27, 2004, also addresses the subject of this AD.

Material Incorporated by Reference

(l) You must use the service information that is specified in Table 1 of this AD to perform the actions that are required by this AD, unless the AD specifies otherwise. (Only the first pages of EMBRAER Service Bulletins 170–31–0002 and Service Bulletin 170–31–0003 contain the issue date of those documents; no other page of those documents is dated.) The Director of the Federal Register approves the incorporation by reference of those documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. You can review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW, room PL–401, Nassif Building, Washington, DC; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

TABLE 1.—MATERIAL INCORPORATED BY REFERENCE

EMBRAER Service Document	Revision level	Date
Operational Bulletin 170–011/04	1	December 23, 2004.
Service Bulletin 170–31–0002	Original	December 23, 2004.
Service Bulletin 170–31–0003	Original	December 23, 2004.

Issued in Renton, Washington, on December 23, 2004.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–28707 Filed 12–29–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 2003F–0128]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acidified sodium chlorite solutions as an antimicrobial agent on finfish and crustaceans. This action is in response to a petition filed by Alcide Corp.

DATES: The regulation is effective December 30, 2004. Submit written or electronic objections and requests for a hearing by January 31, 2005. See section VI of this document for information on the filing of objections.

ADDRESSES: You may submit written objections and requests for a hearing identified by Docket No. 2003F–0128, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments.* Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov.* Include Docket No. 2003F–0128 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm,* including any personal information provided. For detailed instructions on submitting objections, see the "Objections" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mical E. Honigfort, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1278.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of April 10, 2003 (68 FR 17656), FDA announced that a food additive petition (FAP 3A4743) had been filed by Alcide Corp., 8561 154th Ave. NE., Redmond, WA 98052–3557. The petition proposed to amend the food additive regulations in § 173.325

Acidified sodium chlorite solutions (21 CFR 173.325) to expand the permitted use concentration and to expand the pH range for acidified sodium chlorite solutions as an antimicrobial agent in water and ice intended for use on seafood (fresh or saltwater).

Under the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA) (Public Law 105–324), the use of acidified sodium chlorite solutions as an antimicrobial agent on seafood is subject to regulation by FDA as a food additive. Such solutions are to be used on food in the preparing, packing, or holding of the food for commercial purposes, and therefore, such use is exempt from the definition of the term "pesticide chemical" (21 U.S.C. 321(q)(1)(B)(i)). Moreover, in the "Legal and Policy Interpretation of the Jurisdiction Under the Federal Food, Drug, and Cosmetic Act of the Food and Drug Administration and the Environmental Protection Agency Over the Use of Certain Antimicrobial Substances" (63 FR 54532 at 54541, October 9, 1998), FDA discussed, in the context of its jurisdiction over antimicrobial substances, what constitutes "processing" of seafood; this interpretation is unchanged by ARTCA. FDA stated that fish that is harvested is "processed." Consequently, activities done postharvest to seafood, such as handling, storing, preparing, heading, eviscerating, shucking, or holding, would be activities done to "processed food," not raw agricultural commodities. Therefore, under ARTCA, fish processing operations and commercial fishing vessels would not be considered a "field" or a "treatment facility where raw agricultural commodities are the only food treated" (21 U.S.C. 321(q)(1)(B)(i)), and thus, an antimicrobial applied to seafood at such locations would not be subject to regulation as a "pesticide chemical," but instead would be subject to regulation as a "food additive" under the Federal Food, Drug, and Cosmetic Act (the act).

Although the use of acidified sodium chlorite solutions as an antimicrobial agent on seafood is regulated under section 409 of the act (21 U.S.C. 348) as a food additive, this intended use may nevertheless be subject to regulation as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Therefore, manufacturers intending to market acidified sodium chlorite solutions for such use should contact the Environmental Protection Agency to determine whether this use requires a pesticide registration under FIFRA.

II. Conclusion

In consultation with the agency, the petitioner agreed to limit the proposed use of the additive to a concentration of 1,200 parts per million (ppm) and pH ranging from 2.3 to 2.9 as an antimicrobial agent to reduce pathogenic bacteria on finfish and crustaceans. FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe and the additive will achieve its intended technical effect. Therefore, 21 CFR part 173 is amended as set forth in this document.

The agency is including as a condition of use that seafood treated with acidified sodium chlorite solutions at a concentration of 1,200 ppm must be cooked prior to consumption to ensure that there are no detectable residues on the treated products (Ref. 1).

III. Public Disclosure

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the contact person listed in this document. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner's environmental assessment. FDA received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Chemistry Review Group to the Regulatory Review Group II, "Acidified solutions of sodium chlorite in processing waters intended for use on seafood or freshwater fish," June 21, 2004.

List of Subjects in 21 CFR Part 173

Food additives.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Section 173.325 is amended by redesignating paragraph (d) as paragraph

(d)(1) and by adding new paragraph (d)(2) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(d)(1) * * *

(2) The additive is used as a single application in processing facilities as an antimicrobial agent to reduce pathogenic bacteria due to cross-contamination during the harvesting, handling, heading, evisceration, butchering, storing, holding, packing, or packaging of finfish and crustaceans; or following the filleting of finfish; in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is used at levels that result in a sodium chlorite concentration of 1,200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treated seafood shall be cooked prior to consumption.

* * * * *

Dated: December 21, 2004.

Leslye M. Fraser,

Director, Office of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 04–28577 Filed 12–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to add the approved withdrawal time to the limitations to conditions of use for chlortetracycline Type C medicated feeds for chickens when fed at the 500 gram per ton level. This change is being made to improve the accuracy of the regulations.

DATES: This rule is effective December 30, 2004.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4567, e-mail: *george.haibel@fda.gov*.

SUPPLEMENTARY INFORMATION: FDA has found that the April 1, 2004, edition of Title 21, Parts 500 to 599 of the Code of Federal Regulations (CFR) does not reflect the approved withdrawal time for chlortetracycline in Type C medicated feeds for chickens when fed at the 500 gram per ton level. The approved 24-hour withdrawal time at this dose level was inadvertently removed for all sponsors at the time of a supplemental approval of a zero-day withdrawal time for AUREOMYCIN Type C medicated chicken feeds under NADA 48–761 (63 FR 57245 at 57247, October 27, 1998). At this time, FDA is amending the regulations to correct this error in 21 CFR 558.128. This action is being taken to improve the accuracy of the regulations.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. Section 558.128 is amended by revising paragraph (e)(1)(iv) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(1) * * *

Chlortetracycline amount	Indications for use	Limitations	Sponsor
*	*	*	*
(iv) 500 g/ton	Chickens: For the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.	1. Feed for 5 d; 0-day withdrawal time when formulated from AUREOMYCIN Type A medicated articles or Type B medicated feeds under NADA 48–761. 2. Feed for 5 d; withdraw 24 h prior to slaughter; do not feed to chickens producing eggs for human consumption.	046573 017519, 046573, 048164, 066104
*	*	*	*

Attachment 3

8. Chemical Abstract Data and Labeled Products & MSDS Forms

ECOLAB®

51090

Net Contents: 55 U.S. gal/208.2 L
Part 1 Base Concentrate

SANOVA BASE (25%)

Active Ingredient	Wt. %
Sodium Chlorite* (CAS 7758-19-2)	25.0%
Inert ingredients	75.0%
Total	100.0%
*Available Chlorine	39%

Contains 2.58 lbs. of Sodium Chlorite Per Gallon at 70°F

The mixed solution contains 1200 ppm acidified sodium chlorite when SANOVA® Base and Activator are mixed in the SANOVA® Food Processing Equipment or a similar closed system.

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Highly corrosive. May be fatal if swallowed. Do not get in eyes, on skin, or clothing. Do not get on bare hands. Wear goggles or face shield and neoprene gloves and use only thoroughly clean, dry utensils when handling. Irritating to nose and throat. Avoid breathing fumes. Remove and wash contaminated clothing to avoid fire.

EPA Reg. No. 1677-219
EPA Est. No. 765-7-IL-1

Ecolab Inc., Food & Beverage Division
370 Wabasha Street N.
St. Paul, Minnesota 55102-1390 U.S.A.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with plenty of water for at least 15 minutes. Remove contact lenses, if present after 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing and shoes. Rinse skin immediately with plenty of water for 15-20 minutes. Call poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment.

IF SWALLOWED: Call poison control center immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

FOR EMERGENCY MEDICAL INFORMATION IN USA OR CANADA, CALL: 1-800-328-0026.
FOR EMERGENCY MEDICAL INFORMATION WORLDWIDE, CALL: 1-651-222-5352 (IN THE USA).

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State water Board or Regional Office of the EPA.

CHEMICAL HAZARDS

Dry Sodium chlorite is a strong oxidizing agent. This product becomes a fire or explosive hazard if allowed to dry. Mix only into water. Contamination may start a chemical reaction with generation of heat. Liberation of hazardous gases (chlorine dioxide is a poisonous, explosive gas), and possible fire and explosion. Do not contaminate with garbage, dirt, organic matter, household products, chemicals, soap products, paint products, solvents, acids, vinegar, beverages, oils, lime oil, dirty rags, or any other foreign matter.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For use in the generation of acidified sodium chlorite in a food processing facility. To be used in conjunction with the SANOVA® Activator and the SANOVA® Food Quality System. For maximum efficacy, the mixed solution prepared from SANOVA® Base and SANOVA® Activator solution should remain in contact with fruits and vegetables for a minimum of 15 to 30 seconds at a solution temperature of 4° C to 20° C (39° F to 68° F).

Consult the product technical bulletin for specific application instructions. Your Ecolab representative can guide you in the installation and operation of the SANOVA® Food Quality System.

Acidified sodium chlorite, generated from sodium chlorite and citric acid, is cleared for knife-spray or immersion use on pre-process raw agricultural commodities by the U.S. Food and Drug Administration under 21 CFR, part 173. This regulation permits the use of acidified sodium chlorite in the preparation, packing, or holding of raw agricultural commodities for commercial purposes and when followed by a potable water rinse or by blanching or cooking.

STORAGE AND DISPOSAL

STORAGE: Do not contaminate water, food or feed by storage or disposal. Keep product in tightly closed container when not in use. Do not drop, roll or skid drum. Keep upright. Always replace cover. Store in a cool, dry well-ventilated area away from heat or open flame.

In case of contamination or decomposition, do not reseal container. If possible, isolate container in open and well ventilated area. Flood with large volumes of water. If fire occurs, extinguish fire by applying large quantities of water. Any unopened drums near the fire should be cooled by spraying with water.

PESTICIDE DISPOSAL: Pesticide wastes are hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative of the nearest EPA Regional Office for guidance.

Triple rinse container. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incinerate if allowed to do so by State and Local Authorities. If containers are burned, stay out of smoke.

Chlorite Solution,
UN 1908

Material Safety Data Sheet

ECOLAB

SANOVA BASE (25%)

Section 1. Chemical product and company identification

Trade name	: SANOVA BASE (25%)
Product use	: Food additive.
Supplier	: Ecolab Inc. Food & Beverage Division 370 N. Wabasha Street St. Paul, MN 55102 1-800-392-3392
Code	: 911022
Date of issue	: **19-August-2005**
EPA Registration No.	: 1677-219

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Composition, Information on Ingredients

Name	CAS number	% by weight
sodium chlorite	7758-19-2	20 - 50

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)

Emergency overview : DANGER!

CAUSES EYE AND SKIN BURNS.
CAUSES RESPIRATORY TRACT IRRITATION.
HARMFUL IF SWALLOWED. MAY BE FATAL IF SWALLOWED.
OXIDIZER. CONTACT WITH OTHER MATERIAL MAY CAUSE FIRE.
Do not get in eyes, on skin or clothing. Incompatible with chlorinated solvents. Avoid breathing vapor or mist. Store in tightly closed container. Avoid contact with combustible materials. Use only with adequate ventilation. Wash thoroughly after handling. Avoid all possible sources of ignition (spark or flame). Keep away from heat and direct sunlight. Decomposes on heating.

Potential acute health effects

Eyes	: Corrosive to eyes.
Skin	: Corrosive to the skin.
Inhalation	: Irritating to respiratory system.
Ingestion	: Harmful if swallowed. May be fatal if swallowed. Causes burns to mouth, throat and stomach.

See toxicological Information (section 11)

Section 4. First aid measures

Eye contact	: In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention immediately.
Skin contact	: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention immediately.
Inhalation	: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion	: Rinse mouth; then drink one or two large glasses of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Get medical attention immediately.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.

Products of combustion : These products are halogenated compounds, hydrogen chloride.

Fire fighting media and instructions : Use an extinguishing agent suitable for surrounding fires.

Dike area of fire to prevent product run-off.
This material increases the risk of fire and may aid combustion. Contact with combustible material may cause fire.

Special protective equipment for fire-fighters : Fire fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full facepiece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Immediately contact emergency personnel. Eliminate all ignition sources. Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Do not touch or walk through spilled material.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) and use a non-sparking or explosion proof means to transfer material to a sealed, appropriate container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.--

Section 7. Handling and storage

Handling : Do not get in eyes, on skin or on clothing. Do not add water directly to product. Slowly stir product into water. Keep container closed. Use only with adequate ventilation. Avoid breathing vapor or mist. Store in original container protected from direct sunlight. Avoid contact with combustible materials. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area. Separate from reducers and flammable/combustible materials, etc. in storage. Store between -10 and 50°C

Section 8. Exposure Controls, Personal Protection

Engineering controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Personal protection

Eyes : Use chemical splash goggles. For continued or severe exposure wear a face shield over the goggles.

Hands : Use chemical resistant, impervious gloves.

Skin : Wear suitable protective clothing.

Respiratory : Avoid breathing vapor or mist.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Colorless to light yellow. (Light.)

Odor : chlorine

pH : 12.5 (100%)

Boiling/condensation point : >100 °C

Specific gravity : 1.265 (Water = 1)

Dispersion properties : Easily dispersed in cold water, hot water.

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : Decomposes on heating.

Reactivity : Reactive with reducing agents, acids.
Slightly reactive to reactive with organic materials.

Hazardous decomposition products : These products are halogenated compounds, hydrogen chloride, Oxygen.

Section 11. Toxicological information

Potential acute health effects

Eyes : Corrosive to eyes.

Skin : Corrosive to the skin.

Inhalation : Irritating to respiratory system.

Ingestion : Harmful if swallowed. May be fatal if swallowed. Causes burns to mouth, throat and stomach.

Chronic effects on humans : Contains material which causes damage to the following organs: mucous membranes, skin, eye, lens or cornea, stomach.

Section 12. Ecological information

Products of degradation : These products are sulfur oxides (SO_2, SO_3...), halogenated compounds. Some metallic oxides.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Waste classification : Unused product is D002 (Corrosive)

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	UN1908	Chlorite solution	8	II	**Limited quantity** Yes. **Special provisions** A3, A6, A7, B2, IB2, N34, T7, TP2, TP24

APPLIES ONLY DURING ROAD TRANSPORT

Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Oxidizing material
Corrosive material
Target organ effects

U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: None.
SARA 302/304 emergency planning and notification: None.

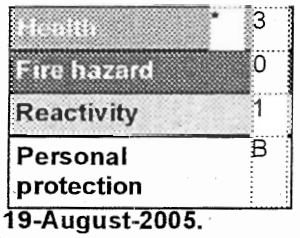
TSCA 8(b) inventory : All materials are listed or exempt.

California prop. 65 : No products were found.

EPA Registration No. : 1677-219

Section 16. Other information

Hazardous Material Information System (U.S.A.) :



Date of issue : 19-August-2005.
Responsible name : Regulatory Affairs
Date of previous issue : 19-August-2005.

Notice to reader

The above information is believed to be correct with respect to the formula used to manufacture the product in the country of origin. As data, standards, and regulations change, and conditions of use and handling are beyond our control, NO WARRANTY, EXPRESS OR IMPLIED, IS MADE AS TO THE COMPLETENESS OR CONTINUING ACCURACY OF THIS INFORMATION.

SANOVA

ANTIMICROBIAL FOOD ADDITIVE BASE (25%)

FOR COMMERCIAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

DANGER

STRONG OXIDIZING AGENT. CORROSIVE. Contains Sodium chlorite. May cause blindness. Causes chemical burns. Harmful or fatal if swallowed. Harmful if inhaled.

PRECAUTIONARY STATEMENTS

Protect skin, eyes, mucous membranes and clothing. Wear impervious gloves, chemical goggles (in case of severe or prolonged exposure, wear a face shield over the goggles), and an apron when handling this product and its solutions.

Use in well ventilated areas. Do not breathe vapors. If needed, wear an appropriate NIOSH/MSHA approved respirator when handling concentrated product. Use proper confined space entry procedures.

Consult your Ecolab Representative for specific use instructions and recommended use through the Sanova Food Quality System . Please refer to the Material Safety Data Sheet before use.

CHEMICAL /PHYSICAL HAZARDS

Strong Oxidizer. Avoid heat or contamination of any kind. Avoid contact with combustible materials. Drying of this product on clothing or other combustible materials may cause fire. Contamination from any source may cause rapid decomposition, generation of oxygen gas and high pressure.

Ecolab Food & Beverage Division
Ecolab Inc., 370 Wabasha Street N.
St. Paul, Minnesota 55102-1390 U.S.A.

FIRST AID

If in Eyes: Immediately flush eyes with plenty of cool, running water. Remove contact lenses; then continue flushing for at least 15 minutes, holding eyelids apart. SEEK MEDICAL ATTENTION IMMEDIATELY.

If on Skin: Immediately flush skin with plenty of cool, running water for at least 15 minutes while removing contaminated clothing. SEEK MEDICAL ATTENTION IMMEDIATELY. Remove and wash contaminated clothing.

If Swallowed: Rinse mouth; then immediately drink 1 or 2 large glasses of water. DO NOT induce vomiting. Never give anything by mouth to an unconscious person. SEEK MEDICAL ATTENTION IMMEDIATELY.

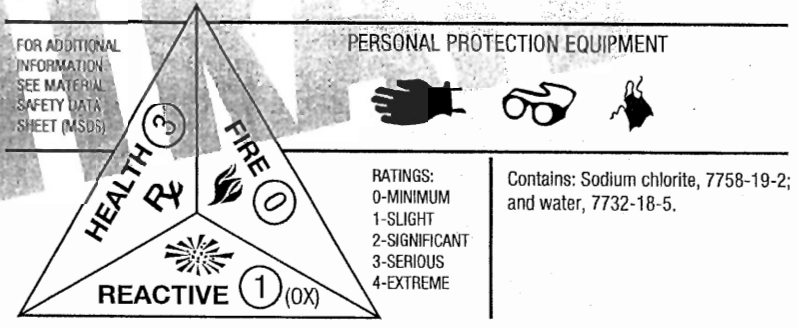
If Inhaled: Immediately move to fresh air. SEEK MEDICAL ATTENTION IMMEDIATELY.

FOR EMERGENCY MEDICAL INFORMATION IN USA OR CANADA, CALL: 1-800-328-0026.
FOR EMERGENCY MEDICAL INFORMATION WORLDWIDE, CALL: 1-651-222-5352 (IN THE USA).

DIRECTIONS FOR USE

This product is approved for use on red meat and poultry, in accordance with 21 CFR 173,325. To be used in conjunction with the Sanova Food Additive Activator Concentrate and the Sanova Food Quality System. Consult the product technical bulletin for specific application instructions.

User is responsible for compliance with applicable Federal, State and local laws regarding proper use and disposal of the waste generated.



Formula ingredients contain no Phosphorus.

Plant Master File: size: 15 x 6" 709346/53 Inks: Black & PMS 176 Pink , Reflex Blue
Label type: affixed label. Contact Ecolab Purchasing for current paper type/adhesive information.

Material Safety Data Sheet

ECOLAB®

ANTIMICROBIAL FOOD ADDITIVE BASE (25%)

Section 1. Chemical product and company identification

Trade name : ANTIMICROBIAL FOOD ADDITIVE BASE (25%)

Product use : Food additive.

Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392

Code : 911022-01

Date of issue : **26-January-2005**

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352

Section 2. Composition, Information on Ingredients

Name	CAS number	% by weight
sodium chlorite	7758-19-2	20 - 50

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)

Emergency overview : Danger!

CAUSES EYE AND SKIN BURNS.
OXIDIZER.
CAUSES SEVERE RESPIRATORY TRACT IRRITATION.
CONTACT WITH OTHER MATERIAL MAY CAUSE FIRE.

Do not get in eyes, on skin or clothing. Incompatible with chlorinated solvents. Avoid breathing vapor or mist. Store in tightly closed container. Avoid contact with combustible materials. Use only with adequate ventilation. Wash thoroughly after handling.

Potential acute health effects

Eyes : Corrosive to eyes.

Skin : Corrosive to the skin.

Inhalation : Severely irritating to the respiratory system.

Ingestion : Harmful if swallowed. May cause burns to mouth, throat and stomach.

See toxicological Information (section 11)

Section 4. First aid measures

Eye contact : In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention immediately.

Skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention immediately.

Inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

Ingestion : Rinse mouth; then drink one or two large glasses of water. Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention immediately.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.

Products of combustion : These products are halogenated compounds, hydrogen chloride.

Fire fighting media and instructions : Use an extinguishing agent suitable for surrounding fires.

Dike area of fire to prevent product run-off.

This material increases the risk of fire and may aid combustion. Contact with combustible material may cause fire.

Special protective equipment for fire-fighters : Fire fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full facepiece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Immediately contact emergency personnel. Eliminate all ignition sources. Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Do not touch or walk through spilled material.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) and use a non-sparking or explosion proof means to transfer material to a sealed, appropriate container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.--

Section 7. Handling and storage

Handling : Do not get in eyes, on skin or on clothing. Do not add water directly to product. Slowly stir product into water. Keep container closed. Use only with adequate ventilation. Avoid breathing vapor or mist. Store in original container protected from direct sunlight. Avoid contact with combustible materials. Incompatible with chlorinated solvents. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area. Separate from reducers and flammable/combustible materials, etc. in storage.

Store between -10 and 50°C

Section 8. Exposure Controls, Personal Protection

Engineering controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Personal protection

Eyes : Use chemical splash goggles. For continued or severe exposure wear a face shield over the goggles.

Hands : Use chemical resistant, impervious gloves.

Skin : Use synthetic apron, other protective equipment as necessary to prevent skin contact.

Respiratory : Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Colorless to light yellow. (Light.)

Odor : chlorine

pH : 12.5 (100%)

Boiling/condensation point : >100 °C

Specific gravity : 1.265 (Water = 1)

Dispersion properties : Easily dispersed in cold water, hot water.

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : The product is stable.

Reactivity : Reactive with oxidizing agents, reducing agents, acids.
Slightly reactive to reactive with organic materials.

Hazardous decomposition products : These products are halogenated compounds, hydrogen chloride.

Section 11. Toxicological information

Potential acute health effects

Eyes : Corrosive to eyes.

Skin : Corrosive to the skin.

Inhalation : Severely irritating to the respiratory system.

Ingestion : Harmful if swallowed. May cause burns to mouth, throat and stomach.

Potential chronic health effects

Chronic effects on humans : Contains material which causes damage to the following organs: mucous membranes, skin, eye, lens or cornea, stomach.

Section 12. Ecological information

Products of degradation : These products are sulfur oxides (SO_2, SO_3...), halogenated compounds. Some metallic oxides.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Waste classification : Unused product is D002 (Corrosive)

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	UN1908	Chlorite solution	8	II	**Limited quantity** Yes. **Packaging instruction** **Passenger Aircraft** Quantity limitation: 1 L **Cargo Aircraft** Quantity limitation: 30 L **Special provisions** A3, A6, A7, B2, IB2, N34, T7, TP2, TP24

APPLIES ONLY DURING ROAD TRANSPORT

Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Oxidizing material
Corrosive material
Target organ effects

U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: None.

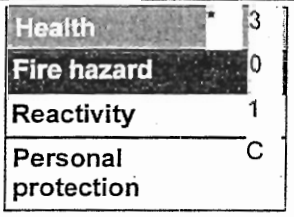
SARA 302/304 emergency planning and notification: None.

TSCA 8(b) inventory : All materials are listed or exempt.

California prop. 65 : No products were found.

Section 16. Other information

Hazardous Material Information System (U.S.A.) :



Date of issue : **26-January-2005.**

Responsible name : **Regulatory Affairs**

Date of previous issue : **No Previous Validation.**

Notice to reader

The above information is believed to be correct with respect to the formula used to manufacture the product in the country of origin. As data, standards, and regulations change, and conditions of use and handling are beyond our control, NO WARRANTY, EXPRESS OR IMPLIED, IS MADE AS TO THE COMPLETENESS OR CONTINUING ACCURACY OF THIS INFORMATION.

SANOVA

51205

Net Contents: 55.7 U.S. gal/210.8 L

FOOD ADDITIVE ACTIVATOR CONCENTRATE

FOR COMMERCIAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

WARNING

Contains Citric acid. Causes severe eye irritation. Causes skin and respiratory tract irritation.

PRECAUTIONARY STATEMENTS

Protect skin and eyes. Wear impervious gloves and chemical goggles when handling this product. Avoid breathing vapors or mists.

Do not mix with chlorinated detergents or sanitizers, will generate chlorine gas.

Consult your Ecolab Representative for specific use instructions and recommended dispensing equipment. Please refer to the Material Safety Data Sheet before use.

DIRECTIONS FOR USE

To be used in conjunction with *Sanova Antimicrobial Food Additive Base (25%)* and the *Sanova Food Quality System.* Consult the *Sanova* product technical bulletin for specific application instructions.

User is responsible for compliance with applicable Federal, State and local laws regarding proper use and disposal of the waste generated.

Ecolab Food & Beverage Division
Ecolab Inc., 370 Wabasha Street N.
St. Paul, Minnesota 55102-1390 U.S.A.

FIRST AID

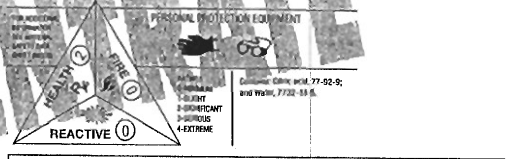
If in Eyes: Immediately flush eyes with plenty of cool, running water. Remove contact lenses; then continue rinsing for at least 15 minutes, holding eyelids apart. SEEK MEDICAL ATTENTION IMMEDIATELY.

If on Skin: Wash with soap and water. SEEK MEDICAL ATTENTION IF IRRITATION OCCURS. Wash clothing before reuse.

If Swallowed: Rinse mouth, then immediately drink 1 or 2 large glasses of water. DO NOT induce vomiting. Never give anything by mouth to an unconscious person. If large quantities are swallowed, seek medical attention immediately.

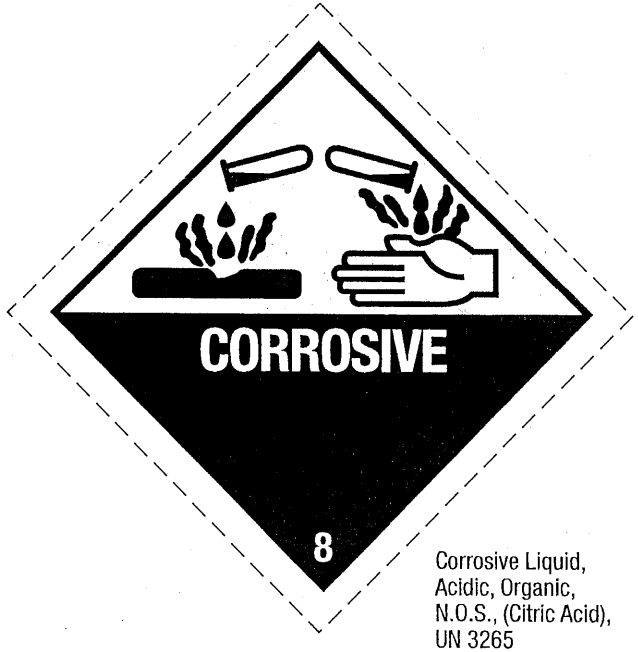
If Inhaled: Immediately move to fresh air. If irritation or discomfort persists, call a physician.

FOR EMERGENCY MEDICAL INFORMATION IN USA OR CANADA, CALL: 1-800-328-0026.
FOR EMERGENCY MEDICAL INFORMATION WORLDWIDE, CALL: 1-651-222-5352 (IN THE USA).



Formula ingredients contain no Phosphorus.

Plant Master File: size: 17.25 x 8.5" 708880/53 Inks: Black & PMS Rubine Red
Label type: affixed label. Contact Ecolab Purchasing for current paper type/adhesive information.



Corrosive Liquid, Acidic, Organic, N.O.S., (Citric Acid), UN 3265

Material Safety Data Sheet

ECOLAB

FOOD ADDITIVE ACTIVATOR CONCENTRATE

Section 1. Chemical product and company identification

Trade name : FOOD ADDITIVE ACTIVATOR CONCENTRATE

Product use : Food additive.

Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392

Code : 911021-01

Date of issue : **11-May-2005**

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Composition, Information on Ingredients

Name	CAS number	% by weight
citric acid	77-92-9	20 - 50

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)

Emergency overview : WARNING!

CAUSES SEVERE EYE IRRITATION.
CAUSES RESPIRATORY TRACT IRRITATION.
MAY CAUSE SKIN IRRITATION.

Avoid contact with eyes. Avoid breathing vapor or mist. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling. Incompatible with chlorinated solvents.

Potential acute health effects

Eyes : Severely irritating to the eyes.

Skin : Moderately irritating to the skin.

Inhalation : Irritating to respiratory system.

Ingestion : No known significant effects or critical hazards.

See toxicological Information (section 11)

Section 4. First aid measures

Eye contact : In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention immediately.

Skin contact : Wash with soap and water. Get medical attention if irritation occurs. Wash clothing before reuse.

Inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion : Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.

Fire fighting media and instructions : Use an extinguishing agent suitable for surrounding fires.

Dike area of fire to prevent product run-off.

No specific hazard.

Special protective equipment for fire-fighters : Fire fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full facepiece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Ventilate area of leak or spill. Do not touch damaged containers or spilled material unless wearing appropriate protective equipment (Section 8). Stop leak if without risk. Prevent entry into sewers, water courses, basements or confined areas.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.--

Section 7. Handling and storage

Handling : Avoid contact with eyes. Do not add water directly to product. Slowly stir product into water. Keep container closed. Use only with adequate ventilation. Avoid breathing vapor or mist. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area.

Store between 10 and 50°C

Section 8. Exposure Controls, Personal Protection

Engineering controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits.

Personal protection

Eyes : Use safety eyewear designed to protect against splash of liquids.

Hands : For prolonged or repeated handling, use Impervious gloves.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : Avoid breathing vapor or mist.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Colorless.

Odor : Sweetish.

pH : 0.8 (100%)

Boiling/condensation point : >100 °C

Specific gravity : 1.24 (Water = 1)

Dispersion properties : Easily dispersed in cold water, hot water.

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : The product is stable.

Reactivity : Reactive with alkalis. Incompatible with chlorinated solvents.

Section 11. Toxicological information

Potential acute health effects

Eyes : Severely irritating to the eyes.

Skin : Moderately irritating to the skin.

Inhalation : Irritating to respiratory system.

Ingestion : No known significant effects or critical hazards.

Section 12. Ecological information

Products of degradation : These products are carbon oxides (CO, CO_2) and water.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Waste classification : Unused product is D002 (Corrosive)

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	UN3265	Corrosive liquid, acidic, organic, n.o.s. (citric acid)	8	III	Limited quantity Yes. Special provisions IB3, T7, TP1, TP28

APPLIES ONLY DURING ROAD TRANSPORT

Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Irritating material

U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: None.

SARA 302/304 emergency planning and notification: None.

TSCA 8(b) inventory : All materials are listed or exempt.

California prop. 65 : No products were found.

Section 16. Other information

Hazardous Material Information System (U.S.A.) :

	2
Fire hazard	0
Reactivity	0
Personal protection	B

Date of issue : 11-May-2005.

Responsible name : Regulatory Affairs

Date of previous issue : 11-May-2005.

Notice to reader

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ECOLAB®

50223

Net Contents: 55 U.S. gal/208.2 L

OXXIUM™ 203

25% Active Sodium Chlorite

ACTIVE INGREDIENT:
Sodium Chlorite* 25%
OTHER INGREDIENTS: 75%

*AVAILABLE CHLORINE: 10%
*Contains 2.50 LBS. of Sodium Chlorite per gallon at 70°F.

KEEP OUT OF REACH OF CHILDREN
DANGER

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE. Causes irreversible eye damage and skin burns. Harmful if swallowed. Irritating to nose and throat. Do not get in eyes, on skin or clothing. Wear protective eyewear (splashproof goggles). Wear protective clothing and rubber gloves when handling this product. Avoid breathing mists or fumes. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse to avoid fire.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Manufactured for:
Ecolab Inc., Food & Beverage Division
370 Wabasha Street N.
St. Paul, Minnesota 55102-1390 U.S.A.
© 2005 Ecolab Inc. Made in U.S.A. [illegible]/0605
All Rights Reserved

CHEMICAL HAZARDS: Dry sodium chlorite is a strong oxidizing agent. This product becomes a fire or explosive hazard if allowed to dry. Mix only into water. Contamination may start a chemical reaction with generation of heat, liberation of hazardous gases (chlorine dioxide is poisonous, explosive gas), and possible fire and explosion. Do not contaminate with garbage, dirt, organic matter, household products, chemicals, soap products, paint products, solvents, acids, vinegar, beverages, oils, pine oil, dirty mops, or any other foreign matter.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor immediately for treatment advice.
IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice if burning or irritation of the skin persists.
IF SWALLOWED: Have person drink a glass of water immediately if able to swallow. Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF INHALED: Move person to fresh air and monitor for respiratory distress. If cough or difficulty in breathing develops, consult a physician immediately. If person is not breathing, call 911 or an ambulance, then give artificial respiration. Call a poison control center or doctor for further treatment advice.
FOR EMERGENCY MEDICAL INFORMATION IN USA OR CANADA,
CALL: 1-800-328-0026.
FOR EMERGENCY MEDICAL INFORMATION WORLDWIDE,
CALL: 1-651-222-5352 (IN THE USA).
Have the product container or label with you when calling a poison control center or doctor or going for treatment.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Directions for Controlling the Growth of Algae in Recirculating Cooling Water Towers: 1. Clean badly fouled systems before starting treatment. 2. When algae are visible, add an initial dosage of 8.4 fluid ounces of Sodium Chlorite per 1,000 gals. of water in the system. Repeat if necessary until control is evident. 3. When algae control is evident, use a subsequent dose of 4.2 fluid ounces of Sodium Chlorite solution per 1,000 gals. of water in the system twice a week or as needed to maintain control. 4. Add Sodium Chlorite directly to the cooling tower drip pan (cold water basin) near the inlet to the recirculating pump.

Directions for Use in the Mechanical or Electrolytic Generation of Chlorine Dioxide as a Disinfectant, or for Microorganism or Mollusk Control and as a Chemical Oxidant in Aquatic Systems.
Feed Requirements: Feed rates of *Oxxium 203* will depend on the severity of contamination and the degree of control desired. The exact dosage will depend on the size of the system and residual necessary for effective control. Depending on the generator type, *Oxxium 203* may be diluted at the point of use to prepare a 3% to 25% active aqueous solution for use in the chlorine dioxide generators.

Some examples of industrial applications of chlorine dioxide include:
- Potable water disinfection and removal of sulfide.
- Control of bacterial slime and algae and mollusks in industrial recirculating and one-pass cooling systems.
- Biocontrol in food processing flumes, water-using equipment, cooling water, and recycled waters.
- Disinfection of sewage and plant wastes.
- Destruction of phenolics, simple cyanides and sulfides by chemical oxidation.
- Bacterial slime control in white water paper mill systems.
- Bacterial control in oil well and petroleum systems.

See product bulletins (or Technical Data Sheets) for specific application instructions. Your ECOLAB representative can guide you in the application techniques.

Method of feed: Large amounts of chlorine dioxide can be generated by several common methods, including:
1. The chlorine method which utilizes a Sodium Chlorite solution and chlorine gas, or
2. The hypochlorite method which utilizes a Sodium Chlorite solution, a hypochlorite solution, and an acid or
3. The Acid-chlorite method which utilizes a Sodium Chlorite solution and an acid, or
4. The electrolytic method which utilizes a Sodium Chlorite solution, with sodium chloride added as needed.

Your ECOLAB representative can guide you in the selection, installation and operation for feed systems. Consult product bulletin and also the instructions on the chlorine dioxide generation system before using *Oxxium 203*.

User is responsible for compliance with applicable federal, state and local laws regarding proper use and disposal of the chlorine dioxide generated.

Directions for Use in Controlling Microbial Population in Poultry Processing Water: Chlorine dioxide generated from *Oxxium 203* may be used as an antimicrobial agent in water used in poultry processing, provided that the residual concentration of chlorine dioxide does not exceed 3 ppm, as determined by an appropriate method in accordance with 21 CFR 173.300.

For treatment of poultry chill water, apply *Oxxium 203* as necessary through a chlorine dioxide generation system to maintain a residual concentration of up to 3 parts per million (ppm) chlorine dioxide in the chiller water.

Food Plant Process Water Treatment: Chlorine dioxide generated from sodium chlorite is effective for use in controlling microbiological growth in flume water and other food processing water systems such as chill water systems and hydrocoolers. The required dosages will vary with process conditions and the degree of contamination present. Depending on the requirements of the specific water system, sodium chlorite should be applied continuously or intermittently through a chlorine dioxide generating system to achieve a chlorine dioxide residual concentration between 0.25 and 5.0 ppm.

Water containing up to 3 ppm residual chlorine dioxide may be used for washing fruits and vegetables that are not raw agricultural commodities in accordance with 21 CFR 173.300. Treatment of the fruits and vegetables with chlorine dioxide must be followed by a potable water rinse, or by blanching, cooking or canning.

Industrial Cooling Water Treatment: For control of bacterial slime and algae in industrial recirculating and one-pass cooling systems, the required dosages will vary depending on the exact application and the degree of contamination present. The required chlorine dioxide residual concentrations range between 0.1 and 5.0 ppm. Chlorine dioxide may be applied either continuously or intermittently. The typical chlorine dioxide residual concentration range is 0.1 - 1.0 ppm for continuous doses, and 0.1-5.0 ppm for intermittent doses. The minimum acceptable residual concentration of chlorine dioxide is 0.1 ppm for a minimum one minute contact time.

Potable Water Treatment: Chlorine dioxide (ClO_2) is used as both an oxidant and a disinfectant in drinking water treatment. The required dosages will vary with source water conditions and the degree of contamination present. For most municipal and public water systems, a chlorine dioxide residual concentration of up to 2 ppm is sufficient to provide adequate disinfection. Residual disinfectant byproducts must be monitored as required by the National Primary Drinking Water Regulations (40CFR Part 141) and state drinking water standards.

Bacterial Slime Control in Paper Mills
Chlorine dioxide generated from sodium chlorite is effective for use in controlling microbiological growth in white water paper mill systems. The required dosages will vary with the degree of microbiological and process contamination present. Depending on the specific requirements of the system, sodium chlorite should be applied continuously or intermittently through a chlorine dioxide generating system to achieve a chlorine dioxide residual concentration between 0.1 and 5.0 ppm. Intermittent treatments should be repeated as often as necessary to maintain control.

Mollusk Control in Water Systems
Chlorine dioxide generated from sodium chlorite may be used for mollusk control in commercial and industrial recirculating and one-pass cooling water systems. The required dosages will vary with the system type, system conditions, the degree of water contamination present and the desired level of control. Depending on the extent of the infestation, sodium chlorite may be applied either continuously or intermittently through a chlorine dioxide generating system to achieve the necessary chlorine dioxide residual concentration.

Veliger Control: Maintain a continuous chlorine dioxide residual of 0.1 – 0.5 ppm.

Intermittent Dose: Apply chlorine dioxide to obtain a chlorine dioxide residual concentration of 0.2 – 25 ppm. Repeat as necessary to maintain control.

Continuous Dose: Maintain a chlorine dioxide residual concentration of up to 2 ppm.

Bacterial Control in Oil Wells and Petroleum Systems
Chlorine dioxide is effective in the remediation of bacterial and sulfide contamination commonly found in oilfield production, injection and disposal fluids. The required dosages will vary with process conditions. Sodium chlorite may be applied either continuously or intermittently through a chlorine dioxide generating system to oil well production water as it is separated from the oil, and before it is re-injected into the well.

For continuous feeds, chlorine dioxide may be applied at dosages slightly higher than sulfide's oxidative demand as determined by a demand study. For intermittent treatment, chlorine dioxide should be applied at a shock dosage of 200 – 3000 ppm.

Wastewater Treatment: Chlorine dioxide (ClO_2) is effective as both a disinfectant and an oxidant in wastewater treatment. The required dosages will vary with water conditions and the degree of contamination present. For most municipal and other wastewater systems, a chlorine dioxide residual concentration of up to 5 ppm is sufficient to provide adequate disinfection.

For sulfide odor control, between pH 5-9, a minimum of 5.2 ppm (wt) of chlorine dioxide should be applied to oxidize 1 ppm of sulfide (measured as sulfide ion). For phenol destruction, at pH less than 8, 1.5 ppm chlorine dioxide will oxidize 1 ppm phenol; at pH greater than 10, 3.3 ppm chlorine dioxide will oxidize 1 ppm phenol.

STORAGE AND DISPOSAL

STORAGE: Do not contaminate water, food or feed by storage or disposal. Keep product in tightly closed container when not in use. Don't drop, roll or skid drum. Keep upright. Always replace cover. Store in a cool, dry, well-ventilated area away from heat or open flame.
EMERGENCY HANDLING: In case of contamination or decomposition, do not reseal container. If possible, isolate container in open and well-ventilated area. Flood with large volumes of water. If fire occurs, extinguish fire by applying large quantities of water. Any unopened drums near the fire should be cooled by spraying with water.
PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.
CONTAINER DISPOSAL: Triple rinse container. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

EPA Reg. No. 5389-[illegible]-1077
EPA Est. No. 5389-[illegible]-01

Plant EPA Master File: size: 17.25 x 8.5"   742043/53   Inks: Black & PMS 151 Orange Label type: affixed label. Contact Ecolab Purchasing for current paper type/adhesive information.

Material Safety Data Sheet

ECOLAB

OXXIUM 203

Section 1. Chemical product and company identification

Trade name : OXXIUM 203
Product use : Intermediate.
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 901073-05
Date of issue : **02-March-2006**
EPA Registration No. : 5382-43-1677

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Composition, information on ingredients

Name	CAS number	% by weight
sodium hydroxide	1310-73-2	1
sodium chlorite	7758-19-2	20 - 50
sodium carbonate	497-19-8	1 - 5
sodium chlorate	7775-09-9	1 - 5

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : DANGER!

CAUSES EYE AND SKIN BURNS.
CAUSES RESPIRATORY TRACT IRRITATION.
HARMFUL IF SWALLOWED.
Do not ingest. Do not get in eyes, on skin or on clothing. Avoid breathing vapor or mist. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling.

Potential acute health effects

Eyes : Corrosive to eyes.
Skin : Corrosive to the skin.
Inhalation : Irritating to respiratory system.
Ingestion : Harmful if swallowed. Causes burns to mouth, throat and stomach.

See toxicological information (section 11)

Section 4. First aid measures

Eye contact : In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention immediately.

Skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse. Get medical attention immediately.

Inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

Ingestion : Rinse mouth; then drink one or two large glasses of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Get medical attention immediately.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.

Products of combustion : These products are halogenated compounds, hydrogen chloride.

Fire-fighting media and instructions : Use an extinguishing agent suitable for the surrounding fire.

Dike liquid for later disposal.
No specific hazard.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Ventilate area of leak or spill. Do not touch damaged containers or spilled material unless wearing appropriate protective equipment (Section 8). Stop leak if without risk. Do not allow to enter drains or watercourses.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills, add absorbent (soil may be used in the absence of other suitable materials), scoop up material and place in a sealable, liquid-proof container for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

Section 7. Handling and storage

Handling : Do not ingest. Do not get in eyes or on skin or clothing. Avoid breathing vapor or mist. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area.
Store between -30 and 40°C

Section 8. Exposure controls, personal protection

Engineering controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits. Provide eyewash and safety shower in area if contact or splash hazard exists.

Personal protection

Eyes : Use chemical splash goggles. For continued or severe exposure wear a face shield over the goggles.

Hands : Use chemical-resistant, impervious gloves.

Skin : Wear suitable protective clothing.

Respiratory : Avoid breathing vapors, spray or mists.

Name	Exposure limits
sodium hydroxide	**OSHA PEL (United States, 8/1997).** TWA: 2 mg/m^3 8 hour(s). Form: All forms **ACGIH TLV (United States, 1/2004).** CEIL: 2 mg/m^3 CEIL: 2 mg/m^3 Form: All forms

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Colorless to light yellow.

Odor : chlorine

pH : 12.75 (100%)

Boiling/condensation point : 100 °C

Specific gravity : 1.222 (Water = 1)

: Easily dispersed in cold water, hot water.

Dispersibility properties

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : The product is stable.

Reactivity : Highly reactive with acids.
Reactive with metals.
Slightly reactive to reactive with organic materials.

Hazardous decomposition products : These products are halogenated compounds, hydrogen chloride.

Section 11. Toxicological information

Potential acute health effects

Eyes : Corrosive to eyes.

Skin : Corrosive to the skin.

Inhalation : Irritating to respiratory system.

Ingestion : Harmful if swallowed. Causes burns to mouth, throat and stomach.

Potential chronic health effects

Chronic effects on humans : Contains material which causes damage to the following organs: lungs, mucous membranes, upper respiratory tract, skin, eye, lens or cornea.

Section 12. Ecological information

Products of degradation : These products are carbon oxides (CO, CO_2) and water, halogenated compounds. Some metallic oxides.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Waste classification : Unused product is D002 (Corrosive)

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	UN1908	Chlorite solution	8	II	**Limited quantity** Yes. **Special provisions** A3, A6, A7, B2, IB2, N34, T7, TP2, TP24

APPLIES ONLY DURING ROAD TRANSPORT

Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Corrosive material
Target organ effects

U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: No products were found.
SARA 302/304 emergency planning and notification: No products were found.

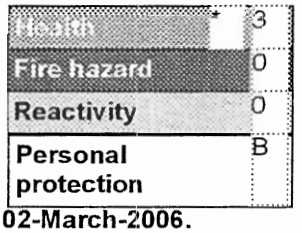
TSCA 8(b) inventory : All materials are listed or exempt.

California Prop. 65 : No products were found.

EPA Registration No. : 5382-43-1677

Section 16. Other information

Hazardous Material Information System (U.S.A.) :



Date of issue : 02-March-2006.

Responsible name : Regulatory Affairs

Date of previous issue : No previous validation.

Notice to reader

The above information is believed to be correct with respect to the formula used to manufacture the product in the country of origin. As data, standards, and regulations change, and conditions of use and handling are beyond our control, NO WARRANTY, EXPRESS OR IMPLIED, IS MADE AS TO THE COMPLETENESS OR CONTINUING ACCURACY OF THIS INFORMATION.

ECOLAB®

50977

Net Contents: 5 U.S. gal/18.9 L
Part 1 Base Concentrate

EXSPOR® BASE CONCENTRATE

4:1:1 Sterilant-Disinfectant

The 3-Minute System for Controlling Cross-Contamination from Treated Hard, Non-porous Inanimate Surfaces

FOR USE WITH EXSPOR® ACTIVATOR CONCENTRATE (Part 2)

BACTERICIDAL-VIRUCIDAL-FUNGICIDAL-TUBERCULOCIDAL-PSEUDOMONACIDAL-SPORICIDAL

ACTIVE INGREDIENTS:

Sodium Chlorite	1.52%
OTHER INGREDIENTS:	98.48%
TOTAL:	100.00%

DISINFECTING LEVEL—Kills all bacteria including *Pseudomonas aeruginosa* and *Mycobacterium sp.*, pathogenic fungi and viruses* on hard, non-porous environmental surfaces in 3 minutes (SEE DIRECTIONS FOR USE).

Sterilizes laboratory equipment and other non-medical immersible items in 10 hours at 20°C. (See directions for use. See side panel for precautionary information.)

*Kills Influenza Virus Type A2 (Hong Kong); Herpes Simplex Virus Types 1 and 2; Poliovirus Type 1; Coxsackievirus; Adenovirus Type 2; Echovirus Type 2; Vaccinia Virus and Vesicular Stomatitis Virus (VSV).

KEEP OUT OF REACH OF CHILDREN
CAUTION

This statement refers only to the unmixed EXSPOR Base Concentrate.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

Ecolab Inc.
Ecolab Food & Beverage Division
370 Wabasha Street N.
St. Paul, Minnesota 55102-1390 U.S.A.

FIRST AID STATEMENTS

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center or doctor for treatment advice.

ADDITIONAL PRECAUTIONARY STATEMENTS FOR MIXED SOLUTION

Use of mixed solutions in a confined or large volume area may lead to respiratory irritation. If irritation occurs, leave the area immediately, and seek medical attention if irritation persists. Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

ADDITIONAL FIRST AID STATEMENTS FOR MIXED SOLUTION

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IF IN EYES: Hold eye open and rinse slowly and gently, with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center or doctor for treatment advice.

FOR EMERGENCY MEDICAL INFORMATION IN USA OR CANADA, CALL: 1-800-328-0026.
FOR EMERGENCY MEDICAL INFORMATION WORLDWIDE, CALL: 1-651-222-5352 (IN THE USA).

CAUTION: This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to precleanse or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

EXSPOR Sterilant–Disinfectant is recommended for use as a disinfectant in schools, hospitals, medical, dental, industrial and institutional facilities to control human health-related microorganisms on hard, non-porous environmental surfaces and for sterilizing laboratory and other non-medical immersible items.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product is not for use as the final sterilization step or as a high level disinfectant for medical instruments.

USE IN A WELL-VENTILATED AREA. AVOID BREATHING FUMES.
EXSPOR Base Concentrate must be diluted with water prior to adding EXSPOR Activator Concentrate. Improper preparation can result in excessive generation of chlorine dioxide fumes.

PREPARATION:

1. Measure 1 part EXSPOR Base Concentrate (Part 1) into a clean, empty, NON-METALLIC container.
2. Add 4 parts cool tap water (at or below 25°C).
3. Add 1 part EXSPOR Activator Concentrate (Part 2) and stir.

The final solution should appear colorless or pale yellow. Variations in local water hardness may result in dark color and/or strong odor. Deionized or distilled water may be substituted to minimize these effects.

STERILIZATION OF LABORATORY AND OTHER NON-MEDICAL EQUIPMENT

Prepare EXSPOR solution as described above. Moderate amounts of organic load, such as soil, will not lower the efficacy of EXSPOR solutions. However, to ensure best results, surfaces should be rinsed and, if possible, equipment dismantled and rinsed free of heavy soil and gross debris. Hollow objects must be flushed and filled. Immerse equipment for a minimum of 10 hours at 20°C to destroy resistant pathogenic spores as represented by *Clostridium sporogenes* and *Bacillus subtilis*. Remove equipment from EXSPOR solution using sterile technique and rinse thoroughly with sterile water prior to drying. Mix and use right away; do not reuse. Discard solution after each use.

DISINFECTION: Prepare EXSPOR solution as described above. Disinfection is not affected by water hardness up to 400 ppm (calculated as $CaCO_3$).
Mixed solution needs to be used within 24 hours of mixing. Discard used solution after each use. Although efficacy at a 30-second contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. EXSPOR solution will inactivate bacteria (including M. tuberculosis), fungi and viruses in 3 minutes at 20°C.
Soaking is the best method of application. However, the solution may be sprayed or wiped on by any convenient means (mop, cloth, sponge, etc). The surface should be thoroughly wet with solution. To minimize potential for oxidation or corrosion, a contact time of 3 minutes on metal surfaces or equipment should not be exceeded.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS POSSIBLY CONTAINING THE HUMAN IMMUNODEFICIENCY (AIDS) VIRUS

- Wear protective barriers such as disposable latex gloves, gowns, masks and/or eye covering when handling items soiled with blood and body fluids.
- Blood and other body fluids must be thoroughly cleaned from surfaces and objects before use of EXSPOR.
- Such fluids and contaminated cleaning materials should be autoclaved and disposed of according to local regulations for infectious waste disposal.

NOTE: EXSPOR solution may be safely used on most plastics, ceramic, and glass. Never soak items in metal vessels. Prolonged or repeated exposure will oxidize metals, including aluminum and stainless steel. Do not use on copper, brass or bronze. Do not apply to surfaces containing residues from bleach, strong acids, or other chemicals, without first rinsing surface thoroughly with water.
Ventilation: Always use in a well-ventilated area. Avoid breathing fumes. When used in a confined or large-volume area, the quantity of chlorine dioxide in the air may exceed OSHA Permissible Exposure Limits (PEL's) and may require respiratory protection. Limits are defined as 0.1 ppm for an 8-hour time weighted average, and 0.2 ppm for a 15-minute short term exposure limit (29 CFR PART 1910.134 and Section 1910.1000, Air Contaminants, Table Z-1). Personnel should contact their resident safety officer or Ecolab, Inc. for information on appropriate protective gear when such application is undertaken.

STORAGE AND DISPOSAL

Store unmixed concentrates in a cool, dark, dry place in the original containers. Always replace covers. Keep upright. Thoroughly wash empty concentrate containers with water and discard in a safe place. Do not reuse containers. Used and outdated EXSPOR solution may be flushed down the drain.

EPA Reg. No. 1677-216
EPA Est. No. 35347-CA-001
EXSPOR is a registered trademark of Ecolab Inc., St Paul, MN. 55102

Material Safety Data Sheet

ECOLAB

EXSPOR BASE

Section 1. Chemical product and company identification

Trade name : EXSPOR BASE
Product use : disinfectant
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 910906
Date of issue : **29-July-2005**
EPA Registration No. : 1677-216

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Composition, Information on Ingredients

Name	CAS number	% by weight
sodium dodecylbenzene sulfonate	25155-30-0	1
sodium chlorite	7758-19-2	1 - 5

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : CAUTION!

CAUSES SKIN IRRITATION.
HARMFUL IF ABSORBED THROUGH SKIN.
MAY CAUSE RESPIRATORY TRACT AND EYE IRRITATION.
Avoid prolonged contact with eyes, skin, and clothing. Avoid breathing vapor or mist. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling.

Potential acute health effects

Eyes : Moderately irritating to the eyes.
Skin : Harmful in contact with skin. Irritating to skin.
Inhalation : Moderately irritating to the respiratory system.
Ingestion : No known significant effects or critical hazards.

See toxicological Information (section 11)

Section 4. First aid measures

Eye contact : In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention if irritation persists.

Skin contact : In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Inhalation : If inhaled, remove to fresh air.

Ingestion : Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.

Products of combustion : These products are halogenated compounds, hydrogen chloride.

Fire fighting media and instructions : Use an extinguishing agent suitable for surrounding fires.

Dike area of fire to prevent product run-off.
No specific hazard.

Special protective equipment for fire-fighters : Fire fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full facepiece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Ventilate area of leak or spill. Do not touch damaged containers or spilled material unless wearing appropriate protective equipment (Section 8). Stop leak if without risk. Prevent entry into sewers, water courses, basements or confined areas.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.--

Section 7. Handling and storage

Handling : Avoid contact with eyes, skin and clothing. Keep container closed. Use only with adequate ventilation. Avoid breathing vapor or mist. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area.
Store between -10 and 40°C

Section 8. Exposure Controls, Personal Protection

Engineering controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits.

Personal protection

Eyes : Eye protection recommended.

Hands : Use chemical resistant, impervious gloves.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : Avoid breathing vapor or mist.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Yellow.

Odor : chlorine

pH : 11.5 (100%)

Boiling/condensation point : 100 °C

Specific gravity : 1.02 (Water = 1)

Dispersion properties : Easily dispersed in cold water, hot water.

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : The product is stable.
Reactivity : Reactive with acids.
Hazardous decomposition products : These products are halogenated compounds, hydrogen chloride.

Section 11. Toxicological information

Potential acute health effects

Eyes : Moderately irritating to the eyes.
Skin : Harmful in contact with skin. Irritating to skin.
Inhalation : Moderately irritating to the respiratory system.
Ingestion : No known significant effects or critical hazards.

Potential chronic health effects

Chronic effects on humans : Contains material which causes damage to the following organs: skin, eye, lens or cornea.

Section 12. Ecological information

Products of degradation : These products are carbon oxides (CO, CO_2) and water, sulfur oxides (SO_2, SO_3 ...), halogenated compounds. Some metallic oxides.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	Not regulated.	-	-	-	-

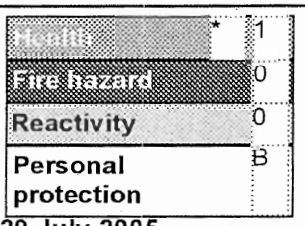
APPLIES ONLY DURING ROAD TRANSPORT
Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Irritating material
Target organ effects
U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: None.
SARA 302/304 emergency planning and notification: None.
TSCA 8(b) inventory : All materials are listed or exempt.
California prop. 65 : No products were found.
EPA Registration No. : 1677-216

Section 16. Other information

Hazardous Material Information System (U.S.A.) :



Date of issue : 29-July-2005.
Responsible name : Regulatory Affairs
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Notice to reader

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ECOLAB®

50974

Net Contents: 5 U.S. gal/18.9 L
Part 2 Activator Concentrate

EXSPOR® ACTIVATOR CONCENTRATE

4:1:1 Sterilant-Disinfectant

The 3-Minute System for Controlling Cross-Contamination from Treated Hard, Non-porous Inanimate Surfaces

FOR USE WITH EXSPOR® BASE CONCENTRATE (Part 1)

Contains 9.5% Organic Acid

PRINCIPAL FUNCTIONING AGENTS:

Lactic acid, 88%	10.8%
CONSTITUENTS INEFFECTIVE AS SPRAY ADJUVANTS	89.2%
TOTAL:	100.0%

All ingredients are exempted from the requirements of a tolerance under 40 CFR 180.

KEEP OUT OF REACH OF CHILDREN
CAUTION

This statement only refers to the unmixed Activator Concentrate:

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

CA Reg. No. 1677-50012

Packaged for:
Ecolab Inc., Food & Beverage Division
370 Wabasha Street N.
St. Paul, Minnesota 55102-1390 U.S.A.

FIRST AID STATEMENTS

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center or doctor for treatment advice.

ADDITIONAL PRECAUTIONARY STATEMENTS FOR MIXED SOLUTION

Use of mixed solutions in a confined or large volume area may lead to respiratory irritation. If irritation occurs, leave the area immediately, and seek medical attention if irritation persists. Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

ADDITIONAL FIRST AID STATEMENTS FOR MIXED SOLUTION

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center or doctor for treatment advice.

FOR EMERGENCY MEDICAL INFORMATION IN USA OR CANADA, CALL: 1-800-328-0026.
FOR EMERGENCY MEDICAL INFORMATION WORLDWIDE, CALL: 1-651-222-5352 (IN THE USA).

DIRECTIONS FOR USE

Follow directions for mixing, use, storage and disposal on the EXSPOR Base Concentrate label. Wash measuring container before use. EXSPOR Base Concentrate must be diluted with water prior to adding Activator Concentrate (see "Preparation" section of Base Concentrate label). Improper preparation can result in excessive generation of chlorine dioxide fumes.

For additional DIRECTIONS FOR USE see EXSPOR BASE CONCENTRATE label.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.

Store unmixed concentrates in a cool, dark, dry place in the original containers. Always replace covers. Keep upright. Thoroughly wash empty concentrate containers with water and discard in a safe place. Do not reuse containers. Used and outdated EXSPOR solution may be flushed down the drain.

Manufactured by:
Packaging Advantage Corporation
4633 Downey Road
Los Angeles, CA 90058-2511

Material Safety Data Sheet

ECOLAB

EXSPOR ACTIVATOR

Section 1. Chemical product and company identification

Trade name : EXSPOR ACTIVATOR
Product use : Additive
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 910905
Date of issue : **05-August-2005**

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Composition, Information on Ingredients

Name	CAS number	% by weight
propanoic acid, 2-hydroxy-, (s)-	79-33-4	5 - 20

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : CAUTION!

MAY CAUSE RESPIRATORY TRACT, EYE AND SKIN IRRITATION.
HARMFUL IF ABSORBED THROUGH SKIN.
Avoid contact with skin and clothing. Avoid breathing vapor or mist. Keep container closed.
Use only with adequate ventilation. Wash thoroughly after handling.

Potential acute health effects
Eyes : Moderately irritating to the eyes.
Skin : Harmful if absorbed through the skin. Moderately irritating to the skin.
Inhalation : Moderately irritating to the respiratory system.
Ingestion : No known significant effects or critical hazards.
See toxicological Information (section 11)

Section 4. First aid measures

Eye contact : In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention if irritation persists.
Skin contact : Wash with soap and water. Get medical attention if irritation occurs. Wash clothing before reuse.
Inhalation : If inhaled, remove to fresh air.
Ingestion : Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.
Fire fighting media and instructions : Use an extinguishing agent suitable for surrounding fires.

Dike area of fire to prevent product run-off.
No specific hazard.
Special protective equipment for fire-fighters : Fire fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full facepiece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Ventilate area of leak or spill. Do not touch damaged containers or spilled material unless wearing appropriate protective equipment (Section 8). Stop leak if without risk. Prevent entry into sewers, water courses, basements or confined areas.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.--

Section 7. Handling and storage

Handling : Avoid contact with eyes, skin and clothing. Do not add water directly to product. Slowly stir product into water. Keep container closed. Use only with adequate ventilation. Avoid breathing vapor or mist. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area.
Store between -10 and 40°C

Section 8. Exposure Controls, Personal Protection

Engineering controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits.

Personal protection

Eyes : Eye protection recommended.

Hands : Use chemical resistant, impervious gloves.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : Avoid breathing vapor or mist.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Colorless to light yellow.

Odor : Faint Odor

pH : 1.8 (100%)

Boiling/condensation point : >100 °C

Specific gravity : 1.023 (Water = 1)

Dispersion properties : Easily dispersed in cold water, hot water.

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : The product is stable.

Reactivity : Reactive with alkalis.

Section 11. Toxicological information

Potential acute health effects

Eyes : Moderately irritating to the eyes.

Skin : Harmful if absorbed through the skin. Moderately irritating to the skin.

Inhalation : Moderately irritating to the respiratory system.

Ingestion : No known significant effects or critical hazards.

Potential chronic health effects

Section 12. Ecological information

Products of degradation : These products are carbon oxides (CO, CO_2) and water.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Waste classification : Unused product is D002 (Corrosive)

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	UN3265	Corrosive liquid, acidic, organic, n.o.s. (Lactic acid)	8	III	**Limited quantity** Yes. **Special provisions** IB3, T7, TP1, TP28

APPLIES ONLY DURING ROAD TRANSPORT

Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Irritating material

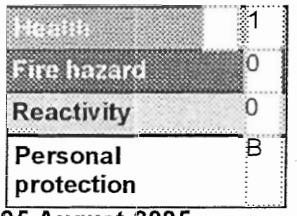
U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: None.
SARA 302/304 emergency planning and notification: None.

TSCA 8(b) inventory : All materials are listed or exempt.

California prop. 65 : No products were found.

Section 16. Other information

Hazardous Material Information System (U.S.A.) :



Date of issue : **05-August-2005.**

Responsible name : **Regulatory Affairs**

Date of previous issue : **No Previous Validation.**

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Melvin, Jonathan

From: Caceres, Miguel
Sent: Tuesday, March 06, 2007 6:49 PM
To: Melvin, Jonathan
Cc: Bradley, Mark; ARCbranch
Subject: Labeling Question
Importance: High
Attachments: Made with Label.pdf

JD,
If a product has 97% organic ingredients and it states so on the primary panel and it is labeled as "**Made with organic**" can it then use the USDA Seal? (I don't know why they don't just label the product as "Organic"). Even though the product contains more than 95% of organic ingredients **§205.301(c)** states that "If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to 205.304." **§205.304(c)** states that packages described in **§205.301(c)** must not display the USDA Seal.

So even thought the product is compliant to use the seal the labeling appears to be non-compliant. I think this is minor but I would like the NOP stance on this since the seal can be used on products with more than 95% Organically produced ag products. I have included the label for your review.

Thank You,

Miguel A. Caceres
Agricultural Marketing Specialist
Phone: 407-823-9567
Fax: 407-823-9567
For comments to our service visit::
http://www.ams.usda.gov/lsg/arc/arcsurvey.htm

Attachment 4

9. Substance Physical Properties and Mode of Action:

(a) Chemical Interactions With Other Substances, Used in Organic Production; (b) Toxicity and Environmental Persistence. (c) Environmental Imports From Its Use or Manufacturer; (d) Effects On Human Health; (e) Effects on Soil Organisms, Crops or Livestock.

9.) **The substance's physical properties, chemical mode of action, including (a) chemical interactions with other substances, (b) toxicity and environmental persistence, (c) environmental impacts from it's use, (d) effects on human health, (e) effects on crops or produce.**

The food additive, "Acidified sodium chlorite solutions ", consists of an aqueous mixture of sodium chlorite (CAS No. 7758-19-2) and a suitable food-grade acid sufficient to render the solution a pH in the range of ~2.5 - 2.9. Sodium chlorite is available as a white powder or flaked product, as an ~80% technical grade. It decomposes at 180° to 200°C, and is readily soluble in water (39 g/100 g at 17°C). Sodium chlorite is also available in liquid form at various concentrations, such as a 25% (w/w) solution, referred to as 31.25 technical sodium chlorite. In both solid and liquid forms, on a solids basis, the sodium chlorite technical grade product, in addition to ~80% sodium chlorite, may contain up to ~14% of sodium chloride and lesser amounts of sodium carbonate, sulfate, chlorate and hydroxide (see Raw Material Specification Sheet, attached).

The ASC solutions have specific gravities approximating 1.0, and are colorless. When used as an antimicrobial agent on products which are the subject of this petition either as a spray or dip, the diluted acid and chlorite components are combined directly before use. If the solutions are allowed to stand, or pool after dripping from the treated meat surfaces, and in a non-vented area, a low-level chlorine-like odor from chlorine dioxide may be noticeable.

ASC is a very strong oxidizing agent having a stronger oxidation potential than chlorine or chlorine dioxide in aqueous solutions. It is a clear, colorless liquid with no foaming capability. It has a mild chlorine-like odor, pH is acid (2.3—3.2), specific gravity of use-solutions (50—1200 ppm) is essentially that of water (1.01—1.05), and weighs approximately 8.39 pounds per gallon. ASC solutions are mixed and immediately applied on site.

HClO2/ClO2- Mixture: Acidified sodium chlorite (ASC) solutions are mixtures of sodium chlorite (a salt) and citric acid. Citric acid is the principle component of lemon juice. Sodium chlorite is an inorganic salt made from the reduction of chlorine dioxide.

Sodium chlorite is used in municipal drinking water treatment as a precursor for making chlorine dioxide. The MCL (Maximum Contaminant Level) for chlorite in drinking water is 1.0 ppm.

(a) **Chemical interaction with other substances**

In aqueous solution, metastable chlorous acid is consumed through several pathways ultimately producing chlorate ions and chloride ions. The extent and rate of consumption will be determined by bacterial load and reaction with any minerals or other contaminants present. A small portion of chlorous acid is expected to produce chlorine dioxide, itself is a strong antimicrobial agent which is not persistence in the presence of bacteria or organic loading.

ACIDIFIED SODIUM CHLORITE CHEMISTRY

Acidified Sodium Chlorite (ACS) chemistry is principally the chemistry of chlorous acid ($HClO_2$), a metastable oxychlorine species which decomposes to form chlorate ion, chlorine dioxide, and chloride ion[4]. To better understand chlorous acid chemistry, a brief overview of the chemistry of various oxychlorine species will be given.

As illustrated in Table I, chlorine can exhibit oxidation states from –1 to +7. As a consequence, its chemistry is varied and complex.

Table 1. Oxidation States of Chlorine

ClO_4^-	+7	Perchlorate ion
ClO_3^-	+5	Chlorate ion
ClO_2	+4	Chlorine dioxide
ClO_2^-	+3	Chlorite ion
ClO^- or OCl^-	+1	Hypochlorite ion
Cl_2	0	Chlorine (molecular)
Cl^-	- 1	Chloride ion

Oxychlorine species are important as oxidants in a number of applications. The strength of an oxidant is measured by its oxidation strength, or oxidation potential. Table 2 lists some of the more common oxidants, the associated oxidation reaction, the oxidation strength (measured in volts), and the oxidation capacity (the number of electrons accepted by the oxidant. The chlorous acid ($HClO_2$) reaction, with its 1.57 V oxidation strength and 4-electron oxidation capacity, ranks just below ozone and the hydroxyl-radical generation reaction of hydrogen peroxide.

Table 2. Common Oxidation Reactions

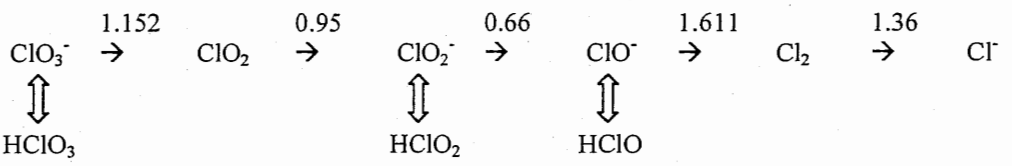
Oxidant Reaction	Oxidant	Oxidation Capacity	Oxidation Strength (V)
$0_3 + H_2O + 2\ e^- \rightarrow O_2 + OH^-$	Ozone	$2e^-$	2.07
$H_2O_2 + 2e^- \rightarrow 2\ OH^-$	Hydrogen Peroxide	$2e^-$	1.78
$HClO_2 + 3\ H^+ + 4\ e^- \rightarrow Cl^- + 2\ H_2O$	Chlorous Acid (Acidified Sodium Chlorite	$4e^-$	1.57
$ClO_2\ (v) + e^- \rightarrow ClO_2^-$	Chlorine Dioxide (Vapor Phase)	$1e^-$	1.56
$HOCl + H^+ + 2\ e^- \rightarrow Cl^- + H_2O$	Hypochlorous acid	$2e^-$	1.49
$HOBr + H^+ + 2\ e^- \rightarrow Br^- + H_2O$	Hypobromous acid	$2e^-$	1.33
$ClO_2 + 4\ H^+ + 5\ e^- \rightarrow Cl^- + 2\ H_2O$	Acidified Chlorine Dioxide	$5e^-$	1.51
$ClO_2\ (aq) + e^- \rightarrow ClO_2^-$	Chlorine Dioxide (Aqueous Phase)	$1e^-$	0.95
$ClO_2^- + 2H_2O + 4e^- \rightarrow Cl^- + 4\ OH^-$	Chlorite	$4e^-$	0.78

As mentioned before, oxychlorine chemistry is varied and complex. Listed below are oxidation half-cell reactions and their corresponding oxidation potentials for several additional reactions of oxychlorine species given by Gordon *et al.* in the AWWA publication, *Disinfectant Residual Measurement Methods*:

$HClO_2 + 3\ H^+ + 4\ e^- \rightarrow Cl^- + 2\ H_2O$	1.57 V
$HClO_2 + 2\ H^+ + 2\ e^- \rightarrow HClO + H_2O$	1.645V
$HOCl + H^+ + e^- \rightarrow \frac{1}{2}\ Cl_2 + H_2O$	1.611 V
$HOCl + H^+ + 2\ e^- \rightarrow Cl^- + H_2O$	1.49 V
$ClO_3^- + 6\ H^+ + 5\ e^- \rightarrow \frac{1}{2}\ Cl_2 + 3\ H_2O$	1.47 V
$ClO_3^- + 6\ H^+ + 6\ e\text{-} \rightarrow Cl^- + 3\ H_2O$	1.451 V
$Cl_2 + 2\ e^- \rightarrow 2\ Cl^-$	1.36 V
$ClO_2 + H+ + e^- \rightarrow HClO_2^-$	1.25 V
$ClO_3^- + 3\ H^+ + 2\ e^- \rightarrow HClO_2 + H_2O$	1.214 V
$ClO_3^- + 2\ H^+ + e^- \rightarrow ClO_2 + H_2O$	1.152 V
$ClO_2 + e^- \rightarrow ClO_2^-$	0.95 V
$OCl^- + 2\ H_2O + 2\ e^- \rightarrow Cl^- + 2\ OH^-$	0.81 V
$ClO_2^- + 2\ H_2O + 4\ e^- \rightarrow Cl^- + 4\ OH^-$	0.76 V
$ClO_2^- + H_2O + 2\ e^- \rightarrow ClO^- + 2\ OH^-$	0.66 V

$$ClO_3^- + 3\,H_2O + 6\,e^- \rightarrow Cl^- + 6\,OH^- \qquad 0.62\ V$$

The oxidation potential diagram given below shows that chlorous acid is unstable with respect to disproportionation, i.e., chlorous acid is a metastable species.



Numerous researchers have determined that the decomposition reaction of chlorous acid is approximately second order with respect to chlorous acid. At pH values above 2.0 where $[ClO_2^-] > [HClO_2]$, the rate law can be written as follows:

$$\frac{-d[HClO_2]}{dt} = k\,[HClO_2]^2$$

(where $k = 0.023\ M^{-1}\,sec^{-1}$ at 25°C)

It is known that chloride ion accelerates the decomposition of chlorous acid and also alters the stoichiometry, Hong[11,12] developed the following empirical rate expression for the decomposition of chlorous acid, with the effect of chloride taken into account;

$$\frac{d[ClO_2]}{dt} = (m + nx)\left(1 - \frac{x}{p + qx}\right)$$

where $m = 2\{k_1[HClO_2]^2 + k_2\,[ClO_2^-][HClO_2]\}$

$n = 4\,k_5\,[H+][HClO_2]$

$$p = \frac{k_3(k_7 + k_8)[HClO_2]}{k_6 k_7[H^+]}$$

$$q = \frac{k_7 + k_8}{k_7}$$

$x = [Cl^-]$

(Where the various rate constants refer to the following set of reactions:)

$$2\,HClO_2 \xrightarrow{k_1} H^+ + HOCl + ClO_3^-$$

$$HClO_2 + ClO_2^- \xrightarrow{k_2} HOCl + ClO_3^-$$

$$HOCl + HClO_2 \xrightarrow{k_3} H_2O + Cl_2O_2$$

$$Cl_2O_2 + HClO_2 \xrightarrow{k_4} H^+ + Cl^- + 2\,ClO_2$$

$$H^+ + Cl^- + HClO_2 \xrightarrow{k_5} 2\,HOCl$$

$$H^+ + Cl^- + HOCl \xrightarrow{k_6} Cl_2 + H_2O$$

$$Cl_2 + HClO_2 + H_2O \xrightarrow{k_7} 3\,H^+ + 2\,Cl^- + ClO_3^-$$

$$Cl_2 + HClO_2 \xrightarrow{k_8} H^+ + Cl^- + Cl_2O_2$$

In the absence of chloride, only the first four reactions need be considered. Doing this, Hong gives the following reaction equation, valid over the pH range of 0 to 3, for the initial rate law for the formation of chlorine dioxide:

$$\frac{d[ClO_2]}{dt} = k\,[HClO_2]^2 + k'\,[HClO_2][ClO_2^-]$$

The rate of formation of chlorine dioxide given above can be related approximately to the disappearance of chlorous acid by the following relation:

$$-d[HClO_2]/4 = d[ClO_2]/2$$

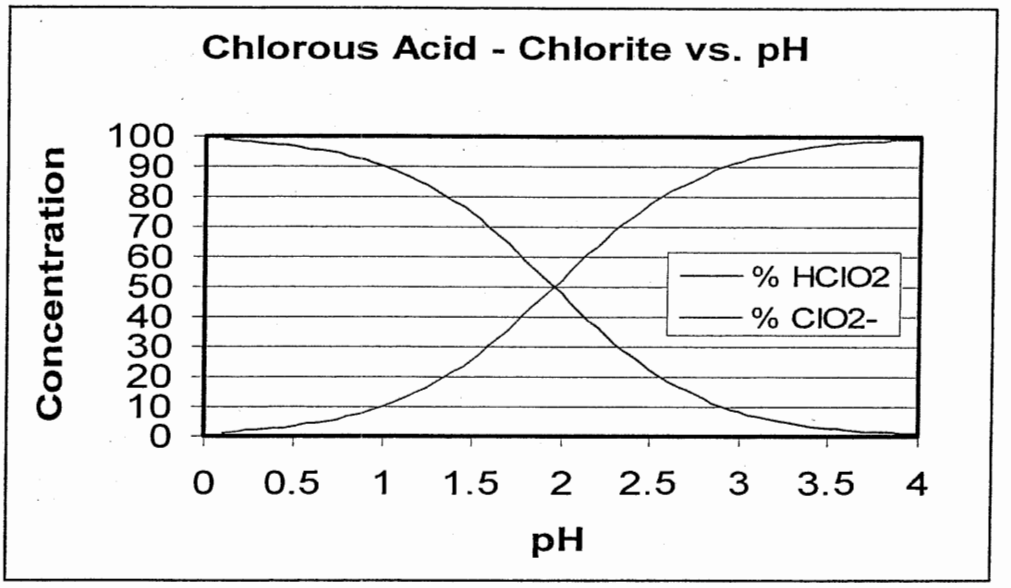
In aqueous solution, chlorous acid, a relatively weak acid, dissociates as follows:

$$HClO_2 \overset{K_a}{\Leftrightarrow} H^+ + ClO_2^-$$

Where K_a, the acid dissociation constant, is 1.01×10^{-2} at 23°C. In terms of the acid dissociation constant (ionization constant) and the hydrogen ion concentration of the solution (=10-pH), the chlorous acid concentration can be found from the total titratable chlorite concentration as follows:

$$\% HClO_2 = \frac{1}{1 + (1.1 \times 10^{-2})/[H^+]} \times 100\%$$

The following is a graph of this relationship.



The optimal parameters for application of the Acidified Sodium Chlorite process as a short-term antimicrobial intervention have therefore been determined to be:

i) A pH range of approximately 2.3 to 2.9;

ii) A sodium chlorite concentration ranging from 500 ppm to 1200 ppm.

CHLORINATION POTENTIAL

One of the prime virtues of oxychlorine chemicals, when used for food or water disinfection, is their minimal tendency for chlorination of food components or water impurities. It has been shown that no detectable chlorinated organics are present in the lipids or proteins of exposed surfaces; neither has the presence of any oxidation products been noted following ASC treatment of poultry and red meat. There is no reason to expect any differences for the current, petitioned use of the same ASC solutions for the

use an antimicrobial agent to reduce pathogenic microorganisms prior to packaging on the products which are the subject of this petition prior to packaging.

(b) **Toxicity and environmental persistence**

"Residues of sodium chlorite or chlorine dioxide are not expected in livestock. A 1987 National Research Council report entitled "Drinking Water and Health: Disinfectants and Disinfectant By-Products, Volume 7" (National Academy Press) discusses available tissue distribution data of ^{36}Cl-labeled chlorite and chlorate following administration of either chlorite at 10 mg/L or chlorate at 5 mg/L. The NRC report concluded that "[available data] suggests that neither [sodium] chlorite nor chlorate bioaccumulates" (page 101).

22921--22 Federal Register / Vol. 66, No. 88 / Monday, May 7, 2001 / Rules and Regulations

> "The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch address above) between 9 a.m. and 4 m., Monday through Friday."

The National Research Council (1987)[16] selected a no-observed-effect-level (NOEL) for chlorite and chlorate in drinking water of 0.034 mg/kg body weight per day. Using this factor and an uncertainty factor of 100 they estimated the suggested-no-adverse-response-levels (SNARL) for chronic exposure to chlorite and/or chlorate to be 0.024mg/L for a 70 kg adult consuming 2 liters water/day,

and 0.007 mg/L for a 10 kg child consuming 1 liter water/day. This translates to a maximum level of chlorite and/or chlorate ingestion, from drinking water, of 48 mcg of chlorite/chlorate daily for a 70 kg adult, and 7 mcg daily for a 10 kg child.

(c) **Environment impacts from its use**

FDA stated [61 FR 17829, April 23, 1996] the following:

> "The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environment impact statement is not required. The agency's fining of so significant impact and the evidence support that finding, contained in an environment assessment, may be seen in the Dockets Management Branch..."

ASC breaks down to citric acid, water, and common table salt, all of which occur in the agroecosystem. ASC solutions (chlorite ion and chlorous acid) do not chlorinate organics. Therefore, ASC has the advantage over treatment with chlorine, which can seriously damage aquatic life and form chlorinated hydrocarbons with mutagenic or carcinogenic properties.

(d) **Effects on human health**

The acute and chronic toxicity of chlorine dioxide (and its primary degradant, sodium chlorite) has been tested extensively. (Federal Vol. 62(38) 8734—8735)

***Short and Intermediate Term Toxicity*:** For short term Margin-of-Exposure calculations, the NOEL of 3.0 mg/kg/day from the developmental toxicity study of Orme et al. was recommended.

***Chronic Toxicity*:** For chronic MOE calculations, the NOEL of 3.0 mg/kg/day was selected from the developmental toxicity study of Orme et al. Long-term toxicity studies exist for chlorine dioxide, but the EPA Antimicrobials Division adhered to the determination of the EPA Office of Water regarding study selection for determination of chronic risk.

***Cancer Toxicity*:** Neither sodium chlorite nor chlorine dioxide has been formally evaluated by USEPA or by IARC for carcinogenic potential.

Dermal Penetration: A dermal penetration factor for chlorine dioxide or chlorite ion has not been determined.

"FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and, therefore, that the regulation in § 173.325 should be amended as set forth below."

(e) **Effects on crops or produce**

The principal byproducts of acidified sodium chlorite (ASC) solution degradation are sodium chloride (common table salt) and sodium chlorate ($NaClO_3$).

Sodium chlorate is exempted from the requirements for a tolerance when used as a defoliant, desiccant, or fungicide on various raw agricultural commodities in accordance with good agricultural practice (40 CFR 180.1020).

United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7510P)

EPA 738-R-06-007
August 2006

Reregistration Eligibility Decision (RED) for Chlorine Dioxide and Sodium Chlorite (Case 4023)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the draft risk assessments for the antimicrobials, chlorine dioxide and sodium chlorite. The enclosed Reregistration Eligibility Decision (RED) document was approved on August 3, 2006. Public comments and additional data received were considered in this decision.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for chlorine dioxide and sodium chlorite and the associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for chlorine dioxide are available to the public in EPA's Pesticide Docket EPA-HQ-**OPP-2006-0328** at: http://www.regulations.gov.

The chlorine dioxide and sodium chlorite RED was developed through EPA's public participation process, published in the Federal Register on April 26, 2006, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision-making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the chlorine dioxide and sodium chlorite risk assessment and the attached RED document concern only these particular pesticides. This RED presents the Agency's conclusions on the dietary, drinking water, residential, occupational and ecological risks posed by exposure to chlorine dioxide and sodium chlorite alone. This document also contains both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be sent to registrants at a later date. Additionally, for product-specific DCIs, the first set of required responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that chlorine dioxide and sodium chlorite will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. Sections IV and V of this RED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by chlorine dioxide and sodium chlorite. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, ShaRon Carlisle, (703) 308-6427. For questions about product reregistration and/or the Product DCI that will follow this document, please contact Emily Mitchell at (703) 308-8583.

Sincerely,

Frank Sanders, Director
Antimicrobials Division (7510C)

REREGISTRATION ELIGIBILITY

DECISION

for

Chlorine Dioxide and Sodium Chlorite

Case Number 4023

Approved by:

_____

Frank T. Sanders, Director
Antimicrobials Division

_____

Date

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Glossary of Terms and Abbreviations

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.

MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NTP	National Toxicology Program
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RAC	Raw Agricultural Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for Chlorine Dioxide and Sodium Chlorite and is issuing its risk management decision and tolerance reassessment. The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products and additional information received through the public docket. After considering the risks identified in the revised risk assessments, comments received, and mitigation suggestions from interested parties, the Agency developed its risk management decision for uses of chlorine dioxide and sodium chlorite that pose risks of concern. As a result of this review, EPA has determined that chlorine dioxide and sodium chlorite containing products are eligible for reregistration, provided that risk mitigation measures are adopted and labels are amended accordingly. That decision is discussed fully in this document. The Inorganic Chlorates Reregistration Eligibility Decision (RED) (PC code 073301), determined that sodium chlorate tolerances were safe provided a safety finding could be made for chlorine dioxide and sodium chlorite. This decision fulfills that condition.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require reregistration assessments of the prior to 1984 chemicals. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency's revised human health and ecological risk assessments; and the Reregistration Eligibility Decision (RED) for chlorine dioxide and sodium chlorite.

Chlorine dioxide and sodium chlorite are active ingredients in numerous products used in the control of bacteria, fungi, and algal slimes. In addition, chlorine dioxide and sodium chlorite are used as material preservatives and as disinfectants. At this time, products containing chlorine dioxide and sodium chlorite are intended for agricultural, commercial, industrial, medical and residential use. The agricultural premises and equipment uses include the disinfection of hard surfaces and equipment (such as hatching facilities and mushroom houses) and water systems (such as chiller water and humidification water in poultry houses). Commercial, industrial, and medical uses include disinfection of ventilation systems, hard surfaces (e.g., floors, walls, and laboratory equipment), water systems, pulp/paper mills, and food rinses. Residential uses include disinfection of hard surfaces (e.g., floors, bathrooms), heating ventilating and air-conditioning (HVAC) systems, and treatment of pool & spa water circulation systems. In addition, there is a continuous release gas product (sachet) for the home to control odors.

The Agency has concluded that the FQPA Safety Factor for chlorine dioxide should be removed (equivalent to 1X) based on: (1) the existence of a complete developmental and reproductive toxicity database; (2) the endpoint selected for assessment of risk from dietary and non-dietary exposure to chlorine dioxide is protective of potentially susceptible populations including children and (3) the risk assessment does not underestimate the potential exposure for infants and children.

Risks summarized in this document are those that result only from the use of the active ingredients chlorine dioxide and sodium chlorite. The FFDCA requires that the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for chlorine dioxide and sodium chlorite and any other substances. Chlorine dioxide and sodium chlorite do not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that chlorine dioxide and sodium chlorite has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative .

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of chlorine dioxide and sodium chlorite. In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for chlorine dioxide and sodium chlorite referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.epa.gov/edocket (EPA-HQ-OPP-2006-0328).

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of chlorine dioxide and sodium chlorite and its regulatory history. Section III, Summary of Chlorine Dioxide and Sodium Chlorite Risk Assessment, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

II. Chemical Overview

A. Regulatory History

EPA first registered the aqueous form of chlorine dioxide for use as a disinfectant and a sanitizer in 1967. In industrial processes, chlorine dioxide is used as a disinfectant in water treatment, ammonia plants, pulp mills, oil fields, scrubbing systems, odor control systems, and the electronics industry. In 1988, EPA registered chlorine dioxide gas as a sterilant. Chlorine dioxide gas is registered for sterilizing manufacturing and laboratory equipment, environmental surfaces, tools, and clean rooms. One of the major antimicrobial uses of chlorine dioxide is to treat drinking water. In addition, the largest use of chlorine dioxide is the non-pesticidal bleaching use in the pulp and paper industry.

Both sodium chlorite and the active ingredient sodium chlorate are used as a precursor in the generation of chlorine dioxide. Sodium chlorite is a strong oxidizing agent that under oxidizing conditions is readily reduced to chlorite, another strong oxidizing agent, and to a lesser extent, chlorate. Sodium chlorate (included in the group of inorganic chlorates) is predominantly used in the pulp and paper manufacturing process and as a herbicide in agriculture. The antimicrobial uses of sodium chlorate are a minor part of the use pattern. The uses of sodium chlorate were assessed separately in the Inorganic Chlorates Reregistration Eligibility Decision (RED) (PC code 073301). The RED for the inorganic chlorates is available in the public docket at www.regulations.gov in docket number EPA-HQ-OPP-2005-0507. This RED will focus on the uses of chlorine dioxide/sodium chlorite.

B. Chemical Identification

CHLORINE DIOXIDE: PHYSICAL/CHEMICAL CHARACTERISTICS

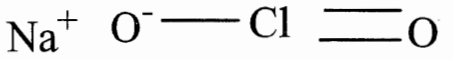
Chemical Name:	Chlorine dioxide, Chlorine (IV) oxide
Chemical Formula:	ClO_2
Chemical Structure:	
CAS#:	10049-04-4
Molecular Weight:	67.45 g/mol
Color:	Gas phase- Yellow green to orange Liquid phase- reddish brown
Melting Point:	-59 ° C
Boiling Point:	11 ° C
Odor:	Strongly pungent, chlorine-like
Physical State:	Gas at room temperature
Density:	1.64 g/ml at 0 ° C (liquid) 1.614 g/ml at 10 ° C (liquid)

Vapor Pressure:	490 mm Hg (0° C) >760 mm Hg (25 ° C)
Stability:	Unstable, estimated half life in water ~ 25 minutes*
Solubility (water):	3.01 g/L at 25 ° C and 34. 5 mm Hg**

Chlorine dioxide is explosive at > -40 ° C, and its explosive velocity in air is 50 m/s. It is highly miscible in water up to 60 g/L and is highly unstable in sunlight.

In aqueous solutions at pH>10, chlorine dioxide will hydrolyze to form chlorate and chlorite ions. In neutral or near neutral solutions (4< pH <10) chlorine dioxide is relatively stable and exists as a free radical in water. The rate of the hydrolysis reaction between water and chlorine dioxide is about ten million times slower than that of chlorine at neutral pH.

SODIUM CHLORITE: PHYSICAL/CHEMICAL CHARACTERISTICS

Chemical Name:	Sodium chlorite
Synonyms(s):	Chlorous acid, sodium salt
Chemical Formula:	$NaClO_2$
Chemical Structure:	
CAS#:	7758-19-2
Molecular Weight:	90.45 g/mol
Color:	White
Melting Point:	180-200 ° C (decomposes)
Boiling Point:	n/a
Physical State:	Solid
Density:	2.468 g/ml (as a solid)
Vapor Pressure:	n/a
Stability:	*Stable at Room Temperature*
Solubility (water):	390 g/L at 30 ° C
Compatibility:	Incompatible with organic matter, sulfur, powdered coal, and is a powerful oxidizer.

C. Use Profile

The following is information on the currently registered uses of chlorine dioxide and sodium chlorite, including an overview of use sites and application methods. A detailed table of the uses of sodium chlorate eligible for reregistration is available in Appendix A.

Type of Pesticide: Antimicrobial

Target Pests: Bacteria, fungi, and algal slimes.

Use Site:

Agricultural uses:	The agricultural premises and equipment uses include the disinfection of hard surfaces and equipment (such as hatching facilities and mushroom houses) and water systems (such as chiller water and humidification water in poultry houses).
Non-agricultural uses:	Commercial, industrial, and medical uses include disinfection of ventilation systems, hard surfaces (e.g., floors, walls, and laboratory equipment), water systems, pulp/paper mills, and food rinses
Residential:	Residential uses include disinfection of hard surfaces (e.g., floors, bathrooms), heating ventilating and air-conditioning (HVAC) systems, and treatment of pool & spa circulation systems. In addition, there is a continuous release gas product (sachet) for the home to control odors.
Use Classification:	General Use

Method and Rates of Application:

Equipment:	Foaming wand, sprayer, injector systems, mist and fogger, dip carcass, mop, pump, cloth and add to systems
Application Rates:	Concentrations of chlorine dioxide and sodium chlorite range from 5ppm to 5000ppm

Formulation Types: Soluble concentrates and ready-to-use liquid solutions

III. Summary of Chlorine Dioxide and Sodium Chlorite Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for chlorine dioxide and sodium chlorite. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket, located at http://www.regulations.gov, under docket number EPA-HQ-OPP-2006-0328. Hard copies of these documents may be found in the OPP public docket under this same docket number. The OPP public docket is located in Room S-4400, One Potomac Yard (South Building), 2777 South Crystal Drive, Arlington, VA, 22202 and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

The human health risk assessment for chlorine dioxide and sodium chlorite incorporates potential exposure and risks from all sources, which include food, drinking water, residential (if applicable), and occupational scenarios. Aggregate assessments combine food, drinking water, and any residential or other non-occupational (if applicable) exposures to determine potential exposures to the U.S. population. The Agency's human health assessment is protective of all U.S. populations, including infants and young children. For more information on the chlorine dioxide and sodium chlorite human health risk assessment, see Revised Chlorine Dioxide Risk Assessment, dated July 27, 2006, available at www.regulations.gov (EPA-HQ-OPP-2006-0328).

The Agency's use of human studies in the sodium chlorite risk assessment is in accordance with the Agency's Final Rule promulgated on January 26, 2006, related to Protections for Subjects in Human Research, which is codified in 40 CFR Part 26.

1. Toxicity of Chlorine Dioxide and Sodium Chlorite

A brief overview of the toxicity studies used for determining endpoints in the dietary risk assessments are outlined in Table 2. The Agency has reviewed all toxicity studies submitted for chlorine dioxide and has determined that the toxicological database is complete, reliable, and sufficient for reregistration. For more details on the toxicity and carcinogenicity of the chlorine dioxide and sodium chlorite, see the Chlorine Dioxide Toxicology Disciplinary Chapter, Case 4023, dated April, 5, 2006, which is available under docket number EPA-HQ-OPP-2006-0328.

Major features of the toxicology profile are presented below. The acute toxicity of chlorine dioxide is moderate by the oral route (toxicity category II). The acute toxicity of chlorine dioxide using sodium chlorite as the test material is considered minimal by the dermal route (toxicity category III). By the inhalation route using sodium chlorite as the test material, chlorine dioxide was moderately toxic. For primary eye irritation, chlorine dioxide was a mild irritant (toxicity category III), but the technical test material was not used. For primary dermal irritation, sodium chlorite was a primary irritant (toxicity category II). For dermal sensitization, there are no acceptable studies for chlorine dioxide or sodium chlorite. The acute toxicity profile

for chlorine dioxide is summarized in Table 1 below.

Table 1. Acute Toxicity Profile for Chlorine Dioxide/ Sodium Chlorite

Guideline Number	Study Type[a] / Test substance (% a.i.)	MRID Number/ Citation	Results	Toxicity Category
870.1100 (§81-1)	Acute oral (79% chlorine dioxide)	43558601	LD_{50} = 292 mg/kg (males) LD_{50} = 340 mg/kg (females)	II
870.1200 (§81-2)	Acute dermal (80% sodium chlorite)	40168704	LD_{50} > 2000 mg/kg	III
870.1300 (§81-3)	Acute inhalation (80.6% sodium chlorite)	42484101	LC_{50} = 0.29 mg/L	II
870.2400 (§81-4)	Primary eye irritation (2% chlorine dioxide)	43441903	Mild irritant	III
870.2500 (§81-5)	Primary dermal irritation (80% sodium chlorite)	40168704	Primary irritant	II
870.2600 (§81-6)	Dermal sensitization	No acceptable sensitization study available.		

[a] The available acute studies are all graded as acceptable. An acceptable dermal sensitization study is not available in the database.

The doses and toxicological endpoints selected for the dietary exposure scenarios are summarized in Table 2 below.

Table 2: Summary of Toxicological Doses and Endpoint Selection for Chlorine Dioxide/ Sodium Chlorite

Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	UF/MOE for Risk Assessment	Study and Toxicological Effects
Acute Dietary	An acute dietary endpoint was not identified in the database for chlorine dioxide. This risk assessment is not required.		
Chronic Dietary	NOAEL = 3 mg/kg/day	UF = 100 (10x inter-species extrapolation, 10x intra-species variation) **Chronic PAD** = 0.03 mg/kg/day	Two-generation reproduction toxicity study (CMA, 1996) - decreases in absolute brain and liver weight, and lowered auditory startle amplitude at LOAEL of 6 mg/kg/day Developmental Toxicity - Rat (Orme et al., 1985)- neurobehavioral and exploratory deficits in rat pups
Carcinogenicity	No cancer data is available for chlorine dioxide.		

General Toxicity Observations

Subchronic

Subchronic oral toxicity studies conducted with chlorine dioxide showed significant reductions in body weight increases and decreases in food consumption at 200 mg/L, the highest dose tested. Significant reductions in water consumption were observed in males and in females. Absolute liver weights were decreased in males at ‡ 50 mg/L, and absolute spleen weights were decreased in females at ‡ 25 mg/L. The LOAEL is 25 mg/L, based on a significant increase in the incidence of nasal lesions. No exposure-related deaths were reported in this study.

Subchronic oral toxicity studies conducted with sodium chlorite showed increased salivation, significantly decreased erythrocyte counts, and decreased total serum protein levels, and effects in the blood. During this study four animals died during treatment. It should be noted that one exposure-related death was observed in a range-finding study for the subchronic oral toxicity study each sex in the 200 mg/kg/day group on treatment days 2 and 3.

Dietary

An acute dietary endpoint was not identified in the database for chlorine dioxide; this risk assessment is not required for chlorine dioxide/sodium chlorite. The chronic dietary endpoint is 3 mg/kg/day, based on decreases in absolute brain and liver weight, and lowered auditory startle amplitude at LOAEL of 6 mg/kg/day in a two-generation reproduction toxicity study and is supported by a developmental toxicity study in rats. The target MOE is 100 for all dietary exposures.

Incidental Oral

The short-and intermediate-term oral endpoint is 3 mg/kg/day, based on decreases in absolute brain and liver weight, and lowered auditory startle amplitude at LOAEL of 6 mg/kg/day in a two-generation reproduction toxicity study and is supported by a developmental toxicity study in rats. The target MOE is 100 for all incidental oral exposures.

Dermal

The short-, intermediate-, and chronic-term dermal endpoint is based on decreases in absolute brain and liver weight, and lowered auditory startle amplitude at LOAEL of 6 mg/kg/day in a two-generation reproduction toxicity study and is supported by a developmental toxicity study in rats. The target MOE is 100 for all dermal exposures.

Inhalation

The inhalation route of exposure to chlorine dioxide is assessed for three distinct subpopulations: (1) occupational exposures (8 hours/day, 5 days/week), (2) one-time exposures

for residential uses (e.g., HVAC systems, mopping floors, etc), and (3) long-term exposure for continuous release products in the home (24 hours/day, 7 days/week). Several animal studies were used to develop reference concentrations (RfCs). The effects seen at various concentrations include rhinorrhea, altered respiration, respiratory infection, bronchial inflammation, alveolar congestion and hemorrhage, vascular congestion, and peribronchiolar edema. Readers are referred to USEPA (2000a) for a detailed review of the effects seen at specific concentrations and exposure durations along with the derivation of the RfC. In summary, the occupational RfC is determined to be 0.003 ppm and represents an 8-hour time weighted average (TWA). The one-time residential exposure scenario is represented by the RfC of 0.05 ppm and the RfC for long-term, continuous exposure is 0.00007 ppm. The RfC methodology incorporates the uncertainty factors into the concentration. For inhalation, the RfC is compared directly to the air concentration of interest. Inhalation risks are of concern if the air concentrations people are exposed to exceed the RfC.

Carcinogenicity

Chlorine dioxide has not been assessed for carcinogenic potential. The available dermal carcinogenicity studies do not definitively characterize the carcinogenicity of chlorine dioxide, and additional studies are required, and will be included in a data call-in (DCI) to follow this RED. One subchronic rat study, examined the effects of administration of chlorine dioxide at dose levels of 0, 25, 50, 100, or 200 mg/L for 90 days in drinking water. In this subchronic rat study, a significant increase in the incidence of nasal lesions was found at all dose levels tested. The significance of these findings is uncertain, as they have not been observed in other long-term studies of chlorine dioxide.

Mutagenicity

The Agency reviewed data from submitted studies as well as open literature. Data on the mutagenicity of chlorine dioxide indicate that negative effects were reported in one study from a 400-fold drinking water concentrate of chlorine dioxide, whereas a 4000-fold concentrate was mutagenic only in the absence of metabolic activation. In another study, chlorine dioxide was positive for forward mutations under non-activated conditions. Chlorine dioxide was positive for structural chromosome aberrations under non-activated and activated conditions and was negative for increased transformed foci up to cytotoxic levels. In one mouse study on chlorine dioxide, *In vivo* micronucleus and bone marrow chromosomal aberration assays were negative, as was a sperm-head abnormality assay.

Developmental/Reproductive

One developmental toxicity study conducted using rats was conducted for chlorine dioxide and sodium chlorite. In this study, a NOAEL of 20 mg/L was established based on decreased exploratory and locomotor activities in the offspring of rats exposed to chlorine dioxide in drinking water. Another developmental toxicity study conducted in rabbits using sodium chlorite established a NOAEL for developmental and maternal toxicity at 200 ppm, based on a dose-related increase of does with reduced fecal output during the dosing period, consistent with decreased food consumption.

A two-generational reproductive toxicity study was performed using sodium chlorite. The NOAEL for this study is 35 ppm (2.9 mg/kg-day) and the LOAEL is 70 ppm (5.9 mg/kg-day chlorite) based on lowered auditory startle amplitude and absolute brain weights in two generations. There were no significant effects of chlorine dioxide on body weight of dams or pups at any dose level tested.

Endocrine Disruption Potential

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

2. FQPA Safety Factor Considerations

The FQPA Safety Factor (as required by FQPA) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. For chlorine dioxide and sodium chlorite, the FQPA Safety Factor has been removed (i.e., reduced to 1X). This safety factor has been removed because the endpoint selected for both dietary and non-dietary exposures was based upon adverse effects observed in offspring from developmental and reproductive toxicity data. This approach is consistent with that used by the EPA's Office of Water for use of chlorine dioxide as a drinking water disinfectant (Federal Register Vol. 63, No. 61, pages 15673-15692, March 31, 1998) and the updated guidance on selection of a safety factor under FQPA. The endpoint selected for assessment of risk from dietary and non-dietary exposure to chlorine dioxide and sodium chlorite is believed to be protective of potentially susceptible populations, including children, based upon the selection of an endpoint and effects observed in offspring and the use of a NOAEL value based on those effects. Therefore, it was concluded that an additional safety factor under FQPA is not necessary in this case. Further, the risk assessment does not underestimate the potential exposure for infants and children.

3. Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for

the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern.

a. Acute PAD

Acute dietary risk is assessed by comparing acute dietary exposure estimates (in mg/kg/day) to the acute Population Adjusted Dose (aPAD). Acute dietary risk is expressed as a percent of the aPAD. The aPAD is the acute reference dose, modified by the FQPA safety factor. Although several studies were considered, an acute reference dose (aRfD) was not identified for chlorine dioxide. None of the available studies provided an endpoint of toxicity attributable to a single exposure. Therefore, no acute dietary endpoint for chlorine dioxide and sodium chlorite was selected.

b. Chronic PAD

Chronic dietary risk for chlorine dioxide is assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the chronic Population Adjusted Dose (cPAD). Chronic dietary risk is expressed as a percent of the cPAD. The cPAD is the chronic reference dose modified by the FQPA safety factor. The cPAD was derived from a two-generation reproduction toxicity study and a developmental toxicity study in which the NOAEL (3 mg/kg/day) and LOAEL (6 mg/kg/day) were determined. The chlorine dioxide and sodium chlorite cPAD is 0.03 mg/kg/day based on a reference does of 0.03 mg/kg/day, which incorporates the FQPA safety factor (1X) for the overall U.S. population and all population subgroups.

Metabolites and Degradates

Sodium chlorite is a strong oxidizing agent and under proper reducing conditions is readily reduced to chloride, and to a lesser extent, chlorate. In strong acidic conditions, chlorite can change into chlorine dioxide. The main source of chlorite ion exposure in the soil, water, or indirect food contacts is through the disinfectant applications. However, it is likely that some chlorate in these media is formed through use of antimicrobial applications (disinfectant) of chlorine dioxide, sodium chlorite, and sodium/calcium hypochlorites.

In aqueous media, these oxyanions (chlorite, chlorate, and hypochlorite) exist because of the unique chemistry of chlorine, that has a tendency to change its oxidation states (charges). Thus, in chlorate, chlorine has a +5 charge, in chlorite it bears a +3 charge, in hypochlorite a + 1 charge, while in chloride a net -1 charge exists. These variations in charges (hence the speciations) are dependent on factors such as: pH of the medium, temperature, redox potential of the medium, presence of oxidizing or reducing species, etc. Similarly, chlorate itself can undergo redox reactions, depending on the pH of the aqueous medium to form, chloride, chlorine, hypochlorite, chlorous acid, chlorine dioxide.

The Agency lacks data that would quantify the interconversions between chlorate, chlorine dioxide, sodium chlorite, and sodium/calcium hypochlorite. Simultaneous conversions of these species are not likely to occur as these factors (mentioned above) do not work in tandem.

Thus at this time, any additional dietary risks from interconversions in drinking water (non-cancer risks), and food (non-cancer risks) cannot be estimated. The Agency has included the highest possible dietary contribution of chlorite ion from use of sodium chlorate from the most sensitive subpopulation in the dietary risk estimates of sodium chlorite. Therefore, the Agency has conservatively determined that there are no additional risks other than the ones that have been estimated in chlorine dioxide/sodium chlorite Risk Assessment and sodium chlorate RED.

The inorganic chlorates were evaluated in the Inorganic Chlorates Reregistration Eligibility Decision (case number 4049) (hereinafter referred to as the "Inorganic Chlorates RED"). That assessment considered the contribution of chlorate ion from the use of chlorine dioxide and sodium chlorate. Please see *Revised Sodium Chlorite Risk Assessment,* dated July 27, 2006, for additional details.

4. Exposure Assumptions

The use of chlorine dioxide and sodium chlorite on food or feed contact surfaces, agricultural commodities, in animal premises and poultry premises including hatcheries and application to food-grade eggs may result in pesticide residues in human food. No residue chemistry data were required to support these uses in the past; therefore, no residue data was available for the assessment of these uses

To estimate chlorine dioxide residues on food due to migration of this chemical from sanitizing and/or disinfecting hard non-porous surfaces, the Agency has used the US Food and Drug Administration (FDA) model to determine the Estimated Daily Intake (EDI). Potential use sites include: (1) poultry hatcheries, (2) food handling establishments, (3) post-harvest potato treatments, (4) poultry house disinfection, poultry chiller water/carcass spray or dip, (5) food processing plants (meat and fish), (6) dairies, breweries, and bottling plants, and (7) pulp/paper, polymer slurries, paper adhesive, and paper coating. The EDI calculations presented in this assessment assumes that food can contact 2,000 cm^2 or 4,000 cm^2 (50% and 100% respectively of the FDA worst case scenario) of treated surfaces, and that 10% of the pesticide would migrate to food. The use of the 10% transfer rate, instead of the 100% transfer rate was used for all indirect food contact surfaces except for food bottling and packaging surfaces. The 10% migration rate is based on Agency Residential Standard Operation Procedures. These daily estimates were conservatively used to assess both acute (i.e. percent acute population adjusted dose or %aPAD) and chronic dietary risks (i.e. percent chronic population adjusted dose or %cPAD). The maximum application rate of 1000 ppm for chlorine dioxide from the various labeled products was used. Additional details about the dietary assessment can be found in "*Dietary Risk Assessment for Chlorine Dioxide and Sodium Chlorite Indoor Uses as Disinfectants/Sanitizers*," dated July 22, 2006.

The Agency has conservatively added the highest chronic dietary exposure to chlorite ion from consumption of food treated with inorganic chlorates to the total chronic dietary exposure from chlorine dioxide/sodium chlorite. This assumes that all residues on food resulting from the use of inorganic chlorates are sodium chlorite. The Agency has decided to include these exposures as part of the chlorine dioxide/sodium chlorite dietary assessment in order to ensure

that the most conservative dietary assumptions are used. The inclusion of these exposures is considered to be highly conservative because it is unlikely that significant chlorite residues will result from the use of inorganic chlorates on food crops. As mentioned previously, the inorganic chlorates have been reassessed separately from chlorine dioxide.

There is no evidence that there will be residues of chlorine dioxide or sodium chlorite in mushrooms following its use as a mushroom house disinfectant. Further, if dietary exposures from mushroom house uses occurred they would be expected to be much lower than the dietary exposures resulting from the surface disinfectant and sanitizing uses. The labels associated with mushroom house use state that the product is not to be applied to the mushroom crop, compost or casing and that treated surfaces are to be rinsed with potable water before contact with the crop, compost or casing. Because any potential exposures would not likely pose risks of concern and the sanitizing uses represent a worst-case scenario, these uses were not assessed.

5. Dietary (Food) Risk Assessment

The Agency conducted a dietary exposure/risk assessment for chlorine dioxide and sodium chlorite. Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concerns. A summary of acute and chronic risk estimates are shown in Table 3.

a. Acute Dietary Risk

No acute dietary endpoint was selected because effects attributable to a single dose were not seen in the available data; therefore, an acute dietary risk assessment was not conducted.

b. Chronic Dietary Risk

A chronic dietary risk assessment was conducted for chlorine dioxide/sodium chlorite direct and indirect application to food. For indirect food applications, the highest individual subpopulation percent cPAD calculated is 4.2% for children's consumption of milk. For direct food uses, the chronic risk from the post-harvest use of fruit and vegetable washes is 42% of the cPAD for children. For the chlorite exposure resulting from the use of inorganic chlorate application to agricultural crops, exposure to children (most highly exposed subpopulation) resulted in risk estimate of 28 % of the cPAD. As a conservative measure, the dietary risk estimates of sodium chlorite include the highest dietary risk estimate for sodium chlorate for the most sensitive subpopulation.

Although there is not a concern for chronic dietary risk estimates alone, it is important to note that the individual exposure received from the post-harvest application of sodium chlorite to fruits and vegetables is an extremely high-end estimate. This assessment was conducted with the most conservative assumptions and resulted in an estimate of 42% of the cPAD for children ages 1-2. For example, this assessment assumed that all fruits and vegetables in the U.S. had a chlorine dioxide solution applied and that these commodities were not washed, cooked or processed prior to consumption. However, the Chlorine Dioxide Panel has agreed to limit the

residual concentration of chlorine dioxide to 3 ppm for post-harvest application to fruits and vegetables that are not Raw Agricultural Commodities. In order to get to this residual, the panel has agreed to label restrictions that require that fruits and vegetables treated with chlorine dioxide must be blanched, cooked, or canned before consumption or distribution in commerce. Although the Agency cannot quantify the reduction of chlorine dioxide dietary exposure resulting from this mitigation measure at this time, it is believed that this measure would significantly reduce the percent of chlorine dioxide cPAD resulting from this use.

The dietary risks for adult and children from food uses are shown in Table 3. As there is no acute dietary endpoint for chlorine dioxide, only chronic dietary risk is presented. For adults, the total chronic dietary risk is 9.1% of the cPAD and is not of concern. For children (1–2 years), and infants less than 1 year old, the total dietary exposure is 76%, and 32% of the cPAD, respectively. These risks are below the Agency's level of concern, less than 100% of the cPAD. As stated above, this risk scenario is very conservative. For example, the Agency does not believe that 100% treatment of fruits and vegetables is a realistic scenario. If 50% of this food is treated, which we think is still unrealistic, the cPad for children (1-2 years) would be approximately 54%. The Agency will issue a DCI requiring data be submitted on how much food is washed with these pesticides.

Table 3. Summary of Dietary Exposure and Risk for Chlorine Dioxide					
Use Site	Food Type	Population Subgroup	EDI (mg/person/day)	Chronic Dietary	
				Dietary Exposure[a] (mg/kg/day)	% cPAD [b]
Indirect Food Use					
Food handling establishments/ kitchens	NA	Adult	2.00×10^{-1}	9.5E-07	0.00316
		Child		8.8E-06	0.0293
Dairies, Breweries, Bottling Plants, Food Contact Surfaces/Food Processing Plants for Meats and Fish[d]	Beverages, alcoholic, beer	Adult	1.2×10^{-3}	1.70E-05	0.56
	Beverages, non-alcoholic	Adult	1.6×10^{-3}	2.40E-05	0.08
		Child		1.00E-04	0.33
	Egg Products, Mayonnaise	Adult	1.4×10^{-4}	2.00E-06	0.0086
		Child		9.33E-06	0.031
	Milk	Adult	1.9×10^{-2}	2.70E-04	0.66
		Child		1.30E-03	4.2
Pulp/Paper, Polymer Slurries, Paper Adhesive, Paper Coating	NA	Adult	1.1×10^{-1}	9.8E-05	0.326
		Child		2.3E-04	0.766
Total Indirect Food-Contact Exposure		**Adult**	**3.3×10^{-1}**	**4.12E-04**	**1.64**
		Child 1-2 years	**2.7×10^{-1}**	**1.65E-03**	**5.35**
		Infant <1			**<5.35[f]**
Direct Food Use					
Post Harvest Application	Fruit and Vegetable Wash	Adult		2.24E-03[c, e]	7.5
		Child		1.27E-02 [c, e]	42.3
Total Direct Food-Contact Exposure		**Adult**		**2.24E-03**	**7.5**
		Child 1-2 years		**1.27E-02**	**42.3[g]**
		Infant <1		**3.49E-03**	**11.6[f]**
Inorganic Chlorate Use					
Highest Exposure from Agricultural Use		**Child 1 – 2 years**		**8.38E-03[c]**	**28**
		Infant <1 year		4.511E-03	**15[f]**
Total Dietary Exposure					
Total Direct and Indirect Food-Contact Exposure		**Adult**		**2.65E-03**	**9.1**
		Child 1-2 years		**2.27E-02**	**75.7**
		Infant <1 year			**<31.95[f]**

a-- For adults, acute and chronic exposure analysis is based on a body weight of 70 kg. For adult females, the body weight is 60 kg. For children, exposure is based on a body weight of 15 kg.
*b--%PAD = dietary exposure (mg/kg/day) * 100 / cPAD, where cPAD for adults and children = 0.03 mg/kg/day;*
c--children 1-2 years of age, adults 20-49 years of age
d--food processing plants for meats/fish have exposures which are similar to other food contact surfaces, exposure numbers not included for this scenario.
e-- includes all fruits and vegetables and apple and orange juices; assumes 100% of fruit is washed with chlorine dioxide.
f--Infants (<1 year) are included in this table for comparison purposes and were not added to the total dietary exposure as it was not the most highly exposed subpopulation.
g--Assuming 50% of fruits/vegetables are treated, the dietary risk for children (1 – 6) would represent 21% of the cPAD.

6. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through surface and groundwater contamination. Chronic dietary (water only) risk assessments were conducted using DEEM-FCID™ Version 2.03 and drinking water consumption data from the USDA's CSFII from 1994-1996 and 1998. Exposures were single point estimates; no residue decline was utilized.

Chlorine dioxide is commonly used as an antimicrobial material preservative and for disinfecting non-porous surfaces indoors. These use patterns are not expected to result in surface or groundwater contamination. However, chlorine dioxide is commonly used for drinking water treatment. Therefore, the drinking water discussion will focus on the dietary risks that result from drinking water treatment.

In the U.S., there are two primary methods of drinking water treatment that do not involve filtration. The first method is the generation of chlorine dioxide. In the second method, either gaseous chlorine or hypochlorite is used to produce free chlorine. Except when gaseous chlorine is used, these methods produce chlorate as a disinfection byproduct (DBP). The American Water Works Association (AWWA) Disinfection Systems Committee tracks disinfection practices in US community water systems. AWWA's most recent comprehensive survey (completed in 1998) estimated that, of all community water systems (CWS), approximately 20% of CWSs serving populations greater than 10,000 use sodium hypochlorite (2% generated it on-site), 8% use chlorine dioxide, and <1% use calcium hypochlorite. For CWSs using groundwater and serving populations less than 10,000, the survey estimated that approximately 34% use sodium hypochlorite, none use chlorine dioxide, and at least 4.5% use calcium hypochlorite. For CWSs using surface water and serving less than 10,000, the survey estimated that 17% use sodium hypochlorite, 6% use chlorine dioxide, and 9% use calcium hypochlorite.

For chlorine dioxide generation, both sodium chlorate and sodium chlorite are used as precursor materials in the water disinfection process. Sodium chlorite is more commonly used than sodium chlorate. The free chlorine disinfection process involves the use of either gaseous chlorine, or sodium or calcium hypochlorite, as precursor materials. Historically, gaseous chlorine has been far more widely used than hypochlorite to produce free chlorine. In recent years, primarily as a result of various homeland security measures, many drinking water systems are switching from gaseous chlorine to hypochlorite. These processes (except for the use of gaseous chlorine) result in chlorate byproduct in finished drinking water, exposure to which was considered in the Inorganic Chlorates RED.

The chlorite ion (ClO_2^-) is a major degradation product resulting from the reaction of chlorine dioxide with inorganic and organic constituents in the water. When free chlorine is used after the application of chlorine dioxide in the treatment process, chlorite is oxidized to chlorate. This conversion will continue over time as the water travels through the distribution system. Chlorate ion is also formed by photodecomposition of chlorine dioxide when treated water is exposed to bright sunlight in open basins. The rate at which chlorate forms affects the amount of chlorine dioxide or chlorite that remain in the finished drinking water. Formation of chlorate from chlorite and chlorine dioxide was considered in the Inorganic Chlorates RED.

a. Drinking Water Exposure

Data on the occurrence of sodium chlorite in drinking water were available from the Information Collection Rule (ICR) Auxiliary 1 Database, Version 5.0. The water systems represented in the ICR database serve 60% of the total U.S. population. The EPA Office of Water (OW) issued the ICR in order to collect data to support future regulation of microbial contaminants, disinfectants, and disinfection byproducts. Monitoring for sodium chlorite was included in the ICR. Source water and drinking water were monitored for sodium chlorite ion between July 1997 and December 1998. Water systems serving a population of at least 100,000 were required to monitor for chlorite ion at treatment plants using chlorine dioxide or hypochlorite solutions in the treatment process. Plants using chlorine dioxide collected monthly samples of the source water entering the plant, the finished water leaving the plant, and at three sample points in the distribution system (near the first customer, an average residence time, and a maximum residence time). Plants using hypochlorite solutions were required to collect quarterly samples of the water entering and leaving the plant. If chlorine dioxide or hypochlorite solutions were used intermittently at a plant, chlorite ion samples were only required in sample periods in which they were in use.

Monitoring data were collected from 29 water treatment plants using chlorine dioxide treatment. The minimum reporting level (MRL) was established at 20 µg/L, all samples below this value were considered zero. Data from 418 samples (point of entry to the distribution) showed chlorite ion concentration ranged from 20 µg/L to 2,029 µg/L. Data from 1,115 samples (collected from within the distribution system) showed the concentration of chlorite ion between 20 µg/L to 1,850 µg/L. The average concentration of chlorite ion from 27 out of 29 treatment plants when averaged from the three distribution system sample points ranged from 20µg/L to 801 µg/L.

Based on the results of this monitoring data, the Agency established a maximum contaminant level goal (MCLG) and a maximum contaminant level (MCL) for chlorite ions. The MCLG and MCL are 0.8mg/L and 1.0 mg/L, respectively. In the original ICR monitoring data a number of samples and distribution systems showed large exceedences based on the MCL and MCLG. Currently, water systems have indicated that treatment is generally designed to meet a level of at least 20% below the MCL in order to ensure compliance. Based on this assumption, the Agency has readjusted all reported concentrations over 1000µg/L to 800 µg/L and recalculated the data. Table 4 below shows the adjusted values for chlorite concentrations.

Based on the values obtained from the monitoring data, the Agency conducted a drinking water assessment using chlorite concentrations at the maximum, 90th percentile, and median annual averages of chlorite concentrations of 0.7, 0.63, and 0.39 mg/L, respectively. The 90th percentile exposure values will be used in the aggregate risk assessments, with children represented by the 1-6 year old age category.

Table 4. Chlorine Dioxide Water Monitoring Data (μg/L) – ICR Data[a]

	Distribution System Entry Point	Near First Customer	Average Residence Time	Maximum Residence Time	Distribution System Average[2]
10th Percentile	60	52	58	30	45
20th Percentile	99	79	87	81	84
50th Percentile	440	380	360	310	390
80th Percentile	590	580	600	510	550
90th Percentile	660	660	640	650	630
Maximum	800	740	680	680	700
Number of Water Treatment Plants	29	27	27	27	27
Number of Public Water Systems	22	21	21	21	21

[a]ICR Data Adjusted for MCL Compliance

b. Acute Dietary Risk (Drinking Water)

No acute dietary endpoint was selected because effects attributable to a single dose were not seen in the available data; therefore, an acute dietary risk assessment was not conducted.

c. Chronic Dietary Risk (Drinking Water)

The chronic dietary (water only) risk assessment for sodium chlorite in drinking water estimated at 49 % of the cPAD for the general U.S. population and is below 100% of the cPAD, and therefore, is below the Agency's level of concern. All risks for the U.S. population subgroups are below 100 % of the cPAD except infants (<1 year of age). The highest exposed subgroup, infants, was 161% of the cPAD, based on the highest annual average concentration of sodium chlorite, and therefore, above the Agency's level of concern. The 90th percentile exposure values will be used in the aggregate risk assessments, with children represented by the 1-6 year old age category. See Table 5 below for details.

Table 5. Chlorite Exposure by Population Group						
Population subgroup	Maximum Concentration		90th Percentile Concentration		Median Concentration	
	Total exposure (mg/kg/day)	% cPAD	Total exposure (mg/kg/day)	% cPAD	Total exposure (mg/kg/day)	% cPAD
U.S. Population	0.014754	49	0.013279	44	0.008220	27
Infants < 1 year	0.048372	161	0.043535	145	0.026950	90
Children 1-6 years	0.020613	69	0.018552	62	0.011485	38
Children 7 -12 years	0.013402	45	0.012062	40	0.007467	25
Females 13-50	0.014274	48	0.012846	43	0.007952	27

7. Residential Exposure

Residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food or in drinking water. Residential exposure may occur during cleaning or mopping of hard surfaces, application of chlorine dioxide to swimming pools and spas and through application to HVAC systems. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate NOAEL. Based on its use pattern, the residential handler assessment evaluated application of chlorine dioxide-containing products by homeowners to control mold and mildew. The post-application assessment evaluated risks from dermal, inhalation and incidental oral exposure for children due to hand-to-mouth exchange.

a. Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary risks for chlorine dioxide and sodium chlorite are listed in Table 6.

A MOE greater than or equal to 100 is considered adequately protective for the residential exposure assessment for the dermal, incidental oral and inhalation routes of exposure. The MOE of 100 includes 10x for inter-species extrapolation, 10x for intra-species variation.

Table 6. Summary of Toxicological Doses and Endpoint Selection for the Chlorine Dioxide/ Sodium Chlorite Residential Assessment			
Exposure Scenario	Dose Used in Risk Assessment (mg/kg/day)	UF/MOE for Risk Assessment	Study and Toxicological Effects
Incidental Oral (short and intermediate term)	NOAEL = 3 mg/kg/day	MOE = 100	Two-generation reproduction toxicity study (CMA, 1996) - decreases in absolute brain and liver weight, and lowered auditory startle amplitude at LOAEL of 6 mg/kg/day Developmental Toxicity - Rat (Orme et al., 1985)- neurobehavioral and exploratory deficits in rat pups at LOAEL of 14 mg/kg/day
Dermal All Durations (1-30 days)	NOAEL = 3 mg/kg/day	MOE = 100	Two-generation reproduction toxicity study (CMA, 1996) - decreases in absolute brain and liver weight, and lowered auditory startle amplitude at LOAEL of 6 mg/kg/day Developmental Toxicity - Rat (Orme et al., 1985)- neurobehavioral and exploratory deficits in rat pups at LOAEL of 14 mg/kg/day
Inhalation (occupational and homeowner short-term)	Homeowner short-term: LOAEL = 28 mg/m^3 (10 ppm) Occupational exposure: LOAEL = 2.8 mg/m^3 (1.0 ppm) NOAEL = 0.28 mg/m^3 (0.1 ppm).	Homeowner short-term 'RfC' = **0.14 mg/m^3** (0.05 ppm) Occupational 'RfC' = **0.009 mg/m^3** (0.003 ppm)	Inhalation toxicity studies- Rat Dalhamn, 1957; Paulet and Debrousses, 1970, 1972.
Inhalation (homeowner long-term)	Agency RfC methodology used to derive an RfC value of 2 x 10^{-4} mg/m^3 (USEPA, 2000a)		(Paulet and Desbrousses, 1970, 1972) selected as co-critical studies (USEPA, 2000a)

b. Residential Handler

i. Exposure Scenarios, Data and Assumptions

Residential exposure to chlorine dioxide can occur through mopping, spraying, and applying products to pools and spas. A number of assumptions, or estimates, such as adult body weight and area treated per application, are made by the Agency for residential risk assessment. Also, note that residential handlers are addressed somewhat differently than occupational handlers in that homeowners are assumed to complete all elements of an application (mix/load/apply) without the use of personal protective equipment. In addition, for residential handlers it is assumed that all exposures are short-term.

The residential handler risk assessment based on these scenarios:
(1) Mopping: 1 gal/use
(2) Trigger-pump sprayers: 0.5 liters or 0.13 gal/day
(3) Swimming pools: 160 g ai/20,000 gallons of water

Chlorine dioxide and sodium chlorite products are widely used and have a large number of use patterns that are difficult to completely capture in the risk assessment. As such, the Agency has selected representative scenarios for each use site that are believed to be high-end estimates for the vast majority of chlorine dioxide uses, based on end-use product application methods and use amounts.

For the residential handler risk assessment, dermal unit exposure values were taken from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study, 1999, (MRID 42587501) or from the Pesticide Handler Exposure Database (PHED, 1998). The scenarios evaluated for dermal and inhalation risks in the residential handler assessment are as listed below:

- Mopping floors;
- Applying trigger-pump sprays to hard surfaces; and
- Placing solid tablets in swimming pools or spas
- Off-gassing during application of the aqueous solution.

The potential exposures from mopping and cleaning are expected to be best represented by the short-term duration. Dermal and inhalation exposures were assessed for all residential handler scenarios. For the mopping application and application of tablets to swimming pools and spas, values from the Chemical Manufacturers Association (CMA) antimicrobial study (U.S. EPA, 1999) were used. For the application of chlorine dioxide products with a trigger-pump spray, the Pesticide Handler Exposure Database (PHED, 1998) was used to determine exposure. To determine the potential inhalation handler exposure resulting from the vapor of chlorine dioxide as a general purpose cleaner, the model EFAST (Exposure and Fate Assessment Screening Tool) was used to estimate the chlorine dioxide air concentrations. For additional information, please refer to "Chlorine Dioxide Occupational and Residential Exposure Assessment," dated August 2, 2006.

ii. **Residential Handler Risk Estimates**

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments. A summary of the residential handler exposures and risk are presented on Table 7. The exposure duration of most homeowner applications of cleaning products and pools are believed to be best represented by the short-term duration. The toxicological endpoint is based on an oral study and no dermal absorption value is available. Therefore 100% dermal absorption was assumed for chlorine dioxide or chlorite ion residues. While there is some evidence that chlorine dioxide is readily absorbed in skin, this assessment is very conservative. The dermal MOEs for the floor mopping, and application to hard surfaces, are above the target MOE of 100, and therefore, are not of concern. The short-term dermal MOE for pool or spa treatments is 46 without the use of gloves and is of concern to the Agency; therefore, the labels must be amended to require gloves. Based on the average daily air concentration, the handler inhalation exposures of chlorine dioxide are not of concern (i.e., the average air concentration estimated by EFAST of 0.003 ppm is below the RfC of 0.05 ppm).

Table 7. Calculation of Short-term Dermal MOEs for Residential Handlers

Exposure Scenario		Application Rate[a] (lb ai/gal)	Amount Handled/ Treated Daily[b] (gal)	Baseline Dermal Unit Exposure[c] (mg/lb ai)	Baseline Dermal Dose[d,e] (mg/kg/day)	Baseline Dermal MOE[f] (Target MOE = 100)
Mopping (CMA data)	Hard Surfaces	0.002	1	71.6	0.0024	1300
Trigger-pump sprayer (Aerosol can PHED data used as surrogate)	Hard Surfaces	0.002	0.13	220	0.00095	3200
Solid Place (Tablets)	Pools & Spa water Circulation Systems	1.8E-5 (4 tablets /10,000 gal. Pool tablet is 100 g x 4 tablets x 20%ai = 80 g ai/10,000 gal = 1.8E-5 lb ai/gal)	20,000 gal	10.8 (no gloves)	0.065 (no gloves)	46 (no gloves)
				0.412 (with gloves)	0.006 (with gloves)	500 (with gloves)

c. Residential Post-Application

i. Exposure Scenarios, Data and Assumptions

Residential post-application exposures result when bystanders (adults and children) come in contact with chlorine dioxide in areas where pesticide end-use products have recently been applied (e.g., treated hard surfaces/floors), or when children incidentally ingest the pesticide residues through hand-to-mouth contact of the treated surface. The residential post-application scenarios considered in this assessment are exposure to residues from hard surfaces (i.e., floors) that have been mopped or cleaned with a product containing chlorine dioxide, the use of continuous release air deodorizers, and a single treatment of HVAC systems with chlorine dioxide.

Chlorine dioxide and/or sodium chlorite can be applied as an aqueous solution to hard surfaces such as floors and potentially result in inhalation exposure. The Agency assessed these risks based on dilution and ventilation along with the half-life of chlorine dioxide. This assessment estimated an 8-hour time weighted average air concentration starting immediately after application.

Typically, most products used in a residential setting result in exposures occurring over short-term time duration (1 – 30 days). For the purposes of this screening-level assessment, post application scenarios have been developed that encompass multiple products, but still represent a high-end scenario for all products represented.

Four scenarios have been evaluated in the residential post-application assessment.

1. Exposure to residue from hard floors that have been cleaned with a solution containing chlorine dioxide;
2. Exposure to chlorine dioxide used to clean residential HVAC systems;
3. Exposure to a continuous release (gas) deodorizer; and
4. Swimming in treated pools or spas.

ii. Residential Post-Application Risk Estimates

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal, incidental oral and inhalation exposure assessments. As noted previously, MOEs greater than or equal to 100 are considered adequately protective for the residential exposure assessment.

A summary of the residential handler exposures and risk are presented on Table 8. The risks from dermal and incidental oral exposures for all scenarios are below the Agency's level of concern.

For children, the short- and intermediate-term oral and dermal MOEs for contact of hard surfaces following disinfection are above the target MOE of 100 for applications in residential and daycare settings. Therefore, the risks from these uses are not of concern.

Inhalation exposures due to post application activities could occur for children after the treatment of floors; adults and children after the treatment of HVAC systems; and adults and children after the use of continuous release (gas) deodorizers. Chlorine dioxide/sodium chlorite can be applied as an aqueous solution to hard surfaces such as floors and potentially result in inhalation exposure. For this assessment, the Agency estimated the air concentration to be 0.003 ppm, which is below the short-term RfC of 0.05 ppm, and therefore not of concern. For application to HVAC systems, this use is not of concern. For the continuous release deodorizer, the estimated constant air concentration was 0.52 ppm, assuming no air exchange and no build up of chlorine dioxide over time because of the short half-life. This risk is of concern to the Agency. The RfC for long-term continuous exposure is 0.00007 ppm; therefore this risk is of concern to the Agency. The registrant has agreed to delete residential uses of these products.

The application of chlorine dioxide to swimming pools or spas, is not assessed quantitatively. Based on use directions on current labels, dermal, incidental oral, and inhalation exposures to chlorine dioxide residual levels after the dilution in the water, and cleaning of the circulation systems are expected to be minimal. Table 8 shows a representative sample of the short- and intermediate-term residential post-application risks.

There is also the potential for inhalation exposure as a result of the use of chlorine dioxide as a dust on carpets. The registrant has agreed to mitigate any potential risk from this use by limiting it to professional carpet applicators, packaging only in containers that are large enough to discourage retail sale and requiring an REI of one hour prior to entry into a treated room.

Table 8. Summary of Short- and Intermediate-Term Residential Post-application Exposures and Risks

Scenario		Dose [a] (mg/kg/day)	MOE[b]
Dermal Exposure			
Hard surface Disinfection	Residential Setting and Daycare Center	0.017 [a]	280
Incidental Oral Exposure			
Hard surface Disinfection	Residential Setting and Daycare Center	0.0013[a]	2,300

Inhalation Exposure			
Scenario		Estimated Air Concentration	RfC (level of concern)
Application to HVAC Systems	Residential Setting and Daycare Center	<0.01 ppm	0.05 ppm [c]
Continuous Release Deodorizer	Residential Setting and Daycare Center	<0.52 ppm	0.00007 ppm [d]

[a] Dose calculations for each scenario above are outlined in the attached Occupational/Residential Assessment.
[b] MOE= NOAEL (mg/kg/day) / Dose (mg/kg/day). Oral and dermal NOAEL is 3 mg/kg/day.
[c] RfC - short-term target is 0.05 ppm.
[d] RfC - long-term target is 0.00007 ppm.

8. Aggregate Risk

The FQPA amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there is reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure.

In accordance with FQPA, the Agency must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and if applicable, residential or other non-occupational exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard (e.g., a NOAEL), or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, the Agency considers both the route and duration of exposure. Aggregate exposure and risk assessments for sodium chlorite include the following: food + water + residential handler. For the aggregate of the inhalation route of exposure, only use of the continuous release air deodorizer product is assumed to co-occur with the other uses. In addition, the HVAC applications will not occur frequently (single exposure); therefore it was not included in the aggregate assessment. The inhalation risk for the continuous release is of concern by itself. Because we have agreement that the residential application of the continuous release deodorizer will be canceled, it has been removed from consideration in the aggregate assessment. However, the continuous release air deodorizer will be allowed in spaces where extended exposure is not likely, e.g., dumpsters. This mitigation will result in aggregate risks that are no longer a concern. Results of the aggregate risk assessment are summarized here, and are discussed more extensively in the document: *Revised Chlorine Dioxide Risk Assessment,* dated July 27, 2006, which is available in the public docket.

a. Acute Aggregate Risk

For chlorine dioxide, the acute and chronic aggregate risk assessments include only dietary, drinking water, and residential exposures. An acute dietary risk assessment was not conducted for chlorine dioxide because there were no acute dietary endpoints of concern.

b. Short- and Intermediate -Term Aggregate Risk

The short- and intermediate-term aggregate assessments were conducted for adults and children. Table 9 shows the exposure scenarios that were included in the aggregate assessment for chlorine dioxide. Use patterns involving exposure by inhalation (continuous use deodorizer) were not aggregated because these use patterns were above the Agency's level of concern on their own and the Agency has agreement that the use will be voluntarily cancelled, therefore these aggregate risks are no longer a concern.

Table 9. Exposure Scenarios Included in the Aggregate Assessments

	Short-term Aggregate	Intermediate-Term Aggregate
Adults	▪ chronic dietary (direct and indirect) ▪ handling cleaning products – spray (dermal only) ▪ handling cleaning products – mopping (dermal only) ▪ chronic drinking water	Not Assessed
Children	▪ chronic dietary – (direct and indirect) ▪ post-app to cleaning product (dermal and oral) ▪ chronic drinking water	▪ chronic dietary – (direct and indirect) ▪ post application to cleaning product (dermal and oral) ▪ chronic drinking water

a Dietary (indirect + direct food contact) exposures = sum of dietary exposures presented in Table 3.
b Aggregate Dietary Exposures = sum of both dietary (direct and indirect food contact) exposures and drinking water exposures.

The toxicity endpoints for the oral and dermal routes of exposure are based on the same study and same toxic effect; therefore, these two routes of exposure are aggregated together. Table 10 presents a summary of these exposures, including the aggregate dietary exposure (all direct and indirect food contact exposures) as well as a total dietary aggregate exposure value (drinking water plus direct/indirect dietary exposures). Table 10 presents a summary of the short- and intermediate-term aggregate exposures and the corresponding aggregate risks.

The short-term and immediate-term aggregate risks are not of concern for adults (total MOE=130). The short-term and immediate-term aggregate risks are of concern for children (MOE=44) and infants (MOE=41). The primary driver for these risks is dietary exposures.

Table 10. Short- and Intermediate-term Aggregate Risks (MOEs)					
Exposure Routes	Aggregate Dietary Risks	Dermal Risks (MOE)			Aggregate Risks (MOE)
		Hard Surface Cleaning			
		Applicator		Post-Application	
		Mop	Spray		
Adults					
Oral Ingestion MOEs	150	NA	NA	NA	150
Dermal MOEs	NA	1300	3200	NA	900
Total MOE	150	1300	3200	NA	130
Children (age 1 – 6)					
Oral Ingestion MOEs	60	NA	NA	2300	58
Dermal MOEs	NA	NA	NA	180	180
Total MOE	60	NA	NA	160	44
Infants < 1					
Oral Ingestion	55	NA	NA	2300	55
Dermal MOEs	NA	NA	NA	180	180
Total MOE	55	NA	NA	160	41

MOE = NOAEL/dose
Aggregate MOE = $1/((1/MOE_{dietary}) + (1/_{MOEdrinking\ water}) + (1/MOE_{dermal})$
All NOAELs = 3 mg/kg/day
Target MOE oral = 100
Target MOE dermal = 100

c. Chronic Aggregate Risk

The chronic aggregate risk estimates associated with chlorine dioxide from dietary uses are below the Agency's level of concern for adults at 53% of the cPAD. However the dietary risks are above the level of concern for children aged 1 to 6 (133% of the cPAD).

The chronic aggregate risks are not of concern for adults, as the total aggregate of the cPAD is 53% (excluding the continuous use deodorizer), below the target of 100%. For children, the aggregate risk estimates are above 100% (133% cPAD) and thus are of concern. Table 11 presents the chronic aggregate exposures and risks.

Table 11. Chlorine Dioxide Chronic Aggregate Exposures and Risks				
Exposure Routes	Chronic Dietary Exposures (mg/kg/day)			
	Dietary (indirect + direct food contact+ chlorate) Exposures[a]	Drinking water exposures	Aggregate Dietary Exposures[b]	Aggregate Dietary Risks (%cPAD)
Adults				
Oral Ingestion	2.65E-03	1.33E-02	1.6E-02	53.3%
Children (age 1 – 6)				
Oral Ingestion	2.27E-02	1.86E-02	4.13e-02	133%

a Dietary (indirect + direct food contact) exposures = sum of dietary exposures presented in Table 6.
b Aggregate Dietary Exposures = sum of both dietary (direct and indirect food contact) exposures and drinking water exposures.

9. Occupational Exposure and Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of chlorine dioxide and sodium chlorite include workers in a variety of occupational settings. Additionally, post-application exposures are likely to occur in these settings. The representative scenarios selected for assessment were evaluated using maximum application rates as recommended on the product labels for chlorine dioxide and sodium chlorite.

Occupational risk is assessed for exposure at the time of application (termed "handler" exposure) and is assessed for exposure following application, or post-application exposure. Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the application rate required to achieve an efficacious dose.

Occupational risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from toxicological studies. In the case of chlorine dioxide and sodium chlorite, MOEs greater than 100 for dermal exposures and inhalation exposures are not of concern to the Agency. For workers entering a treated site, MOEs are calculated for each day after application to determine the minimum length of time required before workers can safely re-enter.

For more information on the assumptions and calculations of potential risk of chlorine dioxide to workers, see the Occupational Exposure Assessment section in the "Chlorine Dioxide Risk Assessment," dated July 27, 2006.

a. Occupational Toxicity

Table 6 provides a listing of the toxicological endpoints used in the occupational risk assessment for chlorine dioxide and sodium chlorite.

b. Occupational Handler Exposure

Potential occupational handler exposure can occur at various use sites, including agricultural, food handling, commercial and institutional, and medical premises; human drinking water systems; industrial processes and water systems; application to materials as preservatives; and swimming pools and other aquatic areas.

The Agency has assessed the handler risks from the use of chlorine dioxide using unit exposure data from both the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study and the Pesticide Handlers Exposure Database (PHED). Table 12 lists the handler exposure scenarios assessed for chlorine dioxide. These scenarios are considered representative of high-end exposures for the industrial applications.

Table 12. Exposure Scenarios Associated with Occupational Exposure Assessed in this Document

Representative Use	Application Method	EPA Registration Number (chemical associated with use)	Application Rate (lb ai/gal)	Exposure Scenario Assessed
Use Site Category I (Agricultural Premises and Equipment)[a]				
Application to Hard Surfaces and Equipment	low-pressure hand wand	74602-2 (Sodium Chlorite)	(Application rate from label, 2.5 fl oz/gal)*(1 gal/128 oz)*(0.75 lb ai/gal) = 0.015	Short- and Intermediate-term (ST and IT) Adult Handler (dermal and inhalation) and Adult Bystander and Post Application (dermal and inhalation)
	trigger-pump sprayer fogger (1 hour REI after fogging)	74602-2 (Sodium Chlorite)	(Application rate from label, 2.5 fl oz/gal)*(1 gal/128 oz)*(0.75 lb ai/gal) = 0.015	
	mop	9150-2 (Chlorine Dioxide)	(Application rate from label, 3.25 fl oz/gal)*(1 gal/128 oz)*(0.69 lb ai/gal) = 0.018	

Table 12. Exposure Scenarios Associated with Occupational Exposure Assessed in this Document				
Representative Use	Application Method	EPA Registration Number (chemical associated with use)	Application Rate (lb ai/gal)	Exposure Scenario Assessed
	foaming wand	9150-11 (Chlorine Dioxide)	(Application rate from label, 0.25 gal of product*0.10 lb ai/gal) = 0.025 lb ai/gal.) Apply at rate of 4 to 6 gallons/minute to inside/outside of animal trucks/equipment.	
	ULV fogger (e.g., Dramm fogger)	74602-2 (Sodium Chlorite)	(Egg house label rate, 1 gal product x 5% ClO2) per 50 gal = 0.0083)	
Use Site Categories II (Food Handling), III (Commercial/Institutional), and V (Medical)				
Application to Hard Surfaces and Equipment Without Food Contact	mop	9150-10 active (10589-3 transferred) (Chlorine Dioxide)	(Application rate from label, 5 oz/gal)*(1 gal/128 oz)*(0.49 lb ai/gal) = 0.019	ST/IT Adult Handler (dermal and inhalation) and Adult Post Application/Bystander (dermal and inhalation)
	trigger-pump sprayer	21164-3 (Sodium Chlorite)	(Application rate from label, 12 fl oz/gal)*(1 gal/128 oz)*(0.86 lb ai/gal) = 0.08	
Application to foods (Fruit/Vegetable Rinse)	dip	74602-2 (Sodium Chlorite)	(Application rate from label, 1.9 oz/gal)*(1 gal/128 oz)*(0.75 lb ai/gal) = 0.011	
Use Site Category VI (Human Drinking Water Systems)				
Application to Water Systems (Water Treatment and Water Storage Systems)	metering pump	9804-1 (Chlorine Dioxide)	(Application rate from label, 3.25 fl oz/gal)*(1 gal/128 oz)*(0.27 lb ai/gal) = 0.007	ST/IT Adult Handler; Potential for inhalation exposure unknown at this time.

Table 12. Exposure Scenarios Associated with Occupational Exposure Assessed in this Document				
Representative Use	Application Method	EPA Registration Number (chemical associated with use)	Application Rate (lb ai/gal)	Exposure Scenario Assessed
Use Site Category VII (Material Preservatives)				
Applications to Metal Working Fluids	liquid pour	9150-2 (Chlorine Dioxide)	batch method: 0.0001 (per week) continuous method: 8E-7 (per day) badly contaminated systems: 4E-6 (slug dose)	ST/IT Adult Handler (dermal and inhalation) and Long-term Dermal and Inhalation for Machinists.
Use Site Category VIII (Industrial Processes and Water Systems)				
Application to Pulp and Paper White Water Systems	metering pump	74602-3 (Sodium Chlorite)	(Application rate from label, 15 gal/100,000 gal white water to be treated or 4 gal/100 tons paper produced)*(0.86 lb ai/gal) = 0.0001 lb ai/gal white water or 3.44 lb ai/100 ton paper produced	ST/IT Adult Handler (dermal and inhalation) and Adult Bystander (inhalation)

Table 12. Exposure Scenarios Associated with Occupational Exposure Assessed in this Document				
Representative Use	Application Method	EPA Registration Number (chemical associated with use)	Application Rate (lb ai/gal)	Exposure Scenario Assessed
Application to Oil Systems (oil Wells During Secondary Recovery Operations)	liquid pour	9150-2 (Chlorine Dioxide)	(Application rate from label, 1 gal/10 gal)*(0.69 lb ai/gal) = 0.069. Label indicates to portion 1 part of this solution to 150 parts reinjection water.	ST/IT Adult Handler (dermal and inhalation) and Adult Bystander (inhalation)
Use Site Category XI (Swimming Pools)				
Application to Public Swimming Pool Circulation Water Systems (Swimming Pools)	solid place (tablets)	70060-20 (Sodium chlorite)	4 tablet /10,000 gal (Pool tablet is 100 g x 4 tablets x 20%ai = 80 g ai/10,000 gal = 1.8E-5 lb ai/gal)	Short-term Adult Handler (dermal and inhalation)
Use Site Category XII (Aquatic Areas)				
Non-potable Water Systems (e.g., retention basins and ponds, decorative pools and fountains)	liquid pour	9150-11 (Chlorine Dioxide)	0.00001 (18 fl oz x 0.72% ai per 100 gallons water)	ST/IT Adult Handler (dermal and inhalation)
Use Site Category XIII (HVAC)				

Table 12. Exposure Scenarios Associated with Occupational Exposure Assessed in this Document				
Representative Use	Application Method	EPA Registration Number (chemical associated with use)	Application Rate (lb ai/gal)	Exposure Scenario Assessed
Application to Ventilation Systems (HVAC)	airless sprayer fogger (1hour REI after fogging)	9804-1 (Chlorine Dioxide)	(Application rate from label, 3.25 fl oz/gal)*(1 gal/128 oz)*(0.27 lb ai/gal) = 0.007	ST/IT Adult Handler (dermal and inhalation) and Short-term Child and Adult Post Application (inhalation)

c. Occupational Handler Risk Summary

i. Dermal Risks

For the occupational handler dermal risk assessment, the short- and intermediate- term risks calculated at baseline exposure (no gloves and no respirators) were above target MOEs for all scenarios (i.e., dermal MOEs were >100), except for the following:

Agricultural premises and equipment:

- application to hard surfaces: low pressure handwand (MOE=31);
- application to hard surfaces: mopping (MOE=70); and
- application to hard surfaces: foam applicator equipment (MOE=8).

Food Handling, Commercial/Institutional, and Medical Premises and Equipment:
application to hard surfaces:

- mopping (MOE=66 commercial; 3 medical).

Swimming pools:

- placement of tablets (MOE=5)

A summary of the occupational handler assessment is provided in Table 13.

Table 13. Short-, Intermediate-Term Dermal Risks for Occupational Handlers					
Exposure Scenario	Method of Application	Application Rate (lb ai/ gallon)	Quantity Handled/ Treated per day (gallons)	Dermal MOE[c]	
				Baseline Dermal[a] (Target MOE>100)	PPE Gloves Dermal[b] (Target MOE>100)
1Agricultural Premises and Equipment					
Application to Hard Surfaces	Low pressure handwand	0.015	2	**31**	No data
	Liquid Pour		0.188	1,300	6,300
	Trigger-pump sprayer		0.26	240	570
	Mopping	0.018	2	**70**	No data
	Foam applicator equipment	0.025	60	**3**	**8**
Food Handling, Commercial/Institutional, and Medical Premises and Equipment					
Application to Hard Surfaces	Mopping (general)	0.019	2	**66**	No data
	Trigger-pump sprayer	0.08	0.26	**46**	110
	Mopping (medical)	0.019	45	**3**	No data
Human Drinking Water Systems					
Water and Storage Systems	Metering pump	0.007	34,000	No data	120
Material Preservatives					
Metal Working Fluid	Liquid pour	0.0001	300	No data	33,000
Industrial Processes and Water Systems					
Paper and Pulp White Water Systems	Metering pump	0.0344 lb ai/ton paper	500 tons paper	No data	2,300
Oil Systems	Open pour	0.069	2.8	NA	6,900

Table 13. Short-, Intermediate-Term Dermal Risks for Occupational Handlers					
Exposure Scenario	Method of Application	Application Rate (lb ai/ gallon)	Quantity Handled/ Treated per day (gallons)	Dermal MOE[c]	
				Baseline Dermal[a] (Target MOE>100)	PPE Gloves Dermal[b] (Target MOE>100)
			5.6		3,500
Swimming Pools and Aquatic Areas					
Retention Ponds/ Fountain	Liquid pour	0.00001	10,000 gal	No data	670
Swimming Pools (public)	Solid place	1.8E-5	200,000 gal	**5**	120
HVAC Systems					
HVAC	Airless sprayer	0.007	5	140	NA
	Fogger (liquid pour)		0.25	2,000	NA

a Baseline Dermal: Long-sleeve shirt, long pants, no gloves.
b PPE Dermal with gloves: baseline dermal plus chemical-resistant gloves.
c MOE = NOAEL (mg/kg/day) / Daily Dose [Where short-and intermediate-term NOAEL = 3 mg/kg/day for dermal exposure]. Target MOE is 100 for dermal exposure.

ii. Inhalation Risks

Inhalation exposures and risks were not assessed separately for the handlers. Instead, the occupational inhalation handler exposures are combined as part of the full work-day for handler/bystanders to be comparable to EPA's inhalation toxicological endpoint which is based on an 8-hour time-weighted average. For the peak, short-term exposures to chlorine dioxide gas experienced during mixing/loading and/or system leaks/failures, EPA will rely on the American Conference of Governmental Industrial Hygienists (ACGIH) Short-term Exposure Limit (STEL) and Immediately Dangerous to Life or Health (IDLH) standards to mitigate risks.

For most of the bystander/post application occupational scenarios, the inhalation risks for the bystander/post application occupational exposures are of concern using the EPA's selected inhalation toxicological endpoint (RfC). The occupational RfC, 0.003 ppm, is below the limit of detection for chlorine dioxide. Based on OSHA's Integrated Management Information System (IMIS) data available for chlorine dioxide, all air concentration measurements, even those that were undetectable, are above the RfC. EPA is aware of the discrepancy between the EPA risk-based RfC and current OSHA standards, reconciliation will occur at a later date.

d. Occupational Post-application

i. Dermal Post-Application Exposure

No information is available to assess post application/bystander dermal exposure to uses in agricultural premises as well as food handling, commercial/institutional and medical premises; human drinking water facilities; industrial processes; and retention ponds. However, dermal post application exposure to chlorine dioxide is expected to be less than that of the dermal contact of children playing on treated floor surfaces. Therefore, the dermal exposure route is not believed to be of concern in these industries.

ii. Inhalation Post-Application Exposure

Non-Fogging Uses

Post-application/bystander inhalation exposures were assessed by obtaining air concentration measurements from the Occupational Safety and Health Administration (OSHA) for the non-fogging uses. The data selected for this analysis include only those samples that are reported as 8-hour time-weighted average (TWA) measurements from personal air samplers. Other samples, such as peak concentrations and/or area monitors, have been omitted. The inhalation endpoint selected by EPA is 0.003 ppm, just below the OSHA LOD for an 8-hour TWA air sample. The summary results of the 33 observations taken from 8-hour TWA personal air samplers for chlorine dioxide are above the EPA selected inhalation reference concentration (RfC) of 0.003 ppm, and therefore, are of concern.

Fogging Uses

The fogging use of chlorine dioxide is unique such that no persons are present during the actual application/fogging. There is also a greater potential for chlorine dioxide gas formation from fogging than an aqueous-based application such as mopping. Therefore, a separate assessment was developed for foggers that indicate potential inhalation exposure and reentry recommendations. The air concentration in a fogged area should be below the occupational RfC of 0.003 ppm before the room is entered by persons not wearing respiratory protection.

One scenario based on labeled application rates allows chlorine dioxide fogging and misting applications while workers are in the room if the level of chlorine dioxide does not exceed the TLV-TWA of 0.1 ppm. The occupational RfC of 0.003 ppm could be exceeded based on these use directions (i.e., workers do not need to leave treatment area unless the TLV-TWA of 0.1 ppm is exceeded). This scenario is of potential concern to the Agency. To mitigate this risk, labels must be changed to prohibit re-entry into treated areas for one hour after treatment.

EPA's Risk-based RfC versus OSHA PEL

It is also important to note that the OSHA Permissible Exposure Limit (PEL) for chlorine dioxide is 0.1 ppm. Air concentrations above the PEL are assumed to be mitigated at each facility. Facilities using chlorine dioxide are not required to mitigate inhalation exposures until the air concentration reaches 0.1 ppm. Based on the occupational inhalation toxicological endpoint selected for chlorine dioxide (i.e., RfC of 0.003 ppm), levels at or near the PEL are of concern. In fact, the capability (i.e., LOD) of the OSHA sampling method is insufficient for the occupational RfC presented in this document. Reconciliation of the EPA risk-based RfC and the current OSHA standards will be made at a later date.

e. Human Incident Data

The Agency reviewed available sources of human incident data for incidents relevant to chlorine dioxide/sodium chlorite. EPA consulted the following sources of information for human poisoning incidents related to TCMTB use: **(1) OPP Incident Data System (IDS)** - The Office of Pesticide Programs (OPP) **Incident Data System** contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992; (2) **California Department of Pesticide Regulation (1982-2004)** – The California Department of Pesticide Regulation pesticide poisoning surveillance program consists of reports from physicians of illness suspected of being related to pesticide exposure since 1982. (3) **National Pesticide Information Center (NPIC)** - NPIC is a toll-free information service supported by OPP that provides a ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991.

There are some reported incidents associated with exposure to end-use products containing chlorine dioxide. Inhalation is the primary route of exposure. Most of the incidents are related to irritation type reactions to bronchial and nasal passages, and the eyes.

The most common symptoms reported for cases of inhalation exposure were respiratory irritation/burning, irritation to mouth/throat/nose, coughing/choking, shortness of breath, dizziness, flu-like symptoms, and headache.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for chlorine dioxide and sodium chlorite use sites and any associated uncertainties.

For a detailed discussion of all aspects of the environmental risk assessment, see the document "**Environmental Hazard and Risk Assessment**," dated July 13, 2006.

1. Environmental Fate and Transport

In the environment, chlorine dioxide and sodium chlorite are assessed together because chlorine dioxide is produced by a reaction of sodium chlorite (and sometime sodium chlorate) and hypochlorite/acid. In addition, chlorite is a breakdown product of chlorine dioxide.

Chlorine dioxide has a short half-life and in the presence of sunlight will break down into chloride and chlorate ions (between pH 4 and 7). At pH lower than 4, its breakdown products are chlorite and chlorate. Chlorite is the dominant breakdown product.

Chlorate and chlorite ions tend to only undergo biodegradation only under anaerobic conditions. Biodegradation of chlorate and chlorite has been observed in anoxic groundwater, sediments and some soils. The end products are the chloride and oxygen. No adsorption/desorption constants (K_ds) have been measured or reported in published literature for either chlorite or chlorate. These ions are likely to be mobile and may travel from surface to groundwater easily. The estimated log K_{ow} of chlorine dioxide is -3.22 and for sodium chlorite is -7.17. It is not expected that either would bioaccumulate in aquatic organisms.

2. Ecological Exposure and Risk

Chlorine dioxide and sodium chlorite are used as antimicrobial pesticides at numerous use sites. Sodium chlorite is used as a precursor in the generation of chlorine dioxide. The antimicrobial registered uses of chlorine dioxide/sodium chlorite fall into several major categories including use in the treatment of human drinking water systems; in industrial process and water systems; as a materials preservative; and as a general disinfectant in medical, residential, agricultural, commercial and industrial settings. The indoor uses of sodium chlorite will not result in exposure to the environment.

The use of chlorine dioxide in cooling towers was modeled because it represents the worst-case scenario for the chlorine dioxide uses. For terrestrial animals, the results of studies show that toxicity of chlorine dioxide/sodium chlorite to birds ranges from highly to slightly toxic to birds on an acute oral basis and from slightly toxic to practically non-toxic on a subacute dietary basis.

For freshwater aquatic animals, the results of studies examining the toxicity of chlorine dioxide/sodium chlorite to freshwater fish indicate these chemicals range from slightly toxic to practically non-toxic on an acute basis. For aquatic invertebrates, the studies indicate that chlorine dioxide and sodium chlorite range from very highly toxic for technical grade sodium chlorite to practically non-toxic for the formulated product on an acute basis. Results of toxicity studies indicate that chlorine dioxide/sodium chlorite are slightly toxic to estuarine/marine fish on an acute basis and range from highly toxic to slightly toxic to estuarine/marine invertebrates on an acute basis.

For terrestrial plants, results of toxicity studies indicate that chlorine dioxide/sodium chlorite are moderately toxic to terrestrial plants. For aquatic plants, toxicity study results

indicate chlorine dioxide/sodium chlorite are moderately toxic to aquatic plants.

For aquatic organisms, acute risk is anticipated from the use of chlorine dioxide/sodium chlorite in once-through cooling towers based on the modeling conducted. At the highest doses, there is risk to freshwater and marine/estuarine fish and invertebrates and aquatic plants, and at the lowest doses there is risk only to freshwater invertebrates. Chronic risk to aquatic organisms cannot be assessed at this time due to the lack of chronic toxicity endpoints for fish and aquatic invertebrates. When the required aquatic chronic toxicity testing described above is submitted, chronic risk to these organisms will be assessed.

The once-through cooling tower use of chlorine dioxide/sodium chlorite has been selected for risk assessment because out of all the uses of these chemicals, it is the one expected to have the most potential for environmental exposure. The environmental risk assessment was conducted using sodium chlorite endpoints because under environmental conditions, chlorine dioxide converts mostly into chlorite ions.

3. Listed Species Consideration

a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA, 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

Acute risk to listed birds and mammals is not anticipated from the use of chlorine dioxide and sodium chlorite products due to low exposure and low toxicity. Further evaluation is needed before it can be determined if there are risks to listed aquatic organisms from the once through cooling tower use of chlorine dioxide/sodium chlorite. Chronic risks to listed aquatic organisms cannot be assessed at this time; this risk will be assessed when required chronic toxicity data are submitted to and evaluated by the Agency. These conclusions are based solely on EPA's screening-level assessment and do not constitute "may effect" findings under the Endangered Species Act for any listed species.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing chlorine dioxide and sodium chlorite as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all supported products containing chlorine dioxide and sodium chlorite.

The Agency has completed its assessment of the dietary, occupational, drinking water, and ecological risks associated with the use of pesticide products containing the active ingredient chlorine dioxide and sodium chlorite. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient chlorine dioxide and sodium chlorite, the Agency has sufficient information on the human health and ecological effects of chlorine dioxide and sodium chlorite to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that all chlorine dioxide and sodium chlorite pesticide-containing products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of chlorine dioxide and sodium chlorite that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of chlorine dioxide and sodium chlorite, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of chlorine dioxide and sodium chlorite, the Agency has determined that chlorine dioxide and sodium chlorite products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of chlorine dioxide and sodium chlorite. If all changes outlined in this document are incorporated into the product labels, then all current risks for chlorine dioxide and sodium chlorite will be substantially mitigated for the purposes of this determination. Once an Endangered Species assessment is completed, further changes to these registrations may be necessary as explained in Section III of this document.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for chlorine dioxide and sodium chlorite. During the public comment period on the risk assessments, which closed on June 26 ,2006, the Agency received comments from the registrants, Chlorine Dioxide Panel and other

interested parties. These comments in their entirety, as well as the risk assessments for chlorine dioxide, are available in the public docket (EPA-HQ-OPP-2006-0328) at http://www.regulations.gov/. The Agency's responses to these comments are incorporated into the risk assessment and revised chapters, which are also available in the public docket.

C. Regulatory Position

1. Food Quality Protection Act Findings

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. The Agency has determined that, if the mitigation described in this document is adopted and labels are amended, human health risks as a result of exposures to sodium chlorite are within acceptable levels. In other words, EPA has concluded that the exemptions from tolerances for sodium chlorite meet FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as exposures to sodium chlorite from all possible sources.

b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with chlorine dioxide and sodium chlorite. The Agency has determined that, taking into consideration that a safety finding was made for sodium chlorate in the Inorganic Chlorates RED, the established tolerance exemptions for chlorine dioxide and sodium chlorite, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the use of chlorine dioxide and sodium chlorite. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of chlorine dioxide and sodium chlorite. As discussed in Section III, the acute, and chronic dietary (food and drinking water) risks from chlorine dioxide and sodium chlorite are below the Agency's level of concern, provided that mitigation measures outlined in this document and the and the Inorganic Chlorates RED are adopted and labels are amended.

c. Determination of Safety to Infants and Children

EPA has determined that the tolerance exemptions for chlorine dioxide and sodium chlorite, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors of the toxicity, use practices, and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of chlorine dioxide and sodium chlorite residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from exposure to residues of chlorine dioxide/sodium chlorite, the Agency considered the completeness of the hazard database for developmental and reproductive effects, the nature of the effects observed, and other information. On the basis of this information, the FQPA safety factor has been reduced to 1X for chlorine dioxide/sodium chlorite. The rational for the decisions are based on: (1) the existence of a complete developmental and reproductive toxicity database; (2) the endpoint selected for assessment of risk from dietary and non-dietary exposure to chlorine dioxide is protective of potentially susceptible populations including children and (3) the risk assessment does not underestimate the potential exposure for infants and children.

d. Endocrine Disruptor Effects

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

e. Cumulative Risks

Risks summarized in this document are those that result only from the use of chlorine dioxide and sodium chlorite. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances

individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for chlorine dioxide and sodium chlorite. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

2. Tolerance Reassessment Summary

Table 12 summarizes the reassessment of the chlorine dioxide tolerance exemptions for sodium chlorite.

In order to support the use of chlorine dioxide/sodium chlorite as a fruit and vegetable wash for Raw Agricultural Commodities that will not be processed, a petition to establish a tolerance exemption must be submitted.

a. Tolerances Currently Listed Under 40 CFR §180.940(b)(c) and Tolerance Reassessment

Table 12. Tolerance Information Listed Under 40 CFR 180.1070

Expression	Commodity	Current Tolerance	Tolerance Reassessment	Use
Sodium chlorite	*Brassica* (cole) leafy vegetables	Exempt	Exempt [1]	seed soak treatment in the growing of the raw agricultural commodities crop group *Brassica* (cole) leafy vegetables and radishes
Sodium chlorite	Radishes	Exempt	Exempt [1]	seed soak treatment in the growing of the raw agricultural commodities crop group *Brassica* (cole) leafy vegetables and radishes
Tolerance Exemption Expression	**CAS No.**	**40 CFR**	**Use Pattern**	**Limits**

Oxychloro species(including chlorine dioxide) generated by acidification of an aqueous solution of sodium chlorite	N/A	180.940 (b)[2](c)[3]	Food-contact surface sanitizing solution	When ready for use, the end-use concentration is not to exceed 200 ppm chlorine dioxide
Tolerance Exemption Expression	**CAS No.**	**40 CFR**	**Use Pattern**	**Limits**
Oxychloro species (predominately chlorite, chlorate and chlorine dioxide in an equilibrium mixture) generate either (i) by directly metering a concentrated chlorine dioxide solution prepared just prior to use, into potable water, or (ii) by acidification of an aqueous alkaline solution of oxychloro species (predominately chlorite and chlorate) followed by dilution with potable water	N/A	180.940 (c)[3]	Food-contact surface sanitizing solution	When ready for use, the end-use concentration is not to exceed 200 ppm chlorine dioxide

1. Residues listed under 40 CFR §180.1070 are exempted from the requirement of a tolerance when used as a seed soak treatment in the growing of the raw agricultural commodities group listed
2. Under 40 CFR §180.940(b), chemical substances when use as ingredients in an antimicrobial pesticide formulation may be applied to dairy processing equipment, and food-processing equipment and utensils.
3. Under 40 CFR §180.940 (c), chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to food-processing equipment and utensils.

b. Codex/International Harmonization

There are no Codex maximum residue limits (MRLs) for sodium chlorite.

D. Regulatory Rationale

The Agency has determined that chlorine dioxide and sodium chlorite are eligible for reregistration provided that additional required data confirm this decision and that the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures.

The following is a summary of the rationale for managing risks associated with the use of chlorine dioxide and sodium chlorite. Where labeling revisions are warranted, specific language is set forth in the Table 13 of Section V of this document.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

Acute Dietary (Food) Risk

No acute dietary endpoint was selected because effects attributable to a single dose were

not seen in the available data; therefore, an acute dietary risk assessment was not conducted.

Chronic Dietary (Food) Risk

Although there is not a concern for chronic dietary risk estimates for all populations. Dietary exposure from food did have an impact of the aggregate assessment for children which is of concern (MOE = 44). The individual exposure received from the post-harvest application of sodium chlorite to fruits and vegetables is an extremely high-end estimate. This assessment was conducted with the most conservative assumptions and resulted in an estimate of 42% of the cPAD for children. For example, this assessment assumed that all fruits and vegetables in the U.S. had a chlorine dioxide solution applied and that these commodities were not washed, cooked or processed prior to consumption. Additionally, the Chlorine Dioxide Panel has agreed to limit the residual concentration of chlorine dioxide to 3 ppm for post-harvest application to fruits and vegetables that are not raw agricultural commodities. Therefore, fruits and vegetables treated with chlorine dioxide must be followed by blanching, cooking or canning. Although the Agency cannot quantify the reduction of chlorine dioxide dietary exposure at this time, it is believed that this measure would significantly reduce the percent of chlorine dioxide cPAD resulting from this use. No additional dietary risk mitigation measures are required to address exposure to chlorine dioxide and sodium chlorite residues in food. Further, these conservatisms and label changes also mitigate the aggregate risks to children so that they are no longer of concern.

b. Safe Drinking Water Act

When determining whether a pesticide tolerance is safe, EPA must consider the factors listed in section 408(d) of the FFDCA. One of these factors is the consideration of other non-occupational pesticidal exposures. For chlorine dioxide and sodium chlorite, exposures occur through drinking water from treatment plant disinfection. These exposures need to be considered when reassessing the tolerances associated with the registered uses of these pesticides.

Chlorine dioxide and sodium chlorite are used to disinfect water in treatment plants in order to meet the Safe Drinking Water Act's (SDWA) requirements to protect drinking water. In addition to the statute, 40 C.F.R. section 141.72 states, "A public water system that uses a surface water source and does not provide filtration treatment must provide the disinfection treatment . . . ." The required residual of the disinfectant chlorine dioxide is specified in 40 C.F.R. 141.74.

The SDWA was originally passed by Congress in 1974 to protect public health by regulating the nation's public drinking water supply. The law was amended in 1986 and 1996 and requires many actions to protect drinking water and its sources: rivers, lakes, reservoirs, springs, and ground water wells. (SDWA does not regulate water systems, which serve fewer than 25 individuals.) SDWA authorizes the EPA to set national health-based standards for drinking water to protect against both naturally-occurring and man-made contaminants that may be found in drinking water. EPA, states, and water systems then work together to make sure that these standards are met.

Drinking water that is not properly treated or disinfected, or which travels through an improperly maintained distribution system, may pose a health risk. SDWA applies to every public water system in the United States. The responsibility for making sure these public water systems provide safe drinking water is shared among EPA, states, tribes, water systems, and the public.

EPA sets national standards for drinking water based on sound science to protect against health risks, considering available technology and costs. These National Primary Drinking Water Regulations set enforceable maximum contaminant levels (MCL) for particular contaminants in drinking water or required ways to treat water to remove contaminants. Each standard also includes requirements for water systems to test for contaminants in the water to make sure standards are achieved. As listed in 40 CFR 141.53 EPA has set the MCL at 0.1 mg/L for sodium chlorite.

To ensure that drinking water is safe, SDWA sets up multiple barriers against pollution. One such barrier is treatment. Public water systems are responsible for ensuring that contaminants in tap water do not exceed the standards. Water systems treat the water, and must test their water frequently for specified contaminants and report the results to states. If a water system is not meeting these standards, it is the water supplier's responsibility to notify its customers.

EPA sets primary drinking water standards through a three-step process:

- First, EPA identifies contaminants that may adversely affect public health and occur in drinking water with a frequency and at levels that pose a threat to public health. EPA identifies these contaminants for further study, and determines contaminants to potentially regulate.
- Second, EPA determines a maximum contaminant level goal for contaminants it decides to regulate. This goal is the level of a contaminant in drinking water below which there is no known or expected risk to health. These goals allow for a margin of safety.
- Third, EPA specifies a maximum contaminant level, the maximum permissible level of a contaminant in drinking water which is delivered to any user of a public water system. These levels are enforceable standards, and are set as close to the goals as feasible. SDWA defines feasible as the level that may be achieved with the use of the best technology, treatment techniques, and other means which EPA finds (after examination for efficiency under field conditions) are available, taking cost into consideration. When it is not economically or technically feasible to set a maximum level, or when there is no reliable or economic method to detect contaminants in the water, EPA instead sets a required Treatment Technique which specifies a way to treat the water to remove contaminants.

EPA sets national standards for tap water which help ensure consistent quality in our nation's water supply. EPA prioritizes contaminants for potential regulation based on risk and how often they occur in water supplies. (To aid in this effort, certain water systems monitor for the

presence of contaminants for which no national standards currently exist and collect information on their occurrence). EPA sets a health goal based on risk (including risks to the most sensitive populations, e.g., infants, children, pregnant women, the elderly, and the immuno-compromised). EPA then sets a legal limit for the contaminant in drinking water or a required treatment technique. This limit or treatment technique is set to be as close to the health goal as feasible.

EPA also performs a cost-benefit analysis and obtains input from interested parties when setting standards.

EPA promulgated regulations to control microbial pathogens and disinfectants/disinfection byproducts in drinking water in a multi-stage process that dates back to a 1992-93 negotiated rulemaking, which was affirmed by Congress in the 1996 Amendments to the SDWA. The regulations address complex risk trade-offs between the two different types of contaminants and were promulgated with significant stakeholder input. (65 FR 83016)

Even though, the FFDCA standard in section 408 is a risk-based standard and the SDWA is a cost-benefit standard, the Agency believes we must consider the harm to human health broadly. In doing so, the EPA does not believe it to be prudent to cancel the drinking water disinfectant use of chlorine dioxide and sodium chlorite as that action could potentially result in harming the public at large. The Agency believes the mitigation measures required in this document for the food uses that require pesticide tolerances will reduce exposures from those uses such that the exposures will result in a minimal addition to the exposure that occurs from drinking water. The Agency is reasonably certain that this minimal addition does not cause harm to human health, and is therefore safe under section 408(b) of the FFDCA.

c. Drinking Water Risk Mitigation

Drinking water risks of concern were identified for infants. Drinking water exposure also played a role in the aggregate risks of concern for children.

The chlorite ion (ClO_2^-) is a major degradation product resulting from the reaction of chlorine dioxide with inorganic and organic constituents in the water. When free chlorine is used after the application of chlorine dioxide in the treatment process, chlorite is oxidized to chlorate. Chlorite oxidizes to chlorate over a period of time in water and soil. This conversion will continue over time as the water travels through the distribution system. Treatment of public water supplies is necessary to kill pathogens that may exist in the drinking water, such as cholera, typhoid, and dysentery. Outbreaks of these diseases decreased significantly when disinfection of the water systems was introduced in the early 1900s. While there are many important public functions of water treatment, the Agency is taking steps to limit the exposure of chlorite ion as a disinfection byproduct to the public. Approximately six percent of U.S. water treatment facilities use chlorine dioxide for water disinfection.

In addition, the Chlorine Dioxide Panel recently submitted a study that evaluated whether the components of the baby formula react with the chlorite in drinking water to form chloride, which is not of concern in drinking water because it is easily absorbed and metabolized by the

body. A preliminary review of the data suggests that the components of the baby formula, such as ascorbic acid, react with chlorite in the drinking water. Specifically, within five minutes of adding the formula to the water, approximately one third of the chlorite combines with the ingredients in the infant formula to form chloride.

The Agency is not currently able to quantify the reduction of exposure to chlorite that occurs due to binding of chlorite with ingredients present in the baby formula. However, based on its initial evaluation of the existing data, the Agency believes that for all infants the % cPAD will likely be close to the target of 100, and not of concern. The Agency will require additional data on the breakdown of chlorite in baby formula as confirmatory data.

As mentioned above, the aggregate risks to children 1-6 are mitigated by the consideration discussed concerning dietary exposures from food.

d. Residential Risk Mitigation

i. Residential Handler

Residential risks for handlers were calculated for short- and intermediate-term dermal and inhalation exposures. Risks of concern were identified for homeowners who place tablets in swimming pools/spas with their bare hands (MOE=46). This risk will be mitigated if the homeowner wears gloves while placing the tablet in the swimming pool/spa (MOE=500). Although the Agency does not normally require the use of personal protective equipment such as gloves, on pesticidal products that are used in and around the home, the use of gloves in this case is thought to be prudent since the Agency expects that, given the nature of pool products of this kind, residents are likely to wear gloves based on a perception of the danger of the chemicals along with the label warnings and precautions. This is not necessarily expected to be true of most other residential products where Personal Protective Equipment (PPE) would not be considered an effective mitigation measure nor should this be viewed as a precedent for requiring use of PPE for residential use products. All other exposure and risk estimates for residential handler scenarios are below the Agency's level of concern.

ii. Residential Post-Application

The Agency has conducted dermal, incidental oral and inhalation exposure assessments for residential post-application scenarios.

The residential use of chlorine dioxide/sodium chlorite continuous release deodorizers are of concern. To mitigate this risk, the following use sites for the continuous release deodorizer are ineligible for reregistration and must be deleted: shoes, closets, laundry hampers, bags, drawers, basements, boat cabins, trash bags, and additional deodorizing uses. The remaining use sites will be in an outdoor or commercial setting where people are not likely to have prolonged exposure, e.g., dumpsters. Therefore, the risks from this use pattern would be considered to be no longer of concern. The registrant has agreed to voluntarily cancel these use patterns.

Based on the risk assessment, a post-application inhalation concern was identified for adults and children exposed to carpets treated with chlorine dioxide/sodium chlorite. In order to mitigate this risk, the registrants must prohibit residential use; however, a commercial application to carpet will remain registered with a one hour Restricted Entry Interval (REI).

e. Aggregate Risk Mitigation

Intermediate- and Short-Term

The short- and intermediate- risks to infants are primarily driven by exposure to residues in drinking water. These exposures and risks are mitigated as described in the drinking water section above. The short- and intermediate- risks to children are largely driven by the dietary exposure through food. The characterization and mitigation described above for risks from exposure to residues in food address the aggregate risk as well. Based on these characterization and mitigation measures, the Agency believes that aggregate risks are not of concern.

Chronic

The chronic risks to infants are primarily driven by exposure to residues in drinking water. These exposures and risks are mitigated as described in the drinking water section above. The chronic risks to children are largely driven by the dietary exposure through food. The characterization and mitigation described above for risks from exposure to residues in food address the aggregate risk as well. Based on these characterization and mitigation measures, the Agency believes that aggregate risks are not of concern.

f. Occupational Risk Mitigation

i. Occupational Handler

Dermal Risks from Applications in Agricultural and Medical Premises

The Agency has conducted dermal and inhalation exposure assessments for handlers applying chlorine dioxide in an occupational setting. Based on this assessment, dermal risks of concern were identified for handlers applying chlorine dioxide: to hard surfaces using a low pressure hand wand (MOE=31); to hard surfaces using a mop (MOE=70); to animal transport vehicles/tractor trailer using a foam application (MOE=8 w/ gloves); and in food handling, commercial/institutional, and medical premises and equipment using a mop (MOE=66 for commercial and MOE=3 for medical).

These scenarios were evaluated using highly conservative assumptions including the use of a 100% dermal absorption factor that assumes that all chlorine dioxide/sodium chlorite that contacts the skin will be absorbed. Further, high-end application and use parameters were used to develop the risk estimates. Therefore, the Agency does not expect that actual exposures would be as high as those calculated in the risk assessment.

For these scenarios, the risks will be mitigated by requiring handlers to wear gloves during application. Although there is no data to assess most scenarios with handlers wearing gloves, the Agency is confident that this mitigation will protect occupational handlers. Therefore, these risks are not of concern to the Agency.

For the foam application, the Chlorine Dioxide Panel has submitted information indicating that the Agency has overestimated the risks associated with this use. Specifically, the information indicates that the number of vehicles treated in a day is eight, using two quarts of solution per vehicle. The Agency assessed an application rate of 4 to 6 gallons per minute and assumed that this product was applied for ten minutes per day. Subsequently, EPA determined that the assessed application rate was too high. Based on the revised application rate, the Agency does not have a concern with this risk, provided that gloves are worn during the treatment. Additional details can be found in "*Chlorine Dioxide Occupational and Residential Exposure Assessment*," dated August 2, 2006.

Dermal Risks from Swimming Pool Applications

Occupational risks for handlers were calculated for short- and intermediate-term dermal exposures. Risks of concern were identified for handlers who place tablets in public swimming pools with their bare hands (MOE=5). This risk will be mitigated if the handlers wear gloves while placing the tablet in the swimming pool (MOE=120), and no additional mitigation is required.

Inhalation Risks from Non-fogging Applications

There is the potential for the off-gassing of chlorine dioxide during some non-fogging occupational applications that are not totally enclosed (e.g., aqueous solution sprays, mopping, open pouring, etc). To address the potential for inhalation exposure, EPA has obtained worker air concentration measurements from OSHA for 7 industry Standard Industrial Classification (SIC) codes. The monitored air concentrations for workers are stored in OSHA's data base known as the Integrated Management Information System (IMIS). The inhalation endpoint selected by EPA for an 8-hour time-weighted average (TWA) is 0.003 ppm, just below OSHA's limit of detection of 0.004 ppm. Of the 33 TWA measurements available in IMIS, 21 of those measurements were below the limit of detection. In addition, of the 33 TWA measurements, only 3 were at or above the OSHA PEL of 0.1 ppm. At this point in time, monitoring to EPA's level of concern (i.e., 0.003 ppm) is not technically feasible. However, 64 percent of the samples indicate that the air concentrations of chlorine dioxide are near or below the level of concern. Therefore, for non fogging uses of chlorine dioxide such as open pouring of aqueous solutions or bystanders in pulp and paper mills no additional mitigation is deemed necessary at this time.

Inhalation Risks from Fogging Applications

Inhalation exposure to the release of chlorine dioxide gas during the mixing/loading/application of products producing chlorine dioxide may occur. There is a greater potential for chlorine dioxide gas formation from fogging then an aqueous-based application

such as mopping. The air concentration in a fogged area should be below the occupational RfC of 0.003 ppm before the room is entered by persons not wearing respiratory protection.

However, one scenario based on labeled application rates allows chlorine dioxide fogging and misting applications while workers are in the room if the level of chlorine dioxide does not exceed the TLV-TWA of 0.1 ppm. Based on this scenario, the occupational RfC of 0.003 ppm could be exceeded if handlers are present. Therefore, people must vacate the premises during fogging treatments and a one-hour restricted entry interval (REI) is required to address this risk.

2. Environmental Risk Management

Environmental risk for the once-through cooling tower use of chlorine dioxide/sodium chlorite has been assessed because it has the most potential for environmental exposure. The risk assessment was conducted using sodium chlorite endpoints because under environmental these conditions, chlorine dioxide converts mostly into chlorite ions.

Acute risk is anticipated for aquatic organisms from the use of chlorine dioxide/sodium chlorite in once-through cooling towers. At the highest doses on current labels (25 ppm), there is risk to freshwater and marine/estuarine fish and invertebrates and aquatic plants, and at the lowest doses there is risk only to freshwater invertebrates. To mitigate this risk, the maximum application rate for this use pattern must be reduced from 25 ppm to 5 ppm for intermittent applications.

Chronic risk to aquatic organisms cannot be assessed at this time due to the lack of chronic toxicity endpoints for fish and aquatic invertebrates. When the required aquatic chronic toxicity testing described above is submitted, chronic risk to these organisms will be assessed. All other exposure and risk estimates are below the Agency's level of concern.

3. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing chlorine dioxide and sodium chlorite. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

4. Threatened and Endangered Species Considerations

a. The Endangered Species Program

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat.

To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a no effect determination. The screening level model used in this assessment indicates that there may be acute risks to listed aquatic organisms from the once through cooling tower use of chlorine dioxide/sodium chlorite. Further, potential indirect effects on any species dependent upon a species that experiences effects from use of chlorine dioxide/sodium chlorite cannot be precluded based on the screening level ecological risk assessment. These findings are based solely on EPA's screening level assessment and do not constitute "may effect" findings under the Endangered Species Act. Due to these circumstances, the Agency defers making a determination for the cooling tower use of chlorine dioxide and sodium chlorite until additional data and modeling refinements are available. At that time, the environmental exposure assessment of the cooling tower of chlorine dioxide will be revised, and the risks to Listed Species will be reconsidered.

b. General Risk Mitigation

Chlorine dioxide and sodium chlorite end use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing Chlorine dioxide and sodium chlorite specific to federally listed threatened and endangered species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all threatened and endangered species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting threatened and endangered species risk mitigation measures, the more stringent measure(s) must be adopted.

V. What Registrants Need to Do

The Agency has determined that chlorine dioxide and sodium chlorite are eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; and (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Section B below (Table 13). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For chlorine dioxide and sodium chlorite technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call in (DCI):

1. Completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and,

2. Submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. Cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact ShaRon Carlisle at (703) 308-6427 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/AD)
ShaRon Carlisle
US EPA (7510P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/AD)
ShaRon Carlisle
Office of Pesticide Programs (7510P)
One Potomac Yard (South Building),
2777 South Crystal Drive
Arlington, VA 22202

For end use products containing the active ingredient chlorine dioxide and sodium chlorite, the registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. Completed response forms to the PDCI (PDCI response form and requirements status and registrant's response form); and,

2. Submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. Two copies of the confidential statement of formula (CSF) (EPA Form 8570-4);

2. A completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

3. Five copies of the draft label incorporating all label amendments outlined in Table 15 of this document;

4. A completed form certifying compliance with data compensation requirements (EPA Form 8570-34);

5. If applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and,

6. The product-specific data responding to the PDCI.

Please contact Emily Mitchell at (703) 308-8583 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PM-32)
Emily Mitchell
US EPA (7510P)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PM-32)
Emily Mitchell
Office of Pesticide Programs (7510P)
One Potomac Yard (South Building),
2777 South Crystal Drive

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of chlorine dioxide and sodium chlorite has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory data requirements. A generic data call-in will be issued at a later date. Several Ecological studies are being required to support the once-through cooling tower use of chlorine dioxide/sodium chlorite.

The risk assessment noted deficiencies in the surrogate dermal and inhalation exposure data available from the Chemical Manufacturers Association (CMA) data base. Therefore, the Agency is requiring confirmatory data to support the uses assessed with the CMA exposure data within this risk assessment. The risk assessment also noted that many of the use parameters (e.g., amount handled and duration of use) were based on professional judgments. Therefore, descriptions of human activities associated with the uses assessed are required as confirmatory.

Table 15. Confirmatory Data Requirements for Reregistration

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
Fish early life-stage testing-freshwater	850.1300	72-4
Invertebrate life-cycle testing - freshwater	850.1400	72-4b
Seedling emergence dose-response in rice	850.4225	123-1
Vegetative vigor dose-response in rice	850.4250	123-1
Aquatic vascular plant dose-response toxicity- *Lemna* sp.	850.4400	123-2
Acute algal dose-response toxicity - 4 species	850.5400	123-2
Indoor Inhalation Exposure and Applicator Exposure Monitoring Data Reporting	875.1400 and 875.1600	234 and 236
Indoor Dermal Exposure and Applicator Exposure Monitoring Data Reporting	875.1200 and 875.1600	233 and 236
Descriptions of Human Activity	875.2800	133-1
Carcinogenicity	870.4200	83-2
Fate of chlorite in baby formula	Special study	Special study
Use and Usage Information on the Percent of Fruits and Vegetables that are treated with Chlorine Dioxide		

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in Table 16, Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

A product-specific data call-in, outlining specific data requirements, will follow this RED at a later date.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above.

Specific language to incorporate these changes is specified in Table 16.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy," *Federal Register*, Volume 56, No. 123, June 26, 1991.

a. Label Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 16. Labeling Changes Summary Table

Description	Amended Labeling Language	Placement on Label
Manufacturing Use Product		
Supported Use Sites	"Only for formulation into antimicrobial products for use in: agricultural/farm premises, structures, buildings, and equipment; dairy farm milk handling facilities, equipment, storage rooms, houses, and sheds; food processing plants, food handling, food distribution equipment and premises; eating establishments premises and equipment; commercial, institutional, and industrial premises and equipment (floors, walls, storage areas); domestic dwellings, food handling areas, indoor premises; and medical institutional critical care and non-critical care premises, human water systems, swimming pools and industrial processes and water systems." For Formulation into antimicrobial products for use in: animal transport vehicles, carpets, fountains/water displays/decorative ponds/, once- through and recirculating industrial commercial cooling water systems, pulp/paper mill water systems, and swimming pools, mushroom facilities/premises and equipment, egg handling equipment and rooms, egg washing treatment, chick room, poultry houses chiller water/carcass spray, food processing plants/equipment, dairies/breweries and bottling plants/equipment, fruit and vegetable rinse/process water and tank lines, potable drinking water, water storage systems (aircrafts boats, RVs, off-shore oil rigs), water filtration systems, ventilation systems.	Directions for Use
PPE		Precautionary Statements

Description	Amended Labeling Language	Placement on Label
Ecological Effects Language Required by the RED and PR Notice 93-10 and 95-1	"This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Environmental Hazard Statements
End Use Products Intended for Occupational Use		
Application Restrictions-For Occupational Handler -Dermal (*Application to hard surfaces*)	"Handlers applying chlorine dioxide in an occupational setting must wear gloves." • low pressure hand wand (hard surfaces) • mop (hard surfaces) • foam application (animal transport vehicles/tractor trailer) • mop (food handling, commercial/institutional and medical premises/equipment)	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls
Application Restrictions-For Occupational Handler -Dermal (*Tablets into public swimming pools*)	"Occupational handler must wear gloves while placing the tablet in the swimming pool"	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls
Application Restrictions-For Occupational Handler – Inhalation (*Fogging Use*)	"People must vacate the premises during fogging treatments; a one-hour restricted entry interval (REI) is required."	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls

Description	Amended Labeling Language	Placement on Label
Application Restrictions-For Occupational – Inhalation *(Carpet Treatment)*	"Not for residential use. For nonresidential use, a one-hour restricted entry interval is required."	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls
Application Restrictions-For Occupational Post-Application *(Once through use)*	"Reduce the application rate from 25 ppm to 5 ppm for intermittent applications."	
End Use Products Intended for Residential Use		
Application Restrictions-For Residential Handler -Dermal *(Tablets into pools/spas)*	"Residential handler (homeowner) must wear gloves while placing the tablet in the swimming pool/spa"	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls
Application Restrictions-For Residential Post-Application – Inhalation *(Continuous release deodorizers)*	"Restrict to outdoor use only. Do not use indoors (e.g., use in shoes, closets, laundry hampers, bags, drawers, basements, boat cabins, trash bags, and any additional deodorizing uses)"	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls

Description	Amended Labeling Language	Placement on Label
Application Restrictions-For Residential Post-Application – Inhalation *(Carpet Treatment)*	"Residential use is prohibited."	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls
Dietary		
Fruit and vegetable wash	"Fruits and vegetables treated with chlorine dioxide must be blanched, cooked, or canned before consumption or distribution in commerce"	Precautionary Statements under: Hazards to Humans and Domestic Animals (Immediately Following Engineering Controls

VI. APPENDICES

Appendix A - Chlorine Dioxide, PC Code 020503

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Agricultural premises and equipment				
Agricultural Storage Facilities (Containers, Trailers, Rail Cars, Vessels)	Soluble Concentrate 9150-11	Foaming Wand	One quart to system that delivers 4-6 gallons per minute of dilution water 10 minutes contact time	Preclean with water to remove debris and dirt.
Mushroom Facilities: (food Contact) Stainless Steel Tanks, Transfer Lines, On-line Equipment, Picking Baskets	Soluble Concentrate 9150-2, 9150-3 9804-1, 58300-16, 58300-19	Flush equipment with sanitizing solution	Use-solution calls for 100-200 ppm total available chlorine dioxide	Clean equipment and surfaces thoroughly using a suitable detergent and rinse with water before sanitizing.
Mushroom Facilities (non-food contact): disinfect walls ceilings and floors	Soluble Concentrate 9150-2, 9150-3 9804-1, 58300-16, 58300-19	Spraying device	300-500 ppm total available chlorine dioxide 1,000 ppm for control of mold and slime on walls	Remove all gross filth from areas prior to disinfection. Never reuse activated solutions Avoid contact with food or food contact surfaces.
Potato Facilities: (food Contact) Stainless Steel Tanks, Transfer Lines, On-line Equipment, Handling equipment	Soluble Concentrate 9804-1	Fill, flush, immerse or spray	Use-solution calls for 100 ppm total available chlorine dioxide	None stated
Potato Facilities: walls, ceilings floors, planting and harvesting equipment and truck beds	Soluble Concentrate 9804-1	Spray	10 minute contact time	Always use an applicable NIOSH/MSHA approved respirator appropriate for chlorine dioxide.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Disinfection				
Potato Facilities: potato rinse tanks, flumes and lines	Soluble Concentrate 9804-1	Chemical Feed pump or injector system	5 ppm	After Treatment Potatoes must be rinsed with potable water.
Potato Storage: Potato rinse and humidification water	Soluble Concentrate 9804-5 9150-12	Spray, mist and fogger	200 to 400 ppm	No more than 20 gallons of product concentrate per month to humidification water per 500 tons of potatoes in storage. Always use an applicable NIOSH/MSHA approved respirator appropriate for chlorine dioxide.
Disinfection of Animal Confinement Facilities (Poultry Houses, Swine Pens, Calf Barns and Kennels	Soluble Concentrate 9150-2, 9150-3 9804-1	Use Commercial Sprayer to saturate all surfaces	Working Solution containing 300 to 500 ppm available Chlorine Dioxide	Remove all animals and feed from premises. Remove all litter and manure from premises of facilities. Empty all troughs , racks and other feeding equipment/ watering appliances. Thoroughly clean all surfaces with soap and detergent and rinse with water.
	Soluble Concentrate 9150-11	None Stated	1000 ppm	Remove all animals, bedding, litter, droppings and manure. Pre-clean
Animal Transport Vehicles	Soluble Concentrate 9150-11	Foaming Wand	One quart to system that delivers 4-6 gallons per minute of dilution water 10 minutes contact time	Preclean with water to remove debris and dirt.
Control for odor and Slime forming Bacteria in Animal Confinement Facilities	Soluble Concentrate 9150-2, 9150-3	Commercial sprayer to saturate all surfaces	1,000 ppm	Remove all litter and manure from premises and thoroughly clean all surfaces with soap or detergent and rinse with clean water

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Shoe Bath	Soluble Concentrate	Immersion	1 to 2 ounces per galloon of water	Change Shoe bath solution daily or when solution appears soiled.
Poultry House Disinfection: Poultry Chiller Water/ Carcass spray	Soluble concentrate 9150-2, 9150-3	Dip Carcass	0.5 to 3 ppm for Chiller Water 70 ppm for Carcass Spray	None stated
Poultry Drinking Water	Soluble concentrate 9150-2, 9150-3	Add to water	5ppm for fouled water 0.5 to 1.0ppm for control	None stated
Egg Room/ Hatching Area Incubator Room Tray Washing Room and Loading Platform	Soluble Concentrate 9150-2, 9150-3	High pressure sprayer	20 ppm for pre wash w/ sprayer 390 ppm to preclean floors 1,000 ppm treatment w/ fogger	None Stated
	10589-3	Spray	5 oz. per gallon/ 1406 ppm (mixed with DDAC)	Remove gross filth and heavy soil prior to application of the disinfecting solution
Chick Room, Chick Grading Box an Sexing room	Soluble concentrate 9150-2, 9150-3	Fogger, Mop	1,000 ppm w/ fogger 390 ppm to mop floors	None Stated
Hand Dip for Poultry Workers	Soluble concentrate 9150-2, 9150-3	Dip	50 ppm	None Stated
Horticulture uses Work Area and Benches	Ready to use Solution 9150-11	Cloth, mop, sponge or sprayer	9 fl oz per gallon/ 253 ppm	Do not Apply directly to Plant Material

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Horticulture uses Pots and Flats	Ready to use Solution 9150-11	Soak	18 fl oz per gallon/ 506 ppm	Remove all loose soil and plant residue prior to application
Horticulture uses Cutting Tools	Ready to use Solution 9150-11	Soak	9 fl oz per gallon/ 253 ppm	None Stated
Horticulture uses Bulbs	Ready to use Solution 9150-11	Soak	9 to 18 fl oz per gallon/ 253 ppm to 506 ppm	None Stated
Horticulture uses Greenhouse Glass, Walkways and under Bench Areas	Ready to use Solution 9150-11	Spray	4 to 9 fl oz per gallon/ 112 ppm to 253 ppm	None Stated
Evaporative Coolers	Ready to use Solution 9150-11	Add to water	4 to 9 fl. oz per gallon / 112 ppm to 253 ppm. Repeat as needed or every 14 days	None Stated
Rention Basins and Ponds	Ready to use Solution 9150-11	Add to Basin	4-9 fl oz. per 100 gallons/ 2 to 5 ppm	Do not use where fish are present
Decorative Pools, Fountains and Water Displays	Ready to use Solution 9150-11	Add to Pools	9-18 fl oz per 100 gallons/ 5 to 10 ppm	Do not use where fish are present.
Food handling/ storage establishments premises and equipment				
Food Processing Plants (Poultry, Meat, Fish) Food Contact Surface Sanitizer	Soluble Concentrate 9150-2, 9150-3 9804-9 9804-1	1 minute contact time	200ppm- 1,000 ppm total available chlorine Dioxide 50 ppm 100 ppm	Preclean and rinse equipment. Do not reuse solution. Do not rinse treated surface

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Food Processing Plants (Poultry, Meat, Fish) Non-Food contact disinfectant	Soluble Concentrate 9804-9 9804-1	Spray thoroughly wet for 10 minutes	500 ppm	Never reuse activated solutions
	Soluble Concentrate 10589-3	Spray	5 oz. per gallon/ 1406 ppm (mixed with DDAC)	Remove gross filth and heavy soil prior to application of the disinfecting solution
Dairies, Breweries and Bottling Plants Non-Food contact disinfectant	Soluble Concentrate, Ready to use Solution 9804-9 9804-1	Spray thoroughly wet for 10 minutes	500 ppm	Never reuse activated solutions
Dairies	Soluble Concentrate 10589-3	Spray	5 oz. per gallon/ 1406 ppm (mixed with DDAC)	Remove gross filth and heavy soil prior to application of the disinfecting solution
Dairies, Breweries and Bottling Plants Food Contact Surface Sanitizer	Soluble Concentrate, Ready to use Solution 9150-2, 9150-3 9804-9 9804-1	1 minute contact time	200ppm- 1,000 ppm total available chlorine Dioxide 50ppm 100ppm	Preclean and rinse equipment. Do not reuse solution. Do not rinse treated surface
Ice Making Plants and Machinery	Soluble Concentrate, Ready to use Solution 9804-9	Chemical Feed Pump or Injector System	20 ppm	

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	9804-1 9804-5			
Lube Additive for Moving Conveyors and Chains	Soluble Concentrate, Ready to use Solution 9804-9 9804-1	Inject into distribution system	10- 20 ppm	Preclean and sanitize all conveyor surfaces and associated structures
Canning Retort and Pasteurizer Cooling Water	Soluble concentrate, Ready to use Solution 9150-2, 9150-3 9804-9	Controlled Chemical Feed Pump	5ppm	
Stainless Steel Transfer Lines, Hydrocoolers and Pasteurizers	Soluble concentrate, Ready to use Solution 9150-2, 9150-3 9804-9 9804-1	Mix and fill lines and Equipment overnight	20 ppm	Preclean equipment or line thoroughly
Process Water for Vegetable Rinses, Tanks Lines	Soluble Concentrate 9150-2, 9150-3 9804-1	Chemical Feed Pump or injector system	5 ppm	Preclean all tanks, flumes and lines with suitable detergent.
Fruit and Vegetable Rinse	Soluble concentrate 9150-2, 9150-3 9804-1	Immersion	1/3 fl. to 1 gallon of water per 25 gallons of water 5 ppm	Prewash whole fruits and vegetables with clean potable water.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Human Water Systems				
Potable Drinking Water	Ready to Use solution 59055-1	Metering Pump 1 mg/ liter (1ppm) or less 1 gallon per 100,000 gallons of treated water	1 mg/ liter (1ppm) or less 1 gallon per 100,000 gallons of treated water	None Stated
	9150-2, 9150-3 9804-1 9804-5, 9150-9	None stated	5 ppm	None stated
Water Storage systems aboard Aircraft Boats, RV's Off-shore Oil Rigs	Soluble concentrate 9150-2, 9150-3 9804-1	Add to tank and lines	50 to 500 ppm available chlorine dioxide	None stated
Municipal Well Waters	9150-2, 9150-3	None stated	1 ppm	None stated
Commercial water filtration systems	9804-1	Add to system	300 ppm	None Stated
Commercial, institutional and industrial premises and equipment				
Dental Offices Dental Pumice Disinfectant	Soluble Concentrate 9150-3 9804-1	Apply to Dry Pumice	500 ppm	Discard 5 days after preparation
Hospitals and Nursing Homes Institutions and Public Places	Soluble Concentrate 10589-3,	Spray	1000 ppm to 1406 ppm (mixed with DDAC)	Remove gross filth and heavy soil prior to application of the disinfecting solution

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
General disinfectant	9150-11 9804-1			
Hospitals, Laboratories and Institutions Hard Non Porous surfaces (Tile Floors, Walls and Ceilings and Stainless Steel Cold Rooms)	Soluble Concentrate 9150-2, 9150-3 9804-1	Spray, Mop or sponge	Working Solution containing 300 to 500 ppm available Chlorine Dioxide	Clean all surfaces with a suitable detergent and rinse with water prior to disinfection.
Disinfection of Bench Tops, Biological Hoods, Incubators, Stainless Steel Equipment and Instruments	Soluble Concentrate 9150-2, 9150-3 9804-1	Squirt onto surfaces with squeeze bottle	Working Solution containing 300 to 500 ppm available Chlorine Dioxide	Clean all surfaces with a suitable detergent and rinse with water prior to disinfection.
Water Bath Incubator	Soluble Concentrate 9150-2, 9150-3 9804-1	Pour solution into waterbath reservoir	Working Solution containing 300 ppm available Chlorine Dioxide to disinfect 50 ppm for order and slime control	Clean reservoir with a suitable detergent and rinse with water prior to disinfection
Sterilzation of Spent Biologicals in Steam Autoclaves	Soluble Concentrate 9150-2, 9150-3	Spray or pour directly into autoclave buckets	Working Solution containing 1,000 ppm available Chlorine Dioxide	None Stated
To Deodorize Animal Holding Rooms, Sick Rooms, Morgues and	Soluble Concentrate	Spray solution on to walls ceilings and	Working Solution containing 1,000 ppm available Chlorine	Rooms to deodorize should be ina clean condition prior to autoclaving.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Work rooms	9150-2, 9150-3 9804-1	floors	Dioxide	
Industrial Processing Plants	Soluble Concentrate 10589-3	Spray	5 oz. per gallon/ 1406 ppm	Remove gross filth and heavy soil prior to application of the disinfecting solution
Deodorizer- Hospitals, Restaurants, Hotel & Motel Rooms	Ready-to Use 9804-3	Spray	Spray area until covered with mist and let stand for 10 minutes	None stated
Swimming Pools				
Swimming Pools	Ready to use solution 59055-1	Meetering Pump	1 to 5ppm at a pH range from 7.2-7.6	None Stated
Residential and Public Access				
Odors on Pets, Litter Boxes, Carpets and Concrete Floors	Soluble concentrate 9150-2, 9150-3 9804-1	Soak, Mop or rinse	For litter boxes: 625 – 650ppm For carpets: 500 ppm Concrete floors: 1250 ppm Animal Baths: 80-100 ppm	Avoid direct contact with animal's eyes, nose and ears
Ice Fishing in the Round Treatment	Soluble Concentrate 9150-2, 9150-3 9804-1	None stated	20 ppm	None stated
Deodorizer- Restrooms/Bathrooms,	Ready-to Use	Spray	Spray area until covered with mist and let stand	None stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Refuse Containers, diaper Pails, Storage Lockers	9804-3		for 10 minutes	
Industrial Processes and Water Systems				
Water Cooling systems	Ready to Use, Soluble concentrate 59055-1 9804-9 9804-1	Batch load or meter	100 ppm 5.0 ppm	None Stated
Recirculating Cooling Water systems	Soluble concentrate, Ready to use Solution 9150-2, 9150-3 9804-9	None stated	5-20 ppm	None stated
Water Based Cutting Oils	Soluble Concentrate 9150-2, 9150-3	Slug does system	32 oz to 10 gallons per million gallons of cutting oil	None stated
Paper Mills	Soluble Concentrate, Ready to use Solution 9150-2, 9150-3 9804-9, 9804-1	None stated	4.5 gallons product per 100 tons of paper 1.25 – 5.0 ppm (3.2 – 12.8 fluid ounces per 1,000 gallons of water	None stated
Oil Wells : Secondary	Soluble	None Stated	5,000 ppm available	None stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Recovery Operations	Concentrate 9150-2, 9150-3		chlorine dioxide	
Once Through Water Cooling Systems	Soluble Concentrate 9150-2, 9150-3	Slug and Continuous	Slug Dose: 5-25 ppm Continuous Dose: 0.25 to 2.0 ppm	None Stated
Ventilation systems	Soluble concentrate 9804-1	Spray or fog	500 ppm. 10 minute contact time	NIOSH/MSHA approved respirator required

Appendix A - Sodium Chlorite 020502

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Agricultural premises and equipment				
Mushroom Facilities: (food Contact) Stainless Steel Tanks, Transfer Lines, On-line Equipment, Picking Baskets	Soluble Concentrate/ Ready to Use Solution 5382-46 58300-17 74602-2	Flush equipment with sanitizing solution	Use-solution calls for 100 ppm total available chlorine dioxide	Clean equipment and surfaces thoroughly using a suitable detergent and rinse with water before sanitizing.
Mushroom Facilities (non-food contact): disinfect walls ceilings and floors	Soluble Concentrate/ Ready to use Solution 5382-46 58300-17 69151-5 74602-2	Spraying device	500 ppm total available chlorine dioxide 1,000 ppm for control of mold and slime on walls	Remove all gross filth from areas prior to disinfection. Never reuse activated solutions Avoid contact with food or food contact surfaces.
Potato Facilities: (food Contact) Stainless Steel Tanks, Transfer Lines, On-line Equipment, Handling equipment	Soluble concentrate: 53345-20, 56485-4	Fill, flush, immerse or spray	Use-solution calls for 100 ppm total available chlorine dioxide	None stated
Potato Facilities: potato rinse tanks, flumes and lines	Soluble concentrate: 53345-20, 56485-4, 9150-7	Chemical Feed pump or injector system	5 ppm	After Treatment Potatoes must be rinsed with potable water.
Potato Storage: Potato rinse and humidification water	Soluble concentrate: 53345-20, 56485-4,	Spray, mist and fogger	200 to 400 ppm	No more than 20 gallons of product concentrate per month to humidification water per 500 tons of potatoes in storage.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	21164-21			Always use an applicable NIOSH/MSHA approved respirator appropriate for chlorine dioxide.
Disinfection of Animal Confinement Facilities (Poultry Houses, Swine farrowing pens, Calf Barns and Kennels	Soluble Concentrate 70060-18, 45631-23, 74602-2, 70060-6, 74602-3, 70060-19, 69151-5, 8714-8	Mop, sponge or Use Commercial Sprayer to saturate all surfaces	Working Solution containing 300 to 500 ppm available Chlorine Dioxide	Remove all animals and feed from premises. Remove all litter and manure from premises of facilities. Empty all troughs , racks and other feeding equipment/ watering appliances. Thoroughly clean all surfaces with soap and detergent and rinse with water.
Agricultural premises and equipment				
Poultry House Disinfection: Poultry Chiller Water/ Carcass spray	Soluble Concentrate 74602-2 9150-7 9150-8 74602-3	Dip Carcass	0.11 to 0.33 ounces per gallon for Chiller Water or 50 to 150 ppm 500 to 1200 ppm for Carcass Spray	None stated
Poultry Processing Water	Soluble Concentrate, Ready to use Solution 21164-6 21164-8 21164-9 53345-19 53345-20 56485-4 74517-2 53345-21	None stated	3 ppm max	None stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	74517-1 74119-1			
Poultry Drinking Water	Soluble Concentrate 74602-2	Add to water	5ppm for fouled water 0.5 to 1.0ppm for control	None stated
Poultry, swine, cattle and other livestock Drinking Water	Soluble Concentrate 64449-1	Add to water	5ppm for fouled water 0.5 to 1.0ppm for control	None stated
Egg Room/ Hatching Area Incubator Room Tray Washing Room and Loading Platform	Soluble Concentrate 74602-2	High pressure sprayer	20 ppm for pre wash w/ sprayer 390 ppm to preclean floors 1,000 ppm treatment w/ fogger	None Stated
Egg Shells (Food Grade)	Soluble Concentrate 74602-2	Wet Thoroughly	5.0 ppm	Do not reuse solution
Chick Room, Chick Grading Box an Sexing room	Soluble Concentrate 74602-2	Fogger, Mop	1,000 ppm w/ fogger 390 ppm to mop floors	None Stated
Agricultural premises and equipment				
Horticulture uses Work Area and Benches	Soluble Concentrate 70060-6	Cloth, mop, sponge or sprayer	100 ppm	Do not Apply directly to Plant Material
Horticulture uses Pots and Flats	Soluble Concentrate	Soak	100 ppm	Remove all loose soil and plant residue prior to application

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	70060-6			
Horticulture uses Cutting Tools	Soluble Concentrate 70060-6	Soak	100 ppm	None Stated
Horticulture uses Bulbs		Soak	9 to 18 fl oz per gallon/ 253 ppm to 506 ppm	None Stated
Horticulture uses Greenhouse Glass, Walkways and under Bench Areas	Soluble Concentrate 70060-6	Spray	33 to 100 ppm	None Stated
Evaporative Coolers	Soluble Concentrate 70060-6	Add to water	100 ppm	None Stated
Food handling/ Storage establishments premises and equipment				
Non-Porous, Food Contact, hard surface sanitizer	Soluble concentrate: 74986-1, 70060-19, 21164-3, 21164-8, 21164-9, 5382-46	Foamer, Dilution device or spray	5ppm of activated available chlorine dioxide	None stated
Food Processing Plants (Poultry, Meat, Fish)	Soluble Concentrate 74602-2, 21164-3	fogger	0.5 ppm	Ventilate for 15 minutes prior to reentry
Food Processing Plants (Poultry, Meat, Fish) Food Contact Surface Sanitizer	Soluble concentrate: Reg:53345-14 53345-19 53345-20	1 minute contact time	50ppm- 1,000 ppm total available chlorine Dioxide	Preclean and rinse equipment. Do not reuse solution. Do not rinse treated surface

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	69151-3 70060-6 9150-7			
Food handling/ Storage establishments premises and equipment				
Fruit and Vegetables	Soluble Concentrate 9150-8	Spray or dip	500 to 1200 ppm	Rinse with potable water after treatment.
Dairies, Breweries and Bottling Plants	Soluble Concentrate 74602-2 74602-1	Fogger	0.5 ppm	Ventilate for 15 minutes prior to reentry
Dairies, Breweries and Bottling Plants Food Contact Surface Sanitizer	Soluble concentrate: 53345-14 53345-19 53345-20 9150-7 9150-8 21164-6 21164-8 21164-9 74602-2 5382-46 74517-1 53345-21 73139-1	1 minute contact time	50ppm- 1,000 ppm total available chlorine Dioxide	Preclean and rinse equipment. Do not reuse solution. Do not rinse treated surface

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Lube Additive for Moving Conveyors and Chains	Soluble concentrate: 74602-3, 21164-3	Inject into distribution system	10- 20 ppm	Preclean and sanitize all conveyor surfaces and associated structures
Canning Retort and Pasteurizer Cooling Water	Soluble concentrate: 70060-6, 74602-2, 70060-16, 53345-14, 9150-7, 9150-8, 46207-5, 5382-46	Controlled Chemical Feed Pump	0.1-5ppm	None stated
Food handling/ Storage establishments premises and equipment				
Stainless Steel Transfer Lines, Hydrocoolers and Pasteurizers	Soluble concentrate: 70060-6, 74602-2, 5382-46	Mix and fill lines and Equipment overnight	20 ppm	Preclean equipment or line thoroughly
Process Water for Vegetable Rinses, Tanks Lines	70060-6, 5382-46	Chemical Feed Pump or injector system	5 ppm	Preclean all tanks, flumes and lines with suitable detergent.
Fruit and Vegetable Rinse	Soluble concentrate: 45631-22, 45631-20, 74602-2, 45631-19, 53345-	Immersion, spray	1/3 fl. to 1 gallon of water per 25 gallons of water 3-5 ppm	Prewash whole fruits and vegetables with clean potable water.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	20, 56485-4, 45631-22, 69151-5, 9150-7, 9150-8, 21164-21, 45631-19, 5382-46 79814-3			
Ice Making Plants and Machinery	Ready to use: 70060-13	Hang or place the sachet in the ice chamber out of direct contact with water or ice	50 to 200 g sachet per 100 to 400 lbs per day	None stated
	Soluble concentrate: 5382-46	Chemical Feed Pump or Injector System	20 ppm	None stated
Human Water Systems				

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Potable Drinking Water	Soluble concentrate: 53345-14 53345-19 53345-20 53345-22 69151-5 69151-3	Metering Pump 1 mg/ liter (1ppm) or less 1 gallon per 100,000 gallons of treated water	1 mg/ liter (1ppm) or less 1 gallon per 100,000 gallons of treated water	None Stated
	70060-6 9150-7 9150-8 21164-6 21164-8 21164-9 21164-21 74602-2 5382-41 5382-42 5382-45 5382-46 74517-2 74517-1 53345-21 74602-1 79814-3	None stated	5 ppm	None stated
	Ready to use: 70060-22	Tablet	1 tablet per liter of water. Four hour treatment time.	None stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Water Storage systems aboard Aircraft Boats, RV's Off-shore Oil Rigs	Soluble concentrate: 74602-2 5382-46	Add to tank and lines	50 to 500 ppm available chlorine dioxide	None stated
Human Water Systems				
Municipal Well Waters	Soluble concentrate: 53345-23 55050-1 55050-2 70060-6 46207-5 74602-2 5382-46	None stated	1 ppm	None stated
Commercial, institutional and industrial premises and equipment				
Non-Porous, Non-food Contact, hard surface sanitizer	Soluble concentrate: 74986-1, 53345-13, 70060-19, 45631-15,	Dilution device or sprayer	100 ppm-200 ppm	
Odors on Pets, Litter Boxes, Carpets and Concrete Floors	Soluble concentrate: 70060-6, 70060-4	Soak, Mop or rinse	For litter boxes: 625 – 650ppm For carpets: 500 ppm	Avoid direct contact with animal's eyes, nose and ears

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
			Concrete floors: 1250 ppm Animal Baths: 80-100 ppm	
Residential				
Bathroom surfaces, shower stalls, curtains, laundry rooms, hampers and other non specified surfaces for mold and mildew control.	Soluble concentrate 74602-2	Spray, fog, pour, wipe	Dilute 13 fl. oz. solution as needed 5 minutes surface contact	After 30 minutes rinse with water
De-oderizer pouches for Refrigerators, Shoes, Gym Basements, Lockers, Laundry Hampers, Automobiles, Boat Cabins, athletic bags, trash cans pet areas, etc.	Ready to use Solution , Impregnated Materials 9804-10 70060-12	Hang or place sachet (deodorizing pouch)	5 to 200 grams sachet for use from 1 week to 2 months	None Stated.
Carpets	Ready to Use Powder 4822-512	Sprinkle on Carpet	2.5 oz per square yard.	Keep Children and pets off treated areas during application and until area is vacuumed.
Medical premises and equipment				
Hospitals, Laboratories and Institutions Hard Non Porous surfaces (Tile floors, Walls and Ceilings and Stainless	Soluble concentrate: 74602-2, 69151-1, 69151-5	Spray, Mop or sponge	Working Solution containing 300 to 500 ppm available Chlorine Dioxide	Clean all surfaces with a suitable detergent and rinse with water prior to disinfection.

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Steel Cold Rooms)				
Treatment of infectious medial waste (prior to disposal in a in a conventional solid waste landfill)	Soluble concentrate: 69972-1	Approved application system	None listed on label	None stated
Water Bath Incubator	Soluble concentrate: 74602-2, 70060-6	Pour solution into waterbath reservoir	Working Solution containing 300 ppm available Chlorine Dioxide to disinfect 50 ppm for odor and slime control	Clean reservoir with a suitable detergent and rinse with water prior to disinfection
Sterilization of Spent Biologicals in Steam Autoclaves	Soluble concentrate: 70060-6	Spray or pour directly into autoclave buckets	Working Solution containing 1,000 ppm available Chlorine Dioxide	None Stated
To Deodorize Animal Holding Rooms, Sick Rooms, Morgues and Work rooms	Soluble concentrate: 70060-6	Spray solution on to walls ceilings and floors	Working Solution containing 1,000 ppm available Chlorine Dioxide	Rooms to deodorize should be in a clean condition prior to autoclaving.
Swimming Pools				

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Swimming Pools	Tablet form, Ready to Use solution 70060-20	Tablet insert in hair and lint basket	1 tablet for under 10,000 gallons 2 tablets for over 10,000 gallons Apply every 3-4 weeks	Do not add this product through any automatic dispensing device. Apply product when no persons are in the pool.
Industrial Processes and water systems				
Waste water	Soluble concentrate: 53345-20, 55050-1 55050-2 56485-4 69151-4 69151-3 9150-7 10707-32 21164-6 21164-8 21164-9 21164-21 46207-5 5382-41 5382-43 5382-45 74119-1 74517-3 74517-2 53345-10	Batch load or meter	5.0 ppm to 100 ppm	None Stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	79814-3 53345-12 5382-42 74602-1			
Industrial Processes and water systems				
Water Cooling systems	Soluble concentrate: 53345-14 53345-19 53345-22 56485-4 69151-4 10707-32 46207-5 5382-46	Batch load or meter	5.0 ppm to 100 ppm	None stated
Industrial process water	Soluble concentrate: 53345-20 9150-7 21164-8 53345-21 74602-1	Batch load or meter	5.0 ppm to 100 ppm	NIOSH/MSHA approved respirator required
Water Based Cutting Oils	Soluble concentrate: 70060-6	Slug does system	32 oz to 10 gallons per million gallons of cutting oil	None stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
Oil Wells : Secondary Recovery Operations	Soluble concentrate: 69151-3 68329-18 70060-6 10707-32 21164-3 5382-41 74602-3	None Stated	5,000 ppm available chlorine dioxide	None stated
Oilfield Injection	Soluble concentrate: 74602-1 79814-3	Shock dosage	200-3000ppm	None stated
Industrial Processes and water systems				
Recirculating Cooling Towers	Soluble concentrate: 74062-1 79814-3	Cooling tower drip pan	0.1 to 5.0 ppm 55.3 fl. oz per 1000 gallons of water for initial dosage 2.6 fl. oz per 100 gallons of water for subsequent dosage	None Stated
Once Through Water Cooling Systems	Soluble concentrate:	Slug and Continuous	Slug Dose: 5-25 ppm Continuous Dose: 0.25 to 2.0 ppm	None Stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	53345-14 53345-19 53345-20 69151-3 70060-6 9150-7 9150-8 1757-96 5382-41 5382-43 5382-45 74119-1 74517-2 53345-21 74602-1 79814-3			
Paper Mills	Soluble concentrate: 53345-22 56485-4 69151-4 69151-3 70060-6	None stated	4.5 gallons product per 100 tons of paper .01 – 5.0 ppm (3.2 – 12.8 fluid ounces per 1,000 gallons of water	None stated

Use Site	Formulation/ EPA Reg No.	Method of Application	Application Rate/ No. of applications	Use Limitations
	74602-1 9150-7 9150-8 10707-32 21164-6 21164-8 21164-9 21164-21			
Industrial Processes and water systems				
Paper Mills	Soluble concentrate: 46207-5 5382-41 5382-42 5382-43 5382-45 74119-1 74517-2 53345-21 74655-2	None stated	4.5 gallons product per 100 tons of paper 1.25 – 5.0 ppm (3.2 – 12.8 fluid ounces per 1,000 gallons of water	None stated

APPENDIX B: Chlorine dioxide and Sodium Chlorite* (Case 4023)

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Chlorine Dioxide and Sodium Chlorite. These requirements apply to Chlorine Dioxide and Sodium Chlorite in all products, including data requirements for which a technical grade active ingredient is the test substance. The data table is organized in the following formats:

1. **Data Requirement** (Columns 1 and 2). The data requirements are listed by Guideline Number. The first column lists the new Part 158 Guideline numbers, and the second column lists the old Part 158 Guideline numbers. Each Guideline Number has an associated test protocol set forth in the Pesticide Assessment Guidance, which are available on the EPA website.

2. **Guideline Description** (Column 3). Identifies the guideline type.

3. **Use Pattern** (Column 4). This column indicates the standard Antimicrobial Division use patterns categories for which the generic (not product specific) data requirements apply. The number designations are used in Appendix B.

   (1) Agricultural premises and equipment
   (2) Food handling/ storage establishments' premises and equipment
   (3) Commercial, institutional and industrial premises and equipment
   (4) Residential and public access premises
   (5) Medical premises and equipment
   (6) Human water systems
   (7) Materials preservatives
   (8) Industrial processes and water systems
   (9) Antifouling coatings
   (10) Wood preservatives
   (11) Swimming pools
   (12) Aquatic areas

3. **Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement, this column will identity each study by a "Master Record Identification (MRID) number. The listed studies are considered "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of each study.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	1-4, 5, 8, 11	41467601, 41467602
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process	1-4, 5, 8, 11	41467601, 41467602
830.1670	61-2b	Formation of Impurities	1-4, 5, 8, 11	41467601, 41467602
830.1700	62-1	Preliminary Analysis	1-4,, 5, 8, 11	41467601, 41467602
830.1750	62-2	Certification of Limits	1-4, 5, 8, 11	41467601, 41467602
830.1800	62-3	Analytical Method	1-4, 5, 8, 11	41467601, 41467602
830.6302	63-2	Color	1-4, 5, 8, 11	41467601, 41467602
830.6303	63-3	Physical State	1-4, 5, 8, 11	41467601, 41467602
830.6304	63-4	Odor	1-4, 5, 8, 11	41467601, 41467602
830.7200	63-5	Melting Point	1-4, 5, 8, 11	41467601, 41467602
830.7220	63-6	Boiling Point	1-4, 5, 8, 11	41467601, 41467602
830.7300	63-7	Density	1-4, 5, 8, 11	41467601, 41467602
830.7840 830.7860	63-8	Solubility	1-4, 5, 8, 11	41467601, 41467602
830.7950	63-9	Vapor Pressure	1-4, 5, 8, 11	41467601, 41467602
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	1,4, 5, 8, 11	41467601, 41467602
830.7000	63-12	pH	1-4, 5, 8, 11	41467601, 41467602

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
830.6313	63-13	Stability	1-4, 5, 8, 11	41467601, 41467602
830.6314	63-14	Oxidizing/Reducing Action	1-4, 5, 8, 11	41467601, 41467602
830.6315	63-15	Flammability	1-4, 5, 8, 11	41467601, 41467602
830.6316	63-16	Explodability	1-4, 5, 8, 11	41467601, 41467602
830.6317	63-17	Storage Stability	1-4, 5, 8, 11	41467601, 41467602
830.6319	63-19	Miscibility	1-4, 5, 8, 11	41467601, 41467602
ECOLOGICAL EFFECTS				
850.1300	72-4	Fish early life-stage testing-freshwater		Data gap
850.1400	72-4b	Invertebrate life-cycle testing - freshwater		Data gap
850.4225	123-1	Seedling emergence dose-response in rice		Data gap
850.4250	123-1	Vegetative vigor dose-response in rice		Data gap
850.4400	123-2	Aquatic vascular plant dose-response toxicity- *Lemna* sp.		Data gap
850.5400	123-2	Acute algal dose-response toxicity - 4 species		Data gap (only one species tested- MRID 41880403)
850.2100	71-1	Avian Acute Oral Toxicity Test (Quail/Duck)		ACC259373,ACC257341, ACC253378, MRID 31610, ACC254177, ACC252854
850.1075	72-1	Fish Acute Toxicity – Freshwater (Rainbow Trout)		MRID94068007, ACC254181, ACC254180, ACC252854, ACC245697, ACC69810, ACC253379, MRID94068006
850.1010	72-2	Acute Aquatic Invertebrate Toxicity		MRID146162, MRID141149, MRID131350, ACC254182, MRID94068009

DATA REQUIREMENT				CITATION(S)
New Guideline Number	Old Guideline Number	Study Title	Use Pattern	MRID Number
		TOXICOLOGY*		
870.1100	81-1	Acute Oral - Rat		MRID 43558601
870.1200	81-2	Acute Dermal - Rabbit		MRID 40168704
870.1300	81-3	Acute Inhalation - Rat		MRID 42484101
870.2400	81-4	Primary Eye Irritation - Rabbit		MRID 43441903
870.2500	81-5	Primary Dermal Irritation - Rabbit		MRID40168704
870.2600	81-6	Dermal Sensitization		Data gap
870.3100	82-1a	90-Day Oral (gavage) -Rat		MRID 42301601
870.3465	82-4	28/90-Day Inhalation - Rat		Open literature
870.3700	83-3	Developmental Toxicity -Rat		Open literature
870.3700	83-3	Developmental Toxicity - Rabbit		MRID 41715701
870.3800	83-4	Two-generation Reproduction - Rat		MRID 45358901
870.5265	84-2	Bacterial Reverse Mutation Assay		Open literature
870.5300	84-2	Detection of gene mutations in somatic cells		ACC265867
870.5385	84-2	Micronucleus Assay		Open literature
870.4200	83-2	Carcinogenicity		Data gap

**** Databases for chlorine dioxide and sodium chlorite were used interchangeably.***

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket located in Room S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

The docket initially contained the draft risk assessments and related documents as of April 28, 2004. Sixty days later the first public comment period closed. The EPA then considered all comments and revised the risk assessments.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.regulations.gov, docket ID # **EPA-HQ-OPP-2006-0328.**

These documents include:

1. Chlorine Dioxide Draft Risk Assessment, 4/6/2006.
2. Chlorine Dioxide Toxicology Disciplinary Chapter, 4/5/2006.
3. Chlorine Dioxide Occupational and Residential Exposure Assessment, 4/5/2006.
4. Chlorine Dioxide Environmental Fate and Transport Assessment, 4/5/2006.
5. Chlorine Dioxide Product Chemistry Chapter, 4/5/2006.
6. Chlorine Dioxide Dietary Exposure Assessment, 4/6/2006.
7. Chlorine Dioxide Environmental Hazard and Risk Assessment, 4/6/2006.
8. Chlorine Dioxide Incident Reports, 2/23/2006.
9. Chlorine Dioxide Environmental Modeling Chapter, 6/28/2005.

Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Chlorine Dioxide Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

1. MRID Studies

MRID #	Citation
31610	Fletcher, D. 1973. Acute Oral Toxicity Study with Sodium Chlorite in Bobwhite Quail. Unpublished Data. Conducted by Industrial BIO-TEST Laboratories, Inc. for Olin Corporation.
69809	1978. Acute Toxicity of Sodium Chlorite to Bluegill (*Lepomis macrochirus*). Unpublished Data. Conducted by EG&G, Bionomics, Aquatic Toxicology Laboratory for Olin Chemicals.
69810	1979. Acute Toxicity of Sodium Chlorite to Rainbow Trout (*Salmo gairdneri*). Unpublished Data. Conducted by EG&G, Bionomics, Aquatic Toxicology Laboratory for Olin Chemicals.
80194	Sousa, J.V. 1981. Acute Toxicity of Sodium Chlorite to Bluegill(*Lepomis macrochirus*). Unpublished Data. Conducted by EG&G, Bionomics for Olin Chemicals.
118007	Sousa, J.V. and D.C. Surprenant. 1984. Acute Toxicity of AC-66 to Rainbow Trout (*Salmo gairdneri*). Unpublished Data. Conducted by Springborn Bionomics, Inc. for Calgon Corporation.
130649	Fink, R. 1977. Eight-day Dietary LC50 - Bobwhite Quail – Sodium Chlorite. Unpublished Data. Conducted by Wildlife International, Ltd. for Olin Corporation.
130650	Fink, R. 1977. Eight-day Dietary LC50 – Mallard Duck – Sodium Chlorite. Unpublished Data. Conducted by Wildlife International, Ltd. for Olin Corporation.
131350	Vilkas, A.G. 1976. Acute Toxicity of Textone to the Water Flea *Daphnia magna* Strauss. Unpublished Data. Conducted by Aquatic Environmental Sciences for Olin Corporation.
131351	Sleight III, B.H. 1971. Acute Toxicity of Sodium Chlorite to Bluegill (*Lepomis macrochirus*) and Rainbow Trout (*Salmo gairdneri*). Unpublished Data. Conducted by Bionomics, Inc.
141149	Hoberg, J.R. and D.C. Surprenant. 1984. Acute Toxicity of AC-66 to Daphnids (*Daphnia magna*). Unpublished Data. Conducted by Springborn Bionomics, Inc. for Calgon Corporation.

141151 Fletcher, D. 1984. 8-Day Dietary LC50 Study with Sodium Chlorite in Bobwhite Quail. Unpublished Data. Conducted by Bio-Life Associates, Ltd. for Calgon Corporation.

141152 Fletcher, D. 1984. Acute Oral Toxicity Study with Sodium Chlorite in Bobwhite Quail. Unpublished Data. Conducted by Bio-Life Associates, Ltd. for Calgon Corporation.

142327 McMillen, C. 1984. Static Bioassay on Sodium Chlorite to Rainbow Trout and Bluegill Sunfish. Unpublished Data. Conducted by Environmental Research Group, Inc. for Rio Linda Chemical Company, Inc.

143970 Fletcher, D. 1984. 8-Day Dietary LC50 Study with Sodium Chlorite in Mallard Ducklings. Unpublished Data. Conducted by Bio-Life Associates, Ltd. for Calgon Corporation.

144730 Robaidek and Johnson, 1985. Avian Single-dose Oral LD50: Bob White Quail (*Colinus virginianus*). Unpublished Data. Conducted by Hazleton Laboratories America, Inc. for Rio Linda Chemical Company.

145405 Beavers, 1984. An Acute Oral Toxicity Study in the Mallard with Sodium Chlorite. Unpublished Data. Conducted by Wildlife International, Ltd. for TR America Chemicals, Inc.

145406 Beavers, 1984. An Acute Oral Toxicity Study in the Bobwhite with Sodium Chlorite. Unpublished Data. Conducted by Wildlife International, Ltd. for TR America Chemicals, Inc.

145407 Beavers, 1984. A Dietary LC50 Study in the Mallard Duck with Sodium Chlorite. Unpublished Data. Conducted by Wildlife International, Ltd. for TR America Chemicals, Inc.

145408 Beavers, 1984. A Dietary LC50 Study in the Bobwhite with Sodium Chlorite. Unpublished Data. Conducted by Wildlife International, Ltd. for TR America Chemicals, Inc.

145409 Larkin, J. 1984. The Acute Toxicity of Sodium Chlorite to Rainbow Trout (*Salmo gairdneri*). Unpublished Data. Conducted by Biospherics Incorporated for TR America Chemicals, Inc.

145510 Larkin, J. 1984. The Acute Toxicity of Sodium Chlorite to Bluegill Sunfish (*Lepomis macrochirus*). Unpublished Data. Conducted by Biospherics Incorporated for TR America Chemicals, Inc.

145411 Larkin, J. 1984. Acute Toxicity of Sodium Chlorite to *Daphnia magna* Strauss. Unpublished Data. Conducted by Biospherics Incorporated for TR America Chemicals, Inc.

146162 Barrows, 1984. The Acute Toxicity of Sodium Chlorite Technical to the Water Flea, *Daphnia magna* in a Static Test System. Unpublished Data. Conducted by Biospherics Incorporated for Degussa Corporation.

148727 Robaidek, E. 1985. Avian Single-Dose Oral LD_{50} Bobwhite Quail. Unpublished Data. Conducted by Hazleton Laboratories America, Inc. for Degussa Corporation.

161875 1984. 96-Hour LC50 in Juvenile Rainbow Trout. Unpublished Data. Conducted by Microbiological and Biochemical Assay Laboratories for Magna Corporation.

161876 1984. 48-Hour LC50 in *Daphnia magna*. Unpublished Data. Conducted by Microbiological and Biochemical Assay Laboratories for Magna Corporation.

161877 1984. Avian Dietary LC50 in Bob White Quail. Unpublished Data. Conducted by Microbiological and Biochemical Assay Laboratories for Magna Corporation.

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Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the Chlorine Dioxide RED for a list of studies that the Agency plans to require.

Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date.

Appendix G. Batching of Chlorine Dioxide and Sodium Chlorite Products for Meeting Acute Toxicity Data Requirements for Reregistration

The Agency intends to complete batching at a later date.

Appendix H. List of All Registrants Sent the Data Call-In

A list of registrants sent the data call-in will be posted at a later date.

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:
http://www.epa.gov/opprd001/forms/

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit
www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit that contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program—Storage and Disposal Statements

   b. 84-1 Clarification of Label Improvement Program

   c. 86-5 Standard Format for Data Submitted under FIFRA

   d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

   a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

   b. EPA Form No. 8570-4, Confidential Statement of Formula

   c. EPA Form No. 8570-27, Formulator's Exemption Statement

   d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

   e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

   a. Registration Division Personnel Contact List

   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

   c. Antimicrobials Division Organizational Structure/Contact List

   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

   g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: http://npic.orst.edu .

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.
To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.

Attachment 5

10. Safety Information Including MSDS & Substance Report NIEHS

§171.1(c)(E) SAFETY OF THE ACIDIFIED CHLORITE/CHLOROUS ACID SYSTEM

In considering the safety aspects of the acidified chlorite/chlorous acid system as applied to the treatment of poultry surfaces, the known toxicology of oxychlorine species should first be reviewed. This information has been provided in Section 171.1 (c)(A) of this document under "Biology of Inorganic Oxychlorine Species." In that section, an overview is provided on the impact of oxychlorinee on the body, with summary paragraphs on the individual species of sodium chlorite, chlorine dioxide and sodium chlorate. In Exhibit I of the section is a document, prepared for Alcide Corporation by Arthur D. Little, entitled "Review and Evaluation of Published Toxicology and Related Data on Chlorine Dioxide, Sodium Chlorite, Sodium Chlorate, and Chlorous Acid." It is suggested that this document and the summary paragraphs be studied before proceeding further.

The safety of this food-processing disinfection system, as a secondary direct food additive, can be established through the standard approach of determining the maximum amount of residual materials and artifacts resulting from contact with the antimicrobial, and establishing the toxicological implications associated with the levels of such chemicals found. And, in specialized situations where no residues or transformation products are found, establishing the lowest limit of detectability of such materials and the safety associated with residues or artifacts which could be present in amounts just below those detection limits.

The residues or transformation products which could possibly result from poultry processing with acidified chlorite solutions would be as follows:

* Inorganic; oxychlorines (ClO_2^-, ClO_3^-)
* Chloroorganics; chlorinated lipids chlorinated proteins/ derivatives
* Oxidized organics; lipids proteins-component amino acids

Excluded from this listing are residual amounts of any of the activating (GRAS) acids, or anions thereof, and the sodium chloride which forms upon reduction of the chlorite. The low levels of all of these species are much below levels of concern. It should be noted, at this point, that the higher levels of chlorite and GRAS acid are applied to the poultry carcass immediately prior to immersion in a chiller tank, where residues of those molecules are washed from the carcass. Of major interest, therefore, are any foreign chemical species which result from extended contact in the cold chiller waters. Nonetheless it is possible that the brief contact with the pre-spray or dip solutions could effect some rapid change in poultry carcass components (i.e. chlorination and/or oxidation).

Oxychlorine Residues and Safety

OXYCHLORINE RESIDUES:

A study was carried out to determine the levels of chlorite and chlorate which remain on the surface of chicken carcasses as a result of exposure to either the pre-spray/dip or the chiller-water treatment, at maximum exposure levels for each treatment type.

Specifically used were:

- Pre-dip with 1200 ppm sodium chlorite;

  pH = 2.5 ± .05, with phoephoric acid;

  contact time = 5 sec., then 5 min. drip, then 1 hr. immersion in water at ≤ 5°C;

  Control study with 5 sec. immersion in tap water, 5 min. drip and chill tank.

- Chill tank with 150 ppm sodium chlorite;

  pH = 2.8 ± .05, with phosphoric acid;

  contact time = 1 hr. at ≤5°C, then 5 min. drip;

  Control study with 1 hr. immersion in tap water at ≤5°C, then 5 min. drip.

The chiller tank study was divided into two segments, with respect to measurement of residual oxychlorines on the poultry carcasses:

* Level of oxychlorines remaining on the carcasses right after removal from the chiller, while the carcasses are still wet; (time "0");

* Level of oxychlorines remaining on the carcasses after various time periods approximating the subsequent time exposed to air prior to packaging or further processing (e.g. into parts or deboning/skinning).

Pre-Dip Study

The results of the duplicate exposure of two chicken carcasses to the conditions indicated above, representing maximum proposed treatment conditions, were as follows:

* Chlorite ion: (Time "0") None detected, i.e. <0.25 ppm (<250 ppb) per ml of rinse water. Since both rinse waters were diluted

to 65 ml, the level of chlorite per carcass (average weight of 1751 ± 54 gms) was:

Chlorite residue = <0.009 ppm

- Chlorate ion: (Time "0")None detected, i.e. <0.30 ppm (<300 ppb) per ml of rinse water. As above, this corresponds to:

  Chlorate residue = <0.011 ppm

The laboratory report on this study is included in Appendix III.

Chiller Study

Phase I

This phase of the study was designed to determine the level of oxychlorines which remain on the wet carcass, after removal and a 5-minute drip period (Time "0"), but prior to completion of the processing operation. Two maximizing conditions obtain in this exposure study:

- The sodium chlorite level and pH are set at the maximum range of petitioned conditions (i.e., sodium chlorite of 150 ppm [petitioned 50-150 ppm]; pH of 2.8 [petitioned 2.8-3.2]);
- The static chiller exposure provided for a uniform concentration of chlorite and acid for the 1-hour contact, whereas in a commercial chiller operation the acid/chlorite solution would be continuously diluted in the countercurrent movement of carcass and fresh-water infusion (containing the treatment components).

The results of the chiller study, in which two chicken carcasses were exposed to maximum treatment levels of the petitioned chemicals, (measured at time "0"), were as follows:

- Chlorite ion: Carcass (1) - =18 ppm in 65 ml of rinse water, equivalent to:

  chlorite residue = 0.67 ppm on a 1751 gm carcase

  Carcass (2) - =11 ppm in 65 ml of rinse water, equivalent to:

  chlorite residue = 0.41 ppm on a 1751 gm carcass

Average chlorite residue = 0.54 ppm on carcass following removal from a chiller tank, under maximum

conditions.

* Chlorate ion: Carcass (1) - none detected (<0.50ppm)
  Carcass (2) - none detected (<0.50ppm)
  (both per 65 ml of rinse, corresponding to <0.019 ppm)

Average chlorate residhe = <0.019 ppm on carcass following removal from a chiller tank, under maximum conditions.

Even assuming no further degradation of the chlorite on a poultry carcass so exposed, based on the known instability of chlorite ion, particularly when a carcass is exposed to the heat associated with cooking, the likelihood of detecting chlorite on a poultry carcass following chill tank exposure to the acidified chlorite solution at maximum petitioned exposure conditions is considered by the petitioner to be non-existent. Phase II of this study confirmed the fact that the survival of chlorite on the poultry carcass is limited, upon continued exposure of the carcass to ambient conditions.

Phase II

This phase of the treatment study, as detailed in the Report provided in Appendix III, was carried out to determine the fate of any residual chlorite and chlorate ions on poultry carcasses upon exiting from an acidified chlorite-containing commercial chill tank. The study utilized the same exposure conditions as provided in the Phase I chiller exposure, and followed chlorite and chlorate levels on the poultry carcasses after 10 minutes, 1 hour, 2 hours, 4 hours and 20 hours (overnight). The average of the duplicate results were as follows; expressed as a residue with respect to the average 3.5 # chicken carcass.

Time Post-Chiller	Chlorite Level ppm
10 minutes	0.092
1 hour	0.021
2 hours	<0.016
4 hours	<0.016
20 hours	<0.016

Thus, even before the carcass completes the processing operation and leaves the commercial facility, the chlorite levels on the average poultry carcass fall below ~0.016 ppm.

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Safety

To put the potential ingestion of such levels of oxychlorines into proper perspective, reference can be made to the known toxicology of these materials. A summation of known published information has already been provided in §171.1(c)(A) Biological Properties. A relevant practical application of this information has been made by those concerned with the safety of drinking water which has been exposed to chlorine dioxide, as an alternative to chlorine, for disinfection purposes. Chlorite is an immediate reduction product of ClO_2, and some chlorate can form as well, and as a result guidelines have been set for residues of these species in potable water. A good summation of relevant information on chlorite and chlorate may be found in a booklet published jointly by the Chemical Manufacturers Association, The American Water Works Association-Research Foundation and the U.S. Environmental Protection Agency[3]. Relevant sections (from page 178) follow:

> A recently completed rodent 90-day study . . . . . was conducted . . . . . in accordance with current Agency guidelines for sub-chronic studies and Good Laboratory Practice (GLP) standards. (This is considered to be) the most definitive and comprehensive study of chlorite undertaken and is considered to be the most relevant basis for risk assessment. Using the NOEL (no observed effect level) of 7.5 mg/kg/day is considered to be the most relevant basis for risk assessment. (Dividing this NOEL by a 100-fold safety factor yields the
>
> maximum suggested intake of chlorite = 0.075 mg/kg/day)

> Is the Uncertainty (Safety) Factor of 100 Appropriate?
>
> . . . . . All the studies to date with chlorine dioxide, chlorite ion, and chlorate ion have confirmed that there are no cumulative effects and thus the need to use the factor of 10 for extrapolation from sub-chronic NOELs is unnecessary. Based on the overall body of toxicological information that has been developed for these compounds, a safety factor of 100 would be considered appropriate.
>
> (From another consideration, that of the potential for chlorite to decrease erythrocyte glutathione (GSH) by oxidation, a series of studies referred to in the earlier section on Biological Properties has led the Panel at the CMA meeting to conclude:)
>
> It is more relevant in the risk assessment process to use the NOEL for effects on the erythrocyte. Based on the effects on erythrocytes the NOEL is considered to be 5 mg/kg/day. (With a Safety Factor of 100, this would equate to a
>
> maximum suggested intake of chlorite = 0.050 mg/kg/day)

On the basis of this information, the following calculation may be made with respect to ingestion of chlorite levels at the

---

3) See Reference 8.

lowest detectability level of 0.01 ppm on a poultry carcass. A 70 kg person could safely ingest 0.05 mg of chlorite x 70 kg, or 3500 µg of chlorite per day. If 20% of this is derived from food (the rest being from drinking water, as is the current convention by regulatory authorities in the drinking water field), then a maximum safe daily food intake would be 700 µg. That 70 kg person, if ingesting one half pound of chicken daily, containing 0.016ppm of chlorite, would consume 0.016 µg/gm x 227 gm, or 3.63 µg of chlorite. **This is only 0.5% of a safe level of ingestion, taking into account that the safe level includes the 100-fold safety factor based on the lowest NOEL for chlorite, and that only 20% of the daily chlorite derives from poultry. This also assumes ingestion of uncooked chicken, which has not been exposed to heat which will destroy any residual chlorite.**

The same considerations, including the 100-fold safety factor, apply to chlorate, where the publication just cited (Page 180,1) provides a NOEL of 78 mg/kg/day. Using the 100-fold safety factor, a safe intake of 0.78 mg/kg/day is calculated. This corresponds, for chlorate, to a maximum safe daily intake of 54.5 mg/day for a 70 kg individual. That 70 kg person, if ingesting one half pound of chicken daily, containing 0.011 ppm of chlorate, would consume 0.011 µg/gm x 227 gm, or 4.5 µg of chlorate. **This is only 0.009% of a safe level of ingestion, taking into account that the safe level includes the 100-fold safety factor applied to the NOEL for chlorate, and that only 20% of the daily chlorate derives from poultry. It also does not take into account the subsequent cooking of the chicken.**

Chloroorganics and Safety

CHLOROORGANICS

Two studies were carried out, in which the presence of new-formed chloroorganic materials would be evident. One specifically focused on the formation of chlorinated lipids, under exaggerated exposure conditions of concentration and time. The other study involved the examination of poultry carcasses that had been exposed, in a pilot-scale operation, to acidified chlorite systems which would fall within the range requested in the FAP. The latter study, by its nature, would include chloroorganics, whether lipid-like or proteinaceous, as well as any other product that might form and be detectable by GC/MS or amino-acid distribution analysis.

Exaggerated-Exposure Study

Treatment solution*:	Sodium chlorite	2,525 ppm
	Lactic acid	1.393%
	pH	2.78
Temperature:	Ambient	
Contact Time:	5-minute immersion	
Poultry Type:	Chicken wings*:	

* The exposure solution was the Alcide LD high-level disinfectant which contains, in addition to the active ingredients, EDTA (at 0.114%) and Poloxamar-188, a non-ionic surfactant (at 0.25%). The exposure was in duplicate. Two Control samples were run as well, with DI and tap water. There is no intention to include the two above-mentioned additives in acidified chlorite poultry disinfecting solutions. That solution was being considered for food processing disinfection, but it has been simplified to a chlorite solution activated with a GRAS acid.

† Wings were selected as representing the poultry part with the highest surface-to-volume ratio, i.e., the greatest potential for detectable changes per unit weight.

These conditions represent an exaggeration of proposed exposure conditions, on the following basis:

a) The sodium chlorite level is 2.1X the maximum level requested in the FAP for pre-chilling application; the lactic acid is also ~2.1X higher than required for adjustment of the requested chlorite solution.

b) The 5-minute immersion is significantly longer than the brief dip (ca. 5-sec.) or spray contact proposed. This could amplify potential reactions.

The carcasses were rinsed with DI water after exposure, blotted dry, and soaked in AR-grade hexane overnight. They were then submitted to a contract-testing laboratory for gas chromatographic evaluation. The report of that analysis is contained in Appendix IV.

The analytical approach that was followed was based on the fact that the identity of potential chlorinated lipids could not be established *a priori*. The procedure that was used is described in §171.1(c)(D), Chlorinated Organics, Gas Chromatography with Specific Halogen Detection. The hexane extracts were evaporated to obtain the lipid residues, which were then subjected to column partitioning and cleanup and subsequent chromatography. As the report indicates, "No chlorinated organics were found." To obtain an approximate quantification of the lowest limit of detectability of some unknown chlorinated entity, the known detection limits of a wide range of chlorinated pesticides are listed in the report (i.e. not found in the samples). An approximate average detection limit, for singly-chlorinated molecules, is about 0.05 mg/kg (ppm), which can be tentatively assigned to new-formed chlorinated lipids as well. Thus the lipid fractions of the treated poultry carcasses can be assumed to have <ca. 0.05 ppm of chlorinated species. To express this on the basis of the whole carcass, one can factor in the percentage of lipid in the whole carcass, which is normally in the 2%-4% range. Rounding this upward to 5%, the <0.05 x (5/100) = <0.0025 ppm. Thus it can be approximately estimated that the chlorinated

lipids that form in poultry carcasses exposed to a 2-fold concentration of the highest level of proposed acidified/chlorite pre-chilling treatment, for an excessive time period = ≤0.0025 ppm.

Pilot-Scale Study:

This investigation was based on the carcasses that were treated in STUDY NO. IX described in §171.1(c)(C). Specifically, two of each of the Control carcasses, and those that were exposed to phosphoric acid activated sodium chlorite solutions at 61 and 76 ppm, in pilot-scale chill tanks, were quick frozen under dry ice and shipped to the testing laboratory for evaluation. The report provided in Appendix V is a summary of the results. In the various procedures that were followed, which are described in both the study report and §171.1(c)(D), attempts were made to detect the presence of new-formed organic materials, whether through chlorination, oxidation, or other chemical transformation process. Thus, although this description is being included in the FAP section dealing with Chlorcorganics, it is also applicable to the following section dealing with Oxidized Organics.

For purposes of clarification, the designation of the treatments, on Page 1 of the report, as 1:1:400 and 1:1:500, correspond to sodium chlorite concentrations of 76 ppm and 61 ppm, respectively. (The designations refer to Concentrate concentrations of the chlorite and the acid.)

The Conclusion on page 19 of the report, in part, is appropriate to reproduce below, as an overview of their findings:

> The fatty acid and amino acid distributions of flesh from poultry carcasses exposed to an acid/chlorite disinfectant, and tap water have been examined. The fatty acid and amino acid distributions from the control and disinfected carcasses were essentially identical within experimental error . . . . . In conclusion, there is no evidence that exposure of poultry carcasses to chlorous acid resulted in oxidation and/or chlorination of the lipid and amino acids (or proteins).

The quantification of "essentially identical within experimental error" is problematic. Since the results were obtained on duplicate samples, the analyst was able to compare data sets with error bars reflecting the variations between individual results. The results from each sample, and the Control, fall uniformly within the overlap of their error bars. Where occasional trends seem to appear, as for example in Figure 2, with trends in average increases for palmitic, palmitoleic, and stearic acids, and decreases in oleic acid for the series Control->1:400->1:500, this corresponds to changes in chlorite concentration from 0->76 ppm->61 ppm. This "trend" therefore, is counter to logic, and below significance.

A similar conclusion applies to the other determinations, i.e., the sterol-associated components and the amino acid components. The variations in concentrations of individual lipid or amino

acid species, for either treatment or control, have a significant degree of overlap such that no trends can be noted in any of these materials which are consistent with concentration differences.

Safety

The results from the exaggerated exposure study, where chicken parts were exposed to excess levels of chlorite and acid in a pre-chilling exposure, provide a numerical basis for quantifying the absence of chlorinated lipids. The conclusion, that chlorinated materials are present at <0.0025 pm of carcass weight, while only an approximation, are consistent with the known chemistry of oxychlorine sytems, where oxidation is the primary reaction product with unsaturated compounds. No attempts were made to carry out specific studies related to the formation of smaller chloroorganics (e.g. trihalomethanes) from smaller poultry organics, since it has been well documented that oxychlorines have little tendency to create such species (as cf. chlorine/hypochlorite[2,3]).

The pilot-scale exposure study, under more normal exposure conditions in a simulated chiller, confirms the absence of detectable chloro-organics or other treatment artifacts, although a detectability limit could not be practically established. This absence of new materials applies to lipids (fatty acids and sterols) and amino acid components of proteins (acid- and base-hydrolyzed).

Oxidized Organics and Safety

OXIDIZED ORGANICS

Two studies were carried out which directly measured the degree of lipoxidation of poultry lipids, in comparison with that provided by chlorine. The latter is permitted in poultry chill tanks at levels up to 50 ppm, and is also used in processing waters (e.g. sprays, rinses) at lower levels. In addition the study, cited previously, on changes in amino acid compositions bears directly on oxidative effects, since certain amino acids, such as tyrosine, tryptophane, and the sulfur-bearing cystine and methionine, are known to be susceptible to oxidation by the oxychlorines. As in the previous section, the experiments comprised an exaggerated-exposure study and a pilot-scale exposure.

Exaggerated-Exposure Study

Treatment solution*:	Sodium chlorite	150 ppm
	Lactic Acid	0.0828%
	pH	3.05
Temperature:	5°C	
Contact Time:	45 minutes	

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Poultry Type: Skin tissue removed from drumsticks

* The exposure solution was a dilution of the Alcide LD high-level disinfectant which contained upon dilution, in addition to the active ingredients, EDTA (at 68 ppm) and Poloxamer-188, a non-ionic surfactant (at 0.015%). The dilution was prepared in tap water.

The study was run on 10-gram portions of skin carefully dissected from commercially packaged drumsticks in a manner to obtain maximum fatty tissue. Eight replicate studies were carried out on this exposure. Also run, in octuplicate, were Control samples and samples exposed to 50 ppm chlorine (prepared by dilution of commercial 50,000 ppm (5.0%) chlorine bleach, standardized by iodometry). After immersion in the Treatment or Control solutions, the tissues were withdrawn and rinsed for 1-minute in 5°C DI water. The tissues were then transferred to a distillation flask containing 250 ml of DI water adjusted to pH 1.5 with 5N HCl. A 50 ml distillation fraction was collected, over ~35 minutes, and 5 ml of distillate was reacted with 5 ml of TBA reagent, as described in the procedure provided in §171.1(c)(D). The test tube was then heated as described in the procedure, cooled and read spectrophotometrically at 534 nm *vs.* a blank. Absorbance figures were converted to mg malonaldehyde/liter by a calibration graph constructed from 0.4 - 2.2 mg/liter concentrations of TEP (1,1,3,3-tetraethoxypropane). The Absorbance data were individually converted to TBA numbers (mg malonaldehyde/kg) from the following conversion equation:

$$\text{TBA number} = [6.46 \times A - 0.0396] \times 5$$

The averages of the eight (8) results for each set, including the standard deviation at the 95% confidence level, were as follows:

TBA Values

Treatment	TBA Value
	--mg malonald./kg--
150 ppm $NaClO_2$, pH ~3.0	1.062 ± 0.129
50 ppm chlorine	2.418 ± 0.097
Control	0.383 ± 0.065

Subtracting the Control values from each of the treatments, to determine the effects of each of the two systems, gives:

Increased TBA value from [H⁺]/$NaClO_2$ = 0.679 mg/kg

Increaseed TBA value from chlorine = 2.035 mg/kg

The relative increase in TBA value from the 50 ppm chlorine, as

compared with the 150 ppm chiller treatment (maximum requested level in this FAP), was 3.0 fold higher.

Pilot-Scale Study:

This investigation was based on the carcasses that were treated in STUDY NO. IX described in §171.1(c)(C). Specifically, two of each of the Control carcasses, and those that were exposed to phosphoric acid activated chlorite solutions at 61 and 76 ppm, in pilot-scale chill tanks, were quick frozen under dry ice and shipped to the testing laboratory for evaluation. The procedure for determining the TBA value of the extracted lipids, as described in full detail in the Oxidation Products section of §171.1(c)(D) was applied here to the two fractions of the crude lipid extracts isolated from the carcasses. The report on this study, included in Appendix V, provides the resulting data in bar-graph form, in Figure 4, page 16, for both fractions. While the solid phase of the crude extract (presumably containing the sterol fraction of the lipids) shows no significant differences among treatment and control carcasses, the Absorbance of the UV irradiated positive-control sample of lipids reflects a marked increase in oxidation products. The oil phase appears to show a small Absorbance increase with respect to treatment concentration (i.e. 1:500 and 1:400, corresponding to 61 and 76 ppm of sodium chlorite). Again the postive control, of UV irradiated lipids, shows a marked increase in Absorbance proportionate to significantly enhanced lipoxidation.

The latter report does not quantify the data in terms of mg malonaldehyde per kg, as in the earlier study. However, using the actual data used to construct the bar graphs, in conjunction with the earlier figures from the exaggerated exposure on chicken skin, it is possible to compare the two sets of data via the ratios of either TBA values or Absorbance units with respect to their own controls. It would first be instructive to tabulate the Absorbance data from the latter report for the various treatments, as follows:

TBA Absorbance Values

Sample Origin	Oil Phase	Solid Phase
	---Absorbance Units/gm---	
Control	1.20	3.86
61 ppm $NaClO_2$	2.29	4.22
76 ppm $NaClO_2$	2.73	4.20
Positive Control	10.80	27.03

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By referring these data, and the earlier data from the exaggerated exposure study, to their own negative controls (i.e. normalizing the data), the following ratios of TBA values are obtained:

Treatment	Exaggerated Study	Pilot Scale Study	
	--------Relative TBA Values--------		
		Oil Phase	Solid Phase
Negative Control	(1)	(1)	(1)
61 ppm $NaClO_2$	-----	1.90	1.09
76 ppm $NaClO_2$	-----	2.27	1.11
150 ppm $NaClO_2$	2.77	-----	-----
50 ppm Cl_2	6.31	-----	-----
Positive Control	-----	9.00	7.00

Safety

Oxidized Lipids

There is a clear relationship between concentration of acidified sodium chlorite in the chill tanks and the degree of malonaldehyde formation by lipoxidation. The 50 ppm chlorine treatment, which is the maximum approved concentration allowed in poultry chiller tanks, causes the greatest oxidation. It is not feasible to effect a direct comparison between the "exaggerated" and the "pilot-scale" studies, because of the differences in conditions and poultry carcasses, but it can be concluded that **the degree of lipid oxidation by the proposed acidified chlorite treatment is within the range of oxidative effects caused by the federally-approved 50 ppm chlorine use in poultry chiller tanks.**

Oxidized Protein

The data which are included in the report in Appendix V include information on the non-detectable variations that occur in the amino acids which are particularly susceptible to oxidation by oxychlorines. The distibution patterns shown in Figure 5, and the conclusions drawn on page 19 on the basis of those patterns, indicate that no differences can be noted between the amino acid patterns of the treated poultry surfaces and the control sample. Again, it is not feasible to set lower limits of detectability of potential oxidative changes, although it should be noted that the samples for these analyses were taken from exposed carcass

surfaces rather than throughout the bulk tissue of the body. This would emphasize the detectability of changes, through examination of surface tissue most susceptible to oxidative changes. It is thus concluded that exposure of poultry to these acidified chlorite antimicrobial processing agents causes no detectible variations in the amino acid/protein components of the carcasses.

171.3(c)(G) MODIFICATION OF EXISTING REGULATION

NOT APPLICABLE

MATERIAL SAFETY DATA SHEET

SECTION 1: PRODUCT IDENTIFICATION

CHEMICAL NAME: Sodium Chlorite, Dry

CHEMICAL FORMULA: $NaClO_2$

SYNONYMS: Chlorous Acid, Sodium Salt

DOT INDENTIFICATION NO. UN 1496

SECTION 2: COMPONENT DATA

Chemical Name	CAS Number	% Range	Exposure Standards
Sodium chlorite	7758-19-2	74-88%	None Established
Sodium chloride	7647-14-5	2-24%	None Established
Sodium sulfate	7757-82-6	0–4.5%	None Established
Sodium chlorate	7775-09-9	0-6%	None Established
Sodium hydroxide	1310-73-9	0-4.5%	OSHA: 2 mg/m^3
Sodium carbonate	497-19-8	0-3%	None Established
Water	7732-18-2	1.6-20%	None Established

SECTION 3: PHYSICAL DATA

BOILING POINT: No Data

MELTING POINT: 180-200°C (356-392°F)

DECOMPOSITION TEMPERATURE: 175°C (347°F)

SOLUBILITY IN WATER: 39% at 25°C (77°F)

VAPOR PRESSURE at 25°C: No Data

% VOLATILE BY VOLUME No Data

pH at 25°C: >12 (25% solution)

BULK DENSITY: flakes: 69 lbs./cu.ft.

PELLETS: 55 lbs./cu.ft.

SPECIFIC GRAVITY: No Data

APPEARANCE/ODOR: White flakes or pellets, slight chlorine odor

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SECTION 4: REACTIVITY INFORMATION

SUMMARY OF REACTIVITY: Oxidizer

CONDITIONS TO AVOID: Temperatures above 175°C (347°F)

Mechanical shock or impact, if contaminated with combustible material

INCOMPATIBLE MATERIALS: Acids, acid products (aluminum sulfate, ferric chloride, etc.) reducing agents, combustible materials (wood, paper, fuel, oil, saw dust, garbage), oxidizers (such as hypochlorites), sulfur, dirt, soap, solvents, paints

OTHER CONDITIONS TO AVOID: Contamination with foreign materials

HAZARDOUS DECOMPOSITION PRODUCTS: Explosive and toxic chlorine dioxide gas will be generated on contact with acids and chlorine.

HAZARDOUS POLYMERIZATION: Will not occur.

SECTION 5: FIRE AND EXPLOSION DATA

FLASH POINT: Not Applicable

FLAMMABLE LIMITS (%): Not Applicable

EXTINGUISHING MEDIA: Not Applicable – Choose extinguishing media suitable for surrounding materials.

SPECIAL PRECAUTIONS: Do not drop, skid or roll drum; always keep upright.

CHARACTERISTICS: Strong oxidizer. Mixtures with combustible materials (Including wood, fuels, grease, carbon, clothing, etc.) ignite easily and burn fiercely, or may explode. Avoid contact with flame or burning material, such as lighted cigarette.

SPECIAL FIREFIGHTING PROCEDURES: Approach fire from upwind to avoid hazardous vapors and toxic decomposition products. Use flooding quantities of water as fog or spray. Use water spray to keep fire-exposed containers cool. Extinguish fire using agent suitable for surrounding fire. See Section 7 for protective equipment for fire fighting.

SECTION 6: TOXICOLOGY AND HEALTH INFORMATION

EXPOSURE STANDARDS: None established

IMMEDIATELY DANGEROUS TO LIFE OR HEALTH: There is no level established for this chemical.

ODOR THRESHHOLD: There is no data available on the odor threshold of sodium chlorite.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Deficiency in G6PD enzyme and other red blood cell diseases.

INTERACTIONS WITH OTHER CHEMICALS ENHANCE TOXICITY: None known or reported.

ACUTE TOXICITY

ROUTES OF EXPOSURE: Oral, dermal, inhalation and eye contact.

INHALATION: Inhalation may cause irritation of the mucous membranes and respiratory tract. Symptoms may include coughing, bloody nose, and sneezing. Severe overexposures may cause lung damage.

SKIN: Direct contact may cause severe irritation and/or burns with symptoms of redness, itching, swelling and possible destruction of tissue.

EYE: Mist or direct contact may cause severe irritation and possible burns. Symptoms may include tearing, redness, eye damage due to burns.

INGESTION: Gastroenteritis with any or all of the following symptoms: nausea, vomiting, lethargy, diarrhea, bleeding or ulceration. Acute ingestion of large quantities may also cause anemia due to the oxidizing effects of the chemical.

ANIMAL TOXICOLOGY

Inhalation LC_{50}: No available data

Dermal LD_{50}: > 2g/kg (rabbit)

Oral LD_{50}: Approximately 350 mg/kg (rat)

Irritation: Severe irritant with corrosive action to skin (of rabbit)

Severe irritant to eyes (of rabbit)

FIRST AID

EYES: Immediately flush eyes with large amounts of water for at least 15 minutes while frequently lifting the upper and lower eyelids. Consult a physician immediately.

SKIN: Remove contaminated clothing. Immediately flush exposed skin areas with large amounts of water for at least 15 minutes. Consult a physician if burning or irritation of the skin

persists. Contaminated clothing should be kept wet and must be laundered before re-use.

INGESTION: *DO NOT induce vomiting. Drink large quantities of water.* Consult a physician immediately. DO NOT give anything by mouth if the person is unconscious or having seizures.

INHALATION: Move patient to fresh air and monitor for respiratory distress. If cough or difficulty in breathing develops, administer oxygen, and consult a physician immediately. In the event that breathing stops, administer artificial respiration and obtain emergency assistance immediately.

NOTES TO PHYSICIAN: Chlorine dioxide vapors are emitted when this product contacts acids or chlorine. If these vapors are inhaled, monitor patient closely for delayed development of pulmonary edema which may occur up to 48-72 hours post-inhalation.

Following ingestion, neutralization and use of activated charcoal is not indicated.

CHRONIC TOXICITY

INHALATION: There are no data available on the chronic effects of inhaling sodium chlorite.

SKIN: There are no studies or reports on the repeated effects of dermal exposure to sodium chlorite. Because of the acute effects, repeated direct contact may be unlikely.

INGESTION: The chronic ingestions of low concentrations of this product have been studied in laboratory animals. Concentrations in the drinking water of 100 mg/L and higher have been shown to cause mild anemia and a minor suppression of thyroid functions in laboratory animals. All effects were reversible after cessation of treatment.

Clinical studies of communities using sodium chlorite as a disinfectant found no adverse effects in the human population studied. However, other studies have suggested that those individuals deficient in an enzyme (G6PD) utilized in hemoglobin synthesis might be susceptible to the development of anemia if exposed repeatedly.

CHRONIC TARGET ORGAN TOXICITY: Chlorine dioxide may be formed by reaction of sodium chlorite with acids or solutions of chlorine. Repeated exposures to solutions of chlorine dioxide at concentrations of 10-100 mg/L have produced slight effects upon the thyroid in younger animals and the hematologic system. Exposures to these concentrations can reduce the cellular and blood levels of glutathione, an agent which is protective against the oxidizing effect of this chemical. Exposure of laboratory animals above 100 mg/L in the drinking water have shown a decrease in blood cell glutathione, red blood cell count and hemoglobin. In some studies these levels also caused a slight decrease in thyroid hormones, especially in younger animals.

CARCINOGENICITY: Sodium chlorite is not listed by NTP, IARC, OSHA, EPA, or any other authority as a carcinogen. Carcinogenicity studies conducted in mice and rats did not show an increase in tumors in animals exposed to sodium chlorite in their drinking water.

MUTAGENICITY: Sodium chlorite has been evaluated for possible mutagenic effects in several laboratory tests. Sodium chlorite tested positive in the Ames Salmonella reverse mutation assay without metabolic activators and caused chromosomal aberrations in an In Vitro Chinese hamster fibroblast cell line without metabolic activators. Sodium chlorite also

tested positive in the mouse micronucleus assay when administered intraperitoneally (directly into the body cavity), but was not mutagenic when administered orally. The significance of these test results for human health is unclear because the oxidizing effects of the chlorite or salting effects of sodium may significantly affect the ability of the tests to accurately detect mutagens.

REPRODUCTIVE TOXICITY: Sodium chlorite has not been found to be teratogenic in studies in which animals have been exposed up to 100 mg/L in the drinking water. Male rats repeatedly exposed to concentrations of 100 mg/L or greater have shown slight effects on sperm motility. No effects were observed at 10 mg/L and no effects were observed on the fertility rate, histology of the male reproductive system or conception rate of animals exposed at 10 mg/L or higher.

AQUATIC TOXICITY: Sodium chlorite is slightly toxic to fish and other aquatic organisms. For bluegill (Lepomis machrochirus), aquatic toxicity studies have shown a TL_{50} of 208 mg/l and LC_{50} values of 265-310 mg/l. Rainbow trout (Salmo gairdneri) have been tested and shown acute toxicity values of 50.6 mg/l (TL_{50}) and 290 mg/l (LC_{50}). Of the aquatic species tested, Daphnia have been the most sensitive species tested with an LC_{50} of 0.29 mg/l.

Sodium chlorite is acutely toxic to birds when administered by gavage. The acute oral LD_{50} in mallard ducks is 0.49-1.00 g/kg. In bobwhite quail the LD_{50} is 0.66 g/kg. Sodium chlorite in the diet of birds was not acutely toxic. Eight day dietary LC_{50}'s in mallard ducks and bobwhite quail were both greater than 10,000 mg/L in the diet.

SECTION 7: PERSONAL PROTECTIVE EQUIPMENT REQUIREMENTS

PERSONAL PROTECTION FOR ROUTINE USE OF PRODUCT

RESPIRATORY PROTECTION: Wear a NIOSH/MSHA approved acid gas respirator plus dust/mist filters if any exposure to dust or mist is possible.

VENTILATION: Use local exhaust ventilation.

SKIN AND EYE PROTECTIVE EQUIPMENT: Wear Neoprene gloves, boots, chemical goggles, apron or impermeable suit to avoid skin and eye contact. Thoroughly wash all contaminated clothing.

OTHER: Emergency eye wash and safety showers must be provided in the immediate work area. Thoroughly wash all contaminated clothing.

PERSONAL PROTECTION FOR EMERGENCY SPILL AND FIRE-FIGHTING SITUATIONS.

Wear full protective clothing (chemically impermeable, full encapsulated suit) and positive pressure self-contained breathing apparatus.

SECTION 8: PRECAUTIONS FOR SAFE HANDLING AND STORAGE

WARNING STATEMENTS AND WARNING PROPERTIES:

DANGER! STRONG OXIDZER. CONTACT WITH OTHER MATERIAL MAY CAUSE FIRE.

HARMFUL IF SWALLOWED. MAY CAUSE IRRITATION OR BURNS TO SKIN AND EYES.

HARMFUL TO BREATHE.

DO NOT SWALLOW OR BREATHE. AVOID CONTACT WITH SKIN, EYES AND CLOTHING.

UPON CONTACT WITH SKIN OR EYES, WASH OFF WITH WATER.

STORAGE CONDITIONS: Do not store at temperatures above 52°C (125°F). Do not expose to direct light. Do not expose to moisture during storage.

SHELF LIFE LIMITATIONS: 2 years

INCOMPATIBLE MATERIALS FOR PACKAGING: Combustible or readily oxidizable materials; sulfur-containing rubber.

INCOMPATIBLE MATERIALS FOR STORAGE OR TRANSPORT: Acids, reducing agents, combustible material, oxidizers (such as hypochlorites), paints, sulfur, solvents.

SECTION 9: SPILL AND LEAKAGE PROCEDURES

FOR ALL TRANSPORTATION ACCIDENTS, CALL CHEMTREC AT 1-800-424-9300. ALL SPILLS OR LEAKS OF THIS MATERIAL MUST BE HANDLED AND DISPOSED OF IN ACCORDANCE WITH LOCAL, STATE AND FEDERAL REGULATIONS.

REPORTABLE QUANITITY: Per 40 CFR 302.4, for sodium hydroxide component: 1000 lb.

SPILL MITIGATION PROCEDURES: Evacuation procedures must be placed into effect. Evacuate all non-essential personnel. Hazardous concentrations in air may be found in local spill area and immediately downwind. Utilize emergency response personal protective equipment prior to the start of any response. This product may represent an explosion hazard. In the form of explosive chlorine dioxide gas if it contacts acids or chlorine. Remove all sources of ignition, such as flames, hot glowing surfaces or electric arcs. Stop source of spill as soon as possible and notify appropriate personnel.

AIR RELEASE: Vapors may be suppressed by the use of water fog or spray. Contain all liquids for treatment and/or disposal as (potential) hazardous waste.

WATER RELEASE: This material is soluble in water. Notify downstream water users of possible contamination. Divert water flow around spill if possible and safe to do so. Continue to handle as described in LAND SPILL, below.

LAND SPILL: Pick up, keep in closed container and hold for waste disposal. DO not place spill materials back in their original container. Decontaminate all clothing and, if permitted, the spill area using strong detergent and flush with large amounts of water.

SPILL RESIDUES: If this product becomes a waste, it meets the criteria of a

hazardous waste as defined under 40 CFR 261 and would have the following EPA hazardous waste designation: D001. Also, it will be subject to the Land Disposal Restrictions under 40 CFR 268 and must be managed accordingly.

As a hazardous solid waste, it must be disposed of in accordance with local, state and federal regulations in a permitted hazardous waste treatment, storage and disposal facility.

SECTION 10: TRANSPORTATION INFORMATION

This material is regulated as a DOT hazardous material.

DOT Shipping Description (49 CFR 172.101) Placard Required:

Sodium Chlorite, 5.1 UH1496,II Oxidizer, 1496, Class 5.1

This applicable packaging section in 40CFR is 173.212.

SECTION 11: ADDITIONAL REGULATORY STATUS INFORMATION

TOXIC SUBSTANCES CONTROL ACT: The components of the product are listed on the Toxic Substance Control Act Inventory.

SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT (SARA) TITLE III HAZARD CATEGORIES (40CFR370.2):

HEALTH: Immediate (Acute), Delayed (Chronic)

PHYSICAL: Fire

EMERGENCY PLANNING AND COMMUNITY RIGHT TO KNOW (40CFR355,AAP.A)

E H S-THRESHOLD PLANNING QUANTITY: None Established

SUPPLIER NOTIFICATION REQUIREMENTS, PER 40CFR372.45): None Established

Material Safety Data Sheet

ECOLAB

FOOD ADDITIVE ACTIVATOR CONCENTRATE

Section 1. Chemical product and company identification

Trade name : FOOD ADDITIVE ACTIVATOR CONCENTRATE

Product use : Food additive.

Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392

Code : 911021-01

Date of issue : **11-May-2005**

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Composition, Information on Ingredients

Name	CAS number	% by weight
citric acid	77-92-9	20 - 50

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)

Emergency overview : WARNING!

CAUSES SEVERE EYE IRRITATION.
CAUSES RESPIRATORY TRACT IRRITATION.
MAY CAUSE SKIN IRRITATION.

Avoid contact with eyes. Avoid breathing vapor or mist. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling. Incompatible with chlorinated solvents.

Potential acute health effects

Eyes : Severely irritating to the eyes.

Skin : Moderately irritating to the skin.

Inhalation : Irritating to respiratory system.

Ingestion : No known significant effects or critical hazards.

See toxicological Information (section 11)

Section 4. First aid measures

Eye contact : In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention immediately.

Skin contact : Wash with soap and water. Get medical attention if irritation occurs. Wash clothing before reuse.

Inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion : Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.

Fire fighting media and instructions : Use an extinguishing agent suitable for surrounding fires.

Dike area of fire to prevent product run-off.

No specific hazard.

Special protective equipment for fire-fighters : Fire fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full facepiece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Ventilate area of leak or spill. Do not touch damaged containers or spilled material unless wearing appropriate protective equipment (Section 8). Stop leak if without risk. Prevent entry into sewers, water courses, basements or confined areas.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.--

Section 7. Handling and storage

Handling : Avoid contact with eyes. Do not add water directly to product. Slowly stir product into water. Keep container closed. Use only with adequate ventilation. Avoid breathing vapor or mist. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area.

Store between 10 and 50°C

Section 8. Exposure Controls, Personal Protection

Engineering controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits.

Personal protection

Eyes : Use safety eyewear designed to protect against splash of liquids.

Hands : For prolonged or repeated handling, use Impervious gloves.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : Avoid breathing vapor or mist.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Colorless.

Odor : Sweetish.

pH : 0.8 (100%)

Boiling/condensation point : >100 °C

Specific gravity : 1.24 (Water = 1)

Dispersion properties : Easily dispersed in cold water, hot water.

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : The product is stable.

Reactivity : Reactive with alkalis. Incompatible with chlorinated solvents.

Section 11. Toxicological information

Potential acute health effects

Eyes : Severely irritating to the eyes.

Skin : Moderately irritating to the skin.

Inhalation : Irritating to respiratory system.

Ingestion : No known significant effects or critical hazards.

Section 12. Ecological information

Products of degradation : These products are carbon oxides (CO, CO_2) and water.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Waste classification : Unused product is D002 (Corrosive)

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	UN3265	Corrosive liquid, acidic, organic, n.o.s. (citric acid)	8	III	Limited quantity Yes. Special provisions IB3, T7, TP1, TP28

APPLIES ONLY DURING ROAD TRANSPORT

Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Irritating material

U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: None.

SARA 302/304 emergency planning and notification: None.

TSCA 8(b) inventory : All materials are listed or exempt.

California prop. 65 : No products were found.

Section 16. Other information

Hazardous Material Information System (U.S.A.) :

[redacted]	2
Fire hazard	0
Reactivity	0
Personal protection	B

Date of issue : 11-May-2005.

Responsible name : Regulatory Affairs

Date of previous issue : 11-May-2005.

Notice to reader

The above information is believed to be correct with respect to the formula used to manufacture the product in the country of origin. As data, standards, and regulations change, and conditions of use and handling are beyond our control, NO WARRANTY, EXPRESS OR IMPLIED, IS MADE AS TO THE COMPLETENESS OR CONTINUING ACCURACY OF THIS INFORMATION.

Material Safety Data Sheet

ECOLAB

SANOVA BASE (25%)

Section 1. Chemical product and company identification

Trade name : SANOVA BASE (25%)
Product use : Food additive.
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 911022
Date of issue : **19-August-2005**
EPA Registration No. : 1677-219

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Composition, Information on Ingredients

Name	CAS number	% by weight
sodium chlorite	7758-19-2	20 - 50

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : DANGER!

CAUSES EYE AND SKIN BURNS.
CAUSES RESPIRATORY TRACT IRRITATION.
HARMFUL IF SWALLOWED. MAY BE FATAL IF SWALLOWED.
OXIDIZER. CONTACT WITH OTHER MATERIAL MAY CAUSE FIRE.
Do not get in eyes, on skin or clothing. Incompatible with chlorinated solvents. Avoid breathing vapor or mist. Store in tightly closed container. Avoid contact with combustible materials. Use only with adequate ventilation. Wash thoroughly after handling. Avoid all possible sources of ignition (spark or flame). Keep away from heat and direct sunlight. Decomposes on heating.

Potential acute health effects

Eyes : Corrosive to eyes.
Skin : Corrosive to the skin.
Inhalation : Irritating to respiratory system.
Ingestion : Harmful if swallowed. May be fatal if swallowed. Causes burns to mouth, throat and stomach.

See toxicological Information (section 11)

Section 4. First aid measures

Eye contact : In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention immediately.
Skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention immediately.
Inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion : Rinse mouth; then drink one or two large glasses of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Get medical attention immediately.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.

Products of combustion : These products are halogenated compounds, hydrogen chloride.

Fire fighting media and instructions : Use an extinguishing agent suitable for surrounding fires.

Dike area of fire to prevent product run-off.
This material increases the risk of fire and may aid combustion. Contact with combustible material may cause fire.

Special protective equipment for fire-fighters : Fire fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full facepiece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Immediately contact emergency personnel. Eliminate all ignition sources. Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Do not touch or walk through spilled material.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) and use a non-sparking or explosion proof means to transfer material to a sealed, appropriate container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.--

Section 7. Handling and storage

Handling : Do not get in eyes, on skin or on clothing. Do not add water directly to product. Slowly stir product into water. Keep container closed. Use only with adequate ventilation. Avoid breathing vapor or mist. Store in original container protected from direct sunlight. Avoid contact with combustible materials. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area. Separate from reducers and flammable/combustible materials, etc. in storage. Store between -10 and 50°C

Section 8. Exposure Controls, Personal Protection

Engineering controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Personal protection

Eyes : Use chemical splash goggles. For continued or severe exposure wear a face shield over the goggles.

Hands : Use chemical resistant, impervious gloves.

Skin : Wear suitable protective clothing.

Respiratory : Avoid breathing vapor or mist.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Colorless to light yellow. (Light.)

Odor : chlorine

pH : 12.5 (100%)

Boiling/condensation point : >100 °C

Specific gravity : 1.265 (Water = 1)

Dispersion properties : Easily dispersed in cold water, hot water.

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : Decomposes on heating.

Reactivity : Reactive with reducing agents, acids.
Slightly reactive to reactive with organic materials.

Hazardous decomposition products : These products are halogenated compounds, hydrogen chloride, Oxygen.

Section 11. Toxicological information

Potential acute health effects

Eyes : Corrosive to eyes.

Skin : Corrosive to the skin.

Inhalation : Irritating to respiratory system.

Ingestion : Harmful if swallowed. May be fatal if swallowed. Causes burns to mouth, throat and stomach.

Chronic effects on humans : Contains material which causes damage to the following organs: mucous membranes, skin, eye, lens or cornea, stomach.

Section 12. Ecological information

Products of degradation : These products are sulfur oxides (SO_2, SO_3...), halogenated compounds. Some metallic oxides.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Waste classification : Unused product is D002 (Corrosive)

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	UN1908	Chlorite solution	8	II	**Limited quantity** Yes. **Special provisions** A3, A6, A7, B2, IB2, N34, T7, TP2, TP24

APPLIES ONLY DURING ROAD TRANSPORT

Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Oxidizing material
Corrosive material
Target organ effects

U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: None.
SARA 302/304 emergency planning and notification: None.

TSCA 8(b) inventory : All materials are listed or exempt.

California prop. 65 : No products were found.

EPA Registration No. : 1677-219

Section 16. Other information

Hazardous Material Information System (U.S.A.) :

Health	3
Fire hazard	0
Reactivity	1
Personal protection	B

Date of issue : 19-August-2005.
Responsible name : Regulatory Affairs
Date of previous issue : 19-August-2005.

Notice to reader

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Material Safety Data Sheet

ECOLAB

SANOVA ACTIVATOR CONCENTRATE

Section 1. Chemical product and company identification

Trade name : SANOVA ACTIVATOR CONCENTRATE
Product use : Additive
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 911021
Date of issue : **06-June-2006**

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Composition, information on ingredients

Name	CAS number	% by weight
citric acid	77-92-9	50

Section 3. Hazards identification

Physical state : Liquid.
Emergency overview : CAUTION!

MAY CAUSE EYE AND SKIN IRRITATION.
Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Potential acute health effects

Eyes : Moderately irritating to eyes.
Skin : Moderately irritating to the skin.
Inhalation : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

See toxicological information (section 11)

Section 4. First aid measures

Eye contact : In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention if irritation persists.

Skin contact : Flush contaminated skin with plenty of water. Continue to rinse for at least 10 minutes. Get medical attention if irritation persists. Remove contaminated clothing and shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Inhalation : If inhaled, remove to fresh air.

Ingestion : Do not induce vomiting. Never give anything by mouth to an unconscious person. If irritation persists, get medical attention.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.

Fire-fighting media and instructions : Use an extinguishing agent suitable for the surrounding fire.

Dike liquid for later disposal.

No specific hazard.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Ventilate area of leak or spill. Do not touch damaged containers or spilled material unless wearing appropriate protective equipment (Section 8). Stop leak if without risk. Do not allow to enter drains or watercourses.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills, add absorbent (soil may be used in the absence of other suitable materials), scoop up material and place in a sealable, liquid-proof container for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

Section 7. Handling and storage

Handling : Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area.
Store between 10 and 50°C

Section 8. Exposure controls, personal protection

Engineering controls : Good general ventilation should be sufficient to control airborne levels.

Personal protection

Eyes : Wear chemical splash goggles. For continued or severe exposure wear a face shield over the goggles.

Hands : Use chemical-resistant, impervious gloves.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : A respirator is not needed under normal and intended conditions of product use.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid.

Color : Colorless.

Odor : Sweetish.

pH : 0.8 (100%)

Boiling/condensation point : >100 °C

Specific gravity : 1.24 (Water = 1)

Dispersibility properties : Easily dispersed in cold water, hot water.

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : The product is stable.

Reactivity : Reactive with alkalis. Incompatible with chlorinated solvents.

Hazardous polymerization : Yes.

Section 11. Toxicological information

Potential acute health effects

Eyes : Moderately irritating to eyes.

Skin : Moderately irritating to the skin.

Inhalation : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Section 12. Ecological information

Products of degradation : These products are carbon oxides (CO, CO_2) and water.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Waste classification : Unused product is D002 (Corrosive)

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	UN3265	Corrosive liquid, acidic, organic, n.o.s. (citric acid)	8	III	**Limited quantity** Yes. **Special provisions** IB3, T7, TP1, TP28

APPLIES ONLY DURING ROAD TRANSPORT

Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Irritating material

U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: No products were found.

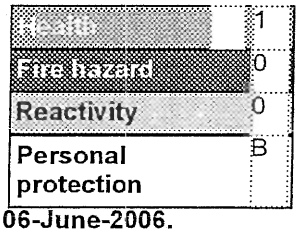
SARA 302/304 emergency planning and notification: No products were found.

TSCA 8(b) inventory : All materials are listed or exempt.

California Prop. 65 : No products were found.

Section 16. Other information

Hazardous Material Information System (U.S.A.) :



Date of issue : **06-June-2006.**

Responsible name : **Regulatory Affairs**

Date of previous issue : **21-July-2005.**

Notice to reader

The above information is believed to be correct with respect to the formula used to manufacture the product in the country of origin. As data, standards, and regulations change, and conditions of use and handling are beyond our control, NO WARRANTY, EXPRESS OR IMPLIED, IS MADE AS TO THE COMPLETENESS OR CONTINUING ACCURACY OF THIS INFORMATION.

Material Safety Data Sheet

ECOLAB

OXXIUM 203

Section 1. Chemical product and company identification

Trade name : OXXIUM 203
Product use : Intermediate.
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 901073-05
Date of issue : **02-March-2006**
EPA Registration No. : 5382-43-1677

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Composition, information on ingredients

Name	CAS number	% by weight
sodium hydroxide	1310-73-2	1
sodium chlorite	7758-19-2	20 - 50
sodium carbonate	497-19-8	1 - 5
sodium chlorate	7775-09-9	1 - 5

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : DANGER!

CAUSES EYE AND SKIN BURNS.
CAUSES RESPIRATORY TRACT IRRITATION.
HARMFUL IF SWALLOWED.
Do not ingest. Do not get in eyes, on skin or on clothing. Avoid breathing vapor or mist. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling.

Potential acute health effects

Eyes : Corrosive to eyes.
Skin : Corrosive to the skin.
Inhalation : Irritating to respiratory system.
Ingestion : Harmful if swallowed. Causes burns to mouth, throat and stomach.

See toxicological information (section 11)

Section 4. First aid measures

Eye contact : In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention immediately.

Skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse. Get medical attention immediately.

Inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

Ingestion : Rinse mouth; then drink one or two large glasses of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Get medical attention immediately.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.

Products of combustion : These products are halogenated compounds, hydrogen chloride.

Fire-fighting media and instructions : Use an extinguishing agent suitable for the surrounding fire.

Dike liquid for later disposal.
No specific hazard.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Ventilate area of leak or spill. Do not touch damaged containers or spilled material unless wearing appropriate protective equipment (Section 8). Stop leak if without risk. Do not allow to enter drains or watercourses.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills, add absorbent (soil may be used in the absence of other suitable materials), scoop up material and place in a sealable, liquid-proof container for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

Section 7. Handling and storage

Handling : Do not ingest. Do not get in eyes or on skin or clothing. Avoid breathing vapor or mist. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area.
Store between -30 and 40°C

Section 8. Exposure controls, personal protection

Engineering controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits. Provide eyewash and safety shower in area if contact or splash hazard exists.

Personal protection

Eyes : Use chemical splash goggles. For continued or severe exposure wear a face shield over the goggles.

Hands : Use chemical-resistant, impervious gloves.

Skin : Wear suitable protective clothing.

Respiratory : Avoid breathing vapors, spray or mists.

Name	Exposure limits
sodium hydroxide	**OSHA PEL (United States, 8/1997).** TWA: 2 mg/m³ 8 hour(s). Form: All forms **ACGIH TLV (United States, 1/2004).** CEIL: 2 mg/m³ CEIL: 2 mg/m³ Form: All forms

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Colorless to light yellow.

Odor : chlorine

pH : 12.75 (100%)

Boiling/condensation point : 100 °C

Specific gravity : 1.222 (Water = 1)

: Easily dispersed in cold water, hot water.

Dispersibility properties

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : The product is stable.

Reactivity : Highly reactive with acids.
Reactive with metals.
Slightly reactive to reactive with organic materials.

Hazardous decomposition products : These products are halogenated compounds, hydrogen chloride.

Section 11. Toxicological information

Potential acute health effects

Eyes : Corrosive to eyes.

Skin : Corrosive to the skin.

Inhalation : Irritating to respiratory system.

Ingestion : Harmful if swallowed. Causes burns to mouth, throat and stomach.

Potential chronic health effects

Chronic effects on humans : Contains material which causes damage to the following organs: lungs, mucous membranes, upper respiratory tract, skin, eye, lens or cornea.

Section 12. Ecological information

Products of degradation : These products are carbon oxides (CO, CO_2) and water, halogenated compounds. Some metallic oxides.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Waste classification : Unused product is D002 (Corrosive)

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	UN1908	Chlorite solution	8	II	**Limited quantity** Yes. **Special provisions** A3, A6, A7, B2, IB2, N34, T7, TP2, TP24

APPLIES ONLY DURING ROAD TRANSPORT

Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Corrosive material
Target organ effects

U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: No products were found.
SARA 302/304 emergency planning and notification: No products were found.

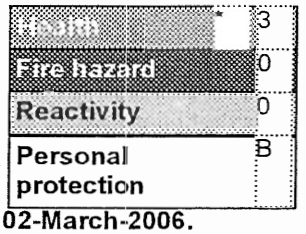
TSCA 8(b) inventory : All materials are listed or exempt.

California Prop. 65 : No products were found.

EPA Registration No. : 5382-43-1677

Section 16. Other information

Hazardous Material Information System (U.S.A.) :



Date of issue : **02-March-2006.**

Responsible name : **Regulatory Affairs**

Date of previous issue : **No previous validation.**

Notice to reader

The above information is believed to be correct with respect to the formula used to manufacture the product in the country of origin. As data, standards, and regulations change, and conditions of use and handling are beyond our control, NO WARRANTY, EXPRESS OR IMPLIED, IS MADE AS TO THE COMPLETENESS OR CONTINUING ACCURACY OF THIS INFORMATION.

Material Safety Data Sheet

ECOLAB

EXSPOR BASE

Section 1. Chemical product and company identification

Trade name : EXSPOR BASE
Product use : disinfectant
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 910906
Date of issue : **29-July-2005**
EPA Registration No. : 1677-216

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Composition, Information on Ingredients

Name	CAS number	% by weight
sodium dodecylbenzene sulfonate	25155-30-0	1
sodium chlorite	7758-19-2	1 - 5

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : CAUTION!

CAUSES SKIN IRRITATION.
HARMFUL IF ABSORBED THROUGH SKIN.
MAY CAUSE RESPIRATORY TRACT AND EYE IRRITATION.
Avoid prolonged contact with eyes, skin, and clothing. Avoid breathing vapor or mist. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling.

Potential acute health effects

Eyes : Moderately irritating to the eyes.
Skin : Harmful in contact with skin. Irritating to skin.
Inhalation : Moderately irritating to the respiratory system.
Ingestion : No known significant effects or critical hazards.

See toxicological Information (section 11)

Section 4. First aid measures

Eye contact : In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention if irritation persists.

Skin contact : In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Inhalation : If inhaled, remove to fresh air.

Ingestion : Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.

Products of combustion : These products are halogenated compounds, hydrogen chloride.

Fire fighting media and instructions : Use an extinguishing agent suitable for surrounding fires.

Dike area of fire to prevent product run-off.
No specific hazard.

Special protective equipment for fire-fighters : Fire fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full facepiece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Ventilate area of leak or spill. Do not touch damaged containers or spilled material unless wearing appropriate protective equipment (Section 8). Stop leak if without risk. Prevent entry into sewers, water courses, basements or confined areas.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.--

Section 7. Handling and storage

Handling : Avoid contact with eyes, skin and clothing. Keep container closed. Use only with adequate ventilation. Avoid breathing vapor or mist. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area.
Store between -10 and 40°C

Section 8. Exposure Controls, Personal Protection

Engineering controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits.

Personal protection

Eyes : Eye protection recommended.

Hands : Use chemical resistant, impervious gloves.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : Avoid breathing vapor or mist.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Yellow.

Odor : chlorine

pH : 11.5 (100%)

Boiling/condensation point : 100 °C

Specific gravity : 1.02 (Water = 1)

Dispersion properties : Easily dispersed in cold water, hot water.

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : The product is stable.
Reactivity : Reactive with acids.
Hazardous decomposition products : These products are halogenated compounds, hydrogen chloride.

Section 11. Toxicological information

Potential acute health effects

Eyes : Moderately irritating to the eyes.
Skin : Harmful in contact with skin. Irritating to skin.
Inhalation : Moderately irritating to the respiratory system.
Ingestion : No known significant effects or critical hazards.

Potential chronic health effects

Chronic effects on humans : Contains material which causes damage to the following organs: skin, eye, lens or cornea.

Section 12. Ecological information

Products of degradation : These products are carbon oxides (CO, CO_2) and water, sulfur oxides (SO_2, SO_3 ...), halogenated compounds. Some metallic oxides.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	Not regulated.	-	-	-	-

APPLIES ONLY DURING ROAD TRANSPORT
Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Irritating material
Target organ effects
U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: None.
SARA 302/304 emergency planning and notification: None.
TSCA 8(b) inventory : All materials are listed or exempt.
California prop. 65 : No products were found.
EPA Registration No. : 1677-216

Section 16. Other information

Hazardous Material Information System (U.S.A.) :

Health	1
Fire hazard	0
Reactivity	0
Personal protection	B

Date of issue : 29-July-2005.
Responsible name : Regulatory Affairs
Date of previous issue : No Previous Validation.

Notice to reader

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Material Safety Data Sheet

ECOLAB

EXSPOR ACTIVATOR

Section 1. Chemical product and company identification

Trade name : EXSPOR ACTIVATOR
Product use : Additive
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 910905
Date of issue : **05-August-2005**

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Composition, Information on Ingredients

Name	CAS number	% by weight
propanoic acid, 2-hydroxy-, (s)-	79-33-4	5 - 20

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : CAUTION!

MAY CAUSE RESPIRATORY TRACT, EYE AND SKIN IRRITATION.
HARMFUL IF ABSORBED THROUGH SKIN.
Avoid contact with skin and clothing. Avoid breathing vapor or mist. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling.

Potential acute health effects

Eyes : Moderately irritating to the eyes.
Skin : Harmful if absorbed through the skin. Moderately irritating to the skin.
Inhalation : Moderately irritating to the respiratory system.
Ingestion : No known significant effects or critical hazards.

See toxicological Information (section 11)

Section 4. First aid measures

Eye contact : In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention if irritation persists.
Skin contact : Wash with soap and water. Get medical attention if irritation occurs. Wash clothing before reuse.
Inhalation : If inhaled, remove to fresh air.
Ingestion : Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.
Fire fighting media and instructions : Use an extinguishing agent suitable for surrounding fires.

Dike area of fire to prevent product run-off.
No specific hazard.
Special protective equipment for fire-fighters : Fire fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full facepiece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Ventilate area of leak or spill. Do not touch damaged containers or spilled material unless wearing appropriate protective equipment (Section 8). Stop leak if without risk. Prevent entry into sewers, water courses, basements or confined areas.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.–

Section 7. Handling and storage

Handling : Avoid contact with eyes, skin and clothing. Do not add water directly to product. Slowly stir product into water. Keep container closed. Use only with adequate ventilation. Avoid breathing vapor or mist. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area.
Store between -10 and 40°C

Section 8. Exposure Controls, Personal Protection

Engineering controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits.

Personal protection

Eyes : Eye protection recommended.

Hands : Use chemical resistant, impervious gloves.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : Avoid breathing vapor or mist.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Colorless to light yellow.

Odor : Faint Odor

pH : 1.8 (100%)

Boiling/condensation point : >100 °C

Specific gravity : 1.023 (Water = 1)

Dispersion properties : Easily dispersed in cold water, hot water.

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : The product is stable.

Reactivity : Reactive with alkalis.

Section 11. Toxicological information

Potential acute health effects

Eyes : Moderately irritating to the eyes.

Skin : Harmful if absorbed through the skin. Moderately irritating to the skin.

Inhalation : Moderately irritating to the respiratory system.

Ingestion : No known significant effects or critical hazards.

Potential chronic health effects

Section 12. Ecological information

Products of degradation : These products are carbon oxides (CO, CO_2) and water.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Waste classification : Unused product is D002 (Corrosive)

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	UN3265	Corrosive liquid, acidic, organic, n.o.s. (Lactic acid)	8	III	**Limited quantity** Yes. **Special provisions** IB3, T7, TP1, TP28

APPLIES ONLY DURING ROAD TRANSPORT

Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Irritating material

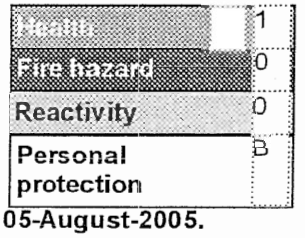
U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: None.
SARA 302/304 emergency planning and notification: None.

TSCA 8(b) inventory : All materials are listed or exempt.

California prop. 65 : No products were found.

Section 16. Other information

Hazardous Material Information System (U.S.A.) :



Date of issue : **05-August-2005.**

Responsible name : **Regulatory Affairs**

Date of previous issue : **No Previous Validation.**

Notice to reader

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Material Safety Data Sheet

ANTIMICROBIAL FOOD ADDITIVE BASE (25%)

Section 1. Chemical product and company identification

Trade name : ANTIMICROBIAL FOOD ADDITIVE BASE (25%)
Product use : Food additive.
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 911022-01
Date of issue : **19-August-2005**

EMERGENCY HEALTH INFORMATION: 1-800-328-0026
Outside United States and Canada CALL 1-651-222-5352 (in USA)

Section 2. Composition, Information on Ingredients

Name	CAS number	% by weight
sodium chlorite	7758-19-2	20 - 50

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : DANGER!

CAUSES EYE AND SKIN BURNS.
CAUSES RESPIRATORY TRACT IRRITATION.
HARMFUL IF SWALLOWED. MAY BE FATAL IF SWALLOWED.
OXIDIZER. CONTACT WITH OTHER MATERIAL MAY CAUSE FIRE.
Do not get in eyes, on skin or clothing. Incompatible with chlorinated solvents. Avoid breathing vapor or mist. Store in tightly closed container. Avoid contact with combustible materials. Use only with adequate ventilation. Wash thoroughly after handling. Avoid all possible sources of ignition (spark or flame). Keep away from heat and direct sunlight. Decomposes on heating.

Potential acute health effects

Eyes : Corrosive to eyes.
Skin : Corrosive to the skin.
Inhalation : Irritating to respiratory system.
Ingestion : Harmful if swallowed. May be fatal if swallowed. Causes burns to mouth, throat and stomach.

See toxicological Information (section 11)

Section 4. First aid measures

Eye contact : In case of contact, immediately flush eyes with cool running water. Remove contact lenses and continue flushing with plenty of water for at least 15 minutes. Get medical attention immediately.
Skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention immediately.
Inhalation : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
Ingestion : Rinse mouth; then drink one or two large glasses of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Get medical attention immediately.

Section 5. Fire fighting measures

Flash point : > 100°C
Product does not support combustion.

Products of combustion : These products are halogenated compounds, hydrogen chloride.

Fire fighting media and instructions : Use an extinguishing agent suitable for surrounding fires.

Dike area of fire to prevent product run-off.
This material increases the risk of fire and may aid combustion. Contact with combustible material may cause fire.

Special protective equipment for fire-fighters : Fire fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full facepiece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions : Immediately contact emergency personnel. Eliminate all ignition sources. Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Do not touch or walk through spilled material.

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Methods for cleaning up : If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) and use a non-sparking or explosion proof means to transfer material to a sealed, appropriate container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.--

Section 7. Handling and storage

Handling : Do not get in eyes, on skin or on clothing. Do not add water directly to product. Slowly stir product into water. Keep container closed. Use only with adequate ventilation. Avoid breathing vapor or mist. Store in original container protected from direct sunlight. Avoid contact with combustible materials. Wash thoroughly after handling.

Storage : Keep out of the reach of children. Keep container tightly closed. Keep container in a cool, well-ventilated area. Separate from reducers and flammable/combustible materials, etc. in storage. Store between -10 and 50°C

Section 8. Exposure Controls, Personal Protection

Engineering controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Personal protection

Eyes : Use chemical splash goggles. For continued or severe exposure wear a face shield over the goggles.

Hands : Use chemical resistant, impervious gloves.

Skin : Wear suitable protective clothing.

Respiratory : Avoid breathing vapor or mist.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Colorless to light yellow. (Light.)

Odor : chlorine

pH : 12.5 (100%)

Boiling/condensation point : >100 °C

Specific gravity : 1.265 (Water = 1)

Dispersion properties : Easily dispersed in cold water, hot water.

Solubility : Easily soluble in cold water, hot water.

Section 10. Stability and reactivity

Stability : Decomposes on heating.

Reactivity : Reactive with reducing agents, acids.
Slightly reactive to reactive with organic materials.

Hazardous decomposition products : These products are halogenated compounds, hydrogen chloride, Oxygen.

Section 11. Toxicological information

Potential acute health effects

Eyes : Corrosive to eyes.

Skin : Corrosive to the skin.

Inhalation : Irritating to respiratory system.

Ingestion : Harmful if swallowed. May be fatal if swallowed. Causes burns to mouth, throat and stomach.

Chronic effects on humans : Contains material which causes damage to the following organs: mucous membranes, skin, eye, lens or cornea, stomach.

Section 12. Ecological information

Products of degradation : These products are sulfur oxides (SO_2, SO_3...), halogenated compounds. Some metallic oxides.

Section 13. Disposal considerations

Waste disposal : The generation of waste should be avoided or minimized wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Waste classification : Unused product is D002 (Corrosive)

Consult your local or regional authorities.

Section 14. Transport information

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
DOT Classification	UN1908	Chlorite solution	8	II	**Limited quantity** Yes. **Special provisions** A3, A6, A7, B2, IB2, N34, T7, TP2, TP24

APPLIES ONLY DURING ROAD TRANSPORT

Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Oxidizing material
Corrosive material
Target organ effects

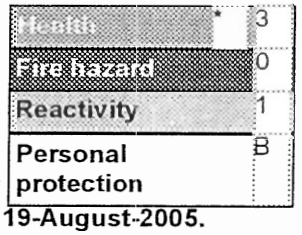
U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: None.
SARA 302/304 emergency planning and notification: None.

TSCA 8(b) inventory : All materials are listed or exempt.

California prop. 65 : No products were found.

Section 16. Other information

Hazardous Material Information System (U.S.A.) :



Date of issue : 19-August-2005.

Responsible name : Regulatory Affairs

Date of previous issue : 19-August-2005.

Notice to reader

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International Chemical Safety Cards

SODIUM CHLORITE

ICSC: 1045

Chlorous acid, sodium salt
$NaClO_2$
Molecular mass: 90.44

ICSC # 1045
CAS # 7758-19-2
RTECS # VZ4800000
UN # 1496

TYPES OF HAZARD/ EXPOSURE	ACUTE HAZARDS/ SYMPTOMS	PREVENTION	FIRST AID/ FIRE FIGHTING
FIRE	Not combustible but enhances combustion of other substances. Gives off irritating or toxic fumes (or gases) in a fire.	NO contact with combustibles reducing agents	Water in large amounts, water spray. NO carbon dioxide.
EXPLOSION	Risk of fire and explosion on contact with reducing agents		In case of fire: keep drums, etc., cool by spraying with water.
EXPOSURE		PREVENT DISPERSION OF DUST!	
•INHALATION	Cough. Sore throat.	Ventilation (not if powder), local exhaust, or breathing protection.	Fresh air, rest.
•SKIN	Redness. Pain.	Protective gloves.	First rinse with plenty of water, then remove contaminated clothes and rinse again.
•EYES	Redness. Pain.	Safety goggles.	First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then take to a doctor.
•INGESTION	Abdominal pain. Vomiting.	Do not eat, drink, or smoke during work. Wash hands before eating.	Rinse mouth. Induce vomiting (ONLY IN CONSCIOUS PERSONS!). Refer for medical attention.

SPILLAGE DISPOSAL	STORAGE	PACKAGING & LABELLING
Sweep spilled substance into sealable containers; if appropriate, moisten first to prevent dusting. Carefully collect remainder, then remove to safe place. Do NOT absorb in saw-dust or other combustible absorbents. (Extra personal protection: P3 filter respirator for toxic particles).	Separated from combustible and reducing substances, acids, incompatible materials See Chemical Dangers. Cool. Dry. Keep in a well-ventilated room.	R: S: UN Hazard Class: 5.1 UN Packing Group: II

SEE IMPORTANT INFORMATION ON BACK

ICSC: 1045

Prepared in the context of cooperation between the International Programme on Chemical Safety & the Commission of the European Communities (C) IPCS CEC 2000. No modifications to the International version have been made except to add the OSHA PELs, NIOSH RELs and NIOSH IDLH values.

International Chemical Safety Cards

SODIUM CHLORITE

ICSC: 1045

IMPORTANT DATA		
	PHYSICAL STATE; APPEARANCE: HYGROSCOPIC WHITE CRYSTALS OR FLAKES **PHYSICAL DANGERS:** **CHEMICAL DANGERS:** The substance decomposes on heating to 200° C, producing toxic and corrosive fumes , causing fire and explosion hazard. The substance is a strong oxidant and reacts violently with combustible and reducing materials. Reacts violently with acids, ammonium compounds, phosphorus, sulfur, sodium dithionate, causing explosion hazard. **OCCUPATIONAL EXPOSURE LIMITS:** TLV not established.	**ROUTES OF EXPOSURE:** The substance can be absorbed into the body by inhalation of its aerosol and by ingestion. **INHALATION RISK:** Evaporation at 20°C is negligible; a harmful concentration of airborne particles can, however, be reached quickly when dispersed, especially if powdered. **EFFECTS OF SHORT-TERM EXPOSURE:** The substance irritates the eyes, the skin and the respiratory tract. **EFFECTS OF LONG-TERM OR REPEATED EXPOSURE:**
PHYSICAL PROPERTIES	Decomposes below melting point at 180-200°C Solubility in water, g/100 ml at 17°C: 39 Density: 2.5 g/cm^3	
ENVIRONMENTAL DATA		

NOTES

Will turn shock-sensitive if contaminated with organic matter. Rinse contaminated clothes (fire hazard) with plenty of water. Textone is a trade name.

Transport Emergency Card: TEC (R)-209 or 51G02
NFPA Code: H1; F0; R1; OX

ADDITIONAL INFORMATION

IRIS Database entry on sodium chlorite

Source: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~BAARhayYQ:1

Chlorite (sodium salt)

CASRN: 7758-19-2

Status:

STATUS OF DATA FOR Chlorite
(File First On-Line 11/01/95)

Category (section)	Status	Last Revised
Oral RfD Assessment (I.A.)	On-line	10/12/00
Inhalation RfC Assessment (I.B.)	On-line	10/12/00
Carcinogenicity Assessment (II.)	On line	10/12/00

Substance Identification:

Substance Name:

Chlorite (sodium salt)

CAS Registry Number: 7758-19-2

I. Chronic Health Hazard Assessment for Noncarcinogenic Effects:

I.A. Reference Dose for Chronic Oral Exposure (RfD):

Chlorite (sodium salt)
CASRN -- 7758-19-2
Last Revised -- 10/12/00

The oral reference dose (RfD) is based on the assumption that thresholds exist for certain toxic effects such as cellular necrosis. It is expressed in units of mg/kg-day. In general, the RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including

sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Please refer to the Background Document for an elaboration of these concepts. RfDs can also be derived for the noncarcinogenic health effects of substances that are also carcinogens. Therefore, it is essential to refer to other sources of information concerning the carcinogenicity of this substance. If the U.S. EPA has evaluated this substance for potential human carcinogenicity, a summary of that evaluation will be contained in Section II of this file.

I.A.1. Oral RfD Summary:

Critical Effect	Experimental Doses*	UF	MF	RfD
Neurodevelopmental effects	NOAEL: 3 mg/kg-day (35 ppm sodium chlorite)	100	1	3×10^{-2} mg/kg-day
Two-generation rat drinking water study CMA, 1996	LOAEL: 6 mg/kg-day (70 ppm sodium chlorite)			

*Conversion Factors and Assumptions -- MW of sodium chlorite = 90.5; MW of chlorite = 67.5. Doses (mg sodium chlorite/kg-day) were estimated by the study authors using measured water consumption and body weight data. To express doses as the chlorite ion, the estimated doses were multiplied by the molecular weight ratio of sodium chlorite to chlorite.

I.A.2. Principal and Supporting Studies (Oral RfD):

CMA (Chemical Manufacturers Association). (1996) Sodium chlorite: drinking water rat two-generation reproductive toxicity study. Quintiles Report Ref. CMA/17/96.

CMA (1996) conducted a two-generation study to examine reproductive, developmental neurotoxicity, and hematological endpoints in rats exposed to sodium chlorite. Thirty male and 30 female Sprague-Dawley rats (F0) generation received drinking water containing 0, 35, 70, or 300 ppm sodium chlorite for 10 weeks and were then paired for mating. Males were exposed throughout mating and then were sacrificed. Exposure for the females continued through mating, pregnancy, and lactation until necropsy following weaning of their litters. Twenty-five males and females from each of the first 25 litters to be weaned in a treatment group were chosen to produce the F1 generation. The F1 pups were continued on the same treatment regimen as their parents. At approximately 14 weeks of age, they were mated to produce the F2a generation. Because of a reduced number of litters in the 70 ppm F1-F2a generation, the F1 animals were cremated following weaning of the F2a to produce the F2b generation. Pregnant F1 females were allowed to litter and rear the F2a and F2b generations until

weaning at postnatal day (PND) 21. Using water consumption and body weight data, the study authors calculated doses (adjusted for molecular weight) of 0, 3.0, 5.6, and 20.0 mg chlorite/kg-day for F_0 males; 0, 3.8, 7.5, and 28.6 mg chlorite/kg-day for F_0 females; 0, 2.9, 5.9, and 22.7 mg chlorite/kg-day for F_1 males; and 0, 3.8, 7.9, and 28.6 mg chlorite/kg-day for F_1 females. Numerous parameters were measured or calculated, including body weight, food and water consumption, estrus cycle in the F0 and F1, hematology and T3 and T4 levels in the F1 (blood samples collected from one male and one female from the first 20 F1 litters at age PND 25 and another group at 13 weeks), reproductive/developmental toxicity parameters (i.e., gestation duration, litter size, pup body weight, pup developmental landmarks), total caudal sperm number and percent motile, sperm morphology in the F0 and F1, and organ weight and histopathological examination (brain, pituitary gland, liver, adrenal, spleen, thymus, kidneys, and reproductive organs) of all F0 and F1 controls and high-dose animals. An additional group of F1 pups was chosen for neurohistopathology on PND 11 (examination of the brain and spinal cord) or PND 60 (sensory ganglia, dorsal and ventral nerve roots, and several peripheral nerves and muscles). Another group of F1 rats was examined for neurotoxicological endpoints (motor activity in a "Figure 8" Activity System and neuropathology on PND 60, auditory startle in the SR-Screening System, learning and memory retention in a water E-maze). A functional observational battery (FOB) was also conducted on the pups undergoing the auditory and learning assessments. This group was composed of 2 males and 2 females from 20 litters, and exposure was discontinued after weaning. A reevaluation of the auditory startle response was conducted in 20 males and 20 females in the F2a and F2b generations.

There were reductions in water consumption, food consumption, and body weight gain in both sexes in all generations at various times throughout the experiment, primarily in the 70 and 300 ppm groups. The authors attributed these reductions to a lack of palatability of the drinking water solution, but did not show data to support this contention. Significant alterations related to treatment at 300 ppm include reductions in absolute and relative liver weight in F0 females and F1 males and females, reduced pup survival (increase in number of pups found dead and/or killed prematurely during lactation) and reduced body weight at birth and throughout lactation in F1 and F2, lower thymus and spleen weight in both generations, lowered incidence of pups exhibiting a normal righting reflex and with eyes open on PND 15, alteration in clinical condition in F2 animals chosen for neurotoxicity, decreases in absolute brain weight for F1 males and F2 females, delays in sexual development in males (preputial separation) and females (vaginal opening) in F1 and F2, and lower red blood cell parameters in F1. It is possible that the reported alterations in pup sexual maturation measures may be due to reduced pup body weight, but a definitive conclusion cannot be drawn. In the 70 ppm groups, reduced absolute and relative liver weight in F0 females and F1 males was observed. Minor, statistically significant changes in hematological data at the 35 and 70 ppm concentrations (generally 1%-7%) in the F1 appear to be within normal ranges based on historical data and are, therefore, not considered clinically or biologically significant or adverse. In

addition, a significant decrease in maximum response to an auditory startle stimulus was noted in the 70 and 300 ppm groups on PND 24, but not on PND 60. The NOAEL for this study is 35 ppm (3 mg chlorite/kg-day) and the LOAEL is 70 ppm (6 mg chlorite/kg-day) based on lowered auditory startle amplitude and altered liver weights in two generations.

I.A.3. Uncertainty and Modifying Factors (Oral RfD):

The composite uncertainty factor (UF) of 100 includes a factor of 10 to account for uncertainties associated with interspecies extrapolation and a factor of 10 for intrahuman variability. Because the critical effect is developmental toxicity in a database that includes chronic studies, it is not necessary to use an additional uncertainty factor to account for use of a less-than-lifetime study.

MF = 1.

I.A.4. Additional Studies/Comments (Oral RfD):

Lubbers et al. (1981, 1982, 1984a) examined the toxicity of chlorite in normal healthy adults. In the single-exposure study (Lubbers et al., 1981, 1982), 10 male adults consumed two (separated by 4 hours) 500 mL solutions containing 2.4 mg/L chlorite (0.034 mg/kg, assuming a reference body weight of 70 kg). In a 12-week study (Lubbers et al., 1984a), groups of 10 men drank 500 mL solutions of 0 or 5 mg/L chlorite (0.04 mg/kg-day assuming a 70 kg body weight). No physiologically relevant alterations in general health (observations and physical examination), vital signs, hematological (including erythrocyte and total and differential leukocyte counts, hemoglobin, hematocrit, and methemoglobin) or serum clinical chemistry (including glucose, electrolytes, calcium, urea nitrogen, enzyme levels, and cholesterol) parameters, or serum T3 or T4 levels were found in either study.

In a companion study, three healthy glucose-6-phosphate dehydrogenase (G6PD) deficient male subjects were given deionized water containing 5 mg/L chlorite (0.04 mg/kg-day, assuming a reference body weight of 70 kg) for 12 weeks (Lubbers et al., 1984b). Compared with the control group in Lubbers et al. (1984a), the chlorite exposure did not alter general health, vital signs, hematological parameters, or serum clinical chemistry parameters.

Michael et al. (1981), Tuthill et al. (1982), and Kanitz et al. (1996) examined communities with chlorine dioxide-disinfected water. Michael et al. (1981) found that chlorine dioxide in drinking water rapidly disappeared from the stored water (within 2-4 hours) and chlorite levels concomitantly increased. In an epidemiological study of a community using chlorite as a drinking water disinfectant, adult exposures ranged from 0 to 39.4 mg/day

for chlorite for 10 weeks, and no consistent alterations in hematological parameters were reported (Michael et al., 1981). Tuthill et al. (1982) retrospectively compared morbidity and mortality data for a community that had utilized high levels of chlorine dioxide as a drinking water disinfectant with data from a neighboring community and found a greater postnatal weight loss in infants from the exposed community and no increase in the proportion of premature births when the age of the mother was controlled. The authors reported average monthly levels of 0.32 ppm of chlorine dioxide added post-treatment, but did not report total chlorine dioxide levels in the treated water. Kanitz et al. (1996) followed 598 births to women who lived in a community with filtered water disinfected with chlorine dioxide, sodium hypochlorite, or both, and 128 births to women living in a community with well water that did not undergo disinfection treatment. Levels of chlorine dioxide in the water immediately after treatment were less than 0.3 mg/L, while chlorine residue was less than 0.4 mg/L. The study authors concluded that infants of women who consumed drinking water treated with chlorine compounds during pregnancy were at higher risk for neonatal jaundice, cranial circumference $\leq$ 35 cm, and body length $\leq$ 49.5 cm. However, these studies as a whole are limited by methodological problems such as lack of characterization of exposure to other agents in the drinking water, drinking water consumption data, and control of potential confounding factors.

The subchronic/chronic toxicity of chlorite was investigated by Harrington et al. (1995) and Haag et al. (1949). Harrington et al. (1995) administered via gavage 0, 10, 25, or 80 mg sodium chlorite/kg-day (0, 7.4, 19, or 60 mg chlorite/kg-day) to Sprague-Dawley rats for 13 weeks. At the highest dose, gross effects included increased adrenal, spleen, liver, and kidney weight. Hematological alterations included decreased erythrocyte counts, hemoglobin levels, and hematocrit; increased methemoglobin levels (males) and decreased methemoglobin levels (females). Histologic alterations of the stomach consisted of squamous epithelial hyperplasia, hyperkeratosis, ulceration, chronic inflammation, and edema. At 19 mg/kg-day, stomach lesions (similar to those in the high-dose group) and increases in absolute and relative spleen weights and relative adrenal weights were observed. No effects were observed at 7.4 mg/kg-day.

In the Haag (1949) study, renal pathology, characterized by distention of the glomerular capsule and appearance of a pinkish staining material in the renal tubules, was observed in rats exposed to 100 or 1,000 mg/L chlorite in drinking water for 2 years (9.3 or 81 mg/kg-day). These effects were also observed in a group of animals administered sodium chlorite at a concentration equimolar to 1,000 mg sodium chlorite/L. No other effects were observed. The study was limited because there was an insufficient number of animals tested per group, pathology was conducted on a small number of animals, and it did not provide adequate evaluations of more sensitive parameters, which would have been more useful in the overall assessment of chronic toxicity.

Numerous animal studies have examined neurodevelopmental toxicity of chlorine dioxide and chlorite. These studies consistently show

a LOAEL of 14 mg/kg-day and NOAEL of 3 mg/kg-day for multiple neurodevelopmental endpoints. Decreases in locomotor activity on PND 18-19, but not on days 15-17 or day 20, were observed in Sprague-Dawley rat pups administered gavage doses of 14 mg/kg-day chlorine dioxide on PND 5-20 (Orme et al., 1985). In in utero-exposed pups (dams exposed to 100 mg/L chlorine dioxide in drinking water [14 mg/kg-day] for 2 weeks prior to mating and throughout gestation and lactation), there was a consistent decrease in locomotor activity, but the activity was not statistically significantly lower than controls. Triiodothryonine (T3) and thyroxine (T4) were significantly decreased in the in utero-exposed pups and T4 levels were decreased in the postnatally exposed pups. No significant alterations in locomotor activity or T3 or T4 levels were observed in the offspring of rats exposed to 2 or 20 mg/L (1 or 3 mg/kg-day; exposure protocol the same as 100 mg/L group). However, there was a significant correlation between T4 levels and locomotor activity in all groups. Thus, this study identifies a NOAEL of 3 mg/kg-day and LOAEL of 14 mg/kg-day.

Mobley et al. (1990) found decreases in exploratory activity on postconception days 36-39, but not on days 39-41, in offspring of Sprague-Dawley rats exposed to 100 ppm chlorine dioxide in the drinking water (14 mg/kg-day) for 10 days prior to mating with unexposed males and during the gestation and lactation periods. A significant decrease in litter weight was also observed. Mobley et al. also found significant decreases in exploratory activity on PND 36-39, but not on days 39-41, in the offspring of Sprague-Dawley rats exposed to 40 ppm chlorine dioxide in the drinking water (6 mg/kg-day) for 10 days prior to mating and during gestation and lactation. T3 and T4 levels were not significantly altered. A slight decrease in activity was also observed in the offspring of rats exposed to 20 ppm (3 mg/kg-day). This study identifies a NOAEL of 3 mg/kg-day and LOAEL of 14 mg/kg-day.

Decreases in exploratory activity (PND 60) were also observed by Taylor and Pfohl (1985) in offspring of Sprague-Dawley rats exposed to 100 ppm chlorine dioxide in the drinking water (14 mg/kg-day) for 14 days prior to breeding and throughout gestation and lactation. A nonsignificant decrease in locomotor activity was noted in PND 10-20. Decreases in home cage or wheel-running activity occurred on PND 10 and 18-19 in pups (not exposed in utero) administered gavage doses of 14 mg/kg-day on PND 5-20. In addition to the decreases in motor activity, decreases in brain weight (primarily due to a decrease in cerebellar weight) and total cell numbers in the cerebellum were observed in the in utero-exposed pups. A LOAEL of 14 mg/kg-day was identified in this study; a NOAEL was not identified.

Toth et al. (1990) found decreases in forebrain weight, accompanied by decreases in protein content, on PND 21 and 35 in Long-Evans hooded rat pups receiving gavage doses of 14 mg/kg-day on PND 1-20. Dendritic spine counts in Krieg's area 18 (a visual association region of the cortex) were also significantly decreased. No gross lesions, loss of myelin, or changes in cells staining positive for Nissl substance in the forebrain, cerebellum, or brainstem were observed. T3, T4, and free T4 index

were not significantly altered on PND 11, 21, and 35. The 14 mg/kg-day dose is a LOAEL for neurodevelopmental effects.

I.A.5. Confidence in the Oral RfD:

Study -- Medium
Database -- High
RfD -- Medium-to-High

The overall confidence in this RfD assessment is medium-to-high. Confidence in the CMA (1996) principal study is medium. Although the study design and analytical approaches are consistent with EPA testing guidelines, some limitations in the design and conduct of the study exist. These limitations include (1) lack of pair-watered and -fed controls, which confounds the results and precludes definitive conclusions on whether the alterations in food and water consumption and body weight are related to water palatability or are a direct toxic effect of the agent; (2) developmental landmarks (e.g., vaginal opening in F2a group) were not reported for all groups; (3) grip strength and landing foot splay were not included in the FOB; and (4) discontinuation of exposure for the animals undergoing neurotoxicity testing minimizes the likelihood of finding a positive effect and precludes comparison of the data with those of other rats with continued exposure. Discontinuation of exposure after weaning reduces the opportunity to detect neurological effects from continuous or lifetime exposures similar to those expected from lifetime drinking water exposure in humans. Confidence in the database is high because there are studies in multiple species, chronic duration studies in males and females, reproductive/developmental toxicity studies, and a multigenerational study. The threshold for adverse effects is consistently defined among the animal studies.

I.A.6. EPA Documentation and Review of the Oral RfD:

Source Document -- This assessment is presented in the Toxicological Review of Chlorine Dioxide and Chlorite (CAS No. 10049-04-4 and 7758-19-2) (U.S. EPA, 2000).

This assessment was peer reviewed by external scientists. Their comments have been evaluated carefully and incorporated in finalization of this IRIS summary. A record of these comments is included as an appendix to U.S. EPA, 2000.

Agency Consensus Date -- 9/20/00

I.A.7. EPA Contacts (Oral RfD):

Please contact the Risk Information Hotline for all questions concerning this assessment or IRIS, in general, at (513)569-7254 (phone), (513)569-7159 (FAX), or RIH.IRIS@EPAMAIL.EPA.GOV (Internet address).

I.B. Reference Concentration for Chronic Inhalation Exposure (RfC):

Chlorite (sodium salt)
CASRN -- 7758-19-2
Last Revised -- 10/12/00

The inhalation reference concentration (RfC) is analogous to the oral RfD and is likewise based on the assumption that thresholds exist for certain toxic effects such as cellular necrosis. The inhalation RfC considers toxic effects for the respiratory system (portal-of-entry) and effects peripheral to the respiratory system (extrarespiratory effects). It is generally expressed in units of mg/m^3. In general, the RfC is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily inhalation exposure of the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime. Inhalation RfCs were derived according to the Interim Methods for Development of Inhalation Reference Doses (EPA/600/8-88/066F August 1989) and subsequently, according to Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry (EPA/600/8-90/066F October 1994). RfCs can also be derived for the noncarcinogenic health effects of substances that are carcinogens. Therefore, it is essential to refer to other sources of information concerning the carcinogenicity of this substance. If the U.S. EPA has evaluated this substance for potential human carcinogenicity, a summary of that evaluation will be contained in Section II of this file.

I.B.1. Inhalation RfC Summary:

An RfC for chlorite is not recommended at this time. No human or animal studies examining the toxicity of inhaled chlorite were located. Although the available human and animal data on inhaled chlorine dioxide support the derivation of an RfC for this chemical, these data cannot be used to derive an RfC for chlorite. Under ambient conditions, airborne chlorite is likely to exist as a particulate, whereas inhalation exposure to chlorine dioxide is as a gas. On the basis of their physical and chemical properties, it is anticipated that inhaled chlorine dioxide and chlorite would have very different modes of exposure, and the potential hazard associated with exposure to these two chemicals is also very different. In the absence of data demonstrating parallels in pharmacokinetic behavior following inhalation exposure, as is present following oral exposure, derivation of an RfC for chlorite from the available data for chlorine dioxide is not recommended.

I.B.2. Principal and Supporting Studies (Inhalation RfC):

None

I.B.3. Uncertainty and Modifying Factors (Inhalation RfC):

Not applicable.

I.B.4. Additional Studies/Comments (Inhalation RfC):

Not applicable.

I.B.5. Confidence in the Inhalation RfC:

Not applicable.

I.B.6. EPA Documentation and Review of the Inhalation RfC:

Source Document -- U.S. EPA, 2000

This assessment was peer reviewed by external scientists. Their comments have been evaluated carefully and incorporated in finalization of this IRIS summary. A record of these comments is included as an appendix to U.S. EPA, 2000.

Agency Consensus Date -- 9/20/00

I.B.7. EPA Contacts (Inhalation RfC):

Please contact the Risk Information Hotline for all questions concerning this assessment or IRIS, in general, at (513) 569-7254 (phone), (513) 569-7159 (fax), or RIH.IRIS@EPAMAIL.EPA.GOV (Internet address).

II. Carcinogenicity Assessment for Lifetime Exposure:

Chlorite (sodium salt)
CASRN -- 7758-19-2
Last Revised -- 10/12/00

Section II provides information on three aspects of the carcinogenic assessment for the substance in question, the weight-of-evidence judgment of the likelihood that the substance is a human carcinogen, and quantitative estimates of risk from oral exposure and from inhalation exposure. The quantitative risk estimates are presented in three ways. The slope factor is the result of application of a low-dose extrapolation procedure and is presented as the risk per (mg/kg)/day. The unit risk is the quantitative estimate in terms of either risk per µg/L drinking

water or risk per μg/m³ air breathed. The third form in which risk is presented is a concentration of the chemical in drinking water or air associated with cancer risks of 1 in 10,000, 1 in 100,000, or 1 in 1,000,000. The rationale and methods used to develop the carcinogenicity information in IRIS are described in the Risk Assessment Guidelines of 1986 (EPA/600/8-87/045) and in the IRIS Background Document. IRIS summaries developed since the publication of EPA's more recent Proposed Guidelines for Carcinogen Risk Assessment also utilize those Guidelines where indicated (Federal Register 61(79):17960-18011, April 23, 1996). Users are referred to Section I of this IRIS file for information on long-term toxic effects other than carcinogenicity.

II.A. Evidence for Human Carcinogenicity:

II.A.1. Weight-of-Evidence Characterization:

Under the current guidelines (U.S. EPA, 1986), chlorite is classified as Group D; not classifiable as to human carcinogenicity because of inadequate data in humans and animals. Under the draft Carcinogen Assessment Guidelines (U.S. EPA, 1996), the human carcinogenicity of chlorite cannot be determined because of a lack of human data and limitations in animal studies. Chronic oral studies in rats showed no evidence of carcinogenic activity of chlorite (Kurokawa et al., 1986). The short exposure duration (85 weeks) and high incidence of Sendai viral infection in control and exposed rats limit the use of this study to assess carcinogenicity. The mouse studies (Kurokawa et al., 1986; Yokose et al., 1987) showed an increase in liver and lung tumors in treated male mice. However, relatively short exposure duration (80 weeks) and the high incidence of early mortality in the concurrent control males from excessive fighting make statistical comparisons between concurrent controls and treated animals difficult to interpret. No increases in tumor incidence were seen in female mice in this study. Chlorite did not act as a complete carcinogen in a 51-week dermal carcinogenicity assay in mice (Kurokawa et al., 1984). In the same study, chlorite induced skin tumors following initiation by DMBA, but the increase was not statistically significant. Chlorite has shown both positive and negative results in in vitro and in vivo genotoxicity assays.

II.A.2. Human Carcinogenicity Data:

None

II.A.3. Animal Carcinogenicity Data:

Inadequate. Kurokawa et al. (1986) exposed groups of 50 male and 50 female F344 rats to 0, 300, or 600 ppm sodium chlorite in drinking water for 85 weeks. Using water consumption and body weight data, the study authors estimated the doses to be 18 and 32 mg/kg-day in male rats and 28 and 41 mg/kg-day in female rats.

All groups of rats were infected with the Sendai virus. No adverse effect on survival was observed. A slight dose-related decrease in body weight gain was observed (body weight gain in the high-dose group was within 10% of controls). No chlorite-related increases in tumor incidence were observed.

Kurokawa et al. (1986) also exposed groups of 50 male and 50 female B6C3F1 mice to 0, 250, and 500 ppm sodium chlorite in the drinking water for 80 weeks followed by a 5-week recovery period. The results of this study are also presented in Yokose et al. (1987). Daily doses of 0, 48, and 95 mg sodium chlorite/kg-day (0, 36, and 71 mg chlorite/kg-day) were calculated by U.S. EPA (1994). In the mice, there were no significant chlorite-related alterations in survival or body weight gain; increased mortality observed in the male control group was attributed to severe fighting. Significant increases in liver and lung tumors were observed in the male mice. The incidence of hyperplastic nodules in the liver was significantly increased in the low- and high-dose groups relative to controls (3/35 [reported as 6/35 in Yokose et al., 1987], 14/47, 11/43, in the control, low-, and high-dose groups, respectively) and the combined incidence of liver hyperplastic nodules and hepatocellular carcinoma was increased in the low-dose group (7/35, 22/47, and 17/43, respectively). The incidences of lung adenoma (0/35, 2/47, and 5/43, respectively) and the combined incidence for lung adenoma and adenocarcinoma (0/35, 3/47, and 7/43, respectively) were significantly increased in the high-dose group when compared with the controls. The study authors noted that the incidences of liver hyperplastic nodules and lung adenomas in the treated animals were within the range of historical controls in their laboratory and in the National Toxicology Program laboratories. The high mortality in the control males due to fighting may have contributed to the low tumor incidence in the concurrent control group. In the female mice, the only significant alteration in tumor incidence was a significantly lower incidence of malignant lymphoma/leukemia in the high-dose group (7/47, 5/50, 1/50, respectively).

II.A.4. Supporting Data for Carcinogenicity:

Kurokawa et al. (1984) also conducted dermal carcinogenicity studies. In a study to assess the ability of chlorite to act as a complete carcinogen, groups of 20 female SENCAR mice were exposed twice weekly for 51 weeks to 20 mg sodium chlorite/mL in acetone. The solution (0.2 mL; 100 mg sodium chlorite/kg per application) was applied to the shaved backs of the mice. The sodium chlorite exposure did not result in increased tumor incidence. To test the ability of chlorite to act as a tumor promoter, a single initiating dose of 20 µM of dimethylbenzanthracene (DMBA) was applied to the skin of 20 SENCAR mice. The DMBA application was followed by a 51-week exposure to sodium chlorite (as described for the complete carcinogen study). The tumor incidence was 6/20 (30%) compared with 0/20 in mice that received DMBA followed by acetone treatments for 51 weeks. Squamous cell carcinomas were observed in 5/20 animals in the chlorite group. However, these changes failed to reach statistical significance.

The genotoxicity of chlorite has been assessed in several in vitro and in vivo assays. In in vitro assays, chlorite induced reverse mutations in *Salmonella typhimurium* (with activation) and chromosome aberrations in Chinese hamster fibroblast cells (Ishidate et al., 1984). In general, the results of the in vivo assays have been negative. In the micronucleus assays, negative results were found in ddY mice following an oral gavage dose of 37.5-300 mg/kg single injection (Hayashi et al., 1988) and in Swiss CD-1 mice administered 0.25-1 mg via gavage for 5 consecutive days (0, 8, 20, and 40 mg/kg-day) (Meier et al., 1995). Using the same dosages, Meier et al. (1985) also reported negative results in the bone marrow chromosomal aberration assay in Swiss CD-1 mice and in the sperm-head abnormality assay in B6C3F1 mice. Positive results were found in the micronucleus assay in ddY mice when the chlorite was administered via intraperitoneal injection (7.5-60 mg/kg) (Hayashi et al., 1988).

II.B. Quantitative Estimate of Carcinogenic Risk from Oral Exposure:

None

II.C. Quantitative Estimate of Carcinogenic Risk from Inhalation Exposure:

None

II.D. EPA Documentation, Review, and Contacts (Carcinogenicity Assessment):

II.D.1. EPA Documentation:

Source Document -- U.S. EPA, 2000

This assessment was peer reviewed by external scientists. Their comments have been evaluated carefully and incorporated in finalization of this IRIS summary. A record of these comments is included as an appendix to U.S. EPA, 2000.

II.D.2. EPA Review (Carcinogenicity Assessment):

Agency Consensus Date -- 9/20/00

II.D.3. EPA Contacts (Carcinogenicity Assessment):

Please contact the Risk Information Hotline for all questions concerning this assessment or IRIS, in general, at (513) 569-7254 (phone), (513)569-7159 (fax), or RIH.IRIS@EPAMAIL.EPA.GOV (Internet address)

VI. Bibliography:

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VII. Revision History:

Chlorite (sodium salt) CASRN -- 7758-19-2

Date	Section	Description
09/01/1992	I.A	Oral RfD now under review
05/01/1993	All	CASRN corrected
05/01/1993	I.A	Work group review date added
05/01/1993	II.	Carcinogenicity assessment now under review
07/01/1993	I.A	Work group review date added
12/01/1993	I.A	Work group review date added
01/01/1994	I.A.	Work group review date added
08/01/1995	I.A., II.	EPA's RfD/RfC and CRAVE workgroups were discontinued in May, 1995. Chemical substance reviews that were not completed by September 1995 were taken out of IRIS review. The IRIS Pilot Program replaced the workgroup functions beginning in September, 1995.
11/01/1995	II.	Carcinogenicity assessment on-line
11/01/1995	VI.C.	Carcinogenicity references on-line
04/01/1997	III., IV., V.	Drinking Water Health Advisories, EPA Regulatory Actions, and V. Supplementary Data were removed from IRIS on or before April 1997. IRIS users were directed to the appropriate EPA Program Offices for this information.
10/12/2000	I.,II,VI	Oral RfD on-line, revised carcinogenicity assessment

National Institute for Occupational Safety and Health NIOSH

RTECS

The Registry of Toxic Effects of Chemical Substances

Sodium chlorite

RTECS #: VZ4800000

CAS #: 7758-19-2

UPDATE: July 2000	MW: 91.45	MF: $ClHO_2 \cdot Na$

NOTE:

- **TOXICITY DATA HAVE NOT BEEN EVALUATED. OMISSION OF A SUBSTANCE OR NOTATION DOES NOT IMPLY ANY RELIEF FROM REGULATORY RESPONSIBILITY.**

TABLE OF CONTENTS:

SYNONYMS:

1. Alcide LD
2. Chlorous acid, sodium salt (8CI,9CI)
3. Neo Silox D
4. Textile
5. Textone

SKIN AND EYE IRRITATION DATA AND REFERENCES:

ROUTE/ ORGANISM	DOSE	EFFECT	REFERENCE
N/R	N/R	N/R	N/R

MUTATION DATA AND REFERENCES:

SYSTEM TEST	ROUTE/ ORGANISM/ TISSUE	DOSE	REFERENCE
cytogenetic analysis	hamster fibroblast	20 mg/L	FCTOD7 22,623,1984
DNA inhibition	oral rat	84 mg/kg/12 week-continuous	JEPOEC 6 (1),105,1985
mutation in microorganisms	Salmonella typhimurium	300 µg/plate (-enzymatic activation step)	FCTOD7 22,623,1984
micronucleus test	intraperitoneal mouse	15 mg/kg	FCTOD7 26,487,1988
sperm morphology	oral rat	660 mg/kg/66 day- continuous	ENVRAL 42,238,1987

REPRODUCTIVE EFFECTS DATA AND REFERENCES:

ROUTE/ ORGANISM	DOSE	EFFECT	REFERENCE
intraperitoneal rat	lowest published toxic dose: 160 mg/kg (8-15 day pregnant)	Reproductive: Effects on fertility: Post- implantation mortality (e.g., dead and/or resorbed implants per total number of implants)	EVHPAZ 46,25,1982
intraperitoneal rat	lowest published toxic dose: 80 mg/kg (8-15 day pregnant)	Reproductive: Effects on embryo or fetus: Fetotoxicity (except death, e.g., stunted fetus)	EVHPAZ 46,25,1982
oral mouse	lowest published toxic dose: 22 gm/kg (1-21 day pregnant/28 day after birth)	Reproductive: Effects on newborn: Growth statistics (e.g., reduced weight gain)	BECTA6 25,689,1980
oral rat	lowest published toxic dose: 800 mg/kg (8-15 day pregnant)	Reproductive: Effects on embryo or fetus: Fetotoxicity (except death, e.g., stunted fetus)	EVHPAZ 46,25,1982
oral	lowest published toxic	Reproductive: Effects on fertility: Post- implantation mortality (e.g.,	EVHPAZ

rat	dose: 16 gm/kg (8-15 day pregnant)	dead and/or resorbed implants per total number of implants)	46,25,1982
oral rat	lowest published toxic dose: 660 mg/kg (66 day male)	Reproductive: Paternal effects: Spermatogenesis (including genetic material, sperm morphology, motility, and count)	ENVRAL 42,238,1987
oral rat	lowest published toxic dose: 1,130 mg/kg (8 week male/2 week prior to copulation-3 week after birth)	Reproductive: Effects on newborn: Biochemical and metabolic	TJADAB 35,43A,1987

TUMORIGENIC DATA AND REFERENCES:

ROUTE/ ORGANISM	DOSE	EFFECT	REFERENCE
oral mouse	lowest published toxic dose: 29,750 mg/kg/85 week-continuous	Tumorigenic: Carcinogenic by RTECS criteria Liver: Tumors	EVHPAZ 69,221,1986

ACUTE TOXICITY DATA AND REFERENCES:

ROUTE/ ORGANISM	DOSE	EFFECT	REFERENCE
inhalation rat	lethal concentration (50 percent kill): 230 mg/m^3/4 hour	N/R	NTIS** OTS0534543
oral guinea pig	lethal dose (50 percent kill): 300 mg/kg	N/R	GISAAA 45 (4),6,1980
oral man	lowest published toxic dose: 143 mg/kg	Lung, Thorax, or Respiration: Cyanosis Gastrointestinal: Nausea or vomiting Kidney, Ureter, and Bladder: Changes in tubules (including acute renal failure, acute tubular necrosis)	REFAE8 15,645,1993
oral mouse	lethal dose (50 percent kill): 350 mg/kg	N/R	GISAAA 45 (4),6,1980
		Liver: Jaundice, other or unclassified Kidney, Ureter, and Bladder:	

oral rat	lethal dose (50 percent kill): 165 mg/kg	Interstitial nephritis Biochemical: Metabolism (intermediary): Other	YKYUA6 31,959,1980

OTHER MULTIPLE DOSE DATA AND REFERENCES:

ROUTE/ ORGANISM	DOSE	EFFECT	REFERENCE
oral mouse	lowest published toxic dose: 168 mg/kg/28 day-continuous	Immunological Including Allergic: Uncharacterized (multiple organ involvement)	TOXID9 54,157,2000
oral rat	lowest published toxic dose: 365 mg/kg/1 year-continuous	Blood: Pigmented or nucleated red blood cells Blood: Changes in other cell count (unspecified) Nutritional and Gross Metabolic: Weight loss or decreased weight gain	JEPOEC 6 (1),105,1985
oral rat	lowest published toxic dose: 182 gm/kg/26 week- intermittent	Liver: Liver function tests impaired Blood: Changes in serum composition (e.g. TP, bilirubin, cholesterol) Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: Phosphatases	GISAAA 45 (4),6,1980

REVIEWS:

ORGANIZATION	STANDARD	REFERENCE
International Agency for Research on Cancer (IARC) Cancer Review	Animal Inadequate Evidence	IMEMDT 52,145,1991
International Agency for Research on Cancer (IARC) Cancer Review	Human No Available Data	IMEMDT 52,145,1991
International Agency for Research on Cancer (IARC) Cancer Review	Group 3	IMEMDT 52,145,1991

STANDARDS AND REGULATIONS:

ORGANIZATION	STANDARD	REFERENCE
Environmental Protection Agency (EPA) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 1988	PESTICIDE SUBJECT TO REGISTRATION OR RE-REGISTRATION	FEREAC 54,7740,1989

NIOSH DOCUMENTATION AND SURVEILLANCE:

ORGANIZATION	STANDARD or SURVEY	REFERENCE
National Occupational Hazard Survey 1974	National Occupational Hazard Survey 1974: Hazard Code: 81982; Number of Industries 8; Total Number of Facilities 129; Number of Occupations 13; Total Number of Employees Exposed 1,968	
National Occupational Exposure Survey 1983	National Occupational Exposure Survey 1983: Hazard Code: 81982; Number of Industries 20; Total Number of Facilities 532; Number of Occupations 27; Total Number of Employees Exposed 18,585; Total Number of Female Employees Exposed 4,817	

STATUS IN FEDERAL AGENCIES:

ORGANIZATION	REFERENCE
EPA TSCA Section 8(b) CHEMICAL INVENTORY	
On EPA IRIS database	
EPA TSCA TEST SUBMISSION (TSCATS) DATA BASE, OCTOBER 2000	

REFERENCES:

CODEN	REFERENCE
BECTA6	Bulletin of Environmental Contamination and Toxicology. (Springer-Verlag New York, Inc., Service Center, 44 Hartz Way, Secaucus, NJ 07094) V.1- 1966-

ENVRAL	Environmental Research. (Academic Press, Inc., 1 E. First St., Duluth, MN 55802) V.1- 1967-
EVHPAZ	EHP, Environmental Health Perspectives. (U.S. Government Printing Office, Supt of Documents, Washington, DC 20402) No.1- 1972-
FCTOD7	Food and Chemical Toxicology. (Pergamon Press Inc., Maxwell House, Fairview Park, Elmsford, NY 10523) V.20- 1982-
FEREAC	Federal Register. (U.S. Government Printing Office, Supt. of Documents, Washington, DC 20402)V.1- 1936-
GISAAA	Gigiena i Sanitariya. For English translation, see HYSAAV. (V/O Mezhdunarodnaya Kniga, 113095 Moscow, USSR) V.1- 1936-
IMEMDT	IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man. (WHO PublicationsCentre USA, 49 Sheridan Ave., Albany, NY 12210) V.1- 1972-
JEPOEC	Journal of Environmental Pathology, Toxicology and Oncology. (Chem-Orbital, POB 134, Park Forest, IL 60466) V.5(4)- 1984-
NTIS**	National Technical Information Service. (Springfield, VA 22161) Formerly U.S. Clearinghouse for Scientific & Technical Information.
REFAE8	
TJADAB	Teratology, The International Journal of Abnormal Development. (Alan R. Liss, Inc., 41 E. 11th St., New York, NY 10003) V.1- 1968-
TOXID9	Toxicologist. (Soc. of Toxicology, Inc., 475 Wolf Ledge Parkway, Akron, OH 44311) V.1- 1981-
YKYUA6	Yakkyoku. Pharmacy. (Nanzando, 4-1-11, Yushima, Bunkyo-ku, Tokyo, Japan) V.1- 1950-

Used as bleaching agent for textiles, paper pulp, edible oils

RTECS Compound Description:

Tumorigen
Mutagen
Reproductive Effector
Human Data

Vulcan CHEMICALS
BUSINESS GROUP OF
VULCAN MATERIALS COMPANY

P.O. Box 530390
Birmingham, AL 35253-0390
(205) 877-3000

PRODUCT SPECIFICATION

Sodium Chlorite
($NaClO_2$)

Technical Sodium Chlorite Solution 31.25
(25% Active Sodium Chlorite)

COMPONENT	SPECIFICATIONS
Sodium Chlorite, wt% as $NaClO_2$	24.25 - 25.75
Sodium Chlorate, wt% as $NaClO_3$	0.7 max.
Sodium Chloride, wt% as NaCl	3.0 max.
Total Alkalinity, wt% as NaOH @ pH4	0.5 max.
Hydrogen Peroxide, wt% as H_2O_2	0.01 max.
Water (by difference), wt%	70 - 75

TYPICAL PROPERTIES

Appearance	Clear, slightly yellow liquid
Turbidity, NTU	10 max
Density, lb/gal @ 25°C	10.1 (typical)

Typical properties are listed for information only, and are not to be considered as specification requirements. These items are not analyzed on a routine basis. Product meeting the specification test items will exhibit the listed typical properties.

CONTAINERS:
Tank Trucks (stainless steel) - 3400 gallon
Drums - 55 Gallon Plastic Drums, 565 lbs net
VMC non-returnable 275 gallon tote with steel box and plastic bottle
Customer provided returnable totes

NSF Listed, ANSI/NSF Standard 60 (Wichita, KS)
Meets requirements of AWWA B303a(2)-97
EPA Reg. No: 5382-43

Sterling Pulp Chemicals
Sodium Chlorite Solution
Product Specifications

Sodium Chlorite Solution 37

Chemical Properties	Units	Typical Analysis	Specification Minimum	Specification Maximum
$NaClO_2$	% w/w	38.2	37.0	39.5
NaOH	% w/w	0.38	0.10	0.80
NaCl	% w/w	0.20		0.60
Na_2CO_3	% w/w	0.18		0.50
$NaClO_3$	% w/w	0.07		0.35
Turbidity	NTU	0.2		1.0
Specific Gravity	@ 25°C	1.34	1.33	1.36

EPA Registration Number 53345-12

Sodium Chlorite Solution 31 (ERCOPURE 31)

Chemical Properties	Units	Typical Analysis	Specification Minimum	Specification Maximum
$NaClO_2$	% w/w	31.2	31.0	31.4
NaOH	% w/w	0.31	0.10	0.68
NaCl	% w/w	0.18		0.51
Na_2CO_3	% w/w	0.15		0.42
$NaClO_3$	% w/w	0.06		0.30
Turbidity	NTU	0.2		1.0
Specific Gravity	@ 25°C	1.26		

EPA Registration Number 53345-21

Sodium Chlorite Solution 25 (ERCOPURE 25)

Chemical Properties	Units	Typical Analysis	Specification Minimum	Specification Maximum
$NaClO_2$	% w/w	25.2	25.0	25.4
NaOH	% w/w	0.25	0.10	0.55
NaCl	% w/w	0.14		0.41
Na_2CO_3	% w/w	0.12		0.34
$NaClO_3$	% w/w	0.06		0.25
Turbidity	NTU	0.2		1.0
Specific Gravity	@ 25°C	1.20		

EPA Registration Number 53345-14

000030

Note: Analytical methods per Sterling Pulp Chemicals' standard methods

Issued: 9 August, 1999

Attachment 6

11. Research Information, Substance Reviews and Bibliographies and Citations Which Present Contrasting Positions Presented By the Petitioner

11). **Report reviews and bibliographical citations which present contrasting positions on those presented by petitioner**

No reviews have been found which present a contrasting position.

Acidified sodium chlorite is a safe, effective antimicrobial thoroughly tested and is approved by the FDA and USDA for use on poultry and red meat, by the FDA for seafood, the EPA and FDA for use on fruit and vegetables and the EPA as hard surface disinfectant.

Animal Metabolism, Enforcement Methodology, Storage Stability, and Magnitude of the Residue

The Phase IV Review of sodium chlorite (C. Swartz, 2/2/93) waived animal metabolism, analytical methods, storage stability, and magnitude of the residue data because "...CBRS has determined that although it is not possible to establish with certainty whether finite residues will be incurred in meat, milk, and eggs, there is no reasonable expectation of finite residues significantly above the naturally occurring background levels." (p. 5 of EPA response in p. 20 of Bioxy EPA Petition PP 6F4783: Petition, Releasable Correspondence, Memoranda.

The U. S. Food and Drug Administration, CFSAN, recognizes acidified sodium chlorite solutions as a preventive control measure for control and reduction/elimination of Microbial Hazards on Fresh and Fresh-Cut-Produce (p. 7-8; http://ww.cfsan.gov/~comm/ift3-5.html) (copy attached).

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Bioxy EPA Petition PP 6F4783: Petition, Releasable Correspondence, Memoranda

conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether chlorine dioxide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this tolerance action, therefore, EPA has not assumed that chlorine dioxide has a common mechanism of toxicity with other substances.

DETERMINATION OF SAFETY FOR U.S. POPULATION, INFANTS AND CHILDREN

Because sodium chlorite and chlorine dioxide are not expected to accumulate in meat, milk, poultry, or eggs, exposure of infants and children will not result from the proposed use. The most likely source of human exposure to chlorite or chlorine dioxide is through consumption of drinking water. The OW is currently in the process of regulating chlorite and chlorine dioxide.

OTHER CONSIDERATIONS

Product Chemistry

1. Product chemistry data for Aquatize have been previously reviewed by RD (A.Skapars, 10/22/96, D230356).

Animal Metabolism, Enforcement Methodology, Storage Stability, and Magnitude of the Residue

2. The Phase IV Review of sodium chlorite (C.Swartz, 2/2/93) **waived animal metabolism, analytical method, storage stability, and magnitude of the residue data** because, "... CBRS has determined that although it is not possible to establish with certainty whether finite residues will be incurred in meat, milk, and eggs, there is no reasonable expectation of finite residues significantly above the naturally occurring background levels."

International Residue Limits

3. No CODEX, Canadian, or Mexican MRLs have been established for residues of chlorite or chlorine dioxide in meat, milk, poultry or eggs.

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SUPPLEMENTAL INFORMATION

Residue Chemistry

Residues of sodium chlorite or chlorine dioxide are not expected in livestock. A 1987 National Research Council report entitled "Drinking Water and Health: Disinfectants and Disinfectant By-Products, Volume 7" (National Academy Press) discussed available tissue distribution data of ^{36}Cl-labeled chlorite and chlorate following administration of either chlorite at 10 mg/L or chlorate at 5 mg/L. The NRC report concluded that, "[available data] suggests that neither [sodium] chlorite nor chlorate bioaccumulates" (page 101).

In aqueous solution, sodium chlorite converts to chlorine dioxide, which is then consumed during the reduction of bacterial activity. The extent and rate of consumption will be determined by bacterial load and reaction with any minerals or other contaminants present in the livestock drinking water. The petitioners noted that livestock drinking water is generally obtained from wells, and thus usually high in minerals and slightly acidic.

The maximal proposed use pattern, 1 part Aquatize per 2,000 parts water (0.05% Aquatize) results in 18 ppm sodium chlorite in livestock drinking water. Because sodium chlorite and chlorine dioxide are highly reactive with bacteria and other contaminants present in water, they would be expected to be rapidly consumed during the reduction of bacterial contamination.

Attachments: Chlorine Dioxide, Chlorite, and Chlorate Drinking Water Health Advisory, Office of Water, USEPA

cc with Attachments: PIRAT, Caswell File, TOX
RDI:PIRAT:5/19/97

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U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
September 30, 2001

Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce

Table of Contents

Chapter V

Methods to Reduce/Eliminate Pathogens from Fresh and Fresh-Cut Produce

Scope

In response to the current public health concerns with the microbiological safety of fresh and fresh-cut produce, researchers have investigated the efficiency of numerous physical, chemical, and biological methods for reducing the microbiological load of produce. This chapter focuses on this growing area of research with a particular emphasis on human pathogenic microorganisms; however, research related to mitigation treatment effects on non-pathogenic organisms is also included. There have been several reviews that address this topic and they are pointed out throughout the chapter; therefore, the focus here is on the latest and most significant research findings. A matrix (Table V-1) summarizing the characteristics of intervention methods is also included at the end of the chapter.

1. Introduction

It is well established that pathogenic microorganisms associated with whole or fresh-cut produce can cause disease outbreaks, thereby demonstrating the need for improved mitigation efforts to reduce risks associated with these products. Issues related to outbreaks (see Chapter IV), surface contamination, mild processing, and mitigation strategies for produce have been recently reviewed (Beuchat 1998, 2000; Francis and others 1999; NACMCF 1999; Seymour 1999).

There are a variety of methods used to reduce populations of microorganisms on whole and fresh-cut produce. Each method has distinct advantages and disadvantages depending upon the type of produce, mitigation protocol, and other variables. The best method to eliminate pathogens from produce is to prevent contamination in the first place. However, this is not always possible and the need to wash and sanitize many types of produce remains of paramount importance to prevent disease outbreaks. It should be noted that washing and sanitizing are unlikely to totally eliminate all pathogens after the produce is contaminated. Therefore, it is important to use washing and sanitizing protocols that are efficient. Another important point to consider is that some produce, such as certain berries, cannot be washed due to their delicate structure and problems with mold proliferation. These and some other produce items are

often packaged in the field with minimal postharvest handling or washing.

In reference to food contact surfaces, 21 CFR 110.3(o) (CFR 2000b) defines the word sanitize: "to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance." An additional definition of "sanitize" is found in the FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (FDA 1998): "to treat clean produce by a process that is effective in destroying or substantially reducing the numbers of microorganisms of public health concern, as well as other undesirable microorganisms, without adversely affecting the quality of the product or its safety for the consumer." This definition addresses the need to maintain produce quality while enhancing safety by reducing populations of pathogenic microorganisms of public health significance that might theoretically exist on the produce.

Traditional methods of reducing microbial populations on produce involve chemical and physical treatments. Control of contamination requires that these treatments be applied to equipment and facilities as well as to produce. Methods of cleaning and sanitizing produce surfaces usually involve the application of water, cleaning chemicals (for example, detergent), and mechanical treatment of the surface by brush or spray washers, followed by rinsing with potable water. The rinse step may include a sanitizer treatment. It is important to ensure that water used for washing and sanitizing purposes is clean so that it does not become a vehicle for contamination.

Efficacy of the method used to reduce microbial populations is usually dependent upon the type of treatment, type and physiology of the target microorganisms, characteristics of produce surfaces (cracks, crevices, hydrophobic tendency, texture), exposure time and concentration of cleaner/sanitizer, pH, and temperature. It should be noted that the concentration/level of sanitizers or other intervention methods may be limited by unacceptable sensory impact on the produce. Infiltration of microorganisms into points below the surface of produce is problematic. While it is known that microorganisms can infiltrate into produce under certain handling conditions, the significance of any such infiltration to public health requires further study.

The relationship between human pathogens and the native microflora, including postharvest spoilage organisms, on produce is of interest for at least two reasons. First, it has been suggested that reducing/controlling the native microbial populations by washing and sanitizing or by controlled atmosphere storage can allow human pathogens to flourish on produce surfaces (Brackett 1992). Concern has been expressed that reductions in surface populations reduces competition for space and nutrients thereby providing growth potential for pathogenic contaminants. In theory, this scenario can result in an unspoiled product that is unsafe for consumption. Berrang and others (1989ab) showed that pathogens grow to higher levels on produce stored under controlled atmosphere for extended shelf life than traditionally stored produce. While the cut salad industry traditionally uses natural spoilage as a food safety control measure, lengthening product shelf life would not be desirable if it increases the risk that pathogens would grow before spoilage is detectable. Secondly, a proliferation of postharvest spoilage organisms may compromise peel integrity and alter product pH thereby enhancing the survival and growth of human pathogens (Conway and others 2000).

These issues, along with primary methods of pathogen control for whole and fresh-cut produce are described in more detail below. Although the intent of this report is to describe methods to reduce or eliminate pathogens from produce, information regarding mitigation against non-pathogenic microorganisms is included in the text to illustrate the overall effectiveness of certain intervention technologies.

1.1. Combined methods and hurdles

This report does not specifically address the antimicrobial effects of combinations of various mitigation strategies; however, it would be expected that combinations of sanitizers and/or other intervention

methods, such as heat or irradiation, would have additive, synergistic or antagonistic interactions (Parish and Davidson 1993).

The concept of using multiple intervention methods is analogous to hurdle technology where two or more preservation technologies are used to prevent growth of microorganisms in or on foods (Leistner and Gorris 1995; Leistner 2000; Howard and Gonzalez 2001)

2. Intervention methods

2.1. Temperature

Refrigerated temperatures cannot be relied upon to prevent growth of pathogenic microorganisms on produce. Populations of *Listeria monocytogenes* remained constant or grew on a variety of whole and cut produce stored at refrigerated temperatures (Farber and others 1998). Under certain chilled storage conditions, spoilage of the product by the native microflora might not occur until after pathogen populations reach levels capable of causing disease. Austin and others (1998) reported toxin production by *Clostridium botulinum* on unspoiled onions and butternut squash stored under modified atmosphere at 15 °C (59 °F). Piagentini and others (1997) reported that *Salmonella* Hadar could survive and proliferate on chilled shredded cabbage prior to detection of spoilage. While growth of some pathogens may be inhibited by chilled temperatures, survival can be enhanced under certain conditions. For example, salmonellae and *E. coli* O157:H7 survive for a longer time period in fruit juices under refrigeration than at room temperature (Parish and others 1997; Zhao and others 1993).

Hot water is used as a mitigation treatment of some fruits to control insects and postharvest plant pathogens that cause product spoilage. Fruits investigated for hot water treatment include apple, cherry, grapefruit, lemon, mango, melon, papaya, pear, or tomato (Breidt and others 2000; Puerta and Suslow 2001, personal communication, unreferenced). Although adverse effects on color, texture, and flavor limit the usefulness of this treatment, hot water may have application as a sanitizer of produce, especially for fresh-cut products or unpasteurized juices where inedible outer rinds, skins or peels are discarded during processing. Pao and Davis (1999) determined that immersion of oranges in hot water (70 °C [158 °F] for 2 min, or 80 °C [176 °F] for 1 min) effectively reduced *Escherichia coli* on overall fruit surfaces by 5 log CFU/cm^2, although reductions on the stem-end tissue were not as great. One disadvantage is that thermally treated produce might not be considered "fresh" by FDA based on 21 CFR part 101.95 (CFR 2000a).

The hygiene and temperature of water used during the handling of produce are of primary importance. Immersion of warm whole or fresh-cut produce in cool process solutions may induce infiltration of the solution (including contaminating microorganisms) into the product through openings in the peel such as stem-end vascular tissue, lenticels, stomata, puncture wounds, or other physical disruptions. Research by Bartz (1982), Bartz and Showalter (1981) and Showalter (1979) showed that bacteria in a cool (20 to 22 °C) (68 to 71.6 °F) aqueous suspension penetrate into stem tissue of warm tomatoes after a 10 min exposure. A negative temperature differential of 15 °C (77°F) allowed the infiltration of *Salmonella* Montevideo into the core of tomatoes at significantly higher rates than without a temperature differential (Zhuang and others 1995). The issue of infiltration is of special concern during hydrocooling where water is used to cool the product. It is imperative that water used for this purpose be sanitary and free of human pathogens.

Buchanan, Edelson, Miller and others (1999) determined that *E. coli* O157:H7 can penetrate into the core of warm apples placed in a cool suspension of the pathogen. Results of Burnett and others (2000) suggest that this same pathogen may infiltrate through apple floral tubes regardless of temperature differences although infiltration was greater for apples under a negative temperature differential. These studies point out the importance of maintaining adequate disinfectant levels to eliminate pathogens in water from dump tanks or other handling procedures before they have the opportunity to penetrate into

2.3. Chlorine (Hypochlorite)

Chlorine has been used for sanitation purposes in food processing for several decades and is perhaps the most widely used sanitizer in the food industry (Walker and LaGrange 1991; Cherry 1999). Chemicals that are chlorine based are often used to sanitize produce and surfaces within produce processing facilities, as well as to reduce microbial populations in water used during cleaning and packing operations. Safety concerns about the production of chlorinated organic compounds, such as trihalomethanes, and their impact on human and environmental safety have been raised in recent years, and alternatives to chlorine have been investigated. At the foodservice and household levels, chlorine remains a convenient and inexpensive sanitizer for use against many foodborne pathogens.

The most common forms of free chlorine include liquid chlorine and hypochlorites. (Chlorine dioxide and acidified sodium chlorite will be discussed in the next section.) Liquid chlorine and hypochlorites are generally used in the 50 to 200 ppm concentration range with a contact time of 1 to 2 min to sanitize produce surfaces and processing equipment. Higher concentrations have been investigated for use on seeds for sprout production. Hypochlorous acid (HOCl) is the form of free available chlorine that has the highest bactericidal activity against a broad range of microorganisms. In aqueous solutions, the equilibrium between hypochlorous acid (HOCl) and the hypochlorite ion (OCl^-) is pH dependent with the concentration of HOCl increasing as pH decreases. Typically, pH values between 6.0 and 7.5 are used in sanitizer solutions to minimize corrosion of equipment while yielding acceptable chlorine efficacy. HOCl concentration is also significantly affected by temperature, presence of organic matter, light, air, and metals. For example, increasing levels of organic matter decreases HOCl concentration and overall antimicrobial activity. Maximum solubility in water is observed near 4 °C (39.2 °F); however, it has been suggested that the temperature of processing water should be maintained at least 10 °C (50 °F) higher than that of produce items in order to reduce the possibility of microbial infiltration caused by a temperature-generated pressure differential. The opportunity for infiltration of microorganisms is also minimized when the sanitary condition of the water is maintained. There are readily available commercial systems for inline monitoring and application of chlorine to maintain water cleanliness. This is particularly applicable to water used in dump tanks or for cleaning or cooling purposes.

Effects of chlorine on bacterial pathogens inoculated onto produce have been investigated with mixed results. Studies indicate those chlorine concentrations traditionally used with produce (<200 ppm) are not particularly effective at reducing microbial populations on lettuce. Survival of *E. coli* O157:H7 on cut lettuce pieces after submersion for 90 s in a solution of 20 ppm chlorine at 20 or 50 °C (68 or 122 °F) was not significantly different from the non chlorine treatment (Li and others 2001). Spray treatment of lettuce with 200 ppm chlorine was no more effective at removing *E. coli* O157:H7 than treatment with deionized water (Beuchat 1999). Increasing the exposure time from 1 to 5 min did not result in an increased kill. Likewise, Adams and others (1989) indicated that a standardized washing procedure for lettuce leaves was only slightly improved with inclusion of 100 ppm chlorine over tap water alone. Although a reduction of pH of the chlorine solution to between 4.5 and 5.0 increased lethality up to 4-fold, longer wash times (from 5 to 30 min) did not result in increased removal of microorganisms.

Research reported by Nguyen-the and Carlin (1994) suggests that inactivation of *L. monocytogenes* on vegetables by chlorine is limited. Zhang and Farber (1996) showed that treatment of shredded lettuce and cabbage with 200 ppm chlorine for 10 min reduced the population of *L. monocytogenes* by 1.7 and 1.2 log CFU/g, respectively. Reductions were only marginally greater when exposure time was increased from 1 to 10 min. Similarly, 10-minute exposures of *Yersinia enterocolitica* on shredded lettuce to 100 and 300 ppm chlorine resulted in population reductions of roughly 2 to 3 log (Escudero and others 1999). Results at 4 °C (39.2 °F) and 22 °C (71.6 °F) were not significantly different ($P<0.05$). In this same study, a combination of 100 ppm chlorine and 0.5% lactic acid inactivated *Y. enterocolitica* by greater than 6 log. These results suggest that *Y. enterocolitica* may be more sensitive to chlorine than some other pathogens. Brackett (1987) reported that the reduction in numbers of *L. monocytogenes* on

Brussels sprouts changed from 90% (dipped 10 s in sterile water without chlorine) to 99% with the addition of 200 ppm chlorine. When inoculated into cracks of mature green tomatoes, *Salmonella* Montevideo survived treatment with 100 ppm chlorine (Wei and others 1995).

Treatment of produce with higher concentrations of chlorine (>500 ppm) has been studied. For example, sprouts have unique attributes and microbiological issues that have required investigations of non-traditional sanitation regimens. Treatment of alfalfa seeds and sprouts with chlorine to control salmonellae and *E. coli* O157:H7 has been studied (Jaquette and others 1996; Beuchat and Ryu 1997; Taormina and Beuchat 1999a, 1999b). Chlorine concentrations up to 100 ppm reduced populations of pathogens on alfalfa seeds; however, concentrations between 100 and 1000 ppm were not more effective (Jaquette and others 1996). Treatment of alfalfa sprouts for 2 min with a 500 ppm chlorine dip reduced salmonellae populations by 3.4 log per gram, and, after treatment with 2000 ppm chlorine, salmonellae populations were undetectable (<1 CFU/g) (Beuchat and Ryu 1997). The effect of chlorine treatment on sensory aspects of the sprouts was not reported. *Escherichia coli* O157:H7 populations were reduced significantly after exposure to $Ca(OCl)_2$ at 500 and 1000 ppm; however, treatment with 20,000 ppm $Ca(OCl)_2$ did not eliminate this microorganism from seeds (Taormina and Beuchat 1999a). Application of 2000 ppm sodium or calcium hypochlorite significantly reduced the population of *E. coli* O157:H7 on germinated alfalfa seeds but did not control growth of the pathogen on sprouts during the sprouting process (Taormina and Beuchat 1999b).

Beuchat and others (1998) showed that the maximum reduction in human pathogen populations on apples, tomatoes, and lettuce was 2.3 log CFU/cm^2 after dipping in solutions of 2000 ppm chlorine for 1 min. On fresh-cut cantaloupe cubes, 2000 ppm chlorine resulted in less than a 90% reduction in viable cells of several strains of salmonellae (Beuchat and Ryu 1997). Populations of salmonellae or *E. coli* O157:H7 inoculated onto the surfaces of cantaloupes and honeydew melons were reduced between 2.6 and 3.8 log CFU (as compared to a water wash control) when treated for 3 min with 2000 ppm sodium hypochlorite or 1200 ppm acidified sodium chlorite (Park and Beuchat 1999). These treatments were less effective when applied to asparagus spears, thereby indicating that it may be necessary to customize sanitation treatments for different types of produce. Populations of *Shigella sonnei* inoculated onto whole parsley leaves were reduced more than 7 log CFU/g after treatment for 5 min with 250 ppm free chlorine (Wu and others 2000).

Reduction in populations of microflora on whole and fresh-cut produce is dependent upon the type of produce and the type of natural microflora present. Senter and others (1985) determined that total plate counts and Enterobacteriaceae populations on tomato surfaces decreased when chlorine levels of process water were raised from about 115 to 225 ppm. Pao and Davis (1999) showed that populations of *E. coli* inoculated onto orange surfaces were reduced more than 2 log CFU/cm^2 after immersion in 200 ppm chlorine at 30 °C (86 °F) for 8 min. This reduction was only slightly higher than that resulting from immersion in deionized water alone. Murdock and Brokaw (1958) used water containing 20 to 50 ppm free chlorine to reduce total microbial populations on the surface of oranges by 92 to 99%, as compared to 79% for oranges washed in water. Winniczuk (1994) determined that dipping washed oranges in 1000 ppm HOCl for 15 s reduced the microbial population on the surface by about 90%, as compared to 60% for control oranges dipped in plain water. Populations of *E. coli* inoculated onto lettuce leaves and broccoli florets were generally reduced <1 log CFU/g after a 5 min dip in 100 ppm free chlorine compared to a plain water dip (Behrsing and others 2000).

Results of Mazollier (1988) indicated that microbial reductions on leafy salad greens were essentially the same when treated with 50 or 200 ppm chlorine. Total microbial populations were reduced about 1000-fold when lettuce was dipped in water containing 300 ppm total chlorine, but no effect was seen against microbial populations on red cabbage or carrots (Garg and others 1990). Coliform bacteria were reduced by 81% on parsley, 93% on lettuce, 98% on strawberries, and 85% on coriander after a 10-min contact time in a solution of 300 ppm chlorine (Lopez and others 1988). Microbial populations of cut

potato strips were not effectively controlled by dips in 300 ppm hypochlorite (Gunes and others 1997). Treatment of honeydew melons and cantaloupes with 200 ppm hypochlorite significantly ($P<0.05$) reduced surface microbial populations compared to water-washed controls (Ayhan and others 1998).

Since chlorine reacts with organic matter, components leaching from tissues of cut produce surfaces may neutralize some of the chlorine before it reaches microbial cells, thereby reducing its effectiveness. Additionally, crevices, cracks, and small fissures in produce, along with the hydrophobic nature of the waxy cuticle on the surface of many fruit and vegetables, may prevent chlorine and other sanitizers from reaching the microorganisms. Surfactants, detergents, and solvents, alone or coupled with physical manipulation such as brushing, may be used to reduce hydrophobicity or remove part of the wax to increase exposure of microorganisms to sanitizers. However, such treatments may cause deterioration of sensory quality, thereby limiting their usefulness to applications just prior to consumption (Adams and others 1989; Zhang and Farber 1996).

2.4. Chlorine dioxide and acidified sodium chlorite

The major advantages of chlorine dioxide (ClO_2) over HOCl include reduced reactivity with organic matter and greater activity at neutral pH; however, stability of chlorine dioxide may be a problem. ClO_2 forms fewer organohalogens than HOCl, although its oxidizing power is reported as 2.5 times that of chlorine (Benarde and others 1967). A maximum of 200 ppm ClO_2 is allowed for sanitizing of processing equipment and 3 ppm maximum is allowable for contact with whole produce. Only 1 ppm maximum is permitted for peeled potatoes. Treatment of produce with chlorine dioxide must be followed by a potable water rinse or blanching, cooking, or canning (CFR 2000c).

There is less information about the effectiveness of ClO_2 than HOCl as a sanitizer for produce. As with HOCl, microbial susceptibility to ClO_2 differs with strain and environmental conditions of application. A population of *L. monocytogenes* inoculated onto shredded lettuce and cabbage leaves was reduced an additional 1.1 and 0.8 log at 4 and 22 °C (39.2 and 71.6 °F), respectively, after treatment with 5 ppm ClO_2 for 10 min when compared to washing in tap water (Zhang and Farber 1996). Use of ClO_2 gas reduced the numbers of *E. coli* O157:H7 on injured green pepper surfaces (Han and others 2000). Treatment of surface-injured green peppers with 0.6 and 1.2 ppm ClO_2 gas reduced populations of *E. coli* O157:H7 by 3.0 and 6.4 log cycles, respectively. These researchers noted that no significant growth of *E. coli* O157:H7 was observed on uninjured pepper surfaces, but significant growth occurred on injured pepper surfaces within 24 h at 37 °C (98.6 °F). The use of ClO_2 in a gaseous state, as opposed to an aqueous solution, warrants further study.

Roberts and Reymond (1994) demonstrated mortality of postharvest spoilage fungi to ClO_2. Greater than 99% kill of conidia or sporangiophores was observed after 1 min in water containing 3 or 5 ppm ClO_2. Fungal populations on conveying equipment were reduced upon treatment with foam containing 14 to 18 ppm ClO_2. Costilow and others (1984) reported that 2.5 ppm ClO_2 was effective against microorganisms in wash water, but concentrations as high as 105 ppm did not reduce the microflora in or on cucumbers. Similar results were reported by Reina and others (1995). Immersion of oranges in 100 ppm chlorine dioxide at 30 °C (86 °F) for 8 min produced a 3-log reduction of non-pathogenic *E. coli* compared to about a 2-log reduction when immersed in deionized water only (Pao and Davis 1999).

Acidified sodium chlorite has been approved for use on certain meats, seafood, poultry, and raw fruits and vegetables as either a spray or dip in the range of 500 to 1200 ppm (CFR 2000d). Reactive intermediates of this compound are highly oxidative with broad spectrum germicidal activity. Applications of 500 ppm acidified ClO_2 significantly reduced populations of *E. coli* O157:H7 (>1 log)

on germinated alfalfa seeds, but did not control the growth of the pathogen during the sprouting process (Taormina and Beuchat 1999b). Park and Beuchat (1999) showed that acidified sodium chlorite has a substantial antimicrobial effect against *E. coli* O157:H7 and salmonellae inoculated onto cantaloupes, honeydew melons and asparagus spears. Pathogen reductions were in the range of 3 log. There is a need for more published information on the general usefulness of acidified sodium chlorite for produce.

2.5. Bromine

Little is known about the usefulness of bromine as a sanitizer for produce. Kristofferson (1958) and Shere and others (1962) observed a synergistic antimicrobial relationship when bromine was added to chlorine solutions. Within 15 min at 24 °C (75.2 °F), free bromine (200 ppm) was shown to kill *E. coli*, *Salmonella* Typhosa, and *Staphylococcus aureus*, but not *Pseudomonas aeruginosa* (Gershenfeld and Witlin 1949). Dibromodimethyl hydrantoin was as effective as chlorine against *Streptococcus faecalis* (Ortenzio and Stuart 1964), but was less effective against *Bacillus cereus* spores (Cousins and Allan 1967). As with free chlorine, there are safety concerns about the production of brominated organic compounds and their impact on human and environmental safety.

2.6. Iodine

Iodophors have a broad spectrum of antimicrobial activity, are less corrosive than chlorine at low temperatures, and are less volatile and irritating to skin than other types of iodine solutions (Lawrence and others 1957). However, iodine-containing sanitizer solutions may be corrosive (upon vaporization above 50 °C [122 °F]), have reduced efficacy at low temperature, and may stain equipment, clothes, and skin. The use of iodine-containing solutions as direct contact sanitizers for produce is further limited due to a reaction between iodine and starch that results in a blue-purple color. Despite these limitations, iodine solutions such as iodophors (combinations of elemental iodine and nonionic surfactants or carriers) are commonly used as sanitizers for food contact surfaces and equipment in the food processing industry (Bartlett and Schmidt 1957; Hays and others 1967; Mosley and others 1976; Lacey 1979; Jilbert 1988). Although iodine solutions are not used for direct food contact, a peroxidase-catalyzed chemical solution that included sodium iodide as an antimicrobial constituent was active against salmonellae inoculated onto chicken breast skin (Bianchi and others 1994) and may warrant investigation for some produce items.

As with most sanitizers, iodophors are more active against vegetative cells than bacterial spores. Decimal reduction values for vegetative bacterial cells are between 3 and 15 s at 6 to 13 ppm available iodine at neutral pH (Hays and others 1967; Mosley and others 1976; Gray and Hsu 1979). D values for spores of *Bacilllus cereus, Bacillus subtilis*, and *C. botulinum* Type A treated with 10 to 100 ppm of iodophor are 10- to 1000-fold greater than for vegetative cells (Odlaug 1981). Although iodophors are not approved for direct food contact, they might have some usefulness for treatment of produce items that are peeled before consumption. This type of use would require regulatory approval and a demonstration that produce treated by these compounds are safe for consumption.

2.7. Quaternary ammonium compounds

Commonly called "quats," quaternary ammonium compounds are cationic surfactants that are odorless, colorless, stable at high temperatures, non-corrosive to equipment, nonirritating to skin, and able to penetrate food contact surfaces more readily than other sanitizers (Walker and LaGrange 1991). The antimicrobial activity of quats is greater against the fungi and gram-positive bacteria than gram-negative bacteria. Thus, *L. monocytogenes* is more sensitive to quats than coliforms, *Salmonella* spp., pathogenic *E. coli*, or pseudomonads. Due to their high surface-active capability, the mechanism of activity for quats possibly involves a breakdown of the cell membrane/wall complex (Marriott 1999). Some concern has been expressed about the potential for development of resistance to quats due to the common spread of Class 1 integrons among bacteria. The practical impact of possible quat resistance has not been

demonstrated.

Quat sanitizers form a residual antimicrobial film when applied to most hard surfaces and are relatively stable to organic compounds. They are most effective when used at pH 6 to 10, and are not compatible with acidic environments, soaps or anionic detergents. Although they are not approved for direct food contact, quats may have some limited usefulness with whole produce that must be peeled prior to consumption. As with iodine compounds, direct food contact would require regulatory approval and a demonstration that produce treated by quats is safe for consumption.

Brown and Schubert (1987) determined that a 30 s exposure of oranges to a 500 ppm quat solution reduced *Xanthomonas campestris pv. vesicatoria* as effectively as 150 - 250 ppm chlorine for 2 min. The surface microflora of oranges brushwashed in water and dipped in 200 ppm quat for 15 s was reduced about 95% compared to 60% for washed oranges dipped in plain water (Winniczuk 1994).

2.8. Acidic compounds with or without fatty acid surfactants

Organic acids are commonly used as antimicrobial acidulants to preserve foods either by direct addition or through microbiological fermentation (Foegeding and Busta 1991). Since many pathogens generally cannot grow at pH values much below 4.5, acidification may act to prevent microbial proliferation. Organic acids may also possess bactericidal capabilities. The antimicrobial action of organic acids is due to pH reduction in the environment, disruption of membrane transport and/or permeability, anion accumulation, or a reduction in internal cellular pH by the dissociation of hydrogen ions from the acid. Many types of produce, especially fruit, naturally possess significant concentrations of organic acids such as acetic, benzoic, citric, malic, sorbic, succinic, and tartaric acids, which negatively affect the viability of contaminating bacteria. Fruits such as melons and papayas contain lower concentrations of organic acids than other fruits and therefore are at pH values above 5.0, which does not suppress growth of pathogenic bacterial contaminants.

In contrast to their use as preservatives, organic acids, primarily lactic acid, are also successfully used as sanitizers on food animal carcasses and may have potential for application to produce surfaces for the purpose of reducing populations of microorganisms. Treatment with citric acid in the form of lemon juice has been shown to reduce populations of *Salmonella* Typhi inoculated onto cubes of papaya and jicama (Fernandez Escartin and others 1989). Castillo and Escartin (1994) investigated survival of *C. jejuni* on cubes of watermelon and papaya treated at room temperature with lemon juice. Six hours after treatment, populations of *Campylobacter jejuni* ranged from 0 to 14.3% of the original inoculum on cubes treated with lemon juice, and from 7.7 to 61.8% on cubes not treated with lemon juice. The antimicrobial activity was more pronounced on papaya than watermelon.

Use of acetic acid to inactivate pathogenic bacteria on fresh parsley was studied by Karapinar and Gonul (1992). Populations of *Y. enterocolitica* inoculated onto parsley leaves were reduced > 7 log cycles after washing for 15 min in solutions of 2% acetic acid or 40% vinegar. Treatment in 5% acetic acid for 30 min did not result in any recovery of aerobic bacteria, while treatment with vinegar gave a 3 to 6 log decrease in aerobic counts, depending upon vinegar concentration and exposure time. Treatment of whole parsley leaves for 5 min at 21 °C (69.8 °F) with vinegar (7.6% acetic acid) reduced populations of *S. sonnei* more than 7 log per gram (Wu and others 2000). Vinegar and lemon juice have potential as inexpensive, simple household sanitizers; however, possible negative sensory effects when used on produce would be a disadvantage.

Various combinations of acetic acid, lactic acid and chlorine were observed to reduce populations of *L. monocytogenes* on shredded lettuce (Zhang and Farber 1996). Lactic or acetic acids in combination with 100 ppm chlorine were slightly more antagonistic toward *L. monocytogenes* than either acid or chlorine alone; however, the increased antagonism might be due to an additive effect of the combined compounds or due to an increase in hypochlorous acid at the reduced pH levels of the acid

combinations. A 2 min dip in 5% acetic acid at room temperature was the most effective treatment of several investigated for reducing populations of *E. coli* O157:H7 inoculated onto apple surfaces (Wright and others 2000). The 5% acetic acid treatment reduced the population more than 3 log CFU/cm^2 as compared to less than a 3 log reduction by a commercial preparation with 80 ppm peroxyacetic acid. It was noteworthy that the 2 min dip treatment with a commercial 0.3% phosphoric acid-based fruit wash caused sublethal injury to *E. coli* O157:H7 as measured by a comparison of counts on selective and non-selective media.

Antimicrobial activity varies among the organic acids. Citric acid was much less effective than tartaric acid in preventing growth of microorganisms on salad vegetables (Shapiro and Holder 1960). A concentration of 1500 ppm citric acid did not affect bacterial growth, while treatment with 1500 ppm tartaric acid resulted in a 10-fold reduction in counts after 4 d at 10 °C (50 °F). Priepke and others (1976) reported that microbial populations of cut lettuce, endive, carrots, celery, radishes, and green onions treated with 2000 ppm sorbate and/or 10,000 ppm ascorbate, then stored 10 d at 4.4 °C (40 °F), were not effectively controlled. Coliforms and fecal coliforms were reduced about 2 and 1 log/g, respectively, on mixed salad vegetables treated with 1% lactic acid (Torriani and others 1997). In the same study, treatment of the mixed vegetables with a 3% sterile permeate from a culture of *Lactobacillus casei* reduced the total mesophilic count about 5 log/g and prevented growth of coliforms, enterococci, and *Aeromonas hydrophila* after 6 d at 8 °C (46.4 °F).

Orthophosphoric acid with added surfactants is commonly used in the citrus processing industry for both cleaning and sanitizing purposes. Pao and Davis (1999) demonstrated that immersion of oranges in a 200 ppm phosphoric acid/surfactant solution decreased *E. coli* populations only slightly better than immersion in deionized water alone. Winniczuk (1994) determined that dipping oranges for 15 s in 500 ppm of a commercial phosphoric acid surfactant solution after brushwashing in water reduced surface populations approximately 85%, as compared to 60% for brushwashing alone.

2.9. Alkaline compounds

In a laboratory study of suspended and attached cells of various foodborne pathogens on non-food surfaces, *E. coli* O157:H7 populations were reduced 5 and 6 log after a 30-s treatment with 1% trisodium phosphate (TSP) at 10 °C (50 °F) and room temperature, respectively (Somers and others 1994). *Campylobacter jejuni* was almost as sensitive as *E. coli* O157:H7 to TSP. Treatment with 8% TSP decreased populations of *L. monocytogenes* only 1 log cycle. Resistance of *L. monocytogenes* to TSP was also reported by Zhang and Farber (1996). A 5-min treatment with 2% TSP produced a 1 log reduction of *Salmonella* Chester attached to the surface of apple disks (Liao and Sapers 2000). *Salmonella* Montevideo populations on the surface of tomatoes were reduced from 5.2 log CFU/cm^2 to non-detectable levels after 15 s in 15% TSP (Zhuang and Beuchat 1996). A significant reduction in population was observed after 15 s in 1% TSP. Populations of *S.* Montevideo within the core tissue of tomatoes were less affected by TSP, although significant reductions were observed. A 30-seconds treatment of 4% TSP reduced the numbers of *E. coli* O157:H7 on alfalfa seeds from 2.5 log CFU/g to non-detectable levels (<0.30 log CFU/g) (Taormina and Beuchat 1999a). Reductions of populations of *E. coli* inoculated onto orange surfaces were not significantly different after immersion in 2% TSP for 8 min as compared to immersion in deionized water (Pao and Davis 1999). Various high pH cleaners containing sodium hydroxide, potassium hydroxide, sodium bicarbonate, and/or sodium orthophenylphenate (with or without surfactants) reduced populations of *E. coli* on orange surfaces (Pao and others 2000). These same researchers determined that high pH waxes used on fresh market citrus provided substantial inactivation of *E. coli* on orange fruit surfaces (Pao and others 1999). The high pH of typical alkaline wash solutions (11 to 12) and concerns about environmental discharge of phosphates may be limiting factors for use of certain alkaline compounds on produce.

2.10. Peracetic acid alone and in combination with fatty acids

The efficacy of peracetic acid against microorganisms on produce has not been extensively reported. On stainless steel chips in the presence of organic matter, peracetic acid, and peroctanoic acid inactivated mixed-culture biofilms of *L. monocytogenes* and *Pseudomonas* sp. more effectively than chlorine (Fatemi and Frank 1999). When used at 40 and 80 ppm, a sanitizer that contains peracetic acid (Tsunami^{TM}, Ecolab, Mendota Heights, MN) significantly ($P \leq 0.05$) reduced salmonellae and *E. coli* O157:H7 populations on cantaloupe and honeydew melon surfaces (Park and Beuchat 1999). These treatments were less effective on asparagus spears. The brand of sanitizer used in this study is reported by the manufacturer to maintain its efficacy over a broader pH range and organic demand than hypochlorite, although it is more expensive.

Nearly 100-fold reductions in total counts and fecal coliforms on cut-salad mixtures were observed after treatment with 90 ppm peroxyacetic (peracetic) acid or with 100 ppm chlorine (Masson 1990). The subsequent inhibition of microbial growth during storage of salads was attributed to residual peracetic activity. Microbial populations on the surface of oranges were reduced about 85% after brushwashing in water followed with a 15 s dip in 200 ppm peracetic acid, compared to a 60% reduction on oranges that were brushwashed and dipped in plain water (Winniczuk 1994).

Confidential research results from one company indicated that a static 2-min treatment of inoculated tomatoes with a sanitizer formulation containing 60 ppm peracetic acid in combination with surfactants reduced populations of *Salmonella* Javiana, *L. monocytogenes*, and *E. coli* O157:H7 by 96%, 99.96% and 99.5%, respectively, compared with treatment in sterile water. Similar results were obtained with a second sanitizer formulation containing 40 ppm peracetic and surfactants.

2.11. Hydrogen peroxide

Juven and Pierson (1996) reviewed research reports on the antimicrobial activity of H_2O_2 and its use in the food industry. H_2O_2 possesses bactericidal and inhibitory activity due to its properties as an oxidant, and due to its capacity to generate other cytotoxic oxidizing species such as hydroxyl radicals. The sporicidal activity of H_2O_2 coupled with rapid breakdown makes it a desirable sterilant for use on some food contact surfaces, and packaging materials in aseptic filling operations. Residual H_2O_2 level may vary dependent on the presence or absence of peroxidase in the produce item.

Use of H_2O_2 on whole and fresh-cut produce has been investigated in recent years. *Salmonella* populations on alfalfa sprouts were reduced approximately 2 log CFU/g after treatment for 2 min with 2% H_2O_2 or 200 ppm chlorine (Beuchat and Ryu 1997). Less than 1 log CFU/g reduction was observed on cantaloupe cubes under similar test conditions. Treatment with 5% H_2O_2 bleached sprouts and cantaloupe cubes. Treatment of whole cantaloupes, honeydew melons, and asparagus spears with 1% H_2O_2 was less effective at reducing levels of inoculated salmonellae and *E. coli* O157:H7 than hypochlorite, acidified sodium chlorite or a peracetic acid-containing sanitizer (Park and Beuchat 1999). Use of a 1% H_2O_2 spray on alfalfa seeds and sprouts did not control growth of *E. coli* O157:H7 (Taormina and Beuchat 1999b). H_2O_2 (3%), alone or in combination with 2 or 5% acetic acid sprayed onto green peppers, reduced *Shigella* populations approximately 5 log cycles, compared to less than a 1-log reduction by water alone (Peters 1995). In the same study, *Shigella* inoculated onto lettuce was reduced approximately 4 log after dipping in H_2O_2 combined with either 2 or 5% acetic acid; however, obvious visual defects were noted on the treated lettuce. The same treatment gave similar results for *E. coli* O157:H7 inoculated onto broccoli florets or tomatoes with minimal visual defects.

Microbial populations on whole cantaloupes, grapes, prunes, raisins, walnuts, and pistachios were significantly reduced upon treatment with H_2O_2 vapor (Sapers and Simmons 1998). Treatment by

dipping in H_2O_2 solution reduced microbial populations on fresh-cut bell peppers, cucumber, zucchini, cantaloupe, and honeydew melon, but did not alter sensory characteristics. Treatment of other produce was not as successful. H_2O_2 vapor concentrations necessary to control *Pseudomonas tolaasii* caused mushrooms to turn brown, while anthocyanin-bleaching occurred in strawberries and raspberries. Shredded lettuce was severely browned upon dipping in a solution of H_2O_2. Combinations of 5% H_2O_2 with acidic surfactants at 50 °C (122 °F) produced a 3 to 4 log reduction of non-pathogenic *E. coli* inoculated onto the surfaces of unwaxed Golden Delicious apples (Sapers and others 1999). Further research is necessary to determine the usefulness of H_2O_2 treatment on other fruits and vegetables.

2.12. Ozone

The use of ozone as an antimicrobial agent in food processing was reviewed by Kim and others (1999b) and Xu (1999); however, little has been reported about the inactivation of pathogens on produce. Salmonellae and *E. coli* populations were reduced 3 to 4 log/g in ground black pepper after 60 min treatment with ozonated air (6.7 mg/L at a flow rate of 6 L/min); however, significant changes in the volatile oil profiles were also noted (Zhao and Cranston 1995). Volatile oils in whole black peppercorns treated in ozonated water were not significantly affected.

Ozone is an effective treatment for drinking water and will inactivate bacteria, fungi, viruses, and protozoa (Peeters and others 1989; Korich and others 1990; Finch and Fairbairn 1991; Restaino and others 1995). According to Restaino and others (1995), bacterial pathogens such as *Salmonella* Typhimurium, *Y. enterocolitica, S. aureus*, and *L. monocytogenes* are sensitive to treatment with 20 ppm ozone in water. Finch and Fairbairn (1991) investigated the sensitivity of enteric viruses to ozone, while Korich and others (1990) reported on the ozone inactivation of protozoa such as *Cryptosporidium parvum*. Treatment of *C. parvum* oocysts with 1 ppm ozone for 5 min resulted in < 1 log inactivation. In the same study, *Giardia* spp. cysts were more sensitive than *C. parvum* to ozone treatment. Peeters and others (1989) reported that 2.27 ppm ozone treatment for 8 min eliminated the infectivity of $5x10^5$ *C. parvum* oocysts in water.

Treatment with ozonated water can extend the shelf life of apples, grapes, oranges, pears, raspberries, and strawberries by reducing microbial populations and by oxidation of ethylene to retard ripening (Beuchat 1998). Microbial populations on berries and oranges were reduced by treatment with 2-3 ppm and 40 ppm, respectively. Kim and others (1999a) reported a 2 log/g reduction in total counts for shredded lettuce suspended in water ozonated with 1.3 mM ozone at a flow rate of 0.5 L/min.

In contrast to the use of ozone as an initial treatment to reduce microbial populations on produce surfaces, ozone gas has also been investigated for use during storage of various foods, including fish (Haraguchi and others 1969), poultry (Sheldon and Brown 1986), peanuts and cottonseed meal (Dwankanath and others 1968), pork, beef, dairy products, eggs, mushrooms, potatoes, and fruits (Kaess and Weidemann 1968; Gammon and Kerelak 1973). Apples stored in an atmosphere containing ozone had reduced incidents of spoilage (Bazarova 1982). Fungal growth during storage of blackberries was inhibited by 0.1 to 0.3 ppm ozone (Barth and others 1995). Treatment of grapes by ozone increased shelf life and reduced fungal growth (Sarig and others 1996). Spoilage of vegetables such as onions, potatoes, and sugar beets was reduced upon storage in an ozone containing atmosphere (Kim and others 1999b).

Due to its strong oxidizing activity, ozone may cause physiological injury of produce (Horvath and others 1985). Bananas treated with ozone developed black spots after 8 d of exposure to 25 to 30 ppm gaseous ozone. Carrots exposed to ozone gas during storage had a lighter, less intense color than untreated carrots (Liew and Prange 1994). Ozone can also cause corrosion of metals and other materials in processing equipment. It is capital intensive and may be difficult to monitor and control in situations where highly variable organic loads are likely to occur. As with other sanitizers, employee safety and health issues must be addressed and appropriate safeguards must be in place when using ozone as a

sanitizing agent. Since ozone produces toxic vapors, adequate ventilation is necessary for employee safety. However, since it has excellent ability to penetrate and does not leave a residue, ozone may have usefulness for treatment of process water, food contact surfaces, or whole produce. Industry representatives indicate that the postharvest use of ozone for treatment of produce is increasing.

2.13. Irradiation

Ionizing radiation from ^{60}Co, ^{137}Cs, or machine generated electron beams, alone or in combination with other treatments such as hot water, is used as a means of extending shelf life of produce (Diehl 1995; Thayer and others 1996). Lethality of irradiation is influenced by the target (insect or microorganism), condition of the treated item, and environmental factors. Low dose treatments (<1 kGy) inhibit sprouting of tubers, bulbs and roots, delay produce maturation, eliminate insects in grains, fruits, and nuts, and kill parasites in meats. Medium dose treatments (1 to 10 kGy) reduce microbial populations, including pathogens, on or in foods. Elimination of pathogens on meat, seafood, and poultry by medium dose irradiation has been studied. It should be noted that produce treated by doses above the level of 1 kGy cannot use the term "fresh" (21CFR101.95). High doses of irradiation (10 to 45+ kGy) produce shelf-stable packaged meats and specialized hospital meals.

In a review on irradiation and produce, Thayer and Rajkowski (1999) state, "To date, relatively little effort has been applied to the control of foodborne pathogens on fresh foods. However, ionizing irradiation has recently been used to eliminate *Escherichia coli* O157:H7 from apple juice, *Toxoplasma gondii* and/or *Cyclospora cayetanensis* from raspberries, and *E. coli* O157:H7 and salmonellae from seed and sprouts." Research on the effectiveness of irradiation against human pathogens has been conducted mostly on food products of animal origin (Mossel and Stegeman 1985; Farkas 1989; Monk and others 1995); however, Rajkowski and Thayer (2000) reported that salmonellae were not recovered from alfalfa sprouts irradiated with 0.5 kGy even though the seeds used to produce the sprouts contained detectable levels of the pathogen. These researchers concluded that ionizing radiation can be used to reduce pathogen populations on sprouts. Buchanan and others (1998) determined that 1.8 kGy will produce a 5-log reduction of *E. coli* O157:H7 in apple juice. These same researchers reported that acid-resistant stationary phase cells of enterohemorrhagic *E. coli* are more resistant to irradiation than non-acid-resistant cells (Buchanan, Edelson, and Boyd 1999).

Doses in the range of <1 to 3 kGy have been shown to reduce or eliminate populations of foodborne pathogens, postharvest spoilage organisms, and other microorganisms on produce (Moy 1983; Urbain 1986; Farkas 1997). Most medium and high level doses are not appropriate for produce because they can cause sensory defects (visual, texture, and flavor) and/or accelerated senescence due to irreparable damage to DNA and proteins (Thomas 1986; Barkai-Golan 1992). Treatment of unpasteurized orange juice with 3 kGy electron-beam irradiation reduced *E. coli* populations inoculated into the juice by at least 5 log, but had unacceptable sensory consequences (Parish and Goodrich 2000; personal communication; unreferenced). Strawberry shelf life can be extended with treatments in the range of 2 to 3 kGy (Sommer and Maxie 1966; Zegota 1988; Marcotte 1992; Diehl 1995). Maxie and others (1971) asserted that strawberry is the only domestic fruit or vegetable with adequate potential to utilize irradiation for shelf life extension, since other commodities do not tolerate dosage levels needed to control spoilage. Research conducted since that time suggests that irradiation can be an important treatment to enhance safety of other types of produce. Postharvest disease incidence in apples and Bosc pears was reduced after 0.3 to 0.9 kGy irradiation treatment (Drake and others 1999). Disease incidence of Anjou pears was not reduced.

Use of ionizing radiation to eliminate insect pests, and to control postharvest spoilage organisms on fresh produce has been reviewed (Clarke 1959; Willison 1963; Staden 1973; Moy 1983; CAST 1986, 1989; Barkai-Golan 1992; Wilkinson and Gould 1996) and guidelines for treatment have been issued (Anonymous 1991a, 1991b, 1993). Combinations of ionizing radiation with other treatments have been studied. A combination of 0.75 kGy irradiation with a 10 min dip in 50 °C (122°F) water provided much

better control of postharvest spoilage organisms of papayas and mangoes than either treatment alone (Brodrick and van der Linde 1981). Neither irradiation (0.3 to 0.6 kGy), hot fungicide treatment, nor a combination of the two, satisfactorily prevented postharvest spoilage of mangoes (Johnson and others 1990). Higher doses of irradiation caused unacceptable peel blemishes. A combination of UV and gamma radiation was not more effective than either treatment alone at preventing storage rot of peaches (Lu and others 1993). Irradiation (0.43 kGy average dose) of segments from cut and peeled citrus fruits was not as effective as chemical preservatives at preventing spoilage during chilled storage (Hagenmaier and Baker 1998a).

The shelf life of packaged leaf vegetables stored at 10 °C (50 °F) was extended by treatment with 1 kGy (Langerak 1978). In this study, *Enterobacteriaceae* were eliminated on endive and the shelf life was extended from 1 (for nonirradiated) to 5 d. Chervin and Boisseau (1994) concluded that irradiation of shredded carrots was superior to chlorination and spin-drying. Microbial populations (measured as total plate counts) of shredded carrots treated with 0.5 kGy or chlorine and stored 9 d under refrigeration were 1300 and 87,000 CFU/g, respectively (Hagenmaier and Baker 1998b). The same authors reported a similar reduction of microbial populations on cut iceberg lettuce treated with 0.19 kGy (Hagenmaier and Baker 1997). A combination of hot water dips and 1.0 kGy irradiation doubled the shelf life of mangoes from 25 to 50 d (El-Samahy and others 2000).

As discussed in the recent FDA report, "Kinetics of microbial inactivation for alternative food processing technologies" (FDA 2000), high intensity pulsed X-rays have been shown to reduce *E. coli* O157:H7 populations in ground beef by 3 log cycles, and to decrease *Salmonella* Senftenberg on turkey carcasses. Studies on the use of X-rays to inactivate pathogens on/in produce may be warranted.

Consumer acceptance of irradiated food remains questionable. A publication by USDA-ERS suggests that the number of consumers likely to purchase irradiated food has decreased in recent years from about 70% in 1996 to 50% in 2000 (Frenzen and others 2000). Additionally, there is a need to ensure that research on irradiation addresses sensory aspects, such as taste, appearance and texture, of produce.

2.14. Biocontrol

There are few published reports on the use of biocontrol agents to prevent growth of human pathogens on produce. Janisiewicz and others (1999) reported that *Pseudomonas syringiae* prevented growth of *E. coli* O157:H7 in wounds of apples. Populations of the pathogen increased 2 log in wounds that were not treated with the antagonist but did not increase in wounds treated with *P. syringiae*. *Enterococcus mundtii* did not prevent growth of *L. monocytogenes* on fresh produce but did inhibit growth of the pathogen on vegetable agar (Bennik and others 1999). Mundticin, a bacteriocin produced by *E. mundtii*, was reported to have potential as a biopreservative on modified atmosphere-stored mungbean sprouts. Populations of *L. monocytogenes* inoculated onto endive leaves were inhibited by treatment with a mixed population of microorganisms originally isolated from endive (Carlin and others 1996). Strains of lactic acid bacteria were reported to inhibit *A. hydrophila, L. monocytogenes, Salmonella* Typhimurium, and *S. aureus* on vegetable salads (Vescovo and others 1996).

The application of microorganisms to prevent proliferation of postharvest spoilage organisms has been studied to a greater extent than for control of human pathogens on produce surfaces (Liao 1989; Smilanick and Denis-Arrue 1992; Stanley 1994; Janisiewicz and Bors (1995); Korsten and others 1995; Leibinger and others 1997; Calvente and others 1999; El-Ghaouth and others 2000; Usall and others 2000). Studies suggest that non-pathogenic microorganisms applied to produce surfaces might out-compete pathogens for physical space and nutrients, and/or may produce antagonistic compounds that negatively affect viability of pathogens. Research on biocontrol of human pathogens on produce is warranted.

The use of bacteriophage to reduce populations of *Salmonella* on fresh-cut fruit was recently reported

(Leverentz and others 2001). Application of *Salmonella*-specific phages reduced populations about 3.5 log on honeydew melon slices (pH 5.8) stored at 5 or 10 °C (41 or 50 °F). Salmonellae were not reduced on apple slices possibly due to the fruit's lower pH (4.2). Use of phage for pathogen control deserves further investigation.

The concept of "induced resistance" of plants to microorganisms that cause pathologies in plant systems is worth noting (Hammerschmidt 1999). In recent years groups of researchers have begun to focus efforts on the mechanisms and signaling pathways plants use to resist disease. Additionally, biotech companies are engineering plants to resist pests. While speculative, it is conceivable that research on biocontrol efforts through induced resistance or genetic engineering could lead to plants that resist human pathogens in addition to plant pathogens.

2.15. Miscellaneous

Numerous plant-derived compounds with antimicrobial properties have been studied for use in food systems (Cherry 1999). Although their usefulness may be limited due to undesirable sensory effects, naturally derived food compounds and essences have shown antimicrobial activity against human pathogens in laboratory studies. Compounds such as various bacteriocins, cinnamaldehyde, diacetyl, benzaldehyde, pyruvic aldehyde, piperonal, basil methyl charvicol, vanillin, psoralens, jasmonates, allylisothiocyanate, lactoferricin, hop resins, and essences of garlic, clove, cinnamon, coriander, and mint have been studied for antimicrobial activity in various food systems (Isshiki and others 1992; Tokuoka and Isshiki 1994; Bowles and others 1995; Delaquis and Mazza 1995; Lis-Balchin and others 1996; Cerrutti and others 1997; Ulate-Rodriguez and others 1997; Bowles and Juneja 1998; Buta and Moline 1998; Wan and others 1998; Chantaysakorn and Richter 2000; Fukao and others 2000). Further information is needed regarding the effects of specific plant derivatives, and other naturally occurring compounds, on human pathogens and produce.

2.16. Alternative technologies

Although non-thermal and other alternative technologies, such as high pressure, pulsed electric field, pulsed light, oscillating magnetic fields, ultrasound and UV treatments, have been investigated to reduce or eliminate microorganisms in foods, there is little published research directly related to the impact of these technologies on the safety of fresh whole or cut produce (FDA 2000). Limited data regarding the use of these technologies for unpasteurized juices has been published. Although a recent study showed 4 to 8 log reductions of *Salmonella* spp. or *E. coli* O157:H7 after high pressure processing at 615 MPa, there was no indication if death rates of the non-acid resistant inocula were influenced by the acidic nature of the fruit juices (Teo and others 2001). There is a regulatory question whether produce treated by these technologies may be labeled as "fresh"; however, further research on the effects of alternative treatments on produce is warranted.

3. Summary

The primary method to eliminate, or significantly reduce, pathogens on produce is strict adherence to Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), Hazard Analysis Critical Control Points (HACCP), and other relevant strategies that prevent contamination from occurring. This includes the concept of "good management practices" as described in the Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (FDA 1998). Although the frequency of produce contamination by pathogens is thought to be very small, there are no known mitigation strategies that will completely remove pathogens after contamination has occurred while maintaining produce freshness. A variety of mitigation regimens and sanitizers are available to reduce microbial populations depending upon the type of produce involved. Washing and sanitizing efficiencies depend on several factors, including characteristics of the produce surface, water quality, cleaner/sanitizer used, contact time, and presence and type of scrubbing action. Based on reported data, it is likely that different

sanitation mitigation strategies are needed for different produce items.

4. Research Needs

In order to adequately address safety issues associated with fresh produce, it is necessary to enhance the quantity and quality of research on mitigation strategies. A few of the research needs include:

- Investigate traditional and non-traditional sanitizers on specific pathogen/produce combinations.
- Survey extensively domestic and imported products to determine the frequency of public health microorganisms on specific produce items.
- Survey comprehensively to determine pathogen concentrations on/in various types of produce.
- Determine additive, antagonistic, or synergistic effects of sanitation treatments when used in combination.
- Evaluate the enhancement of physical washing methods by various techniques.
- Investigate the likelihood of pre- or post-harvest microbial infiltration into produce interiors and the significance for produce safety.
- Assess interactions between human pathogens and post-harvest spoilage organisms that may cause pathogen infiltration into produce tissues.
- Investigate biocontrol and competitive exclusion as mitigation strategies.
- Develop new sanitizers and innovative technologies for sanitation treatment of produce.
- Develop treatments to eliminate pathogens in animal wastes used during production of produce.
- Identify treatments to eliminate pathogens in irrigation water.
- Investigate the use of alternative technologies on the safety of whole and cut produce.
- Investigate sanitizer effects on pathogens other than bacteria.

Table V-1. Matrix of methods to mitigate the presence of microorganisms on whole and cut produce.

Mitigation Method	Advantages	Limitations	Comments on current use	Comments on research
Hypochlorite	• Long history of use	• Potential adverse health effects of chlorinated byproducts • Corrosive to equipment • Sensitive to temperature, light,	• Commonly used in the 50 - 200 ppm range with a 1 - 2 min contact time. • Usefulness on many produce commodities has	• Very high concentrations may not eliminate pathogens on produce • Commonly used concentrations produce a maximum 1 to 2 log reduction on many

		air, metals and organic materials • pH dependent • Some resistance by bacterial spores and protozoan oocysts	been investigated	commodities.
Acidified sodium chlorite	• Greater efficacy than hypochlorite due to low pH	• Little information on production of chlorinated byproducts • Limited amount of research conducted	• Studied for use on meats, seafood, poultry, produce • 500 to 1200 ppm range studied	• Usefulness for produce needs further research
Chlorine dioxide	• Less reactivity than hypochlorite with organics • Fewer chlorinated byproducts • Better antimicrobial activity at neutral pH than hypochlorites	• Stability • Not permitted for cut produce	• Up to 5 ppm allowed on whole fruits and vegetables • 1 ppm maximum allowed on peeled potatoes	• Studied concentrations range from about 1 ppm to 500 ppm on commodities such as alfalfa seeds and sprouts, cucumbers, shredded lettuce, cabbage, oranges • Studies conducted with fungal spores, native microflora, Listeria monocytogenes, E. coli, E. coli O157:H7, Salmonella, Cryptosporidium parvum oocycts. • Reductions of a few logs reported
Bromine	• Possible synergy with chlorine compounds	• Information lacking on production of brominated byproducts and their potential health effects	• Not widely used as a sanitizer	• More effective against E. coli, Salmonella Typhosa and Staphylococcus aureus than against Pseudomonas aeruginosa. • Not as effective as hypochlorite against Bacillus cereus spores
Iodine	• Less corrosive than chlorine at low temperature • Broad	• Stains commodities and equipment • Corrosive above	• Commonly used on food contact surfaces and equipment	• May have significant sporocidal capacity • Possible usefulness

	spectrum • Iodophor less volatile than iodine	50°C	• No direct contact use on produce	on some whole produce deserves investigation
Trisodium phosphate	• Less corrosive than most other compounds	• Listeria relatively resistant • Has very high pH (11-12)	• Occasional use on fresh-market citrus • Authorized for use on raw poultry	• Concentrations between 1 and 15% yielded reductions in pathogen populations from 0 to 6 logs
Quaternary ammonium compounds	• Colorless, odorless • Stable at high temperature • Noncorrosive • Good penetrating ability • Relatively stable to organic compounds • Leaves residual	• Limited usefulness at low pH (<6) • Not compatible with soaps or anionic detergents • Costly	• Commonly used on food contact surfaces and equipment	• As effective as chlorine at reducing populations of Xanthomonas campestris pathovar vesicatoria. • Reduced native orange-surface microflora 95% compared to 60% reduction on control fruit.
Acids	• Economical, depending upon type of acid and use	• Low pH use only - Antimicrobial effect dependent upon type of acid and strain of microorganism	• Acidification to preserve foods commonly used • Acid sprays on meat carcasses commercially used • Phosphoric acid/anionic compounds commonly used on citrus at about 200 ppm	• Lemon juice and vinegar may be useful for limited household sanitation of produce. • Organic acids studied for use on several produce commodities for control of native populations as well as specific pathogens (Salmonella spp, Campylobacter spp, Yersinia spp, Shigella spp., Listeria spp.) • Peracetic acid concentrations up to 200 ppm effectively used on whole and cut produce.
Hydrogen peroxide	• Sporicidal - Rapid breakdown to nontoxic products	• Possible effects on product color (browning or bleaching)	• Limited industry use on food contact surfaces and packaging.	• Vapor and aqueous dips (1 to 5% range) studied on numerous produce commodities. • Variable effectiveness reported

				by researchers.
Ozone	• Effective at low concentrations and short contact time • Broad spectrum • Good penetration ability • Effectiveness against protozoa reported • Decomposes to nontoxic products	• Physiological injury of produce possible • Corrosive to equipment • Deterioration of produce flavor and color possible • Unstable; very highly reactive • Possible human toxic effects in processing facilities	• Commonly used for water treatment	• Effective against a variety of postharvest pathogens reported on fruits and vegetables. • Reduced Salmonella and E. coli populations on ground black pepper 3 to 4 log/g. • Further research on produce is warranted
Irradiation	• No chemical treatment • Can be conducted after packaging • Shelf life extension of produce observed	• Image of irradiation by consumers • Negative sensory effects possible	• 1 to 10 kGy used to reduce pathogens in/on foods • <1 kGy used to inhibit sprouting of tubers, bulbs, roots and to eliminate insects from produce	• Variable effectiveness against postharvest pathogens reported in literature • Little information exists regarding effectiveness against human pathogens in produce
Biocontrol	• No chemical treatments	• Limited spectrum • Possible public reaction to consumption of live microorganisms	• Used on apples for control of postharvest plant pathogens • Competitive exclusion useful in poultry to prevent intestinal colonization by pathogens • Starter cultures used for fermented meat and dairy products	• Limited research on use of biocontrol measures against human pathogens on produce

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