AgriSystems International™
The Organic Consultants
Your Link to Organic Agriculture and Sustainable Business

Thomas Harding, President
125 West Seventh Street
Wind Gap, PA 18091 USA
Telephone: 610-863-6700
Fax: 610-863-4622
Email: agrisys1@aol.com

Alesia Bock, Associate Consultant
P.O. Box 445
De Forest, WI 53532
Telephone: 608-345-1301
Email: agrisys2@charter.net
website: www.AgriSysIntl.com

April 25, 2012

Ms. Lisa M. Brines, PhD.
National List Manager
USDA/AMS/NOP Standards Division
1400 Independence Ave., S.W.
Room 2648 – So., Ag Stop 0268
Washington, D.C. 20250-0268

Federal Express Delivery

Dear Dr. Brines:

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 Livestock Production.***

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

- **Category:** *Organic Livestock Production*
- **NOP Reference:** *205.603 – Synthetic Substances Allowed for use in Organic Livestock Production*
- **NOP Sections:** *205.603(a)(b)*
  (a) – As disinfectants, sanitizer, and medical treatments as applicable.
  (b) – As topical treatment (teat dip), external parasiticide, or local anesthetic as applicable.
- **Specific Annotation:** *Allowed for use on Organic Livestock as a pre and post teat dip treatment. Acidified with lactic acid (or other GRAS acid.)*

Please be advised that a petition for the use of ***Acidified Sodium Chlorite (ASC) Solutions in Organic Handling*** was submitted to the NOP, had a full TAP review, was approved by the NOSB, and was placed in a Final Rule.

The use of *Acidified Sodium Chlorite (ASC) Solutions* has a long history of safe, functional, and effective use in direct-contact sanitation and livestock teat dip preventative applications. It has been thoroughly researched, tested, and documented and approved for use by several domestic and foreign food and livestock agencies; therefore we are requesting the NOP-NOSB for an accelerated *TAP Review Process.*

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 Vol. 72, No. 11, January 18, 2007. 7 CFR Part 205 (Docket No. AMS-TM-06-0223; TM-06-12).*

If you have any questions relative to this petition and/or if I can be of further assistance, please contact myself, or Mr. Dan Dahlman of Ecolab, Inc.

Thank you very much for your consideration,

AGRISYSTEMS INTERNATIONAL

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

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Thank you very much for your consideration,

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Mr. 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

ECOLAB

Petitioner

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

Submitted By

AgriSystems International
125 West Seventh Street
Wind Gap, Pennsylvania 18091
Telephone: 610 863-6700
Facsimile: 610 863-4622
Email: agrisys1@aol.com

MATERIALS PETITION

TO:

Ms. Lisa M. Brines, PhD.
National List Manager
USDA/AMS/NOP Standards Division
1400 Independence Ave, S.W.,
Room 2648- So., Ag Stop 0268
Washington, D.C. 20250-0268

PETITIONER:

Ecolab, Inc.
Mr. Dan R. Dahlman
Regulatory Analyst,
Product Registration & Compliance
370 N. Wabasha Street North EUC-9
St. Paul, Minnesota 55102-1390

SUBMITTED FOR PETITIONER BY:

AgriSystems International
Organic Program Consultants
Thomas B. Harding, Jr., President
125 West 7th Street
Wind Gap, PA 18091
Ph: 610-863-6700, Fax 610-863-4622
Cell: 610-392-5435
Email: agrisys1@aol.com

Item A
National List Category Being Petitioned

- **Category:** Organic Livestock Production
- **NOP Reference:** 205.603 – Synthetic substance allowed for use in Organic Livestock Production
- **NOP Sections:** 205.603(a)(b)
  (a)- As disinfectants, sanitizer, and medical treatments as applicable.
  (b)- As topical treatment, external parasiticide or local anesthetic as applicable.
- **Requested Annotation:**
  Allowed for use on Organic Livestock as a pre-and-post teat dip treatment. Acidified with lactic acid (or other GRAS acids.)

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® or SANOVA®~~

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

Livestock Use Products:
- 4XLA Base
- AZTEC Gold Base
- ENCORE Activator

Item B – Continued

References Regulatory (Federal, State, and 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%)
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 dated June 14, 2001)

* Letter of No Objection **(April 22, 2005)** for use of acidified sodium chlorite solutions as an 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, & Telephone Number:**

- **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. As disinfectants, sanitizer, and medical treatments as applicable.

b. As a topical treatment (teat dip), external parasiticide, or local anesthetic as applicable on livestock.

Note Annotation: Allowed for use on Organic livestock as a pre-and-post teat dip treatment.

Other Use(s):

a. **After Direct Food Contact (Secondary Direct Food Additive).**

b. **Indirect Direct Food Contact (Hard Surface Food Contact Sanitation).**

General Reference:

Note: Sodium chlorite, the raw material and the reaction product: *Acidified Sodium Chlorite (ASC)* is produced when mixed with Lactic Acid and/or other GRAS acids.

- *Sodium chlorite* is a precursor in the preparation of *Acidified Sodium Chlorite (ASC) Solutions* approved by FDA 21 CFR 173.325 as a Secondary Direct Food Additive as a secondary direct antimicrobial food treatment, USDA/FSIS 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 EPA evaluated the product chemistry, toxicology, and efficacy data of *Acidified Sodium Chlorite (ASC)* 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 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.

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.

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 that these uses of *Acidified Sodium Chlorite solutions* are "processing aid" and do not require declaration as ingredients on food processor labels.

Specific Reference:

Note: Specific Livestock Use:

- **As a pre-and-post livestock udder preventative treatment, it has been proven to be safe and effective, and environmentally responsible.**

§173.325 Acidified Sodium Chlorite Solutions

Acidified Sodium Chlorite Solutions may safely be 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 pre-chiller or chiller tank.

(ii) In a pre-chiller 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 pre-chiller or chiller solution for application to poultry carcass parts.

(b)(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.

(b)(3) When used in a pre-chiller 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 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 a level 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 practices. Applied as a dip or a spray, the additive is used at levels that result in chlorite concentrations of 500 to 1,200 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 identity in 9 CFR part 319) prior to packaging of the food for commercial purposes, in accordance with current industry standard 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 1,200 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 1200 ppm, in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9.

Additional References:

21 CFR Part 178.1010 Sanitizing Solutions (46)

4. **Substance Mode of Action:**
   - **Livestock Udder Use Preventative Treatment**
     - **Reference Product Labels ad MSDS Forms and the Organic/Standard Operating Procedures (O/SOP's), Pre-and-Post Use Teat Dip.**

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 binary 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 (HC1O2) [CAS No. 13898-47-0] which forms as a predictable fraction of the total chlorite species (C1O2) in the solution virtually instantaneously upon the acidification of the sodium chlorite solution.

H+ + C1O2- Ka HC1O2

Chlorous acid has a Ka of 1.1 x 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:

$$\% HC1O2 = \frac{1}{1 + 10^{(pH - pKa)}} \times 100\%$$

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

pH	% Chlorite as HC1O2
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 (i.e. cysteine, methionine, tyrosine, and tryptophan are all 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 Manufacturing Procedures:

Sodium chlorite the chemical formula (NaC1O3) is made by the reduction of chlorine dioxide. Chlorine dioxide (C1O2) is made from the reduction of sodium chlorate (NaC1O3) 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

NaC1O3 + a mineral acid + a reducing agent (H2O2 or methyl alcohol or NaCl)
→ chlorine dioxide (C1O2)

C1O2 + a reducing agent (H2O2 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 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 (EPA) developed an extensive review of the health and ecological effects of chlorine dioxide, and it's principal byproducts, chlorite and chlorate. It was initially published in the Federal Register on July 29, 1994 (Vol. 59, Section 145, pp. 38668-38829); 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 (EPA), 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 chloride dioxide oxidation/disinfection is the chlorite ion, the EPA considers the toxicology of chlorine dioxide and chlorite ion to be equivalent.

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 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 (MRL's) 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 (i.e. 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 1pg/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.

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, chloride dioxide has been used by thousands of European municipalities for the treatment of drinking water, and ASC's are used throughout Europe and Asia as a general purpose disinfectant and sterilization tool.

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 (NaC1O2)** **CAS No. 7758-19-2**

   - **Chlorous Acid**
     (from acidification of sodium chlorite) **CAS No. 14998-27-7**

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

- **Labeled Products and Material Safety Data Sheets (MSDS)**
   - **4XLA Base & Activator**
   - **AZTEC Gold Base & Activator**
   - **ENCORE Activator & Base**

- **Other Labels:**
   - **SANOVA Base (25%)**
   - **SANOVA Food Additive Base**

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 It's Use or Manufacturer; (d) Effects**

on Human Health; (e) 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 (ASC) Solutions are some of the most effective microbiocides found for the treatment of livestock, poultry, red meat and parts, seafood, and the post harvest treatment of fresh and processed fruits and vegetables.

Specifically for Livestock, they are effective sanitizing agents for the treatment of teat and udder disease prevention, they are environmentally friendly, and provide a good livestock management tool to deliver a safe consumer end product.

From a *Food Safety* perspective, *ASC* has been thoroughly tested and proven effective against some of the most serious and infectious pathogenic and spoilage organisms that threaten the Organic food system (i.e. E. Coli, Salmonella, Campylobacter, Listeria, and Bacillus and Erwinia, Botyritus, Aspergillus, Fusarium respectively to name a few).

There are no natural and/or organic materials and/or treatments approved for pre-and-post use teat dip, or postharvest treatment, beyond hot water and/or steam treatments. These alternatives provide minimal, short term effectiveness in either controlling or reducing these pathogens, fungi, etc.

There are other antimicrobials and sanitizers available, but 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, or in conjunction with an On-Farm GAP Program requirement.

ASC does not chlorinate organics, and is rather benign environmentally when used and handled as required by FDA Labeling. When properly handled, fits well within a sustainable Livestock Management and Food Production system approach.

ASC Solutions quickly break down into its component parts, all of which are found naturally in the agro-ecosystem (i.e. citric acid, salt, and water), therefore having little, if any environmental impact. This is especially true when used in conjunction with a responsible resource recycling program. *ASC* does not damage aquatic life, or form chlorinated hydrocarbons with mutagenic or carcinogenic properties.

Finally, the *Petitioner* believes *ASC 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 providing the consumer with the healthiest and safest Organic food products possible.

13. Commercial Confidential Information Statement

Ecolab, Inc.
National List Petition ASC

LIST OF ATTACHMENTS

ATTACHMENT 1
6. Previous Reviews by State, Federal, & International Agencies

ATTACHMENT 2
7. Additional Information, EPA, FDA, & State Authorities, etc.

ATTACHMENT 3
8. Organic/ Standard Operating Procedures (O/SOP's), Organic Product Labels, and 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 Manufacture**
- **(d) Effects on Human Health**
- **(e) Effects on Soil Organisms, Crops, or Livestock**

ATTACHMENT 5
10. Safety Information Incl. 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

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.

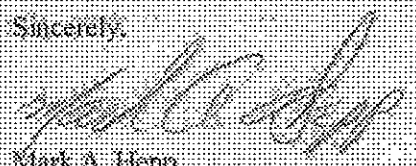
When it is necessary for FDA to establish a tolerance limitation (i.e. a maximum use level) in order to assure that the proposed use of a food additive will be safe, FDA must set the maximum use level at the lowest level that is needed to accomplish the intended technical effect even when higher levels 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

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 | Office of Policy, Program Development and Evaluation | Washington, D.C. 20250/3700

DEC 31 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

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 overload the TAP Reviewers and/or the NOSB we elected to provide the above data access list for your convenience of data choice!

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
#4	Section 17	Safety of the Acidified Chlorite/Chlorous Acid System
		##########
#1	Section 18	Appendix I – Potentiometric Titration of Oxychlorines
#2	Section 19	Appendix III – Oxychlorine Residues on Poultry Surfaces
#3	Section 20	Appendix IV – Chloroorganic Analysis of A.C. – treated chicken parts
#4	Section 21	Appendix VI – Detection of Chlorinated Lipids in Poultry Carcass Extract
#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 1 – 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.

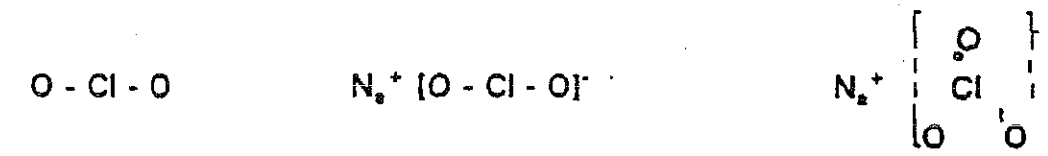
Health Advisories are developed for one-day, ten-day, longer-term (approximately 7 years, or 10 percent of an individual's lifetime), and lifetime exposures based on data describing noncarcinogenic endpoints of toxicity. For those substances that are known or probable human carcinogens, according to 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 ± 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 Soitz, 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, Heller 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 6 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: -

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

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.

IX. REFERENCES

Abdel-Rahman, M.S. 1985. Pharmacokinetics of chlorine obtained from chlorine dioxide, chlorine, chloramine and chloride. In: Jolley, R.L. et al., eds. Water chlorination: environmental impact and health effects, Vol. 5. Chelsea, MI: Lewis Publ. Inc. pp. 281-293.

Abdel-Rahman, M.S., D. Couri and R.J. Bull. 1984a. The kinetics of chlorite and chlorate in the rat. J. Am. Coll. Toxicol. 3:261-267.

Abdel-Rahman, M.S., D. Couri and R.J. Bull. 1984b. Toxicity of chlorine dioxide in drinking water. J. Am. Coll. Toxicol. 3:277-284.

Abdel-Rahman, M.S., D. Couri and R.J. Bull. 1982. Metabolism and pharmacokinetics of alternate drinking water disinfectants. Environ. Health Persp. 46:19-23.

Abdel-Rahman, M.S., D. Couri and R.J. Bull. 1980a. Kinetics of ClO_2 and effects of ClO_2, ClO_2^- and ClO_3^- in drinking water on blood glutathione and hemolysis in rat and chicken. J. Environ. Pathol. Toxicol. 3:431-449.

Abdel-Rahman, M.S., D. Couri and J.D. Jones. 1980b. Chlorine dioxide metabolism in rat. J. Environ. Pathol. Toxicol. 3:421-430.

ACGIH. 1980. American Conference of Governmental Industrial Hygienists. Threshold limit values for chemical substances and physical agents in the workroom environmental with intended changes for 1980. Cincinnati, OH: American Conference of Goveramental Industrial Hygienists.

Aieta, E.M. and J.D. Berg. 1986. A review of chlorine dioxide in drinking water treatment. JAWWA. 78(6):62-72.

APHA. 1995. American Public Health Association. Standards Methods for the Examination of Water and Wastewater (19th ed.), Washington, DC.

Bercz, J.P., L. Jones, L. Garner, D. Murray, D.A. Ludwig and J. Boston. 1982. Subchronic toxicity of chlorine dioxide and related compounds in drinking water in the nonhuman primate. Environ. Health Persp. 46:47-55.

Bianchine, J.R., J.R. Lubberts, S. Chauhan and J. Miller. 1981. Study of chlorine dioxide and its metabolites in man. Final report on EPA grant no. 805643. EPA-600/1-81-068. NTIS PB82-109356.

Bio/dynamics, Inc. 1987a. A subchronic (3 month) oral toxicity study in the dog via gavage administration with sodium chlorate. Report no. 86-3114, prepared for Sodium Chlorate Task Force, Oklahoma City, OK. East Millstone, NJ: Bio/dynamics, Inc. Unpublished. Submitted to the Office of Drinking Water.

Bio/dynamics, Inc. 1987b. A subchronic (3 month) oral toxicity study of sodium chlorate in the rat via gavage. Report no. 86-3112, prepared for Sodium Chlorate Task Force, Oklahoma City, OK. East Millstone, NJ: Bio/dynamics, Inc. Unpublished. Submitted to the Office of Drinking Water.

Bio/dynamics, Inc. 1987c. A teratogenicity study in rats with sodium chlorate. Report no. 86-3117, prepared for Sodium Chlorate Task Force, Oklahoma City, OK. East Millstone, NJ: Bio/dynamics, Inc. Unpublished. Submitted to the Office of Drinking Water.

Bloxham, C.A., N. Wright and J. G. Hoult. 1979. Self-poisoning by sodium chlorate--some unusuall features. Clin. Toxicol. 15(2):185-188.

Bolyard, M, P.S. Fair, and D.P. Hautman. 1993. Sources of chlorate ion in US drinking water. JAWWA. 85(9):81-88.

Bull, R.J. and F.C. Kopfler. 1991. Health effects of disinfectants and disinfectant by-products. Prepared for the American Water Works Association Research Foundation, Denver, CO. August.

Carlton, B.D., D.L. Habash, A.H. Basaran, E.L. George and M.K. Smith. 1987. Sodium chlorite administration in Long-Evans rats: Reproductive and endocrine effects. Environ. Res. 42:238-245.

Carlton, B.D. and M.K. Smith. 1985. Reproductive effects of alternate disinfectants and their by-products. In: Jolley, R.L., et al., eds. Water chlorination: Environmental impact and health effects. Vol. 5. Chelsea, MI: Lewis Publ., Inc. 295-305.

Carlton, B.D., A.H. Basaran, L.E. Mezza, E.L. George and M.K. Smith. 1991. Reproductive effects in Long-Evans rats exposed to chlorine dioxide. Environ. Res. 56(2):170-177.

Condie, L.W. 1986. Toxicological problems associated with chlorine dioxide. JAWWA 78(6):82-72.

Couri, D. and M.S. Abdel-Rahman. 1980. Effect of chlorine dioxide and metabolites on glutathione dependent system in rat, mouse and chicken blood. J. Environ. Pathol. Toxicol. 3:451-460.

Couri, D., C.H. Miller, R.J. Bull, J.M. Delphia and E.M. Ammar. 1982. Assessment of maternal toxicity , embryotoxicity and teratogenic potential of sodium chlorite in Sprague-Dawley rats. Environ. Health Perspective. 46:25-29.

Daniel, F.B., L.W. Condie, M. Robinson, J.A. Stober, R.G. York, G.R. Olsen and S.R. Wang. 1990. Comparative subchronic toxicity studies of three disinfectants. J. AWWA. 82:61-69.

Ellenhorn, M. and D. Barcelaux. 1988. Medical Toxicology, diagnosis and treatment of human poisoning. Elsevier: New York, p. 1097.

Faust, S.D. and O.M. Aly. 1983. Chemistry of Water Treatment. Butterwoth Publishers, Wobury, MA.

Fletcher, D. 1973. Acute oral toxicity study with sodium chorite in bobwhite quail. Industrial Bio-Test Laboratory's report (IBT No. J2119) to Olin Corporation. Dated January 9, 1973. Unpublished.

Gordon, G.B, L. Adam, and B. Bubnis. 1995. Miniminzing chlorate ion formation in drinking water when hypochlorite ion is the chlorinating agent. Prepared for AWWA Research Foundation.

Gordon, G.B, Slootmaekers, S. Tachiyashiki, and D.W. Wood III. 1990. Minimizing chlorite ion and chlorate ion in water treated with chlorine dioxide. J. AWWA, 82:160-165.

Griese, A.D, A. Obolensky, and P.C. Singer. 1992. Combining methods for the reduction of oxychlorine residuals in drinking water. J. AWWA. 84(11):69-75.

Haag, H.B. 1949. The effect on rats of chronic administration of sodium chlorite and chlorine dioxide in the drinking water. Report to the Mathieson Alkali Works from H.B. Haag of the Medical College of Virginia. Dated February 7, 1949. Unpublished.

Harrington, R.M. H.G. Shertzer and J.P Bercz. 1986. Effects of chlorine dioxide on thyroid function in the African green monkey and the rat. J. Toxicol. Environ. Health 19:235-242.

Hayashi, M., M. Kirshi and T. Sofuni, et al. 1988. Micronucleus tests in mice and 39 food additives and eight miscellaneous chemicals. Food Chem. Toxicol. 26(6):287-500.

Heffernan, W.P., C. Guion and R.J. Bull. 1979. Oxidative damage to the erythrocyte induced by sodium chlorite, in vivo. J. Environ. Pathol. Toxicol. 2:1487-1499.

Helliwell, M. and J. Nunn. 1979. Mortality in sodium chlorate poisoning. Brit. Med. J., April 28, p. 1119.

Heywood, R., R.J. Sortwell, P.J. Kelly and A.E. Street. 1972. Toxicity of sodium chlorate to the dog. Vet. Rec. 90:416-418.

Hodson-Walker, G. 1989. Sodium chlorate: Investigation of mutagenic activity at the HGPRT locus in a Chinese hamster V79 cell mutation system. Report to the Sodium Chlorate Task Force, Kerr McGee Chemical Corporation, Oklahoma City, OK by Life Science Research, Suffolk, England (LSR Report 89/0631).

Irvine, L.F.H. 1990. Sodium chlorite: Rabbit teratology study (drinking water administration). EPA MRID #41715701. CMD - /3/4. September 21. An unpublished study submitted to EPA.

Jackson, R.C., W.J. Elder and H. McDonnel. 1961. Sodium chlorate poisoning complicated by acute renal failure. Lancet. 2:1381-1383.

Kurokawa, Y., S. Takayama, Y. Konishi, Y. Hiasa, S. Asahina, M. Takahashi, A. Maekawa and Y. Hayashi. 1986. Long-term in vivo carcinogenicity tests of potassium bromate, sodium hypochlorite and sodium chlorite conducted in Japan. Environ. Health Perspect. 69:221-235.

Kurokawa, Y., N. Takamura, Y. Matsushima, T. Imazawa and Y. Hayashi. 1984. Studies on the promoting and complete carcinogenic activities of some oxidizing chemicals in skin carcinogenesis. Cancer Letters. 24:299-304.

Lee, D.B.N., D.L. Brown, L.R.I. Baker, D.W. Littlejohns and P.D. Roberts. 1970. Haematological complications of chlorate poisoning. Brit. Med. J. 2(700):31-32.

Lubbers, J.R., S. Chauhan and J.R. Bianchine. 1982. Controlled clinical evaluations of chlorine dioxide, chlorite and chlorate in man. Environ. Health Persp. 46:57-62.

Lubbers, J.R., S. Chauhan and J.R. Bianchine. 1981. Controlled clinical evaluations of chlorine dioxide, chlorite and chlorate in man. Fundam. Appl. Toxicol. 1:334-338.

Mackay, J.M. 1989. Sodium chlorate: Assessment of clastogenic action on bone marrow erythrocytes in the micronucleus test. Report to the Sodium Chlorate

Task Force, Kerr McGee Chemical Corporation, Oklahoma City, OK by Life Science Research, Suffolk, England (LSR Report 89/0253).

May, K. 1989a. Sodium choorate: Assessment of its ability to cause lethal DNA damage in strains of Escherichia coli. Report to the Sodium Chlorate Task Force, Kerr McGee Chemical Corporation, Oklahoma City, OK by Life Science Research, Suffolk, England (LSR Report 89/0341).

May, K. 1989b. Sodium chlorate: Assessment of mutagenic potential in histidine auzotrophs of Salomnella typhimurium (The Ames Test). Report to the Sodium Chlorate Task Force, Kerr McGee Chemical Corporation, Oklahoma City, OK by Life Science Research, Suffolk, England (LSR Report 89/0285).

McGuire, M.J. and R.G. Meadow. 1988. AWWARF Trihalomethane Survey. Journal American Water Works Association. January:61-68.

Meier, J.R., R.J. Bull, J.A. Stober and M.C. Cimino. 1985. Evaluation of chemicals used for drinking water disinfection for production of chromosomal damage and sperm-head abnormalities in mice. Environ. Mutagen. 7:201-211.

Meister, R., ed. 1988. Farm Chemicals Handbook. Willoughby, OH: Meister Publishing Company.

Michael, G.E., R.K. Miday, J.P. Bercz, R.G. Miller, D.G. Greathouse, D.F. Kraemer and J.B. Lucas. 1981. Chlorine dioxide water disinfection: A prospective epidemiology study. Arch. Environ. Health 36:20-27.

Miller, R.G., F.C. Kopfler, L.W. Condie, M.A. Pereira, J.R. Meier, H.P. Ringhand, M.Robinson and B.C. Casto. 1986. Results of toxicological testing of Jefferson Parish pilot plant samples. Environ. Health Perspect. 69:129-139.

Mobley, S.A., D.H. Taylor, R.D. Laurie and R.J. Pfohl. 1990. Chlorine dioxide depresses T_3 uptake and delays development of locomotor activity in young rats. In: Jolley, et al., eds. Water chlorinaiton: Chemistry, environmental impact and health effects, vol. 6. Chelsa, MI: Lewis Publisher, Inc., pp. 347-358.

Moore, G.S. and E.J. Calabrese. 1982. Toxicological effects of chlorite in the mouse. Environ. Health Perspect. 46:31-37.

Moore, G.S. and E.J. Calabrese. 1981. Effect of chlorine dioxide, chlorite and nitrite on mice with low and high levels of glucose-6-phosphate dehydrogenase (G6PD) in their erythrocytes. Final report on EPA Grant No. R805-557-01, EPA 600/1-81-014. NTIS PB81-152381.

Moore, G.S. and E.J. Calabrese. 1980. The effects of chlorine dioxide and sodium chlorite on erythrocytes of A/J and C57L/J mice. J. Environ. Pathol. Toxicol. 4:513-524.

Motin, J., Maret, Traeger, Fries and Guibaud. 1970. Attempted suicide with sodium chlorate. Med. Leg. Tox. Med. 13:177-179. (In French: translation).

Musil, J., Z. Knotek, J. Chalupa and P. Schmidt. 1964. Toxicologic aspects of chlorine dioxide application for the treatment of water containing phenols. Technol. Water 8:327-346.

NAS. 1987. National Academy of Sciences. Drinking water and health. Vol. 7. Washington, DC: National Academy Press.

NAS. 1982. National Academy of Sciences. Drinking water and health. Vol. 4. Washington, DC: National Academy Press.

NAS. 1980. National Academy of Sciences. Drinking water and health. Vol. 3. Washington, DC: National Academy Press.

O'Grady, J. and E. Jarecsni. 1971. Sodium chlorate poisoning. Brit. J. Clin. Prac. 25:38-39.

Orme, J., D.H. Taylor, R.D. Laurie and R.J. Bull. 1985. Effects of chlorine dioxide on thyroid function in neonatal rats. J. Toxicol. Environ. Health 15:315-322.

Penn, A., M-Zu Lu and J.L. Parker. 1990. Ingestion of chlorinated water has no effect upon indicators of cardiovascular disease in pigeons. Toxicol. 63:301-313.

Revis, N.W., P. McCauley, R. Bull and G. Holdsworth. 1986. Relationship of drinking water disinfectant to plasma cholesterol and thyroid hormone levels in experimental studies. Proc. Natl. Acad. Sci. 83:1485-1489.

Ridgway, P. 1992. Sodium chlorite: 13 Week oral (gavage) toxicity study in the rat. Report to the Chlorine Dioxide Panel of the Chemical Manufacturers Association, Washington, D.C. by Toxicol Laboratories, Ltd., Ledbury, England (Laboratory project I.D. CMA/13/R).

Robinson, M., R.J. Bull, M. Schamer and R.F. Long. 1986. Epidermal hyperplasia in the mouse skin following treatment with alternate drinking water disinfectants. Env. Health Persp. 69:293-300.

Seebert, A.H. 1989. Unscheduled DNA synthesis (UDS) in HeLa cells in vitro: Test substance: Sodium chlorate. Report to the Sodium Chlorate Task Force, Kerr

McGee Chemical Corporation, Oklahoma City, OK by Life Science Research, Roma Toxicology Centre S.P.A. (LSR-RTC Report No. 102002-M-02289).

Sheahan, B.J., D.M. Pugh and E.W. Winstanley. 1971. Experimental sodium chlorate poisoning in dogs. Res. Vet. Sci. 12:387-389.

Stavrou, A., R. Butcher and A. Sakula. 1978. Accidental self-poisoning by sodium chlorate weed-killer. The Practitioner. 221:397-399.

Steinbergs, C.Z. 1986. Removal of by-products of chlorine and chlorine dioxide by a hemodialysis center. JAWWA 78(6):94-98.

Steffen, C. and R. Seitz. 1981. Severe chlorate poisoning: Report of a case. Arch. Toxicol. 48:281-288.

Suh, D.H., M.S. Abdel-Rahman and R.J. Bull. 1984. Biochemical interactions of chlorine dioxide and its metabolites in rats. Arch. Environ. Contam. Toxicol. 13:163-169.

Suh, D.H., M.S. Abdel-Rahman and R.J. Bull. 1983. Effect of chlorine dioxide and its metabolites in drinking water on fetal development in rats. J. Appl. Toxicol. 3:75-79.

Taylor, D.H. and R.J. Pfohl. 1985. Effects of chlorine dioxide on the neurobehavioral development of rats. In: Jolley, R.L. et al., eds. Water chlorination: Environmental impact and health effects, Vol. 5. Chelsea, MI: Lewis Publ. Inc. pp. 355-364.

Thompson et al. 1987. Chlorite and chlorate residuals in the distribution system. Fall, 1987, WQTC, Baltimore, MD.

Thompson, J.C. 1988. Removal of chlorine dioxide and chlorite with granular activated carbon. AWWA Annual Conference, Orlando, FL.

Timperman, J. and R. Maes. 1986. Suicidal poisoning by sodium chlorate: A report of three cases. J. Forensic Med. 13:123-129.

Toth, G.P., R.E. Long, T.S. Mills and M.K. Smith. 1990. Effects of chlorine dioxide on the developing rat brain. J. Toxicol. Environ. Health. 31:29-44.

Tuthill, R.W., R.A. Giusti, G.S. Moore and E.J. Calabrese. 1982. Health effects among newborns after prenatal exposure to ClO_2 - disinfected drinking water. Environ. Health Persp. 46:39-45.

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

U.S. EPA. 1994b. U.S. Environmental Protection Agency. Final draft for the Drinking Water Criteria Document on chlorine dioxide, chlorite and chlorate. EPA contract no. 68-C2-0139. Washington, DC: Health and Ecological Criteria Division, Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency.

U.S EPA. 1993. EPA method 300.0. The determination of inorganic anions by ion chromatography in the Manual "Methods for the determination of inorganic substances in environmental samples," EPA/600/R/93/100.

U.S. EPA. 1992a. Occurrence and Assessment for Disinfectants and Disinfection By-products (Phase 6a) in Public Drinking Water. August 3, 1992

U.S. EPA. 1992b. U.S. Environmental Protection Agency. Review of the Drinking Water Criteria Document for Chlorine Dioxide. Drinking Water Committee, Science Advisory Board. Memorandum from Ray Loehr and Verne Ray to William K. Reilly. August 12.

U.S. EPA. 1992c. Technology and costs for control of disinfection by-products. Science and Technology Branch, Criteria and Standards Division, Office of Ground Water and Drinking Water. Washington, D.C.

U.S. EPA. 1986a. Reference values for risk assessment. Cincinnati, OH: U.S. Environmental Protection Agency, Environmental Criteria and Assessment Office, Office of Health and Environmental Assessment.

U.S. EPA. 1986b. U.S. Environmental Protection Agency. Guidelines for carcinogen risk assessment. Fed. Reg. 51(185):33992-34003.

U.S. EPA. 1979. U.S. Environmental Protection Agency. Federal Register 44:68624. November 29.

Vakili, M. 1977. Chlorate poisoning in childhood--a case report. J. Trop. Pediatr. 23:119.

Weast, R.C. and M. Astle, eds. 1982. CRC handbook of chemistry and physics -- a ready reference book of chemical and physical data, 63rd ed. Cleveland, OH: CRD Press.

Werdehoff, K.S. and P.C. Singer. 1987. Chlorine dioxide effects on THMTP, TOXFP and formation of inorganic by-products. J. AWWA 79(9):107-113.

WHO. 1982. World Health Organization. IARC monographs on the evaluation of the carcinogenic risk of chemicals to humans. Chemicals, industrial processes and industries associated with cancer in humans. International Agency for Research on Cancer Monographs. Vol. 1 to 29, Supplement 4. Geneva: World Health Organization.

Windholz, M., ed. 1976. The Merck Index: An encyclopedia of chemicals and drugs, 95th ed. Rahway, NJ: Merck and Co., Inc.

Yokose, Y., K. Uchida, D. Nakae, et al. 1987. Studies of carcinogenicity of sodium chlorite in B6C3F1 mice. Environ. Health Persp. 76:205-10.

Yoshida, Y., Y. Hirose, S. Konda, H. Kitada and A. Shinoda. 1977. A cytological study of Heinz body-hemolytic anemia: Report of a case of sodium chlorate poisoning complicated by methemoglobinemia and acute renal failure. Acta Haem. Jap. 40:147-151.

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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

21

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 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 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.

* * * * *

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

§ 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.

* * * *

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

§ 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.

Health Canada

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. (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

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.

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

PREC TIONARY 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, & odenticide Act as amended ...a pesticide, 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.

Ge ...et (_____)

DIRECTIONS FOR US

It is a violation of Federal law to use t... oduct 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 Represen...tive at the nearest EPA Regional Office for ...nce.

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-pyrimidinylmethyl)-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

Top of Page Next Page

Return to Page Top

Navigational Assist

Link to: Inspection References Focus Page

Links to: [Page Top | ORA Home | FDA Home Page | FDA Site Index | FDA ORA Search Page | FDA Reader Comments]

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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

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 Informalton 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.

[44] *Id.*

[45] 15 U.S.C. 78q(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. H4358 (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

Alcide CORPORATION
8561 154th Avenue NE, Redmond, WA 98052-3557 425-882-2555 Fax: 425-861-0173

Subject: Canadian Approval for Sanova, Equivalence to US-FDA Approval.

Date: October 4, 1999.

The following comments relate to the letter of September 27th, 1999 received from the Canadian regulatory authorities (HPB), and indicating their approval to use acidified sodium chlorite as a pre-chill intervention step for microbial reduction on poultry.

At first glance, this approval appears to vary from that of Alcide Corporation's US-FDA approval in that it references the use of chlorous acid. However, the levels that are referenced by HPB (chlorous acid in the range 50 to 266 ppm and within the pH range of 2.5 to 2.9) are derived from the same acidified sodium chlorite system as has been approved and is being used within the US.

The US-FDA approval is for the use of acidified sodium chlorite at levels between 500 ppm to 1200 ppm and within the pH range of 2.3 to 2.9 (21 CFR, Part 173). Chlorous acid is formed upon the acidification of sodium chlorite, the amount that forms being in direct proportion to the pH of the mixed solution. Thus at a pH of 2.5 a 1200 ppm solution of sodium chlorite that has been acidified, has a chlorite rate of dissociation of 22.2% to give a final chlorous acid level of 266 ppm. Likewise at a pH of 2.9, a 500 ppm solution of sodium chlorite that has been acidified has a chlorite rate of dissociation of 10.0%, to give a final chlorous acid level of 50 ppm.

G. Kere Kemp
Executive Vice President
Chief Scientific Officer

Canada
Health Protection Branch

Canada
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

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 acidifi sodium chlorite solution to the poultry product inspection regulations, 9 CFR 381.147(f)(4) a 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

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

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

United States Department of Agriculture

Food Safety 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

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
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

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

DEC 31 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

Attachment 3

8. Chemical Abstract Data and Labeled Products & MSDS Forms

Organic/Standard Operating Procedure (O/SOP)
Organic Livestock

PRE – AND – POST USE TEAT DIP

Notice To: Organic Herd Manager and Milking Team

Products:
* *Ecolab Teat Dip 4XLA Base & Activator*
* *Aztec Gold Base & Activator*
* *Encore Activator & Barrier*

Active Ingredients: Lactic Acid, Sodium Chlorite, Glycerin

Use: External Udder Sanitation Only

Directions for Use: Carefully Read and Follow Label Mixing & Use Instructions

Application: Follow All Product Label Directions

Pre-Milking: If teats are visibly dirty, wash and dry teats with single service towel prior to dipping. Before each cow is milked, dip the teats as far up as possible. Leave Teat Dip on teats for at least 15-30 seconds. Wipe teats dry using a single service towel before milking.

Post-Milking: Immediately after milking, dip teats at least 2/3 to full length in Teat Dip. Allow to air dry. DO NOT WIPE. Teat Dip can be used as a post dip alone, or as a pre-and-post milking teat dip.

Note: Continue to follow *Ecolab Product Use Directions*: Use only fresh product daily, keep good records. Maintain up-to-date *Organic System Plan (OSP)* and *Dairy Materials Use Records.* Notify certifier of all material and/or sanitation procedure changes. Be sure to submit the product label, MSDS form, and O/SOP to your certifier for review and approval.

50987

Distributed by:
Select Sires Inc.
11740 U.S. 42N P.O. Box 143
Plain City, OH 43064-0143
614-873-4683
www.selectsires.com

TEAT DIP

NOT FOR HUMAN USE

4XLA® is a registered trademark of Ecolab Inc., St. Paul, MN 55102

Made in USA
U.S. Patent RE37265, U.S. Patent 5,284,174
Foreign Patents Issued and Pending

4XLA®

GERMICIDAL PRE- & POST-MILKING TEAT DIP

An aid in reducing the spread of organisms which may cause mastitis

BASE

FOR USE ONLY WITH 4XLA® ACTIVATOR

CAUTION: For external use only. Not for use in sanitizing dairy equipment. Do not mix with any other teat dip or other product. Avoid contact with food. Store at room temperature. Protect from heat and freezing. Always store away from continuous artificial light or direct sunlight. Avoid contact with eyes. If contact occurs, flush eyes with large quantities of water. See a physician if irritation develops.

ACTIVE INGREDIENT: 0.6% Sodium Chlorite

DISPOSAL: Unused teat dip may be diluted with water and flushed down drain. Do not reuse containers. Empty containers should be thoroughly rinsed with water and taken to a recycling center.

KEEP OUT OF THE REACH OF CHILDREN

Contents: 55 U.S. Gallon (208.2 Liters)

DIRECTIONS FOR USE: Measure equal volumes of **4XLA® base** and **4XLA activator** into a clean dip cup/container and mix until the color is uniform through-out. Do not dilute. Mix only enough product for one milking of the herd. Dip cups should be washed after each milking.

APPLICATION:

Pre-Milking: If teats are visibly dirty, wash and dry teats with a single service towel prior to dipping. Before each cow is milked, dip the teats as far up as possible. Leave **4XLA Teat Dip** on teats for at least 15-30 seconds. Wipe teats dry using a single service towel before milking.

Post-Milking: Immediately after milking, dip teats at least 2/3 to all their length in **4XLA Teat Dip.** Allow to air dry. **DO NOT WIPE. 4XLA Teat Dip** can be used as a post-dip alone, or as a pre- and post-milking teat dip.

Always use freshly mixed, full strength 4XLA Teat Dip. If product in dip cup becomes visibly dirty, discard contents and fill with fresh 4XLA Teat Dip.

Note 1: If teat irritation occurs, discontinue use until irritation subsides. Consult your veterinarian and milking equipment service personnel if irritation persists.

Note 2: The gold color in the mixed product fades with time. At higher temperatures the fading is more rapid. However, this will not affect the efficacy of the product.

Note 3: 4XLA should be used only with a compatible pre-dip or udder wash.

AVOID FREEZING: If product is exposed to freezing temperatures, components must be mixed thoroughly prior to use.

4XLA®

PRESELLADOR Y SELLADOR GERMICIDA PARA PEZONES

Ayuda a reducir la propagación de gérmenes que pueden causar la mastitis

BASE

USARLA UNICAMENTE CON EL ACTIVADOR DEL 4XLA®

PRECAUCIONES: Sólo de uso externo. No se debe utilizar para higienizar el equipo de ordeño. No se debe mezclar con otros selladores de pezones o productos similares. Evite el contacto con los alimentos. Almacenarlo a temperatura ambiente. Protegerlo del calor y la congelación. Almacenarlo siempre alejado de la luz artificial continua o la luz solar directa. Evite el contacto con los ojos. Si el producto entra en contacto con los ojos lávelos abundantemente con agua. Contacte al médico en caso de irritación.

INGREDIENTE ACTIVO: 0.6% de clorito de sodio

DESECHO: El producto que no sea utilizado se puede diluir con agua y ser desechado por el drenaje. Los envases no se deben volver a utilizar. Los envases vacíos se deben enjuagar completamente y ser llevados a un centro de reciclaje.

MANTENGALO FUERA DEL ALCANCE DE LOS NIÑOS

CONTENIDO: 208.2 litros

INSTRUCCIONES DE USO: Mezcle cantidades iguales de **4XLA® base** y **4XLA® activador** en una copa de aplicación limpia hasta que el color quede uniforme. No se debe diluir. Mezcle solamente la cantidad necesaria para un ordeño del rebaño. Las copas de aplicación deben lavarse después de cada ordeño.

APLICACION:

PRESELLO/ANTES DEL ORDEÑO: Si los pezones se ven sucios lávelos y séquelos con una toalla de papel desechable antes de la aplicación del producto. Antes del ordeño sumerja completamente los pezones en la copa de aplicación. Deje actuar el preselladar **4XLA** en los pezones por el mínimo 15-30 segundos. Seque los pezones con una toalla de papel desechable antes del ordeño.

SELLO/DESPUÉS DEL ORDEÑO: Inmediatamente después del ordeño sumerja al menos dos terceras partes de los pezones o más en la copa aplicadora del 4XLA, y déjelos secar al aire libre sin limpiarlos. El baño de pezones del **4XLA** puede ser usado solamente como sellador después del ordeño, o como preselladar y sellador antes y después del ordeño.

Siempre use el producto recién mezclado a la potencia completa. Si el producto en las copas de aplicación se ve sucio deséchelo y reemplácelo con producto fresco de 4XLA.

Nota 1: Si se presenta una irritación en el pezón interrumpa el uso hasta que la irritación desaparezca. Consulte a su médico veterinario y al técnico de mantenimiento del equipo de ordeño si la irritación persiste.

Nota 2: El color dorado del producto mezclado se desvanece con el tiempo. A temperaturas elevadas el color desaparece más rápidamente; sin embargo esta descoloramiento no afecta la eficacia del producto.

Nota 3: El sellador 4XLA debe ser utilizado solamente con productos compatibles con el sellador ó el baño de la ubre.

EVITE EL CONGELAMIENTO: Si el producto se expone a temperaturas de congelación los componentes deben ser mezclados completamente antes del uso.

707102/5301/0705

5.0" x 14.875" PMS 354 Green and Black

Material Safety Data Sheet

4XLA BASE

Section 1. Chemical product and company identification

Trade name : 4XLA BASE
Product use : Veterinary care
Supplier : Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102
Code : 910911
Date of issue : **08-December-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	<1.0

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : CAUTION!

MAY CAUSE EYE IRRITATION.
Repeated or prolonged contact with irritants may cause dermatitis.
Avoid contact with eyes. Wash thoroughly after handling.

Potential acute health effects
Eyes : Moderately irritating to the eyes.
Skin : Slightly irritating to the skin.
Inhalation : Slightly 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 develops. 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. 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 : Good general ventilation should be sufficient to control airborne levels.

Personal protection

Eyes : Eye protection recommended.

Hands : No protective equipment is needed under normal use conditions.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : No protective equipment is needed under normal use conditions.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Colorless.

Odor : chlorine

pH : 11.75 (100%)

Boiling/condensation point : >100 °C

Specific gravity : 1.01 (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.

Section 11. Toxicological information

Potential acute health effects

Eyes : Moderately irritating to the eyes.

Skin : Slightly irritating to the skin.

Inhalation : Slightly irritating to the respiratory system.

Ingestion : No known significant effects or critical hazards.

Section 12. Ecological information

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.	-	-	-	-

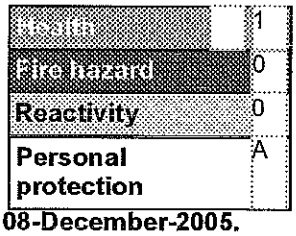
APPLIES ONLY DURING ROAD TRANSPORT
Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Irritating material
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 : 08-December-2005.
Responsible name : Regulatory Affairs
Date of previous issue : 08-December-2005.

Notice to reader

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50983

4XLA®

[illegible]

NOT FOR HUMAN USE

ACTIVATOR

FOR USE ONLY WITH 4XLA® BASE

CAUTION: For external use only. Not for use in sanitizing dairy equipment. Do not mix with any other teat dip or other product. Avoid contact with food. Store at room temperature. Protect from heat and freezing. Always store away from continuous artificial light or direct sunlight. Avoid contact with eyes. If contact occurs, flush eyes with large quantities of water. See a physician if irritation develops.

ACTIVE INGREDIENT: 2.5% Lactic Acid

CONTAINS: 10% Glycerin

DISPOSAL: Unused teat dip may be diluted with water and flushed down drain. Do not reuse containers. Empty containers should be thoroughly rinsed with water and taken to a recycling center.

KEEP OUT OF THE REACH OF CHILDREN

DIRECTIONS FOR USE: [illegible]

APPLICATION:

Pre-Milking: [illegible]

Post-Milking: [illegible] **DO NOT WIPE.** [illegible]

Always use freshly mixed, full strength 4XLA Teat Dip. [illegible]

Note 1: [illegible]

Note 2: [illegible]

Note 3: [illegible]

AVOID FREEZING: [illegible]

Contents: 55 U.S. Gallons (208.2 litres)

Made in USA

4XLA®

[illegible]

ACTIVADOR

USARLO ÚNICAMENTE CON LA BASE DEL 4XLA®

PRECAUCIONES: [illegible]

INGREDIENTE ACTIVO: 2.5% de ácido láctico

CONTIENE: 10% de glicerina

DESECHO: [illegible]

MANTENGALO FUERA DEL ALCANCE DE LOS NIÑOS

INSTRUCCIONES DE USO: [illegible]

APLICACIÓN:

PRESELLO/ANTES DEL ORDEÑO: [illegible]

SELLO/DESPUÉS DEL ORDEÑO: [illegible]

EVITE EL CONGELAMIENTO: [illegible]

CONTENIDO: 208.2 litros

7.0" x 14.0" PMS 354 Green and Black

Material Safety Data Sheet

4XLA ACTIVATOR

Section 1. Chemical product and company identification

Trade name : 4XLA ACTIVATOR
Product use : Teat dip
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 910909
Date of issue : **06-December-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
propan-2-ol	67-63-0	2
glycerin	56-81-5	5 - 20
propanoic acid, 2-hydroxy-, (s)-	79-33-4	1 - 5

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : CAUTION!

MAY CAUSE EYE IRRITATION.
Repeated or prolonged contact with irritants may cause dermatitis.
Avoid contact with eyes. Wash thoroughly after handling.

Potential acute health effects

Eyes : Moderately irritating to the eyes.
Skin : Slightly irritating to the skin.
Inhalation : Slightly 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 develops. 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. 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 : Good general ventilation should be sufficient to control airborne levels.

Personal protection

Eyes : Eye protection recommended.

Hands : No protective equipment is needed under normal use conditions.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : No protective equipment is needed under normal use conditions.

Name	Exposure limits
glycerin	**ACGIH TLV (United States, 1/2004).** TWA: 10 mg/m³ 8 hour(s). Form: Mist **OSHA PEL (United States, 8/1997).** TWA: 5 mg/m³ 8 hour(s). Form: Respirable fraction TWA: 15 mg/m³ 8 hour(s). Form: Total dust
propan-2-ol	**ACGIH TLV (United States, 1/2004).** STEL: 400 ppm 15 minute(s). Form: All forms TWA: 200 ppm 8 hour(s). Form: All forms **OSHA PEL (United States, 8/1997).** TWA: 980 mg/m³ 8 hour(s). Form: All forms TWA: 400 ppm 8 hour(s). Form: All forms

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Yellow.

Odor : Faint Odor

pH : 2.5 (100%)

Boiling/condensation point : 100 °C

Specific gravity : 1.03 (Water = 1)

Viscosity : Dynamic: 50 cP

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 : Slightly irritating to the skin.

Inhalation : Slightly 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: kidneys, upper respiratory tract, skin, central nervous system (CNS), eye, lens or cornea.

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.

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.

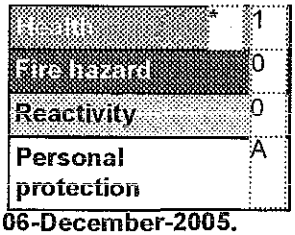
TSCA 8(b) inventory : All materials are listed or exempt.

SARA 313	**Product name**	**Concentration**
Form R - Reporting requirements:	propan-2-ol	2

California prop. 65 : No products were found.

Section 16. Other information

Hazardous Material Information System (U.S.A.) :



Date of issue : **06-December-2005.**

Responsible name : **Regulatory Affairs**
Date of previous issue : **No Previous Validation.**

Notice to reader

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ECOLAB®

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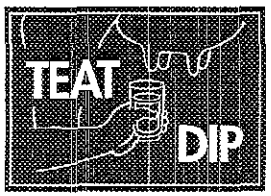


KEEP OUT OF THE REACH OF CHILDREN
NOT FOR HUMAN USE

MANTENGALO FUERA DEL ALCANCE DE LOS NIÑOS
NO ES PARA USO DOMESTICO

Aztec Gold™ is a Trademark of Ecolab Inc.
St Paul, MN 55102 • Made in USA
http://www.ecolab.com

Patent Pending
Foreign Patents Pending

Net Contents/Contenido Neto:
55 U.S. gal/208.2 L

AZTEC GOLD™

GERMICIDAL PRE & POST MILKING TEAT DIP

An aid in reducing the spread of organisms which may cause mastitis

BASE

FOR USE ONLY WITH AZTEC GOLD™ ACTIVATOR

ACTIVE INGREDIENT	
Sodium Chlorite	0.6%
INACTIVE INGREDIENT	99.4%

CAUTION: For external use only. Not for use in sanitizing dairy equipment. Do not mix with any other teat dip or other product. Avoid contact with food. Store at room temperature. Protect from heat and freezing. Always store away from continuous artificial light or direct sunlight. Avoid contact with eyes. If contact occurs, flush eyes with large quantities of water. See a physician if irritation develops. Wash thoroughly after handling.

DISPOSAL: Unused teat dip may be diluted with water and flushed down drain. Do not reuse containers. Empty containers should be thoroughly rinsed with water and taken to a recycling center.

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).

AVOID FREEZING: If product is exposed to freezing temperatures, components must be mixed thoroughly prior to use.

DIRECTIONS FOR USE: Measure equal volumes of **Aztec Gold base** and **Aztec Gold activator** into a clean dip cup/container and mix until the color is uniform throughout. Do not dilute. Mix only enough product for one milking of the herd. Dip cups should be washed after each milking.

APPLICATION:

Pre-Milking: If teats are visibly dirty, wash and dry teats with a single service towel prior to dipping. Before each cow is milked, dip the teats as far up as possible. Leave **Aztec Gold** Teat Dip on teats for at least 15-30 seconds. Wipe teats dry using a single service towel before milking.

Post-Milking: Immediately after milking, dip teats at least 2/3 their length in **Aztec Gold** Teat Dip. Allow to air dry. DO NOT WIPE. **Aztec Gold** Teat Dip can be used as a post-dip alone, or as a pre and post-milking teat dip.

Always use freshly mixed, full strength Aztec Gold Teat Dip. If product in dip cup becomes visibly dirty, discard contents and fill with fresh Aztec Gold Teat Dip.

Note 1: If teat irritation occurs, discontinue use until irritation subsides. Consult your veterinarian and milking equipment service personnel if irritation persists.

Note 2: The gold color in the mixed product fades with time. At higher temperatures the fading is more rapid. However, this will not affect the efficacy of the product.

Note 3: Aztec Gold should be used only with a compatible pre-dip or udder wash.

Lot No. / Lote

Exp. Date / Expiración

AZTEC GOLD™

PRESELLADOR Y SELLADOR GERMICIDA PARA PEZONES

Ayuda a reducir la propagación de gérmenes que pueden causar la mastitis

BASE

USARLA UNICAMENTE CON EL ACTIVADOR DEL AZTEC GOLD™

INGREDIENTE ACTIVO	
Clorito de Sodio	0.6%
INGREDIENTES ACTIVOS	99.4%

PRECAUCIONES: Sólo de uso externo. No se debe utilizar para higienizar el equipo de ordeño. No se debe mezclar con otros selladores de pezones o productos similares. Evite el contacto con los alimentos. Almacenarlo a temperatura ambiente. Protegerlo del calor y la congelación. Almacenarlo siempre alejado de la luz artificial continua o la luz solar directa. Evite el contacto con los ojos. Si el producto entra en contacto con los ojos lávelos abundantemente con agua. Contacte al médico en caso de irritación. Lávese a fondo luego de utilizar el producto.

DESECHO: El producto que no sea utilizado se puede diluir con agua y ser desechado por el drenaje. Los envases no se deben volver a utilizar. Los envases vacíos se deben enjuagar completamente y ser llevados a un centro de reciclaje.

PARA INFORMACIÓN MÉDICA DE URGENCIA EN LOS E.E.U.U. O CANADA, LLAME AL 1-800-328-0026.
PARA INFORMACIÓN MÉDICA DE URGENCIA EN EL RESTO DEL MUNDO, LLAME AL 1-651-222-5352.

EVITE EL CONGELAMIENTO: Si el producto se expone a temperaturas de congelación los componentes deben ser mezclados completamente antes del uso.

INSTRUCCIONES DE USO: Mezcle cantidades iguales de **Aztec Gold** base y **Aztec Gold** activador en una copa de aplicación limpia hasta que el color dorado sea uniforme. No se debe diluir. Mezcle solamente la cantidad necesaria para un ordeño del rebaño. Las copas de aplicación deben lavarse después de cada ordeño.

APLICACION:

PRESELLO/ANTES DEL ORDEÑO: Si los pezones se ven sucios lávelos y séquelos con una toalla de papel desechable antes de la aplicación del producto. Antes del ordeño sumerja completamente los pezones en la copa de aplicación. Deje actuar el preselador **Aztec Gold** en los pezones por al menos 15-30 segundos. Seque los pezones con una toalla de papel desechable antes del ordeño.

SELLO/DESPUÉS DEL ORDEÑO: Inmediatamente después del ordeño sumerja al menos dos terceras partes de los pezones o más en la copa aplicadora del **Aztec Gold**, y déjelos secar al aire libre sin limpiarlos. El baño de pezones del **Aztec Gold** puede ser usado solamente como sellador después del ordeño, ó como preselador y sellador antes y después del ordeño.

Siempre use el producto recién mezclado a la potencia completa. Si el producto en las copas de aplicación se ve sucio deséchelo y reemplácelo con producto fresco de Aztec Gold.

Nota 1: Si se presenta una irritación en el pezón interrumpa el uso hasta que la irritación desaparezca. Consulte a su médico veterinario y al técnico de mantenimiento del equipo de ordeño si la irritación persiste.

Nota 2: El color dorado del producto mezclado se desvanece con el tiempo. A temperaturas elevadas el color desaparece más rápidamente; sin embargo este descoloramiento no afecta la eficacia del producto.

Nota 3: El sellador **Aztec Gold** debe ser utilizado solamente con productos compatibles con el sellador ó el baño de la ubre.

720434/5300/0808

Material Safety Data Sheet

ECOLAB

AZTEC GOLD BASE

Section 1. Chemical product and company identification

Trade name : AZTEC GOLD BASE
Product use : Teat dip
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 901480-01
Date of issue 24-September-2008

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	<1

Section 3. Hazards identification

Physical state : Liquid. [Liquid.]
Emergency overview : CAUTION !
MAY CAUSE EYE IRRITATION.

Avoid contact with eyes. Wash thoroughly after handling.

Potential acute health effects
Eyes : Moderately irritating to eyes.
Skin : No known significant effects or critical hazards.
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 plenty of water. Remove contact lenses and flush again. Get medical attention if irritation persists.
Skin contact : In case of contact, immediately flush skin with plenty of water. Wash clothing 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.
Hazardous thermal decomposition products : No specific data.
Fire-fighting media and instructions : Use an extinguishing agent suitable for the surrounding fire.

Dike area of fire to prevent runoff.

In a fire or if heated, a pressure increase will occur and the container may burst.
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 : Use suitable protective equipment (section 8). 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. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods for cleaning up : 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 it 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. Wash thoroughly after handling.

Storage : Keep out of reach of children. Keep container in a cool, well-ventilated area. Keep container tightly closed.

Do not store below the following temperature: 0°C

Section 8. Exposure controls/personal protection

Engineering measures : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Personal protection :

Eyes : Eye protection recommended.

Hands : No protective equipment is needed under normal use conditions.

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. [Liquid.]

Color : Colorless.

Odor : chlorine

pH : 11.9 [Conc. (% w/w): 100%]

Boiling/condensation point : >100°C (>212°F)

Relative density : 1.023 to 0.993

Solubility : Easily soluble in the following materials: cold water and hot water.

Section 10. Stability and reactivity

Stability : The product is stable. Under normal conditions of storage and use, hazardous polymerization will not occur.

Reactivity : Reactive or incompatible with the following materials: acids.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Hazardous polymerization : Under normal conditions of storage and use, hazardous polymerization will not occur.

Section 11. Toxicological information

Potential acute health effects

Eyes : Moderately irritating to eyes.

Skin : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Section 12. Ecological information

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

Certain shipping modes or package sizes may have exceptions from the transport regulations. The classification provided may not reflect those exceptions and may not apply to all shipping modes or package sizes.

UN Classification Not regulated.

See shipping documents for specific transportation information.

Section 15. Regulatory information

HCS Classification : Irritating material

U.S. Federal regulations : **SARA 302/304/311/312 extremely hazardous substances:** No products were found.

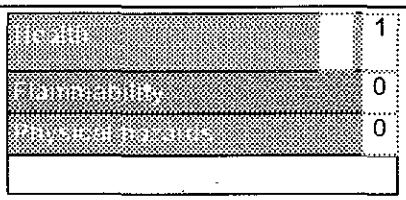
SARA 302/304 emergency planning and notification: No products were found.

TSCA 8(b) inventory : All components are listed or exempted.

California Prop. 65 : No products were found.

Section 16. Other information

Hazardous Material Information System (U.S.A.) :



Date of issue : **24-September-2008.**

Responsible name : **Regulatory Affairs**

Date of previous issue : **No previous validation.**

Notice to reader

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ECOLAB®

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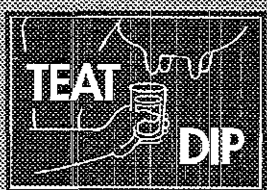


KEEP OUT OF THE REACH OF CHILDREN
NOT FOR HUMAN USE

MANTENGALO FUERA DEL ALCANCE DE LOS NIÑOS
NO ES PARA USO DOMESTICO

Aztec Gold™ is a trademark of Ecolab Inc.
St. Paul, MN 55102 • Made in USA
http://www.ecolab.com

Patent Pending
Foreign Patents Pending

Net Contents/Contenido Neto: 55 U.S. gal/208.2 L

AZTEC GOLD™

GERMICIDAL PRE & POST MILKING TEAT DIP

An aid in reducing the spread of organisms which may cause mastitis.

ACTIVATOR

FOR USE ONLY WITH AZTEC GOLD™ BASE

ACTIVE INGREDIENT	
Lactic Acid	2.5%
INACTIVE INGREDIENT	97.5%
(Contains 10% Glycerin)	

CAUTION: For external use only. Not for use in sanitizing dairy equipment. Do not mix with any undiluted dip or other product. Avoid contact with food. Store at room temperature. Protect from heat and freezing. Always store away from continuous artificial light or direct sunlight. Avoid contact with eyes. If contact occurs, flush eyes with large quantities of water. See a physician if irritation develops. Wash thoroughly after handling.

DISPOSAL: Unused teat dip may be diluted with water and flushed down drain. Do not reuse containers. Empty containers should be thoroughly rinsed with water and taken to a recycling center.

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).

AVOID FREEZING: If product is exposed to freezing temperatures, components must be mixed thoroughly prior to use.

DIRECTIONS FOR USE: Measure equal volumes of **Aztec Gold base** and **Aztec Gold activator** into a clean dip cup/container and mix until the color is uniform throughout. Do not dilute. Mix only enough product for one milking of the herd. Dip cups should be washed after each milking.

APPLICATION:

Pre-Milking: If teats are visibly dirty, wash and dry teats with a single service towel prior to dipping. Before each cow is milked, dip the teats as far up as possible. Leave **Aztec Gold** Teat Dip on teats for at least 15-30 seconds. Wipe teats dry using a single service towel before milking.

Post-Milking: Immediately after milking, dip teats at least 2/3 their length in **Aztec Gold** Teat Dip. Allow to air dry. DO NOT WIPE. **Aztec Gold** Teat Dip can be used as a post-dip alone, or as a pre and post-milking teat dip.

Always use freshly mixed, full strength Aztec Gold Teat Dip. If product in dip cup becomes visibly dirty, discard contents and fill with fresh Aztec Gold Teat Dip.

Note 1: If teat irritation occurs, discontinue use until irritation subsides. Consult your veterinarian and milking equipment service personnel if irritation persists.

Note 2: The gold color in the mixed product fades over time. At higher temperatures the fading is more rapid. However, this will not affect the efficacy of the product.

Note 3: **Aztec Gold** should be used only with a compatible pre-dip or udder wash.

Lot No. Lote	Exp. Date Expiración

AZTEC GOLD™

PRESELLADOR Y SELLADOR GERMICIDA PARA PEZONES

Ayuda a reducir la propagación de gérmenes que pueden causar la mastitis.

ACTIVADOR

USARLO UNICAMENTE CON LA BASE DEL AZTEC GOLD™

INGREDIENTE ACTIVO	
Acido Lactico	2.5%
INGREDIENTES ACTIVOS	97.5%
(Contiene 10% de glicerina)	

PRECAUCIONES: Sólo de uso externo. No se debe utilizar para higienizar el equipo de ordeño. No se debe mezclar con otros selladores de pezones o productos similares. Evite el contacto con los alimentos. Almacénelo a temperatura ambiente. Protéjalo del calor y la congelación. Almacénelo siempre alejado de la luz artificial continua o la luz solar directa. Evite el contacto con los ojos. Si el producto entra en contacto con los ojos, lávelos abundantemente con agua. Consulte al médico en caso de irritación. Lávese a fondo luego de utilizar el producto.

DESECHO: El producto que no sea utilizado se puede diluir con agua y ser desechado por el drenaje. Los envases no se deben volver a utilizar. Los envases vacíos se deben enjuagar completamente y ser llevados a un centro de reciclaje.

PARA INFORMACIÓN MÉDICA DE URGENCIA EN LOS E.E.U.U. O CANADA, LLAME AL 1-800-328-0026.
PARA INFORMACIÓN MÉDICA DE URGENCIA EN EL RESTO DEL MUNDO, LLAME AL 1-651-222-5352.

EVITE EL CONGELAMIENTO: Si el producto se expone a temperaturas de congelación los componentes deben ser mezclados completamente antes del uso.

INSTRUCCIONES DE USO: Mezcle cantidades iguales de **Aztec Gold** base y **Aztec Gold** activador en una copa de aplicación limpia hasta que el color dorado sea uniforme. No se debe diluir. Mezcle solamente la cantidad necesaria para un ordeño del rebaño. Las copas de aplicación deben lavarse después de cada ordeño.

APLICACIÓN:

PRESELLO/ANTES DEL ORDEÑO: Si los pezones se ven sucios lávelos y séquelos con una toalla de papel desechable antes de la aplicación del producto. Antes del ordeño sumerja completamente los pezones en la copa de aplicación. Deje actuar el presellador **Aztec Gold** en los pezones por al menos 15-30 segundos. Seque los pezones con una toalla de papel desechable antes del ordeño.

SELLO/DESPUÉS DEL ORDEÑO: Inmediatamente después del ordeño sumerja al menos dos terceras partes de los pezones y más en la copa aplicadora del **Aztec Gold**, y déjelos secar al aire libre sin limpiarlos. El baño de pezones del **Aztec Gold** puede ser usado solamente como sellador después del ordeño, o como presellador y sellador antes y después del ordeño.

Siempre use el producto recién mezclado a la potencia completa. Si el producto en las copas de aplicación se ve sucio deséchelo y reemplácelo con producto fresco de Aztec Gold.

Nota 1: Si se presenta una irritación en el pezón interrumpa el uso hasta que la irritación desaparezca. Consulte a su médico veterinario y al técnico de mantenimiento del equipo de ordeño si la irritación persiste.

Nota 2: El color dorado del producto mezclado se desvanece con el tiempo. A temperaturas elevadas el color desaparece más rápidamente. Sin embargo este desvanecimiento no afecta la eficacia del producto.

Nota 3: El sellador **Aztec Gold** debe ser utilizado solamente con productos compatibles con el sellador o el baño de la ubre.

720420/5300/0806

Material Safety Data Sheet

AZTEC GOLD ACTIVATOR

Section 1. Chemical product and company identification

Trade name : AZTEC GOLD ACTIVATOR
Product use : Teat dip
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 901366-01
Date of issue 24-September-2008

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
glycerin	56-81-5	5 - 20
lactic acid	50-21-5	1 - 5

Section 3. Hazards identification

Physical state : Liquid. [Liquid.]
Emergency overview : CAUTION !
MAY CAUSE EYE IRRITATION.

Avoid contact with eyes. Wash thoroughly after handling.

Potential acute health effects
Eyes : Moderately irritating to eyes.
Skin : No known significant effects or critical hazards.
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 plenty of water. Remove contact lenses and flush again. Get medical attention if irritation persists.
Skin contact : In case of contact, immediately flush skin with plenty of water. Wash clothing 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.
Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
Fire-fighting media and instructions : Use an extinguishing agent suitable for the surrounding fire.

Dike area of fire to prevent runoff.

In a fire or if heated, a pressure increase will occur and the container may burst.

:

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 : Use suitable protective equipment (section 8). 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. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods for cleaning up : 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 it 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. Wash thoroughly after handling.

Storage : Keep out of reach of children. Keep container in a cool, well-ventilated area. Keep container tightly closed.
Do not store below the following temperature: 0°C

Section 8. Exposure controls/personal protection

Engineering measures : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Personal protection :

Eyes : Eye protection recommended.

Hands : No protective equipment is needed under normal use conditions.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : A respirator is not needed under normal and intended conditions of product use.

Name	Exposure limits
glycerin	**ACGIH TLV (United States, 1/2008).** TWA: 10 mg/m³ 8 hour(s). Form: Mist **OSHA PEL (United States, 11/2006).** TWA: 5 mg/m³ 8 hour(s). Form: Respirable fraction TWA: 15 mg/m³ 8 hour(s). Form: Total dust

Section 9. Physical and chemical properties

Physical state : Liquid. [Liquid.]

Color : Yellow.

Odor : Faint odor.

pH : 2.2 [Conc. (% w/w): 100%]

Relative density : 1.048 to 1.018

Viscosity : Dynamic: 575 cP

Solubility : Easily soluble in the following materials: cold water and hot water.

Section 10. Stability and reactivity

Stability : The product is stable. Under normal conditions of storage and use, hazardous polymerization will not occur.

Reactivity : Reactive or incompatible with the following materials: alkalis.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Hazardous polymerization : Under normal conditions of storage and use, hazardous polymerization will not occur.

Section 11. Toxicological information

Potential acute health effects

Eyes	: Moderately irritating to eyes.
Skin	: No known significant effects or critical hazards.
Inhalation	: No known significant effects or critical hazards.
Ingestion	: No known significant effects or critical hazards.

Potential chronic health effects

Target organs : Contains material which may cause damage to the following organs: kidneys, upper respiratory tract.

Section 12. Ecological information

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

Certain shipping modes or package sizes may have exceptions from the transport regulations. The classification provided may not reflect those exceptions and may not apply to all shipping modes or package sizes.

UN Classification Not regulated.

See shipping documents for specific transportation information.

Section 15. Regulatory information

HCS Classification : Irritating material
Target organ effects

U.S. Federal regulations : **SARA 302/304/311/312 extremely hazardous substances**: No products were found.

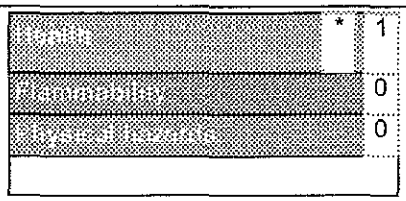
SARA 302/304 emergency planning and notification: No products were found.

TSCA 8(b) inventory : All components are listed or exempted.

California Prop. 65 : No products were found.

Section 16. Other information

Hazardous Material Information System (U.S.A.) :



Date of issue : 24-September-2008.

Responsible name : Regulatory Affairs

Date of previous issue : No previous validation.

Section 16. Other information

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.

41924
Patente pendiente

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DeForest, Wisconsin 53532
www.absglobal.com

MANTÉNGALO ALEJADO DEL ALCANCE DE LOS NIÑOS

PRECAUCIÓN: Causa irritación en los ojos. Puede causar irritación a la piel. No es para uso interno. Protéjase los ojos y las membranas mucosas para evitar el contacto con este producto. Use anteojos de protección cuando maneje este producto. Es para uso externo en vacas lecheras.

PRIMEROS AUXILIOS

Ojos: Enjuáguese inmediatamente los ojos con abundante agua fría de la llave. Quítese los lentes de contacto, si los usa. Siga enjuagándose los ojos durante 15 minutos como mínimo, manteniendo los párpados separados.

Si se traga: NO induzca el vómito. Enjuáguese la boca e inmediatamente tome 1 ó 2 vasos grandes de agua. Jamás dé algo por la boca a una persona en estado inconsciente.

SI LA IRRITACIÓN O EL MALESTAR PERSISTE, LLAME A UN MÉDICO.

Lea la Hoja de Datos de Seguridad antes de usar este producto.

PARA INFORMACION MEDICA DE EMERGENCIA EN LOS EE.UU. O CANADA, LLAME AL 1-800-328-0026. PARA INFORMACIÓN MEDICA DE EMERGENCIA EN EL MUNDO ENTERO, LLAME AL 1-651-222-5352 (EN LOS EE.UU.).

891222/5302/1001

INSTRUCCIONES DE USO

NOTA: Encore Activator está formulado para usarse como un activador con Encore Barrier o con Encore Pre/Post.

Mezclas: Mida dos cantidades iguales de Encore Barrier y Encore Pre/Post y Encore Activator RTU (Listo para usarse) en unos recipientes limpios. Mezcle hasta que el color se vea uniforme. Mezcle una cantidad apropiada para una ordeña y luego, tire el resto.

IMPORTANTE: No agregue Encore Barrier y Encore Pre/Post premezclado y Encore Activator RTU a ningún otro sellador de pezones o a otros productos. Si lo transfiere de este recipiente a otro, verifique que el otro esté minuciosamente limpio y que tenga la etiqueta de Encore Barrier Encore y Pre/Post y Encore Activator RTU.

El uso de un programa completo para el cuidado de ubres incluyendo el pre y postsellado puede reducir la diseminación de organismos que causan la mastitis.

Pre-Ordeña: Antes de ordeñar, prepare los pezones con el pre-sellado adecuado o con un lavado de ubres. Antes de colocar la unidad ordeñadora, saque completamente los pezones utilizando una toalla desechable.

Post-Ordeña: Inmediatamente después de la ordeña, use Encore Barrier y Encore Activator RTU sin diluir. Aplique el producto sumergiendo las 2/3 partes de los pezones en el sellador de pezones Encore Barrier-Encore Pre/Post-Encore Activator RTU. Deje secar al aire. No lo limpie. Siempre use el sellador de pezones Encore Barrier-Encore Pre/Post-Encore Activator RTU cuando está fresco y sin diluir. Si el producto en la copa de sellado se ve sucio, tírelo y vuelva a llenar con producto fresco. No vuelva a usar el producto residual ni lo devuelva al recipiente original. No saque las vacas a la intemperie helada hasta que el sellador de pezones Encore Barrier-Encore Pre/Post-Encore Activator RTU se haya secado completamente.

NOTA: En caso de irritación o agrietamiento, consulte con un médico veterinario para que examine o trate el caso.

Los ingredientes de la fórmula no contienen fosfatos.

ENCORE™

Activator

Unique Component for use only with Encore Barrier or Encore Pre/Post Base Products

Activator – For use exclusively with Encore Base Teat Dip Products

ACTIVE INGREDIENT:

Stabilized Sodium Salt of Chlorous Acid 0.54%

Componente exclusivo para usarse solamente con Encore Barrier, o Productos de Base Pre/Post

Activator – Para usarse exclusivamente con Productos Encore de Base para Sellar Pezones

INGREDIENTE ACTIVO:

Sal estabilizada del ácido cloroso 0.54%

Net Contents: **15 U.S. gal/56.78 L**

Contenido Neto: **15 U.S. gal/56.78 L**

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KEEP OUT OF REACH OF CHILDREN

CAUTION: Causes eye irritation. May cause skin irritation. Not for internal use. Protect eyes and mucous membranes from contact with this product. Wear splash goggles when handling product concentrate. For external use on dairy cows.

FIRST AID

If in Eyes: Immediately flush eyes with plenty of cool running water. Remove contact lenses, continue flushing eyes for at least 15 minutes, while holding eyelids apart.

If Swallowed: DO NOT induce vomiting. Rinse mouth, and then immediately drink 1 or 2 large glasses of water. Never give anything by mouth to an unconscious person.

IF IRRITATION OR DISCOMFORT PERSISTS, CALL A PHYSICIAN.

Read Material Safety Data Sheet (MSDS) before using this product.

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)

891222/5300/1001

DIRECTIONS FOR USE

NOTE: *Encore Activator* is formulated to be used as an activator for both *Encore Barrier* or *Encore Pre/Post*.

Mix Directions: Measure equal volumes of *Encore Barrier* or *Encore Pre/Post* & *Encore Activator RTU* (ready-to-use) into clean containers. Mix until color is uniform. Mix a significant quantity for pre-milking and then discard the remainder.

IMPORTANT: Do not add mixed *Encore Barrier* or *Encore Pre/Post* & *Encore Activator RTU* to any other teat dip or other product. If transferred from this container to any other, make sure the other container is thoroughly pre-cleaned and bears the proper container labeling for *Encore Barrier* or *Encore Pre/Post* & *Encore Activator RTU*.

Use of a complete udder health program including both pre- and post-dipping may aid reducing the spread of organisms which cause mastitis.

Pre-Milking: Prepare teats prior to milking with appropriate pre-dip or udder wash. Teats should then be dried thoroughly with a single-service towel before attaching the milking unit.

Post-Milking: Immediately after milking, use *Encore Barrier* & *Encore Activator RTU* at full strength. Apply product to teats 2/3 their length in *Encore Barrier, Encore Pre/Post-Encore Activator RTU* teat dip. Allow to air dry. Do not wipe. Always use fresh, full-strength *Encore Barrier-Encore Pre/Post-Encore Activator RTU* teat dip. If the product in the teat dip cup becomes visibly dirty, clean it and replenish with fresh product. Do not reuse or return unused product to the original container. Do not turn cows into freezing weather until *Encore Barrier-Encore Pre/Post-Encore Activator RTU* teat dip is completely dry.

NOTE: In case of irritation or chapping, have the condition examined and, if necessary, treated by a veterinarian.

Formula ingredients contain no Phosphorus.

Encore Activator Master 17.25 x 8.5: 891222/53 colors: pms 124 yellow, 200 red, 281 blue, 50% blue and black, 10% black Label type: affixed label. Contact Ecolab Purchasing for current paper type/adhesive information.

Material Safety Data Sheet

ENCORE ACTIVATOR

Section 1. Chemical product and company identification

Trade name : ENCORE ACTIVATOR
Product use : Teat dip
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 901654-02
Date of issue : **09-December-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	<1.0

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : CAUTION!

MAY CAUSE EYE IRRITATION.
Repeated or prolonged contact with irritants may cause dermatitis.
Avoid contact with eyes. Wash thoroughly after handling.

Potential acute health effects

Eyes : Moderately irritating to the eyes.
Skin : Slightly irritating to the skin.
Inhalation : Slightly 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 develops. 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. 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 : Good general ventilation should be sufficient to control airborne levels.

Personal protection

Eyes : Eye protection recommended.

Hands : No protective equipment is needed under normal use conditions.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : No protective equipment is needed under normal use conditions.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Colorless to light yellow.

Odor : Odorless.

pH : 11.75 (100%)

Boiling/condensation point : 100 °C

Specific gravity : 1.002 (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.

Section 11. Toxicological information

Potential acute health effects

Eyes : Moderately irritating to the eyes.

Skin : Slightly irritating to the skin.

Inhalation : Slightly irritating to the respiratory system.

Ingestion : No known significant effects or critical hazards.

Potential chronic health effects

Section 12. Ecological information

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.	-	-	-	-

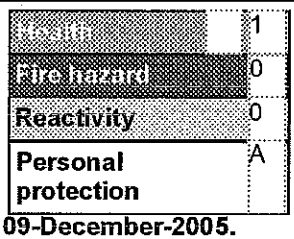
APPLIES ONLY DURING ROAD TRANSPORT
Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Irritating material
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 : **09-December-2005.**
Responsible name : **Regulatory Affairs**
Date of previous issue : **09-December-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.

41932
Patente pendiente

ABS Global, Inc., P.O. Box 459
DeForest, Wisconsin 53532
www.absglobal.com

MANTÉNGALO ALEJADO DEL ALCANCE DE LOS NIÑOS

PRECAUCIÓN: No es para uso interno. Protéjase los ojos y las membranas mucosas para evitar el contacto con este producto. Es para uso externo en vacas lecheras.

PRIMEROS AUXILIOS

Ojos: Enjuáguese inmediatamente los ojos con abundante agua fría de la llave. Quítese los lentes de contacto, si los usa. Siga enjuagándose los ojos durante 15 minutos como mínimo, manteniendo los párpados separados. OBTENGA ATENCIÓN MÉDICA INMEDIATAMENTE. **Si se traga:** Llame inmediatamente a un médico. NO induzca el vómito. Enjuáguese la boca e inmediatamente tome 1 ó 2 vasos grandes de agua. Jamás dé algo por la boca a una persona en estado inconsciente.

SI LA IRRITACIÓN O EL MALESTAR PERSISTE, LLAME A UN MÉDICO.

PARA INFORMACIÓN MÉDICA DE EMERGENCIA, LLAME AL 1-800-328-0026.

FUERA DE LOS ESTADOS UNIDOS, LLAME AL (651)-222-5352.

INSTRUCCIONES DE USO

Mezcla: Mida dos cantidades iguales de Encore Barrier y Encore Activator RTU (Listo para usarse) en unos recipientes limpios. Mezcle hasta que el color se vea uniforme. Mezcle una cantidad apropiada para una ordeña y luego, tire el resto.

IMPORTANTE: No agregue Encore Barrier premezclado y Encore Activator RTU a ningún otro sellador de pezones o a otros productos. Si lo transfiere de este recipiente a otro, verifique que el otro esté minuciosamente limpio y que tenga la etiqueta de Encore Barrier y Encore Activator RTU.

El uso de un programa completo para el cuidado de ubres incluyendo el pre y postsellado puede reducir la diseminación de organismos que causan la mastitis.

Pre-Ordeña: Antes de ordeñar, prepare los pezones con el pre-sellado adecuado o con un lavado de ubres. Antes de colocar la unidad ordeñadora, seque completamente los pezones utilizando una toalla desechable.

Post-Ordeña: Inmediatamente después de la ordeña, use Encore Barrier-Encore Activator RTU sin diluir. Aplique el producto sumergiendo las 2/3 partes de los pezones en el sellador de pezones Encore Barrier-Encore Activator RTU. Deje secar al aire. No lo limpie. Siempre use el sellador de pezones Encore Barrier-Encore Activator RTU cuando esté fresco y sin diluir. Si el producto en la copa de sellado se ve sucio, tírelo y vuelva a llenar con producto fresco. No vuelva a usar el producto residual ni lo devuelva al recipiente original. No saque las vacas a la intemperie helada hasta que el sellador de pezones Encore Barrier-Encore Activator RTU se haya secado completamente.

NOTA: En caso de irritación o agrietamiento, consulte con un médico veterinario para que examine o trate el caso.

Las instrucciones de la fórmula no contienen Rotavec.

ENCORE™ Barrier

Unique Barrier Teat Dip

Base – For use exclusively with Encore Activator

An aid in reducing the spread of organisms which may cause mastitis.

ACTIVE INGREDIENTS:

Lactic Acid 2.64%

INERT INGREDIENTS 97.36%

Base exclusiva para sellar pezones

Base – Para usarse exclusivamente con Encore Activator

Una ayuda para reducir la diseminación de organismos que pueden causar mastitis.

INGREDIENTES ACTIVOS:

Ácido láctico 2,64%

INGREDIENTS INERTES 97,36%

Net Contents:
55 U.S. gal/208.2 L

Contenido Neto:
55 U.S. gal/208,2 L

Service Science Success

41932
Patent Pending

ABS Global, Inc., P.O. Box 459
DeForest, Wisconsin 53532
www.absglobal.com

KEEP OUT OF REACH OF CHILDREN

CAUTION: Not for internal use. Protect eyes and mucous membranes from contact with this product. For external use on dairy cows.

FIRST AID

If in Eyes: Immediately flush eyes with plenty of cool, running water. Remove contact lenses; continue flushing eyes for at least 15 minutes, while holding eyelids apart. GET MEDICAL ATTENTION IMMEDIATELY.

If Swallowed: Call a physician immediately. DO NOT induce vomiting. Rinse mouth, and then immediately drink 1 or 2 large glasses of water. Never give anything by mouth to an unconscious person.

IF IRRITATION OR DISCOMFORT PERSISTS, CALL A PHYSICIAN.

FOR EMERGENCY MEDICAL INFORMATION, CALL 1-800-328-0026.

OUTSIDE NORTH AMERICA, CALL 1-651-222-5352.

DIRECTIONS FOR USE:

Mix Directions: Measure equal volumes of *Encore Barrier* and *Encore Activator RTU* (ready-to-use) into clean containers. Mix until color is uniform. Mix a significant quantity for one milking and then discard the remainder.

IMPORTANT: Do not add mixed *Encore Barrier and Encore Activator RTU* to any other teat dip or other product. If transferred from this container to any other, make sure the other container is thoroughly pre-cleaned and bears the proper container labeling for *Encore Barrier and Encore Activator RTU*.

Use of a complete udder health program including both pre- and post-dipping may aid reducing the spread of organisms which cause mastitis.

Pre-Milking: Prepare teats prior to milking with appropriate pre-dip or udder wash. Teats should then be dried thoroughly with a single-service towel before attaching the milking unit.

Post-Milking: Immediately after milking, use *Encore Barrier-Encore Activator RTU* at full strength. Apply product to teats 2/3 their length in *Encore Barrier-Encore Activator RTU* teat dip. Allow to air-dry. Do not wipe. Always use fresh, full-strength *Encore Barrier-Encore Activator RTU* teat dip. If the product in the teat dip cup becomes visibly dirty, discard and replenish with fresh product. Do not reuse or return unused product to the original container. Do not turn cows into freezing weather until *Encore Barrier-Encore Activator RTU* teat dip is completely dry.

NOTE: In case of irritation or chapping, have the condition examined and, if necessary, treated by a veterinarian.

Formula ingredients contain no Prostaglandins.

Encore Barrier Master 17.25 x 8.5: 891219/53 size: 17 1/4 x 8 1/2 colors: pms 124 yellow, 200 red, 281 blue and black, 10% black label type: affixed side/pressure sensitive vinyl

Material Safety Data Sheet

ENCORE BARRIER

Section 1. Chemical product and company identification

Trade name : ENCORE BARRIER
Product use : Teat dip
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 901653-02
Date of issue : **08-December-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
propylene glycol	57-55-6	1 - 5
lactic acid	50-21-5	1 - 5

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : CAUTION!

MAY CAUSE EYE IRRITATION.
Repeated or prolonged contact with irritants may cause dermatitis.
Avoid contact with eyes. Wash thoroughly after handling.

Potential acute health effects

Eyes : Moderately irritating to the eyes.
Skin : Slightly irritating to the skin.
Inhalation : Slightly 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 develops. 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. 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 0 and 50°C

Section 8. Exposure Controls, Personal Protection

Engineering controls : Good general ventilation should be sufficient to control airborne levels.

Personal protection

Eyes : Eye protection recommended.

Hands : No protective equipment is needed under normal use conditions.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : No protective equipment is needed under normal use conditions.

Name	Exposure limits
propylene glycol	**AIHA WEEL (United States, 1/2004). Notes: 2004 Revised Document** TWA: 10 mg/m³ 8 hour(s). Form: All forms

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Yellowish.

Odor : Odorless.

pH : 2.9 (100%)

Boiling/condensation point : 100 °C

Specific gravity : 1.02 (Water = 1)

Viscosity : Dynamic: 725 cP

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 : Slightly reactive to reactive with alkalis.

Section 11. Toxicological information

Potential acute health effects

Eyes : Moderately irritating to the eyes.

Skin : Slightly irritating to the skin.

Inhalation : Slightly 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.

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.	-	-	-	-

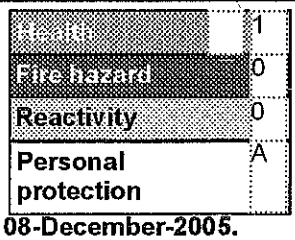
APPLIES ONLY DURING ROAD TRANSPORT
Any variation of the shipping description based on the packaging is not addressed.

Section 15. Regulatory information

HCS Classification : Irritating material
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 : **08-December-2005.**
Responsible name : **Regulatory Affairs**
Date of previous issue : **21-April-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.

41922
Patente pendiente

ABS Global, Inc., P.O. Box 459
DeForest, Wisconsin 53532
www.absglobal.com

INSTRUCCIONES DE USO

Mezcla: Mida dos cantidades iguales de Encore Pre/Post y Encore Activator RTU (Listo para usarse) en unos recipientes limpios. Mezcle hasta que el color se vea uniforme. Mezcle una cantidad apropiada para una ordeña y luego, tire el resto.

IMPORTANTE: No agregue Encore Pre/Post premezclado y Encore Activator RTU a ningun otro sellador de pezones o a otros productos. Si lo transfiere de este recipiente a otro, verifique que el otro esté minuciosamente limpio y que tenga la etiqueta de Encore Pre/Post y Encore Activator RTU.

El uso de un programa completo para el cuidado de ubres incluyendo el pre y postsellado puede reducir la diseminacion de organismos que causan la mastitis.

Pre-Ordeña: Antes de ordeñar, prepare los pezones con el pre-sellado adecuado o con un lavado de ubres. Antes de colocar la unidad ordeñadora, seque completamente los pezones utilizando una toalla desechable.

Post-Ordeña: Inmediatamente despues de la ordeña, use Encore Pre/Post-Encore Activator RTU sin diluir. Aplique el producto sumergiendo las 2/3 partes de los pezones en el sellador de pezones Encore Pre/Post-Encore Activator RTU. Deje secar al aire. No lo limpie. Siempre use el sellador de pezones Encore Pre/Post-Encore Activator RTU cuando está fresco y sin diluir. Si el producto en la copa de sellado se ve sucio, tírelo y vuelva a llenar con producto fresco. No vuelva a usar el producto residual ni lo devuelva al recipiente original. No saque las vacas a la intemperie helada hasta que el sellador de pezones Encore Pre/Post-Encore Activator RTU se haya secado completamente.

NOTA: En caso de irritacion o agrietamiento, consulte con un médico veterinario para que examine o trate el caso.

MANTÉNGALO ALEJADO DEL ALCANCE DE LOS NIÑOS

PRECAUCIÓN: No es para uso interno. Protéjase los ojos y las membranas mucosas para evitar el contacto con este producto. Es para uso externo en vacas lecheras.

PRIMEROS AUXILIOS

Ojos: Enjuáguese inmediatamente los ojos con abundante agua fría de la llave. Quítese los lentes de contacto, si los usa. Siga enjuagándose los ojos durante 15 minutos como mínimo, manteniendo los párpados separados. OBTENGA ATENCION MEDICA INMEDIATAMENTE.

Si se traga: Llame inmediatamente a un médico. NO induzca el vomito. Enjuáguese la boca e inmediatamente tome 1 o 2 vasos grandes de agua. Jamás dé algo por la boca a una persona en estado inconsciente.

SI LA IRRITACIÓN O EL MALESTAR PERSISTE, LLAME A UN MEDICO.

PARA INFORMACIÓN MÉDICA DE EMERGENCIA, LLAME AL 1-800-328-0026.

FUERA DE LOS ESTADOS UNIDOS, LLAME AL (651)-222-5352.

Esta formula no contiene fosforo.

ENCORE™

Pre/Post

Sanitizing Pre/Post Teat Dip

Base – For use exclusively with Encore Activator

An aid in reducing the spread of organisms which may cause mastitis.

ACTIVE INGREDIENTS:

Lactic Acid 2.64%
INERT INGREDIENTS 97.36%

Base exclusiva para sellar pezones

Base – Para usarse exclusivamente con Encore Activator

Una ayuda para reducir la diseminación de organismos que pueden causar mastitis.

INGREDIENTES ACTIVOS:

Ácido láctico 2.64%
INGREDIENTS INERTES 97.36%

Net Contents:
55 U.S. gal/208.2 L

Contenido Neto:
55 U.S. gal/208,2 L

41922
Patent Pending

ABS Global, Inc., P.O. Box 459
DeForest, Wisconsin 53532
www.absglobal.com

DIRECTIONS FOR USE

Mix Directions: Measure equal volumes of *Encore Pre/Post* & *Encore Activator RTU* (ready-to-use) into clean containers. Mix until color is uniform. Mix a significant quantity for one milking and then discard the remainder.

IMPORTANT: Do not add mixed *Encore Pre/Post* & *Encore Activator RTU* to any other teat dip or other product. If transferred from this container to any other, make sure the other container is thoroughly pre-cleaned and bears the proper container labeling for *Encore Pre/Post* & *Encore Activator RTU*.

Use of a complete udder health program including both pre- and post-dipping may aid reducing the spread of organisms which cause mastitis.

Pre-Milking: Prepare teats prior to milking with appropriate pre-dip or udder wash. Teats should then be dried thoroughly with a single-service towel before attaching the milking unit.

Post-Milking: Immediately after milking, use *Encore Pre/Post* & *Encore Activator RTU* at full strength. Apply product to teats 2/3 their length in *Encore Pre/Post* & *Encore Activator RTU* teat dip. Allow to air dry. Do not wipe. Always use fresh, full-strength *Encore Pre/Post* & *Encore Activator RTU* teat dip. If the product in the teat dip cup becomes visibly dirty, discard and replenish with fresh product. Do not reuse or return unused product to the original container. Do not turn cows into freezing weather until *Encore Pre/Post* & *Encore Activator RTU* teat dip is completely dry.

NOTE: In case of irritation or chapping, have the condition examined and, if necessary, treated by a veterinarian.

KEEP OUT OF REACH OF CHILDREN

CAUTION: Not for internal use. Protect eyes and mucous membranes from contact with this product. For external use on dairy cows.

FIRST AID

If in Eyes: Immediately flush eyes with plenty of cool, running water. Remove contact lenses; continue flushing eyes for at least 15 minutes, while holding eyelids apart. GET MEDICAL ATTENTION IMMEDIATELY.

If Swallowed: Call a physician immediately. DO NOT induce vomiting. Rinse mouth, and then immediately drink 1 or 2 large glasses of water. Never give anything by mouth to an unconscious person.

IF IRRITATION OR DISCOMFORT PERSISTS, CALL A PHYSICIAN.

FOR EMERGENCY MEDICAL INFORMATION, CALL 1-800-328-0026.

OUTSIDE NORTH AMERICA, CALL 1-651-222-5352.

Formula ingredients contain no Phosphorus.

Encore Pre/Post Master 17 x 8.5: 891229/53 size: 8.5 x 4.25 colors: pms 124 yellow, 200 red, 281 blue and black, 10% black label type: affixed side/pressure sensitive vinyl

Material Safety Data Sheet

ENCORE PRE/POST

Section 1. Chemical product and company identification

Trade name : ENCORE PRE/POST
Product use : Teat dip
Supplier : Ecolab Inc. Food & Beverage Division
370 N. Wabasha Street
St. Paul, MN 55102
1-800-392-3392
Code : 901655-02
Date of issue : **06-December-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
lactic acid	50-21-5	1 - 5

Section 3. Hazards identification

Physical state : Liquid. (Liquid.)
Emergency overview : CAUTION!

MAY CAUSE EYE IRRITATION.
Repeated or prolonged contact with irritants may cause dermatitis.
Avoid contact with eyes. Wash thoroughly after handling.

Potential acute health effects

Eyes : Moderately irritating to the eyes.
Skin : Slightly irritating to the skin.
Inhalation : Slightly 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 develops. 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. 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 45°C

Section 8. Exposure Controls, Personal Protection

Engineering controls : Good general ventilation should be sufficient to control airborne levels.

Personal protection

Eyes : Eye protection recommended.

Hands : No protective equipment is needed under normal use conditions.

Skin : No protective equipment is needed under normal use conditions.

Respiratory : No protective equipment is needed under normal use conditions.

Consult local authorities for acceptable exposure limits.

Section 9. Physical and chemical properties

Physical state : Liquid. (Liquid.)

Color : Yellow.

Odor : Odorless.

pH : 2.95 (100%)

Boiling/condensation point : 100 °C

Specific gravity : 1.042 (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 : Slightly irritating to the skin.

Inhalation : Slightly 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.

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

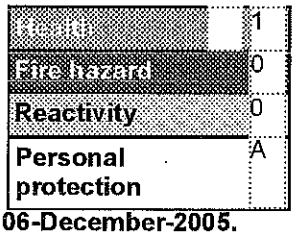
U.S. Federal regulations : SARA 302/304/311/312 extremely hazardous substances: None.
SARA 302/304 emergency planning and notification: None.

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 : **06-December-2005.**

Responsible name : **Regulatory Affairs**

Date of previous issue : **23-November-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.

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 oxychlorines 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 phosphoric 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 2.9 [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 carcass

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 residue = <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.

000142

Safety

To put the potential ingestion of such levels of oxychlorines into proper perespective, 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 3.

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 PAP. 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*†	

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* The exposure solution was the Alcide ID high-level disinfectant which contains, in addition to the active ingredients, EDTA (at 0.114%) and Poloxamer-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 Chlororganics, 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	

000117

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

Increased 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	4.28
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.

171.1(c)(6) MODIFICATION OF EXISTING REGULATION

NOT APPLICABLE

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:

VI.A. Oral RfD References:

CMA (Chemical Manufacturers Association). (1996) Sodium chlorite: drinking water rat two-generation reproductive toxicity study. Quintiles Report Ref. CMA/17/96.

Haag, HB. (1949) The effect on rats of chronic administration of sodium chlorite and chlorine dioxide in the drinking water. Report to the Mathieson Alkali Works from H.B. Haag of the Medical College of Virginia. February 7, 1949.

Harrington, RM; Romano, RR; Gates, D; et al. (1995) Subchronic toxicity of sodium chlorite in the rat. J Am Coll Toxicol 14: 21-33.

Kanitz, S; Franco, Y; Patrone, V; et al. (1996) Associations between drinking water disinfection and somatic parameters at birth. Environ. Health Perspect 104:516-520.

Lubbers, JR;Chauhan, S; Bianchine, JR. (1981) Controlled clinical evaluations of chlorine dioxide, chlorite and chlorate in man. Fundam Appl Toxicol 1:334-338.

Lubbers, JR; Chauhan, S; Bianchine, JR. (1982) Controlled clinical evaluations of chlorine dioxide, chlorite and chlorate in man. Environ Health Perspect 46:57-62.

Lubbers, JR; Chauhan, S; Miller, JK; et al. (1984a) The effects of chronic administration of chlorine dioxide, chlorite and chlorate to normal healthy adult male volunteers. J Environ Pathol Toxicol Oncol 5:229-238.

Lubbers, JR; Chauhan, S; Miller, JK; et al. (1984b) The effects of chronic administration of chlorite to glucose-6-phosphate dehydrogenase deficient healthy adult male volunteers. J Environ Pathol Toxicol Oncol 5:239-242.

Meier, JR; Bull, RJ; Stober, JA; et al. (1985) Evaluation of chemicals used for drinking water disinfection for protection of chromosomal damage and sperm-head abnormalities in mice. Environ Mutagen 7:201-211.

Michael, GE; Miday, RK; Bercz, JP; et al. (1981) Chlorine dioxide water disinfection: a prospective epidemiology study. Arch Environ Health 36:20-27.

Mobley, SA; Taylor, DH; Laurie, RD; et al. (1990) Chlorine dioxide depresses T3 uptake and delays development of locomotor activity in young rats. In: Water chlorination: chemistry, environmental impact and health effects, vol. 6. Jolley, RL, et al., eds. Chelsea, MI: Lewis Publ.; pp. 347-355.

Orme, J; Taylor, DH; Laurie, RD; et al. (1985) Effects of chlorine dioxide on thyroid function in neonatal rats. J Toxicol Environ Health 15:315-322.

Taylor, DH; Pfohl, RJ. (1985) Effects of chlorine dioxide on the neurobehavioral development of rats. In: Water chlorination: chemistry, environmental impact and health effects, vol. 6. Jolley, RL, et al., eds. Chelsea, MI: Lewis Publ.; pp. 356-364.

Toth, GP; Long, RE; Mills, TS; et al. (1990) Effects of chlorine dioxide on the developing rat brain. J Toxicol Environ Health 31:29-44.
Tuthill, RW; Giusti, RA; Moore, GS; et al. (1982) Health effects among newborns after prenatal exposure to ClO_2-disinfected drinking water. Environ Health Perspect 46:39-45.
U.S. Environmental Protection Agency. (U.S. EPA) (1994) Final draft for the Drinking Water Criteria Document on chlorine dioxide, chlorite, and chlorate. Washington, DC: Office of Science and Technology, Office of Water.
U.S. EPA. (2000) Toxicological review of chlorine dioxide and chlorite in support of summary information on Integrated Risk Information System (IRIS). National Center for Environmental Assessment, Washington, DC. Available online from: http://www.epa.gov/iris.

VI.B. Inhalation RfC References:

U.S. EPA. (1994) Methods of derivation of inhalation reference concentrations and application of inhalation dosimetry. Prepared by Environmental Criteria and Assessment Office, Office of Health and Environmental Assessment, Research Triangle Park, NC. EPA/600/8-90/066F.
U.S. EPA. (2000) Toxicological review of chlorine dioxide and chlorite in support of summary information on integrated risk information system (IRIS). National Center for Environmental Assessment, Washington, DC. Available on line from: http://www.epa.gov/iris.

VI.C. Carcinogenicity Assessment References:

Hayashi, M; Kishi, K; Sofuni, T; et al. (1988) Micronucleus test in mice on 39 food additives and eight miscellaneous chemicals. Food Chem Toxicol 26:487-500.
Ishidate, M; Sofuni, T; Yoshikawa, K; et al. (1984) Primary mutagenicity screening of food additives currently used in Japan. Food Chem Toxicol 22:623-636.
Kurokawa, Y; Takayama, S; Konishi, Y; et al. (1986) Long-term in vivo carcinogenicity tests of potassium bromate, sodium hypochlorite, and sodium chlorite conducted in Japan. Environ Health Perspect 69:221-235.
Meier, JR; Bull, RJ; Stober, JA; et al. (1985) Evaluation of chemicals used for drinking water disinfection for production of chromosomal damage and sperm-head abnormalities in mice. Environ Mutagen 7:201-211.
U.S. EPA. (1986) Guidelines for carcinogen risk assessment. Federal Register 51(185):33992-34003.
U.S. EPA. (1996) Proposed guidelines for carcinogen risk assessment. Federal Register 61(79): 17959-18011.
U.S. EPA. (2000) Toxicological review of chlorine dioxide and chlorite in support of summary information on integrated Risk Information System (IRIS). National Center for Environmental Assessment, Washington, DC. Available on line from: http://www.epa.gov/iris.

Yokose, Y; Uchida, K; Nakae, D; et al. (1987) Studies of carcinogenicity of sodium chlorite in B6C3F1 mice. Environ Health Perspect 76:205-210.

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

Form No.: 6-4-0

000029

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 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

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™, 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

References

Adams MR, Hartley AD, Cox LJ. 1989. Factors affecting the efficacy of washing procedures used in the production of prepared salads. Food Microbiol 6:69-77.

[Anonymous]. 1991a. Code of good irradiation practice for insect disinfestation of fresh fruits (as a quarantine treatment) [ICGFI Document No. 7]. International Consultative Group on Food Irradiation.

<http://www.iaea.or.at/programmes/rifa/icgfi/documents/publications.htm>. Accessed 2001 Sept 6.

[Anonymous]. 1991b. Irradiation as a quarantine treatment of fresh fruits and vegetables: report of a task force [ICGFI Document 13]. International Consultative Group on Food Irradiation. <http://www.iaea.or.at/programmes/rifa/icgfi/documents/publications.htm>. Accessed 2001 Sept 6.

[Anonymous]. 1993. F1355 - Guideline for the irradiation of fresh fruits for insect disinfestation as a quarantine treatment. [unknown]: Annual Year Book of the American Society for Testing and Materials (ASTM) Standards. Vol. 15.07.

[Anonymous]. 2000. DBMD traces Salmonella outbreak to mangoes. CDC/NCID Focus 9(4):1-2. <http://www.cdc.gov/ncidod/focus/index.htm> Accessed 2001 Sept 6.

Austin JW, Dodds KL, Blanchfield B, Farber JM. 1998. Growth and toxin production by *Clostridium botulinum* on inoculated fresh-cut packaged vegetables. J Food Prot 61(3):324-8.

Ayhan Z, Chism GW, Richter ER. 1998. The shelf life of minimally processed fresh cut melons. J Food Qual 21:29-40.

Barkai-Golan R. 1992. Suppression of postharvest pathogens of fresh fruits and vegetables by ionizing radiation. In: Rosenthal, editor. Electromagnetic Radiations in Food Science, I. Berlin: Springer-Verlag. p 155-94.

Barth MM, Zhou C, Mercier M, Payne FA. 1995. Ozone storage effects on anthocyanin content and fungal growth in blackberries. J Food Sci 60:1286-7.

Bartlett PG, Schmidt W. 1957. Surface-iodine complexes as germicides. Appl Microbiol 5:355-9.

Bartz JA, Showalter RK. 1981. Infiltration of tomatoes by aqueous bacterial suspensions. Phytopathology 71(5):515-8.

Bartz JA. 1982. Infiltration of tomatoes immersed at different temperatures to different depths in suspensions of *Erwinia carotovora* subsp. *carotovora*. Plant Disease 66(4):302-6.

Bartz JA. 1988. Potential for postharvest disease in tomato fruit infiltrated with chlorinated water. Plant Dis 72(1):9-13.

Bartz JA. 1991. Relation between resistance of tomato fruit to infiltration by *Erwinia carotovora* subsp. *carotovora* and bacterial soft rot. Plant Dis 75(2):152-5.

Bazarova VI. 1982. Use of ozone in storage of apples. Food Sci Technol Abstr 14(11):J1653.

Behrsing J, Winkler S, Franz P, Premier R. 2000. Efficacy of chlorine for inactivation of *Escherichia coli* on vegetables. Postharv Biol Technol 19:187-92.

Benarde MA, Snow WB, Olivieri OP, Davidson B. 1967. Kinetics and mechanism of bacterial disinfection by chlorine dioxide. Appl Microbiol 15:257-65.

Bennik MHJ, Van Overbeek W, Smid EJ, Gorris LGM. 1999. Biopreservation in modified atmosphere stored mungbean sprouts: the use of vegetable-associated bacteriocinogenic lactic acid bacteria to control the growth of *Listeria monocytogenes*. Lett Appl Microbiol 28:226-32.

Berrang ME, Brackett RE, Beuchat LR. 1989a. Growth of *Listeria monocytogenes* on fresh vegetables stored under controlled atmosphere. J Food Prot 52(10):702-5.

Berrang ME, Brackett RE, Beuchat LR. 1989b. Growth of *Aeromonas hydrophila* on fresh vegetables stored under a controlled atmosphere. Appl Environ Microbiol 55(9):2167-71.

Beuchat LR, Ryu J-H. 1997 Oct-Dec. Produce handling and processing practices: special issue. Emerg Infect Dis 3(4):459-65.

Beuchat LR. 1998. Surface decontamination of fruits and vegetables eaten raw: a review. World Health Organization, Food Safety Unit WHO/FSF/FOS/98.2. <www.who.int/fsf/fos982~1.pdf>. Accessed 2001 July 25.

Beuchat LR, Nail BV, Adler BB, Clavero MRS. 1998. Efficacy of spray application of chlorinated water in killing pathogenic bacteria on raw apples, tomatoes, and lettuce. J Food Prot 61(10):1305-11.

Beuchat LR. 1999. Survival of Enterohemorrhagic *Escherichia coli* O157:H7 in bovine feces applied to lettuce and the effectiveness of chlorinated water as a disinfectant. J Food Prot 62(8):845-9.

Beuchat LR. 2000. Use of sanitizers in raw fruit and vegetable processing. In: Alzamora SM, Tapia MS, Lopez-Malo A, editors. Minimally Processed Fruits and Vegetables: Fundamental Aspects and Applications. Gaithersburg [MD]: Aspen.

Bianchi A, Ricke SC, Cartwright AL, Gardner FA. 1994. A peroxidase catalyzed chemical dip for the reduction of *Salmonella* on chicken breast skin. J Food Prot 57:301-4.

Bowles BL, Sackitey SK, Williams AC. 1995. Inhibitory effects of flavor compounds on *Staphylococcus aureus* WRRC B124. J Food Safety 15:337-47.

Bowles BL, Juneja VK. 1998. Inhibition of food-borne bacterial pathogens by naturally occurring food additives. J Food Safety 18:101-12.

Brackett RE. 1987. Antimicrobial effect of chlorine on *Listeria monocytogenes*. J Food Prot 50(12):999-1003.

Brackett RE. 1992. Shelf stability and safety of fresh produce as influenced by sanitation and disinfection. J Food Prot 55(10):804-14.

Breidt R, Hayes JS, Fleming HP. 2000. Reduction of microflora on whole pickling cucumbers by blanching. J Food Sci 65:1354-8.

Brodrick HT, van der Linde HJ. 1981. Technological feasibility studies on combination treatments for subtropical fruits. Combination Processes in Food Irradiation, Proceedings Series. Vienna: International Atomic Energy Agency. p 141-52.

Brown GE, Schubert TS. 1987. Use of *Xanthamonas campestris pv. vesicatoria* to evaluate surface disinfectants for canker quarantine treatment of citrus fruit. Plant Dis 4:319-23.

Buchanan RL, Edelson SG, Snipes K, Boyd G. 1998. Inactivation of *Escherichia coli* O157:H7 in apple juice by irradiation. Appl Environ Microbiol 64(11):4533-5.

Buchanan RL, Edelson SG, Boyd G. 1999. Effects of pH and acid resistance on the radiation resistance of enterohemorrhagic *Escherichia coli*. J Food Prot 62:219-28.

Buchanan RL, Edelson SG, Miller RL, Sapers GM. 1999. Contamination of intact apples after immersion in an aqueous environment containing *Escherichia coli* O157:H7. J Food Prot 62(5):444-50.

Burnett SL, Chen J, Beuchat LR. 2000. Attachment of *Escherichia coli* 0157:H7 to the surfaces and internal structures of apples as detected by confocal scanning laser microscopy. Appl Environ Microbiol 66(11):4679-87.

Buta JG, Moline HE. 1998. Methyl jasmonate extends shelf life and reduces microbial contamination of fresh-cut celery and peppers. J Agric Food Chem 46:1253-6.

Calvente V, Benuzzi D, deTosetti MIS. 1999. Antagonistic action of siderophores from *Rhodotorula glutinis* upon the postharvest pathogen *Penicillium expansum*. Int Biodeter Biodeg 43:167-72.

Carlin F, Nguyen C, Morris CE. 1996. Influence of background microflora on *Listeria monocytogenes* on minimally processed fresh broad-leaved endive (*Cichorium endivia* var. *latifolia*). J Food Prot 59:698-703.

[CAST] Council for Agricultural Science and Technology. 1986. Ionizing energy in food processing and pest control: I. Wholesomeness of food treated with ionizing energy. Ames (IA): CAST. Report nr 109. 50 p.

[CAST] Council for Agricultural Science and Technology. 1989. Ionizing energy in food processing and pest control: II. Applications. Ames (IA): CAST. Report nr 115. 98 p.

Castillo A, Escartin EF. 1994. Survival of *Campylobacter jejuni* on sliced watermelon and papaya [a research note]. J Food Prot 57(2):166-8.

Cerrutti P, Alzamora SM, Vidales SL. 1997. Vanillin as an antimicrobial for producing shelf stable strawberry puree. J Food Sci 62:608-10.

[CFR] Code of Federal Regulations. 2000a. Title 21, Part 101.95. Food Labelling: "Fresh," "freshly frozen," "fresh frozen," "frozen fresh." Available from: <http://www.access.gpo.gov/nara/cfr/index.html>. Accessed 2001 Sept 6.

[CFR] Code of Federal Regulations. 2000b. Title 21, Part 110.3(o). Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food: Definitions. Available from: <http://www.access.gpo.gov/nara/cfr/index.html>. Accessed 2001 Sept 6.

[CFR] Code of Federal Regulations. 2000c. Title 21, Part 173.300. Secondary Direct Food Additives Permitted in Food for Human Consumption: Chlorine dioxide. Available from: <http://www.access.gpo.gov/nara/cfr/index.html>. Accessed 2001 Sept 6.

[CFR] Code of Federal Regulations. 2000d. Title 21, Part 173.325. Secondary Direct Food Additives Permitted in Food for Human Consumption: Acidified sodium chlorite solutions. Available from: <http://www.access.gpo.gov/nara/cfr/index.html>. Accessed 2001 Sept 6.

Chantaysakorn P, Richter RL. 2000. Antimicrobial properties of Pepsin-digested Lactoferrin added to carrot juice and filtrates of carrot juice. J Food Prot 63(3):376-80.

Cherry JP. 1999. Improving the safety of fresh produce with antimicrobials. Food Technol 53(11):54-7.

Chervin C, Boisseau P. 1994. Quality maintenance of "ready-to-eat" shredded carrots by gamma-irradiation. J Food Sci 59:359-61.

Clarke ID. 1959. Possible applications of ionizing radiations in the fruit, vegetable and related industries. Int J Appl Radiat Isot 6:175.

Conway WS, Leverentz B, Saftner RA. 2000. Survival and growth of *Listeria monocytogenes* on fresh-cut apple slices and its interaction with *Glomerella cingulata* and *Penicillium expansum*. Plant Dis 84:177-81.

Costilow RN, Uebersax MA, Ward PJ. 1984. Use of chlorine dioxide for controlling microorganisms during handling and storage of fresh cucumbers. J Food Sci 49:396-401.

Cousins CM, Allan CD. 1967. Sporicidal properties of some halogens. J Appl Bacteriol 30:168-74.

Delaquis PJ, Mazza G. 1995. Antimicrobial properties of isothiocyanates in food preservation. Food Technol 49(11):73-84.

Diehl JF. 1995. Safety of irradiated foods. 2nd revised ed. New York: Marcel Dekker, Inc.

Drake SR, Sanderson PG, Neven LG. 1999. Response of apple and winter pear fruit quality to irradiation as a quarantine treatment. J Food Proc Preserv 23:203-16.

Dwankanath CT, Rayner ET, Mann GE, Dollar FG. 1968. Reduction of aflatoxin levels in cottonseed and peanut meals by ozonation. J Am Oil Chem Soc 45:93-5.

El-Ghaouth A, Smilanick JL, Brown GE, Ippolito A, Wisniewski M, Wilson CL. 2000. Application of *Candida saitoana* and glycochitosan for the control of postharvest diseases of apple and citrus fruit under semi-commercial conditions. Plant Dis 84:243-8.

El-Samahy SK, Youssef BM, Askar AA, Swailam HMM. 2000. Microbiological and chemical properties of irradiated mango. J Food Safety 20:139-56.

Escudero ME, Velazquez L, Di Genaro MS, De Guzman AS. 1999. Effectiveness of various disinfectants in the elimination of *Yersinia enterocolitica* on fresh lettuce. J Food Prot 62:665-9.

Farber JM, Wang SL, Cai Y, Zhang S. 1998. Changes in populations of *Listeria monocytogenes* inoculated on packaged fresh-cut vegetables. J Food Prot 61(2):192-5.

Farkas J. 1989. Microbiological safety of irradiated foods. Int J Food Microbiol 9:1-15.

Farkas J. 1997. Physical methods of food preservation. In: Doyle MP, Beuchat LR, Monteville TJ, editors. Food microbiology: fundamentals and frontiers. Washington, DC: American Society for Microbiology. p 497-519.

Fatemi P, Frank JF. 1999. Inactivation of Listeria monocytogenes/Pseudomonas biofilms by peracid sanitizers. J Food Prot 62:761-5.

[FDA] Food and Drug Administration, Center for Food Safety and Applied Nutrition. 1998 Oct 26. Guide to minimize microbial food safety hazards for fresh fruits and vegetables [Guidance for Industry]. <http://www.foodsafety.gov/~dms/prodguid.html>. Accessed 2001 Aug 10.

[FDA] Food and Drug Administration, Center for Food Safety and Applied Nutrition. 2000. Kinetics of microbial inactivation for alternative food processing technologies. <http://vm.cfsan.fda.gov/~comm/ift-toc.html>. Accessed 2001 Aug 15.

Fernandez Escartin EF, Castillo Ayala A, Saldana Lozano J. 1989. Survival and growth of *Salmonella* and *Shigella* on sliced fresh fruit. J Food Prot 52(7):471-2.

Finch GR, Fairbairn N. 1991. Comparative inactivation of poliovirus type 3 and MS2 coliphage in demand-free phosphate buffer by using ozone. Appl Environ Microbiol 57(11):3121-6.

Foegeding PM, Busta FF. 1991. Chemical food preservatives. In: Block SE, editor. Disinfection, sterilization and preservation. 4th ed. Philadelphia (PA): Lea & Febiger.

Francis GA, Thomas C, O'Beirne D. 1999. The microbiological safety of minimally processed vegetables [review article]. Int J Food Sci Technol 34:1-22.

Frenzen PD, Majchrowicz A, Buzby JC, Imhoff B. 2000. Consumer acceptance of irradiated meat and poultry products. Ag Info Bull 757.

Fukao T, Sawada H, Ohta Y. 2000. Combined effect of hop resins and sodium hexametaphosphate against certain strains of *Escherichia coli*. J Food Prot 63:735-40.

Gammon R, Kerelak K. 1973. Gaseous sterilization of foods. Am Inst Chem Engr Symp Ser 69:91.

Garg N, Churey JJ, Splittstoesser DF. 1990. Effect of processing conditions on the microflora of fresh-cut vegetables. J Food Prot 53:701-3.

Gershenfeld L, Witlin B. 1949. Evaluation of the antibacterial efficiency of dilute solutions of free halogens. J Am Pharm Assoc, Sci Ed. 38:411-4.

Gray RJ, Hsu D. 1979. Effectiveness of iodophor in the destruction of *Vibrio parahaemolyticus*. J Food Sci 44:1097-100.

Gunes G, Splittstoesser DL, Lee CY. 1997. Microbial quality of fresh potatoes: effect of minimal processing. J Food Prot 60:863-6.

Hagenmaier RD, Baker RA. 1997. Low-dose irradiation of cut iceberg lettuce in modified atmosphere packaging. J Ag Food Chem 45:2864-8.

Hagenmaier RD, Baker RA. 1998a. An evaluation of gamma irradiation for preservation of citrus salads in flexible packaging. Proc Florida State Hort Soc 110:243-5.

Hagenmaier RD, Baker RA. 1998b. Microbial population of shredded carrot in modified atmosphere packaging as related to irradiation treatment. J Food Sci 63:162-4.

Hammerschmidt R. 1999. Induced disease resistance: how do induced plants stop pathogens? Physiol Mol Plant Pathol 55:77-84.

Han Y, Sherman DM, Linton RH, Nielsen SS, Nelson PE. 2000. The effects of washing and chlorine dioxide gas on survival and attachment of *Escherichia coli* O157:H7 to green pepper surfaces. Food Microbiol 17:521-33.

Haraguchi T, Slimidu U, Aiso K. 1969. Preserving effect of ozone on fish. Bull Jpn Soc Sci Fish 35 (915-20).

Hays H, Elliker PR, Sandine WE. 1967. Microbial destruction by low concentrations of hypochlorite

and iodophor germicides in alkaline and acidified water. Appl Microbiol 15:575-81.

Horvath M, Bilitzky L, Huttner J. 1985. Ozone. Amsterdam: Elsevier. 68-74, 304-31 p.

Howard LR, Gonzalez AR. 2001. Food safety and produce operations: What is the future? Hort Sci 36:33-9.

Isshiki K, Tokuoka K, Mori R, Chiba S. 1992. Preliminary examination of allyl isothiocyanate vapor for food preservation. Biosci Biotech Biochem 56:1476-7.

Janisiewicz WJ, Bors B. 1995. Development of a microbial community of bacterial and yeast antagonists to control wound-invading postharvest pathogens of fruit. Appl Environ Microbiol 61:3261-7.

Janisiewicz WJ, Conway WS, Leverentz B. 1999. Biological control of postharvest decays of apple can prevent growth of *Escherichia coli* O157:H7 in apple wounds. J Food Prot 62:1372-5.

Jaquette CB, Beuchat LR, Mahon BE. 1996. Efficacy of chlorine and heat treatment in killing *Salmonella stanley* inoculated onto alfalfa seeds and growth and survival of the pathogen during sprouting and storage. Appl Environ Microbiol 62(6):2212-5.

Jilbert WR. 1988. Quality control and sanitation aspects of fresh squeezed citrus juice processing. In: Matthews RF, editor. Food industry short course proceedings. Gainesville (FL): Florida IFT and University of Florida Extension Service.

Johnson GI, Boag TS, Cooke AW, Izard M, Panitz M, Sangchote S. 1990. Interaction of post harvest disease control treatments and gamma irradiation on mangoes. Ann Appl Biol 116:245-57.

Juven BJ, Pierson MD. 1996. Antibacterial effects of hydrogen peroxide and methods for its detection and quantitation. J Food Prot 59(11):1233-41.

Kaess G, Weidemann JF. 1968. Ozone treatment of chilled beef. J Food Technol 3:325-33.

Karapinar M, Gonul SA. 1992. Removal of *Yersinia enterocolitica* from fresh parsley by washing with acetic acid or vinegar. Int J Food Microbiol 16:261-4.

Kenney SJ, Burnett SL, Beuchat LR. 2001. Location of *Escherichia coli* 0157:H7 on and in apples as affected by bruising, washing, and rubbing. J Food Prot 64(9):1328-33.

Kim JG, Yousef AE, Chism GW. 1999a. Use of ozone to inactivate microorganisms on lettuce. J Food Safety 19:17-34.

Kim JG, Yousef AE, Dave S. 1999b. Application of ozone for enhancing the microbiological safety and quality of foods: a review. J Food Prot 62(9):1071-87.

Korich DG, Mead JR, Madore MS, Sinclair NA, Sterling CR. 1990. Effects of ozone, chlorine dioxide, chlorine, and monochloramine on *Cryptosporidium parvum* oocyst viability. Appl Environ Microbiol 56 (5):1423-8.

Korsten L, De Jager ES, De Villiers EE, Lourens A, Kotze JM, Wehner FC. 1995. Evaluation of bacterial epiphytes isolated from avocado leaf and fruit surfaces for biocontrol of avocado postharvest disease. Plant Dis 79:1149-56.

Kristofferson T. 1958. Mode of action of hypochlorite sanitizers with and without sodium bromide. J Dairy Sci 41:942-9.

Lacey RW. 1979. Antibacterial activity of providone iodine towards non-sporing bacteria. J Appl Bacteriol 46:443-9.

Langerak DI. 1978. The influence of irradiation and packaging on the quality of prepacked vegetables. Ann Nutr Aliment 32:569-86.

Lawrence CA, Carpenter CM, Naylor-Foote AWC. 1957. Iodophors as disinfectants. J Am Pharm Assoc 46:500-5.

Leibinger W, Breuker B, Hahn M, Mendgen K. 1997. Control of postharvest pathogens and colonization of the apple surface by antagonistic microorganisms in the field. Phytopathology 87(11):1103-10.

Leistner L, Gorris LGM. 1995. Food preservation by hurdle technology. Trends Food Sci Technol 6:41-6.

Leistner L. 2000. Basic aspects of food preservation by hurdle technology. Intl J Food Microbiol 55:181-6.

Leverentz B, Conway WS, Alavidze Z, Janisiewicz WJ, Fuchs Y, Camp MJ, Chighladze E, Sulakvelidze A. 2001. Examination of bacteriophage as a biocontrol method for *Salmonella* on fresh-cut fruit: a model study. J Food Prot 64(8):1116-21.

Li Y, Brackett RE, Chen J, Beuchat LR. 2001. Survival and growth of *Escherichia coli* 0157:H7 inoculated onto cut lettuce before or after heating in chlorinated water, followed by storage at 5 °C or 15 °C. J Food Prot 64(3):305-9.

Liao CH. 1989. Antagonism of *Pseudomonas putida* strain PP22 to phytopathogenic bacteria and its potential use as a biocontrol agent. Plant Dis 73:223-6.

Liao C-H, Sapers GM. 2000. Attachment and growth of *Salmonella* chester on apple fruit and in vivo response of attached bacteria to sanitizer treatments. J Food Prot 63(7):876-83.

Liew CL, Prange RK. 1994. Effect of ozone and storage temperature on postharvest diseases and physiology of carrots (*Caucus carota* L.). J Am Soc Hortic Sci 119:563-7.

Lis-Balchin M, Hart S, Deans SG, Eaglesham E. 1996. Comparison of the pharmacological and antimicrobial action of commercial plant essential oils. J Herbs Spices Medic Plants 4:69-86.

Lopez LV, Romero JR, Urbina J. 1988. Eficiencia de desinfectantes en vegetales y frutas. Alimentos 13:25-30.

Lu JY, Lukombo SM, Stevens C, Khan VA, Wilson CL, Pusey PL, Chaultz E. 1993. Low dose UV and gamma radiation on storage rot and physiochemical changes in peaches. J Food Qual 16:301-9.

Marcotte M. 1992. Irradiated strawberries enter the U.S. market. Food Technol 46(5):80-6.

Marriott NG. 1999. Principles of Food Sanitation. 4th ed. Gaithersburg (MD): Aspen. p 147-9.

Masson RB. 1990. Recherche de nouveax disinfectants pour les produits de 4eme gamme. In: Proc Congress Produits de 4eme Gamme et de 5eme Gamme; Brussels. C.E.R.I.A. p 101.

Maxie EC, Sommer NF, Mitchell FG. 1971. Infeasibility of irradiating fresh fruits and vegetables. Hort Sci 6:202-4.

Mazollier Jr. 1988. IVe gamme. Lavage-desinfection des salades. Infros-Ctifl 41:19.

Monk JD, Beuchat LR, Doyle MP. 1995. Irradiation inactivation of food-borne microorganisms. J Food Prot 58:197-208.

Mosley EB, Elliker PR, Hays H. 1976. Destruction of food spoilage indicator and pathogenic organisms by various germicides in solution and on a stainless steel surface. J Milk Food Technol 39:830-6.

Mossel DAA, Stegeman H. 1985. Irradiation: An effective mode of processing food for safety. In: Food Irradiation Processing. Proc Int Symp on Food Irrad Processing; 1985 March 4-8; Washington. International Atomic agency for Food and Agriculture Organization of the United Nations. p 251-79.

Moy JH. 1983. Radurization and radication: fruits and vegetables. In: Josephson ES, Peterson MS, editors. Preservation of food by ionizing radiation. Boca Raton (FL): CRC Pr. p 83-108.

Murdock DI, Brokaw CH. 1958. Sanitary control in processing citrus concentrates: some specific sources of microbial contamination from fruit bins to extractors. Food Technol 12:573-6.

[NACMCF] National Advisory Committee on Microbiological Criteria for Foods. 1999. Microbiological safety evaluations and recommendations on fresh produce. Food Control 10:117-43.

Nguyen-the C, Carlin F. 1994. The microbiology of minimally processed fresh fruits and vegetables. Crit Rev Food Sci Nutr 34(4):371-401.

Odlaug TE. 1981. Antimicrobial activity of halogens. J Food Prot 44(8):608-13.

Ortenzio LF, Stuart LS. 1964. A standard test for efficacy of germicides and acceptability of residual disinfecting activity in swimming pool water. J Assoc Off Agric Chem 47:540-7.

Pao S, Davis CL. 1999. Enhancing microbiological safety of fresh orange juice by fruit immersion in hot water and chemical sanitizers. J Food Prot 62(7):756-60.

Pao S, Davis CL, Kelsey DF, Petracek PD. 1999. Sanitizing effects of fruit waxes at high pH and temperature on orange surfaces inoculated with *Escherichia coli*. J Food Sci 64(2):359-62.

Pao S, Davis CL, Kelsey DF. 2000. Efficacy of alkaline washing for the decontamination of orange fruit surfaces inoculated with *Escherichia coli*. J Food Prot 63(7):961-4.

Pao S, Davis CL, Parish ME. 2001. Microscopic observation and processing validation of fruit sanitizing treatments for the enhanced microbiological safety of fresh orange juice. J Food Prot 64:310-4.

Parish ME, Davidson PM. 1993. Methods for evaluation. In: Davidson PM, Branen AL, editors. Antimicrobials in Foods. New York: Marcel Dekker.

Parish ME, Narciso JA, Friedrich LM. 1997. Survival of *Salmonellae* in orange juice. J Food Safety 17:273-81.

Park CM, Beuchat LR. 1999. Evaluation of sanitizers for killing *Escherichia coli* O157:H7, *Salmonella*

and naturally occurring microorganisms on cantaloupes, honeydew melons, and asparagus. Dairy Food Environ Sanit 19:842-7.

Peeters JE, Ares Mazas E, Masschelein WJ, Villacorta Martinez de Maturana I, Debacker E. 1989. Effect of disinfection of drinking water with ozone or chlorine dioxide on survival of *Cryposporidium parvum* oocysts. Appl Environ Microbiol 55(6):1519-22.

Peters DL. 1995. Control of enteric pathogenic bacteria on fresh produce [Master of Science]. Lincoln: Univ of Nebraska Graduate College.

Piagentini AM, Pirovani ME, Guemes DR, Di Pentima JH, Tessi MA. 1997. Survival and growth of *Salmonella hadar* on minimally processed cabbage as influenced by storage abuse conditions. J Food Sci 62:616-8.

Priepke PE, Wei LS, Nelson AI. 1976. Refrigerated storage of prepackaged salad vegetables. J Food Sci 41:379-82.

Rajkowski KT, Thayer DW. 2000. Reduction of *Salmonella* spp. and strains of *Escherichia coli* O157:H7 by gamma radiation of inoculated sprouts. J Food Prot 63(7):871-5.

Reina LD, Fleming HP, Humphries EG. 1995. Microbiological control of cucumber hydrocooling water with chlorine dioxide. J Food Prot 58(5):541-6.

Restaino L, Frampton EW, Hemphill JB, Palnikar P. 1995. Efficacy of ozonated water against against various food-related microorganisms. Appl Environ Microbiol 61(9):3471-5.

Roberts RG, Reymond ST. 1994. Chlorine dioxide for reduction of postharvest pathogen inoculum during handling of tree fruits. Appl Environ Microbiol 60(8):2864-8.

Sapers GM, Simmons GF. 1998. Hydrogen peroxide disinfection of minimally processed fruits and vegetables. Food Technol 52(2):48-52.

Sapers GM, Miller RL, Mattrazzo AM. 1999. Effectiveness of sanitizing agents in inactivating *Escherichia coli* in golden delicious apples. J Food Sci 64(4):734-7.

Sarig P, Zahavi T, Zutkhi Y, Yannai S, Lisker N, Ben-Arie R. 1996. Ozone for control of postharvest decay of table grapes caused by *Rhizopus stolonifer*. Physiol Mol Plant Pathol 48:403-15.

Senter SD, Cox NA, Bailey JS, Forbus Jr. WR. 1985. Microbiological changes in fresh market tomatoes during packing operations [a research note]. J Food Sci 50:254-5.

Seymour IJ. 1999. Review of current industry practice on fruit and vegetable decontamination [review no. 14]. Gloucestershire (UK): Campden & Chorleywood Food Research Association. 1-38 p.

Shapiro JE, Holder IA. 1960. Effect of antibiotic and chemical dips on the microflora of packaged salad mix. Appl Microbiol 8:341.

Sheldon BW, Brown AL. 1986. Efficacy of ozone as a disinfectant for poultry carcasses and chill water. J Food Sci 51(2):305-9.

Shere L, Kelley MJ, Richardson JH. 1962. Effect of bromide hypochlorite bactericides on microorganisms. Appl Microbiol 10:538-41.

Showalter RK. 1979. Postharvest water intake by tomatoes. Hort Sci 14(2):125.

Smilanick JL, Denis-Arrue R. 1992. Control of green mold of lemons with *Pseudomonas* species. Plant Dis 76:481-5.

Somers EB, Schoeni JL, Wong ACL. 1994. Effect of trisodium phosphate on biofilm and planktonic cells of *Campylobacter jejuni*, *Escherichia coli* O157:H7, *Listeria monocytogenes* and *Salmonella typhimurium*. Int J Food Microbiol 22:269-76.

Sommer NF, Maxie EG. 1966. Recent research on the irradiation of fruits and vegetables. Food Irradiation. Vienna: International Atomic Energy Agency. p 571.

Staden OL. 1973. A review of the potential of fruit and vegetable irradiation. Sci Hortic 1:291-308.

Stanley D. 1994. Yeasts and bacteria battle decay. Agric Res 42(5):8-9.

Takeuchi K, Frank JF. 2000. Penetration of *Escherichia coli* O157:H7 into lettuce tissues as affected by inoculum size and temperature and the effect of chlorine treatment on cell viability. J Food Prot 63 (4):434-40.

Taormina PJ, Beuchat LR. 1999a. Behavior of enterohemorrhagic *Escherichia coli* O157:H7 on alfalfa sprouts during the sprouting process as influenced by treatments with various chemicals. J Food Prot 62 (8):850-6.

Taormina PJ, Beuchat LR. 1999b. Comparison of chemical treatments to eliminate enterohemorrhagic *Escherichia coli* O157:H7 on alfalfa seeds. J Food Prot 62(4):318-24.

Teo AY-L, Ravishankar S, Sizer CE. 2001. Effect of low-temperature, high-pressure treatment on the survival of *Escherichia coli* 0157:H7 and *Salmonella* in unpasteurized fruit juices. J Food Prot 64 (8):1122-7.

Thayer DW, Josephson ES, Brynjolfsson A, Giddings GG. 1996. Radiation pasteurization of food. Council for Agricultural Science and Technology Issue Paper Nr. 7(Apr):1-12.

Thayer DW, Rajkowski KT. 1999. Developments in irradiation of fresh fruits and vegetables. Food Technol 53(11):62-5.

Thomas P. 1986. Radiation preservation of foods of plant origin. V. Temperate fruits: pome fruits, stone fruits, and berries. Crit Rev Fd Sci Technol 24:357-400.

Tokuoka K, Isshiki K. 1994. Possibility of application of Allylisothiocyanate vapor for food preservation. Nippon Shokuhin Kogyo Gakkaishi 41(9):595-9.

Torriani S, Orsi C, Vescovo M. 1997. Potential of *Lactobacillus casei*, culture permeate, and lactic acid to control microorganisms in ready-to-use vegetables. J Food Prot 60:1564-7.

Ulate-Rodriguez J, Schafer HW, Zottola EA, Davidson PM. 1997. Inhibition of *Listeria monocytogenes*, *Escherichia coli* 0157:H7, and *Micrococcus lutens* by linear furanocoumarins in a model food system. J Food Prot 60:1050-4.

Urbain WM. 1986. Fruits, vegetables, and nuts. In: Schweigert BS, editor. Food Irradiation. Orlando (FL): Academic Pr. p 170-216. (Food Science and Technology, A series of monographs).

Usall J, Teixido N, Fons E, Vinas I. 2000. Biological control of blue mould on apple by a strain of *Candida sake* under several controlled atmosphere conditions. Int J Food Microbiol 58:83-92.

Vescovo M, Torriani S, Orsi C, Macchiarolo F, Scolari G. 1996. Application of antimicrobial-producing lactic acid bacteria to control pathogens in ready-to-use vegetables. J Appl Bacteriol 81:113-9.

Walker HW, LaGrange WS. 1991. Sanitation in food manufacturing operations. In: Block SE, editor. Disinfection, sterilization, and preservation. 4th ed. Philadelphia (PA): Lea & Febiger.

Wan J, Wilcock A, Coventry MJ. 1998. The effect of essential oils of basil on the growth of *Aeromonas hydrophila* and *Pseudomonas fluorescens*. J Appl Microbiol 84:152-8.

Wei CI, Huang TS, Kim JM, Lin WF, Tamplin ML, Bartz JA. 1995. Growth and survival of *Salmonella montevideo* on tomatoes and disinfection with chlorinated water. J Food Prot 58(8):829-36.

Wells JM, Butterfield JE. 1997. *Salmonella* contamination associated with bacterial soft rot of fresh fruits and vegetables in the marketplace. Plant Dis 81(8):867-72.

Wilkinson VM, Gould GW. 1996. Food Irradiation: a reference guide. Oxford (UK): Butterworth - Heinemann.

Willison SR. 1963. Ionizing radiation for the control of plant pathogens: a review. Can Plant Dis (Survey) 43:39.

Winniczuk PP. 1994. Effects of sanitizing compounds on the microflora of orange fruit surfaces and orange juice [M.S.]. Gainesville (FL): Univ of Florida Graduate School.

Wright JR, Sumner SS, Hackney CR, Pierson MD, Zoecklein BW. 2000. Reduction of *Escherichia coli* O157:H7 on apples using wash and chemical sanitizer treatments. Dairy Food Environ Sanit:120-6.

Wu FM, Doyle MP, Beuchat LR, Wells JG, Mintz ED, Swaminathan B. 2000. Fate of *Shigella sonnei* on parsley and methods of disinfection. J Food Prot 63(5):568-72.

Xu L. 1999. Use of ozone to improve the safety of fresh fruits and vegetables. Food Technol 53(10):58-61, 3.

Zegota H. 1988. Suitability of Dukat strawberries for studying effects on shelf life of irradiation combined with cold storage. Z Levensm Unters Forsch 187:111-4.

Zhang S, Farber JM. 1996. The effects of various disinfectants against *Listeria monocytogenes* on fresh-cut vegetables. Food Microbiol 13:311-21.

Zhao T, Doyle MP, Besser RE. 1993. Fate of enterohemorrhagic *Escherichia coli* O157:H7 in apple cider with and without preservatives. Appl Environ Microbiol 59(8):2526-30.

Zhao J, Cranston PM. 1995. Microbial decontamination of black pepper by ozone and the effect of the treatment on volatile oil constituents of the spice. J Sci Food Agric 68:11-8.

Zhuang R-Y, Beuchat LR, Angulo FJ. 1995. Fate of *Salmonella montevideo* on and in raw tomatoes as affected by temperature and treatment with chlorine. Appl Environ Microbiol 61(6):2127-31.

Zhuang R-Y, Beuchat LR. 1996. Effectiveness of trisodium phosphate for killing *Salmonella*

montevideo on tomatoes. Lett Appl Microbiol 22:97-100.

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