

Acidified Sodium Chlorite

Livestock

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Identification of Petitioned Substance

Chemical Name: Acidified Sodium Chlorite (ASC)	11	CAS Numbers: 13898-47-0 (Chlorous Acid) 7758-19-2 (Sodium Chlorite)
Other Names: Sodium Chlorite, Acidified Chlorous Acid		Other Codes: 231-836-6 (EINECS)
Trade Names: SANOVA®, 4XLA®, Aztec Gold®		

Summary of Petitioned Use

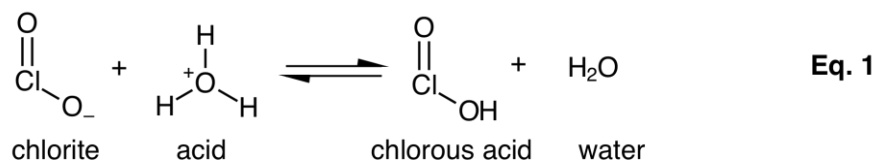
The National Organic Program (NOP) final rule currently allows the use of acidified sodium chlorite (ASC) solutions for antimicrobial food treatment when acidified with citric acid under 7 CFR § 205.605. The petition before the National Organic Standards Board (NOSB) is to add ASC solution as an allowed synthetic in organic livestock production (§ 205.603) for use as a disinfectant/sanitizer and topical treatment (i.e., teat dip).

ASC solutions used as disinfectants and teat dip treatments in livestock production are analogous to those used for secondary direct food processing and handling. However, the potential impacts to the environment and human health resulting from ASC treatments of livestock necessitate consideration of the aqueous chemistry of the parent substance and its breakdown products, and potential for toxic effects to terrestrial organisms and humans potentially exposed to these substances.

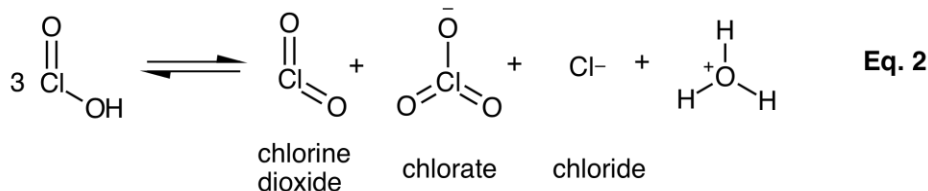
Characterization of Petitioned Substance

Composition of the Substance:

The petitioned substance, acidified sodium chlorite (ASC) solution, is generated through the reaction of any acid categorized as Generally Recognized as Safe (GRAS) by the FDA with an aqueous solution of technical grade (~80% purity) sodium chlorite (NaClO₂). Aqueous solutions of sodium chlorite are made with sodium chlorite crystals or flakes and water, and are commercially available at various concentrations. For example, SANOVA®, a commercial ASC solutions used in food processing, contains 20–50% sodium chlorite by weight of the solution. The chlorite anion (ClO₂⁻) is stable in aqueous solution; however, under acidic conditions – achieved through the addition of a food grade acid (H⁺) to an aqueous sodium chlorite solution – the chlorite anion forms chlorous acid (HClO₂) (Equation 1). Because chlorous acid is unstable, it readily disintegrates to chlorine dioxide (ClO₂), which further degrades to chlorate (ClO₃⁻) and chloride (Cl⁻) (Equation 2) (Shriver, 1994). Chlorinated compounds, such as chlorous acid (HClO₂), chlorite (ClO₂⁻), chlorine dioxide (ClO₂), chlorate (ClO₃⁻), and chloride (Cl⁻), are common constituents of ASC solutions; relative proportions of these chlorinated species are dependent upon the pH, temperature, and alkalinity of the solution. Chloride (Cl⁻) is the ultimate breakdown product of ASC solutions/chlorous acid and related chlorinated compounds. Trace quantities of heavy metal contaminants (e.g., lead, antimony, etc) may be observed depending on the source and purity of the feedstock chemicals, particularly sodium chlorite.



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46 Source or Origin of the Substance:

47 Acidified sodium chlorite (ASC) solutions are made on-site by mixing an aqueous solution of sodium
 48 chlorite with a food-grade acid, such as citric acid. A number of industrial synthetic procedures are utilized
 49 in the production of sodium chlorite. As examples, the treatment of chlorine dioxide, sodium hydroxide,
 50 and a reducing agent (e.g., sodium sulfite) or reaction of chlorine dioxide with sodium peroxide (i.e., Na₂O₂)
 51 or an alkaline solution of hydrogen peroxide, H₂O₂) are commercially utilized methods for the synthesis of
 52 sodium chlorite. GRAS acids, such as citric and lactic acids, are generally produced through fermentative
 53 means; however, these naturally occurring compounds may also be extracted from plant-based sources or
 54 generated using chemical synthetic methods.

55 Properties of the Substance:

56 Of the potential chlorinated compounds, sodium chlorite and chlorous acid are the chlorinated species of
 57 highest concentration in acidified sodium chlorite (ASC) solutions over the pH range 2.3–3.2. Therefore, the
 58 physical and chemical properties of solid and aqueous sodium chlorite as well as chlorous acid are most
 59 pertinent to the evaluation of ASC solutions. A summary of chemical and physical properties for sodium
 60 chlorite and chlorous acid is provided in Table 1.

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Table 1. Properties of Sodium Chlorite (Solid and Aqueous) and Chlorous Acid

Property	Description
Color	White Crystalline Solid (80% Technical Grade) Solutions: Colorless to light green
Density/Specific Gravity	Crystal: 2.468 g/cm ³ Bulk, Packed, 80% Technical Grade: 1.176 25% Aqueous Solution: 1.21 g/mL
Dissociation Constants	pK _a of chlorous acid (HClO ₂) = 1.72 @ 25 °C
Hydrolysis	Sodium chlorite reacts with hydrogen ions to form chlorous acid (pK _a = 1.72 @ 25 °C)
Melting or Crystallization Points (liquids)	25% Aqueous Sodium Chlorite Solution: -8 °C
Melting Point or Range (solids)	180–200 °C
Molecular Weight	Sodium Chlorite (solid): 90.44 g/mole Chlorous Acid: 68.46 g/mole
Odor	Slight chlorinous (i.e., chlorine-like) odor
Oxidation Stability (air)	Stable to air oxidation
Photolysis	80% Technical Grade is stable to photolysis; Photolysis of sodium chlorite solutions produces chlorine dioxide
Physical State	White Crystalline Solid, slightly hygroscopic (80% Technical)
Solubility in Organic Solvents	Sodium Chlorite: Insoluble in nonpolar organic solvents. Sparingly soluble in polar solvents.

Solubility in Water	Sodium Chlorite: 64 g per 100 g water
Thermal Stability	Sodium Chlorite decomposes at 180–200 °C (i.e., melting point)
Vapor Pressure	25% aqueous solution: 21.085 mm Hg @ 25 °C
Viscosity (liquids)	25% aqueous solution: 1.851 cps @ 25 °C

62 Sources: FSANZ, 2003; HSDB, 2009a; Chemical Book, 2007.

63 Specific Gravity = ratio of the density of a substance compared to the density of a reference substance (e.g.,
64 water). CPS = centipoise (one hundredth of a poise), unit of measure for viscosity.

65 **Specific Uses of the Substance:**

66 Acidified sodium chlorite (ASC) solutions are used as antimicrobial processing aids in wash and/or rinse
67 water for agricultural applications. Specifically, ASC solutions are applied to the surface of fresh and
68 processed foods, such as poultry meats, fresh and processed meats, fruits and vegetables, and freshwater
69 fish and seafood, at relatively low levels (i.e., 50–1200 mg L⁻¹) (Rao, 2007). The ASC solution may be
70 applied as a spray or dip prior to or after chilling (e.g., poultry parts/carcass) or cooking (e.g., sausages,
71 deli meats) (Rao, 2007). ASC solutions are also used for the antimicrobial treatment of indirect food contact
72 hard surfaces. The petition before the NOSB is to allow the use of ASC solutions in organic livestock
73 production as a topical disinfectant/sanitizer and, specifically, for pre-and-post livestock udder
74 preventative treatment (i.e., teat dip treatment).

75 Owing to their strong antimicrobial activity and applications to food safety, ASC solutions are increasingly
76 capturing the attention of the scientific community. Animal health researchers from the United Kingdom
77 determined that ASC solutions are as effective as iodophor teat disinfectants in preventing new
78 intramammary infections (IMI) in lactating dairy cows and are tolerated well by teat skin (Hillerton, 2007).
79 Smaller operations generally perform teat dips manually using disinfectant dip cups, while mechanical
80 systems involving a combination of rotating brushes with disinfecting solutions (e.g., ASC) have proven
81 advantageous for large-scale milk producers (Dole, 2012; Eriksson, 2003). ASC solutions have also
82 exhibited superior antimicrobial activity against *Escherichia coli* O157:H7 populations, aerobic mesophilic
83 bacteria, yeast, and mold counts on fresh-cut cilantro when compared to sodium hypochlorite, sodium
84 chlorite, and citric acid treatments (Allende, 2009). Most recently, a study of ASC treatments on fresh-cut
85 tatsoi (spinach mustard) baby leaves indicated efficacy of the ASC solutions on natural microflora and
86 *Escherichia coli* as effective as that of sodium hypochlorite (Tomás-Callejas, 2012).

87 Beyond agricultural applications, various ASC formulations are employed throughout the public sector
88 and in industry. Sodium chlorite acidified with hydrochloric acid is used in many countries, including the
89 U.S. and Australia, as a means of generating chlorine dioxide in high yield for antimicrobial water
90 treatment (U.S. EPA, 1999). As a result, chlorine dioxide gas may be an exposure hazard related to ASC
91 solutions. Substantial amounts of sodium chlorite are also used in the production of chlorine dioxide for
92 applications such as bleaching textiles, and in the processing of pulp and paper (Rao, 2007). Accordingly,
93 drinking water and occupational settings are the primary sources of sodium chlorite in the environment.
94 Commercial, industrial, and medical uses also include the disinfection of hard surfaces (e.g., floors,
95 bathrooms), heating ventilation and air-conditioning (HVAC) systems, and treatment of pool and spa
96 water circulation systems (U.S. EPA, 2006).

97 **Approved Legal Uses of the Substance:**

98 The Food and Drug Administration (FDA) approved acidified sodium chlorite (ASC) solutions as
99 antimicrobial agents at specified sodium chlorite concentrations (ppm) and pH values for treating a variety
100 of food products (21 CFR 173.325) (Table 2). For these applications, ASC solutions must be produced
101 through the combination of aqueous sodium chlorite and any GRAS acid. Poultry processors may include
102 ASC as a component of carcass spray or dip solutions, in prechiller or chiller solutions, as well as post-chill
103 carcass spray or dip solutions. Specifications are also provided for red meat products; processed,
104 comminuted, or formed meat food products; seafood; raw agricultural commodities; and processed fruits
105 and vegetables. According to the FDA's list of Substances Utilized to Control the Growth of
106 Microorganisms, ASC solutions are approved as sanitizing agents for food-processing equipment
107 (including dairy processing equipment) and utensils at sodium chlorite concentrations of 100–200 ppm (21
108 CFR 178.1010(b)(46)).

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Table 2. Summary of 21 CFR 173.325 – Acidified Sodium Chlorite Solutions

Food Product	Application	Sodium Chlorite (ppm)	Solution pH
Poultry intact carcass and parts, meat, organs, related parts or trim	Spray or dip	500–1200	2.3–2.9
Poultry intact carcass and parts	Prechiller or chiller solution	50–150	2.8–3.2
Red meat, red meat parts, and organs	Spray or dip	500–1200	2.5–2.9
Seafood ¹	Water or ice (use to rinse, wash, thaw, transport, or store)	40–50	2.5–2.9
Finfish and crustaceans ²	Spray or dip solution (in processing facilities)	1200	2.3–2.9
Raw agricultural commodities ³	Spray or dip	500–1200	2.3–2.9
Processed, comminuted, or formed meat food products	Spray or dip	500–1200	2.5–2.9
Processed fruits and vegetables ⁴	Spray or dip	500–1200	2.3–2.9

110

¹ Any seafood that is intended to be consumed raw shall be subjected to a potable water rinse prior to consumption.

111

² Treated seafood shall be cooked prior to consumption.

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³ Treatment of the raw agricultural commodities with ASC solutions shall be followed by a potable water rinse, or by blanching, cooking, or canning.

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114

⁴ For processed leafy vegetables and vegetables in the Brassica (Cole) family, application must be by dip treatment only, must be preceded and followed by a potable water rinse, and undergo a 24-hour holding period prior to consumption.

115

116 The USDA Food and Safety Inspection Service (FSIS) identified ASC as an allowed antimicrobial
 117 processing aid in Table 2 (Table of Safe and Suitable Ingredients) of the FSIS Directive 7120.1, Rev. 14
 118 (USDA, 2013). Specifically, ASC solutions may be used to treat poultry products according to the specified
 119 sodium chlorite concentrations and pH ranges established by the FDA (21 CFR 173.325). Further, ASC
 120 solutions of pH 5.0–7.5 and sodium chlorite and chlorine dioxide concentrations not exceeding 1200 and 30
 121 ppm, respectively, may be applied to red meat products (USDA, 2013).

122 Tolerance exemptions for active and inert ingredients promulgated by the U.S. EPA permit the use of oxy-
 123 chloro species, which are generated through acidification of aqueous sodium chlorite solutions, in
 124 antimicrobial formulations. The resulting antimicrobial pesticide formulations may be applied to dairy
 125 processing equipment as well as food processing equipment and utensils. When ready for use, the end-use
 126 chlorine dioxide concentration must not exceed 200 ppm (40 CFR 180.940).

127 **Action of the Substance:**

128 Acidified sodium chlorite (ASC) solutions act to reduce the number of pathogens (e.g., *Escherichia coli*, *E.*
 129 *coli* O157:H7, *Salmonella spp.*, *Campylobacter spp.*, and *Listeria monocytogenes*) as well as spoilage bacteria
 130 found on the surface of foods during processing (Rao, 2007). When aqueous solutions of sodium chlorite
 131 and a food-grade acid are combined, chlorous acid is formed in the equilibrium reaction. Unstable chlorous
 132 acid and a series of powerful oxidant breakdown products (i.e., chlorate, chlorite, and chlorine dioxide) are
 133 capable of killing bacteria, fungi, viruses, and algae. Specific actions of these oxy-chlorine species include
 134 the oxidation of sulfide (S–H) bonds of amino acids and the disulfide (S–S) bonds of enzymes, ultimately
 135 disrupting microbial cellular function (Rao, 2007). Chlorous acid, the primary antimicrobial oxy-chlorine
 136 species in ASC solutions, disinfects through direct disruption of microbial cellular membranes in addition
 137 to the oxidation of cellular components (Rao, 2007). The sustained antimicrobial activity of ASC solutions is
 138 based on reservoirs of chlorite and hydrogen ions, which continue to generate chlorous acid as it is
 139 consumed through oxidative interactions with microorganisms and organic matter.

140 **Combinations of the Substance:**

141 Chlorous acid, the active ingredient in acidified sodium chlorite (ASC) solutions, is produced via the
 142 reaction of sodium chlorite with a proton source (i.e., acid) in aqueous solution. Competing processes
 143 involving these chemicals in water also lead to the formation of chlorate, chlorite, chlorine dioxide and
 144 chloride in this solution. The combination of water, sodium chlorite, and a food-grade acid (e.g., citric acid,
 145 lactic acid) is essential for the formation and use of the petitioned substance. Acidified sodium chlorite is

146 listed at section 205.605(b) of the National List for organic handling. The annotation for acidified sodium
147 chlorite provides use restriction and also indicates that it may be acidified with citric acid only. In addition,
148 citric acid is included on the National List of allowed non-synthetics in organic handling/processing (7
149 CFR 205.605(a)) and is an allowed acid for the pH adjustment of liquid fish products used as soil
150 amendments in organic crop production (7 CFR 205.601(j)(7)). Lactic acid, the acid typically used as the
151 activator for ASC livestock teat dips, is only allowed for the processing/handling of products labeled as
152 “organic” or “made with organic” (7 CFR 205.605 (a)). Phosphoric acid and hydrogen bisulfate are also
153 commonly used in the acidification process; however, only phosphoric acid is included on the National
154 List. Conditioners such as glycerin are also included in the activator (i.e., lactic acid) solution and may be
155 included in topical treatments (7 CFR 205.603 (a)(12)). Otherwise, no additional ingredients (e.g., inert
156 ingredients, stabilizers, preservatives, carriers, anti-caking agents, or other materials) are included during
157 the preparation of ASC solutions.

158 Status

159 Historic Use:

161 Acidified sodium chlorite (ASC) solutions have been used for direct-contact sanitation and livestock teat
162 dip preventative applications in conventional agriculture (Ecolab, 2012). ASC solutions are commonly used
163 in the antimicrobial treatment of food commodities such as meats, processed foods, and produce (i.e., fruits
164 and vegetables) as well as municipal water supplies. Hospitals have used ASC solutions to disinfect clinic
165 rooms and equipment for a hundred years and the US meat industry for about 50 years.

166 Organic Foods Production Act, USDA Final Rule:

167 The National Organic Program (NOP) final rule currently allows the use of acidified sodium chlorite (ASC)
168 solutions for antimicrobial food treatment when acidified with citric acid under 7 CFR §205.605. The
169 petition before the National Organic Standards Board (NOSB) is to add ASC solution as an allowed
170 synthetic in organic livestock production (§205.603) for use as a disinfectant/sanitizer and topical treatment
171 (i.e., teat dip). Citric acid is also allowed for the acidification of liquid fish products used as soil
172 amendments (7 CFR 205.601(j)(7)) and the processing/handling of food products labeled as “organic” or
173 “made with organic.” Certain GRAS acids (e.g., lactic acid) are also included in various sections of the
174 National List.

175 International

176 International regulations regarding the use of acidified sodium chlorite (ASC) solutions in organic
177 agricultural production, processing, and handling are lacking. However, a number of international
178 inspection agencies and risk assessment organizations have approved the application of ASC solutions in
179 the processing/handling of fruits, vegetables, and meat products.

180 *Canadian Food Inspection Agency*

181 It was stated in the petition that the Canadian Food Inspection Agency, Meat Hygiene Directive, listed ASC
182 as an approved microbial control agent. These regulations also specified a sodium chlorite concentration
183 range of 500–1200 ppm and pH of 2.5–2.9 for use on poultry only (Ecolab, 2012). An updated web-based
184 version of this document is currently in development. The Canadian General Standards Board has yet to
185 promulgate regulations regarding the use of ASC in organic agriculture.

186 *European Food Safety Authority (EFSA)*

187 The European Food Safety Authority (EFSA), the European Union (EU) risk assessment body for food and
188 feed safety, recently assessed four antimicrobial treatment substances, including ASC, for contributions to
189 antimicrobial resistance. The Panel on Biological Hazards concluded that there is no evidence suggesting
190 that the use of ASC to remove microbial contamination of poultry carcasses will lead to the occurrence of
191 acquired reduced susceptibility to these substances or microbial resistance to therapeutic antimicrobials
192 (EFSA, 2008). Although this language suggests the EFSA endorsed ASC for antimicrobial treatment of
193 poultry products, the EU has yet to promulgate regulations regarding its use in organic agriculture.

194 *Food Standards Australia New Zealand (FSANZ)*

195 In their final assessment report, FSANZ approved the use of ASC as a food processing aid for antimicrobial
196 use. Their decision was based on the lack of significant public health concerns regarding ASC use, minimal
197 likelihood of observing ASC residues on raw foods prior to sale, as well as a desire to expand the range of
198 antimicrobial agents available to food manufacturers (FSANZ, 2003).

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

200
201 **Evaluation Question #1: Indicate which category in OFPA that the substance falls under: (A) Does the**
202 **substance contain an active ingredient in any of the following categories: copper and sulfur**
203 **compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated**
204 **seed, vitamins and minerals; livestock parasiticides and medicines and production aids including**
205 **netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers? (B) Is**
206 **the substance a synthetic inert ingredient that is not classified by the EPA as inerts of toxicological**
207 **concern (i.e., EPA List 4 inerts) (7 U.S.C. § 6517(c)(1)(B)(ii))? Is the synthetic substance an inert**
208 **ingredient which is not on EPA List 4, but is exempt from a requirement of a tolerance, per 40 CFR part**
209 **180?**

210 (A) Acidified sodium chlorite (ASC) solutions are generated through the treatment of aqueous sodium
211 chlorite with any acid considered GRAS by the FDA (e.g., citric and lactic acids). Although none of the
212 listed substances are intentionally included in ASC, contamination of the sodium chlorite or acid feedstock
213 may lead to minor quantities of these substances in the resulting solution.

214 (B) Since ASC is not an inert ingredient, it is not classified by the EPA as an inert of toxicological concern
215 and is not exempt from a requirement of a tolerance (40 CFR 180). However, EPA exempted sodium
216 chlorite from the requirement of a tolerance for certain applications (40 CFR 180.1070): "Sodium chlorite is
217 exempted from the requirement of a tolerance for residues when used in accordance with good agricultural
218 practices as a seed soak treatment in the growing of the raw agricultural commodities vegetable, brassica,
219 leafy, group 5 radish, roots and radish, tops." Potential acid components citric acid and malic acid are
220 included on List 4A (Minimal Risk Inert Ingredients), while lactic acid and phosphoric acid are on List 4B
221 (use in pesticide products is unlikely to adversely affect public health or the environment).

222 **Evaluation Question #2: Describe the most prevalent processes used to manufacture or formulate the**
223 **petitioned substance. Further, describe any chemical change that may occur during manufacture or**
224 **formulation of the petitioned substance when this substance is extracted from naturally occurring plant,**
225 **animal, or mineral sources (7 U.S.C. § 6502 (21)).**

226 The production of Acidified sodium chlorite (ASC) as well as its feedstock chemicals, sodium chlorite and
227 any Generally Recognized as Safe (GRAS) acid, may be considered chemical synthetic processes. Chlorous
228 acid, the active ingredient of ASC solutions, is produced through the chemical reaction of chlorite and an
229 acidic species. Likewise, sodium chlorite is produced through a series of oxidation-reduction reactions.
230 Many GRAS acids, including citric and lactic acids, are produced via fermentation and listed as allowed
231 non-synthetics in the processing/handling of organic food products (7 CFR 205.605(a)). Below, details
232 regarding the production of ASC and its component chemicals are provided.

233 *Acidified Sodium Chlorite (ASC)*

234 ASC solutions are made on-site and on-demand just prior to use. Sodium chlorite and acids used in ASC
235 preparation are stored in bulk either as concentrates or formulated solutions. In the former scenario, the
236 individual concentrates may be diluted with water to double strength solutions before mixing (Rao, 2007).
237 Industrial applicators may use proportional pumps for the sodium chlorite and GRAS acid solutions in
238 combination with a water dilution module to make the final use dilution product (USDA, 2008).
239 Formulated commercial solutions of sodium chlorite and GRAS acid are mixed in a 1:1 ratio, and the active
240 ASC solution may be applied within one to two minutes of mixing (Rao, 2007).

241 Regarding teat dip treatments, Ecolab's 4XLA® germicidal pre- and post-milking teat dip includes separate
242 Base (i.e., 0.6% sodium chlorite aqueous solution) and Activator (i.e., 1-5% lactic acid solution with
243 isopropanol and glycerin) components. These separate solutions are mixed in a 1:1 ratio until a uniform

244 solution is attained, at which point it may be used for antimicrobial treatments (Ecolab, 2012). In general,
245 the concentration of the active ingredient, chlorous acid, in the ASC solution is dependent upon the pH of
246 the solution and therefore the amount of GRAS acid added to the aqueous mixture.

247 *Sodium Chlorite*

248 Established industrial methods for the production of sodium chlorite involve the treatment of chlorine
249 dioxide with a sodium hydroxide solution containing carbonaceous matter and lime (Merck, 2006a). Initial
250 production steps involve the electrolytic oxidation of sodium chloride (i.e., salt) to provide sodium chlorate
251 with subsequent electrochemical reduction in the presence of hydrochloric acid to afford chlorine dioxide
252 and chlorine (Rao, 2007). Dissolution of gaseous chlorine dioxide in aqueous sodium hydroxide followed
253 by reduction with hydrogen peroxide forms the solid sodium chlorite (Rao, 2007).

254 Two related methods for sodium chlorite synthesis are available in the original patent literature. Both
255 methods involve the reaction of chlorine dioxide, an alkaline material corresponding to the chlorite to be
256 made (e.g., sodium hydroxide), and an independent reducing agent in an aqueous medium. Reducing
257 agents containing sulfur, including elemental sulfur and alkaline sulfites such as sodium sulfite have been
258 successfully employed in the synthesis of sodium chlorite (Vincent, 1937a). In addition, carbonaceous
259 reducing agents (e.g., coke, carbon, charcoal, wood, sawdust, paper pulp, sucrose, glucose and levulose)
260 are effective and inexpensive alternatives for this process (Vincent, 1937b).

261 Methods for the production of high purity alkali metal (e.g., sodium, potassium) chlorites are also
262 described in the recent patent literature. One such invention for the preparation of chlorites with very low
263 carbonate content involves the reduction of chlorine dioxide generated from chlorate in a subatmospheric
264 type chlorine dioxide generator (Cowley, 2003). The process begins with the reduction of chlorate ions to
265 chlorine dioxide in an aqueous acid reaction medium under reduced pressure in the first reaction zone.
266 Gaseous chlorine dioxide is then transferred from the first to a second reaction zone containing an aqueous
267 alkali metal hydroxide (e.g., sodium hydroxide) and hydrogen peroxide as a reducing agent. Concentration
268 of the final reaction mixture provides solid, high purity sodium chlorite (Cowley, 2003).

269 *Generally Recognized as Safe (GRAS) Acids*

270 Acids considered “Generally Recognized as Safe” (GRAS) by the FDA are typically used in the generation
271 of ASC solutions for food handling/processing and teat dip treatments. Specifically, citric acid (21 CFR
272 582.1033) and lactic acid (21 CFR 582.1061) are most commonly employed in ASC solutions and are
273 produced through microbial fermentation almost exclusively. Citric acid is generated through the
274 fermentation of a carbohydrate substrate (e.g., molasses) by citric acid bacteria, *Aspergillus niger* (mold), or
275 *Candida guilliermondii* (yeast) (Merck, 2006b; USDA, 1995b). Recovery from the fermentation broth involves
276 an acid/base process in which citric acid is first precipitate as the calcium salt and then re-acidulated with
277 sulfuric acid (USDA, 1995a). Likewise, lactic acid is produced by fermentation of a suitable carbohydrate
278 substrate using lactic acid bacteria (USDA, 1995b). Methods utilizing genetically modified microorganisms
279 for the fermentative production of lactic acid have been developed in recent years (Zhou, 2012).

280 **Evaluation Question #3: Discuss whether the petitioned substance is formulated or manufactured by a** 281 **chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)).**

282 Acidified sodium chlorite (ASC) solutions are generated through a chemical process involving the reaction
283 of aqueous sodium chlorite and a GRAS acid. As described in Evaluation Question #2 above, this chemical
284 process may be described as an acid/base reaction and involves the mixing of substances or elements.
285 Sodium chlorite is produced via a series of oxidation/reduction and acid/base reactions. Finally, GRAS
286 acids such as citric and lactic acids are produced through microbial fermentation, a naturally occurring
287 biological process, and require processing/purification using chemical reagents.

288 Sodium chlorite is produced from volatile (e.g., chlorine dioxide) and reactive (e.g., sodium hydroxide,
289 hydrogen peroxide) chemicals. As a result, it is unlikely that any residues of these species would persist in
290 the final mineral product. However, small quantities of metal-containing impurities (e.g., lead) from the
291 sodium chlorite feedstock may be introduced during the chlorite-forming reaction (Rao, 2007). The
292 concentration of these impurities in the final product depends upon the contamination of the metal
293 feedstock and the manufacturer’s purification protocol.

294 **Evaluation Question #4: Describe the persistence or concentration of the petitioned substance and/or its**
295 **by-products in the environment (7 U.S.C. § 6518 (m) (2)).**

296 When used as petitioned, acidified sodium chlorite (ASC) and its components exhibit minimal likelihood of
297 persistence or accumulation in the environment. The active ingredient, chlorous acid, is consumed by
298 reacting with microorganisms and other organic matter found on the surface of treated food. As chlorous
299 acid is consumed, the equilibrium shifts resulting in the generation of more chlorous acid from the excess
300 of sodium chlorite and acid in solution. Due to its instability, chlorous acid typically degrades to chlorite
301 via transient intermediates, such as hypochlorous acid (HClO), dichlorine dioxide (Cl₂O₂) and dichlorine
302 tetraoxide (Cl₂O₄) (Rao, 2007). Any leftover chlorite that does not form chlorous acid during the
303 antimicrobial treatment may either remain as chlorite ion in solution or react with water to produce
304 chlorate. As a result of the facile degradation of chlorous acid, the transformation products chlorine
305 dioxide, chlorite, and chlorate are the predominant chemical residues from ASC solutions. It should be
306 noted that the concentration of chlorine dioxide in the final solution is relatively low (<3 mg L⁻¹) when
307 milder acids such as citric and lactic acids are used (Rao, 2007).

308 Technical information regarding the persistence of ASC chemical residues is limited. Although generated
309 in minor quantities, any chlorine dioxide that is formed will either volatilize from solution or revert back to
310 chlorite in solution (HSDB, 2006). Chlorate, on the other hand, may remain in soil for 0.5-5 years,
311 depending upon the rate of application, soil type, fertility, organic matter content, and weather conditions.
312 Chlorate is mobile in soils due to its high water solubility (solubility = 100 g/100 g water at 25 °C), and
313 would be leached from soil as a result of heavy rainfall (HSDB, 2009b). Chlorite water solubility is also high
314 (64 g/100 g water at 17 °C); therefore it is also likely to leach from soils during significant rain events
315 (HSDB, 2009a). The estimated log K_{ow} (octanol-water partition coefficient) values of chlorine dioxide (-
316 3.22) and sodium chlorite (-7.17) suggest that neither are likely to bioaccumulate in aquatic organisms
317 (Shamin, 2006).

318 **Evaluation Question #5: Describe the toxicity and mode of action of the substance and of its**
319 **breakdown products and any contaminants. Describe the persistence and areas of concentration in the**
320 **environment of the substance and its breakdown products (7 U.S.C. § 6518 (m) (2)).**

321 As inorganic oxychlorine compounds, acidified sodium chlorite (ASC) and chlorine dioxide have the
322 potential to form toxic, mutagenic, and carcinogenic by-products such as halogenated organics and
323 semicarbazides. However, in contrast to stronger oxidizing agents such as sodium hypochlorite, ASC does
324 not lead to the formation of halogenated organic compounds. The European Food Safety Authority (EFSA)
325 concluded that studies examining the possibility of reaction products provided no evidence of
326 halomethane formation in water treated with chlorine dioxide. In addition, the report states that no
327 chlorinated organics or semicarbazides have been detected (limit of detection = 1 pg/kg) after treatment by
328 immersion of poultry carcasses in ASC (EFSA, 2006). On the basis of available data and taking into account
329 the processing of poultry carcasses (i.e., washing, cooking), the panel concluded that estimated potential
330 dietary exposure to residues arising from ASC treatments would be of no safety concern. Spraying of
331 poultry carcasses with ASC solutions will further reduce potential exposure to residues and by-products
332 relative to dipping treatments (EFSA, 2006).

333 Toxicological risk assessments from the World Health Organization's International Programme on
334 Chemical Safety (WHO ICPS) and the U.S. EPA provide a compilation of scientific information regarding
335 the toxicity of ASC, sodium chlorite, and chlorine dioxide. Certain scientific studies identified increasing
336 chloroform (i.e., trihalogenated methane) concentrations in various bodily organs/tissues of Sprague-
337 Dawley rats that received ³⁶Cl-labeled chlorine dioxide, chlorite or chlorate from drinking water (IPCS,
338 2008). It should be noted that the experimental concentrations of chlorine dioxide, chlorite, and chlorate
339 (10-100 mg per liter drinking water) in the study were significantly higher than levels anticipated for
340 public consumption following ASC treatments. Further, quantitative details regarding the amount of
341 chloroform generated were not provided as part of the study. Despite the potential carcinogenicity of
342 chloroform and other trihalomethanes, the potential toxicity of chloroform generated from ASC residues
343 and breakdown products could not be assessed (IPCS, 2008).

344 Toxicological studies provide other indicators of acute and chronic toxicity of ASC. Although chlorite does
345 not appear to have a carcinogenic mode of action based on the accumulated information, scientific data

346 regarding the potential carcinogenicity of chronic chlorine dioxide exposure is lacking (U.S. EPA, 2000).
347 Alternatively, oral chlorine dioxide and chlorite exposure may result in an increased risk of developmental
348 and reproductive effects (IPCS, 2008; U.S. EPA, 2000). A number of studies on laboratory animals have
349 consistently demonstrated developmental effects following in utero exposure or postnatal gavage
350 administration of 14 mg/kg-day chlorine dioxide. Reduced rabbit pup weights were observed at higher
351 dietary sodium chlorite concentrations (i.e., 19–28 mg/kg-day), while a two-generation study found no
352 alterations in reproductive performance in rats exposed to 22.7 mg/kg-day in drinking water. Allowed and
353 petitioned uses of ASC should lead to significantly lower levels of oral exposure to chlorite and chlorine
354 dioxide than the above LOAELs (lowest observed adverse effect levels).

355 As a final consideration, the ultimate metabolite of the ASC components chlorine dioxide and chlorite is
356 chloride, a required macromineral for virtually all organisms (U.S. EPA, 2000).

357 **Evaluation Question #6: Describe any environmental contamination that could result from the**
358 **petitioned substance's manufacture, use, misuse, or disposal (7 U.S.C. § 6518 (m) (3)).**

359 While the manufacture and use of acidified sodium chlorite (ASC) solutions have resulted in releases to the
360 environment, the risk of environmental contamination from released ASC is minimal. Certain
361 manufacturing facilities have reported releases of chlorine dioxide, a portion of which was generated
362 through reaction of chlorite with a strong acid, to air, water, and soil (ATSDR, 2004). Strong acids (e.g.,
363 hydrochloric acid) and bases (sodium hydroxide) are used in the commercial production of sodium
364 chlorite, and their release due to improper handling/disposal could lead to serious environmental
365 impairments. Likewise, the release of strong oxidizing agents in large quantities may lead to ecotoxicity in
366 both terrestrial and aquatic environments. This is true of both the chemical feedstocks (e.g., hydrogen
367 peroxide) used in the manufacture of ASC precursors and the chemicals in ASC solutions (i.e., chlorous
368 acid, chlorine dioxide, chlorite). Regarding the former, several lower reactivity sulfur-containing and
369 carbonaceous substances have been evaluated for the conversion of chlorine dioxide to sodium chlorite.

370 Microbial resistance and trihalomethane formation were evaluated as possible consequences of ASC use
371 and misuse. The oxidative mechanism of action for oxychlorines as antimicrobial agents (e.g., ASC,
372 chlorite, chlorine dioxide) does not generate resistance in microorganisms. The European Food Safety
373 Authority (EFSA) conducted a thorough evaluation of the available technical information and found no
374 resistance issues (EFSA, 2008). Ecotoxic trihalomethane compounds, and specifically chloroform, may be
375 generated upon the chemical reaction of oxy-chlorine species (i.e., ASC, chlorite, chlorine dioxide) with
376 organic material in the environment. Quantitative analyses regarding the concentrations of chloroform
377 generated following the oral administration of chlorine dioxide are lacking (IPCS, 2008).

378 When used as petitioned, large-scale releases of ASC to the environment are unlikely to occur and smaller
379 releases would not lead to environmental contamination or impairment. The U.S. EPA states that “the
380 rapid degradation of the chemicals coupled with the generally low toxicity of chlorine dioxide and sodium
381 chlorite to birds and mammals, make risk to these organisms unlikely” (U.S. EPA, 2006). The ions, such as
382 chlorite, chlorate, and chloride, are likely to be mobile and may travel from surface to groundwater easily
383 (U.S. EPA, 2006). Likewise, high soil mobility is expected for these ions. In a study of acute and chronic
384 toxicity of chlorine dioxide and chlorite to larval and adult rainbow trout, the following median lethal
385 concentrations (96-hour LC₅₀) values were derived: 2.2 mg L⁻¹ for larvae and 8.3 mg L⁻¹ for adult fish
386 (Svecevičius, 2005). The 20-day LC₅₀ for larvae was 1.6 mg L⁻¹ chlorine dioxide. In comparison, chlorite was
387 found to be 48 to 18 times less acutely toxic to larvae and adult rainbow fish, with a maximum-acceptable-
388 toxicant-concentration (MATC) of 3.3 mg L⁻¹. Fish are more likely to be exposed to chlorite ion due to the
389 highly reactive nature of chlorine dioxide, and therefore the toxicity risk associated with use of these
390 disinfectant chemicals is minimal (Svecevičius, 2005).

391 **Evaluation Question #7: Describe any known chemical interactions between the petitioned substance**
392 **and other substances used in organic crop or livestock production or handling. Describe any**
393 **environmental or human health effects from these chemical interactions (7 U.S.C. § 6518 (m) (1)).**

394 Chlorous acid, the active ingredient of acidified sodium chlorite (ASC) solutions, readily interacts with
395 organic matter (e.g., proteins, lipids, cellular membranes) as an oxidant. Common interactions for ASC
396 breakdowns products/feedstocks (i.e., chlorite, chlorate, chlorine dioxide) also involve the oxidative

397 transformation of organic materials. The end products of these oxidation/reduction reactions are chloride
398 and oxygen. Degradation of chlorite to chloride and oxygen is also expected when aqueous sodium chlorite
399 comes into contact with suspended soil particles containing ions such as iron(II), manganese(II), iodide,
400 and sulfide (Shamim, 2006). Of these mineral species, sulfates of iron and manganese are allowed synthetic
401 soil amendments on the National List for organic crop production (7 CFR 205.601(j)(6)(ii)). In addition,
402 trace minerals (e.g., iron, manganese, and iodide) are allowed feed supplements in organic livestock
403 production (7 CFR 205.603(d)(2)). Heating of chlorite is also expected to generate the end products chloride
404 and molecular oxygen (Shamim, 2006).

405 **Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical**
406 **interactions in the agro-ecosystem, including physiological effects on soil organisms (including the salt**
407 **index and solubility of the soil), crops, and livestock (7 U.S.C. § 6518 (m) (5)).**

408 The current petition concerns the use of acidified sodium chlorite (ASC) as a disinfectant and topical
409 treatment (pre and post teat dip) when acidified with lactic acid or another generally recognized as safe
410 (GRAS) acid. When used for these purposes, it is unlikely that the petitioned substance will regularly
411 interact with components of the terrestrial agro-ecosystem (i.e., agricultural land). Further, technical
412 information regarding non-target wildlife toxicity resulting from ASC topical treatments in livestock
413 production is lacking. Any potential leakage of ASC, feedstock chemicals and breakdown products near
414 the agro-ecosystem would be neither routine nor widespread.

415 Toxicity toward soil-dwelling organisms may result from the use and manufacture of ASC. Although no
416 studies have been investigated the toxicity of ASC toward soil organisms, the scientific literature is replete
417 with information regarding ASC's efficacy at killing bacterial food contaminants, such as *Escherichia coli*
418 and *Staphylococcus aureus* (Lim, 2004). Owing to their strong oxidizing ability in combination with high
419 water solubility, anticipated mobility in soils, and low tendency to adsorb onto soil particles (Shamim,
420 2006), ASC and its breakdown products may threaten the health of soil-dwelling microorganisms (e.g.,
421 nitrogen-fixing bacteria) if released to the agro-ecosystem in significant quantities.

422 Accidental release of chemical reagents during the production process may also lead to ecological
423 impairment. Strong acids (e.g., hydrochloric acid) and bases (e.g., sodium hydroxide) are used in the
424 preparation of feedstock chemicals sodium chlorite and chlorine dioxide. Improper use or disposal of
425 acidic and basic reagents during the production of trace minerals could affect both the pH and chemical
426 composition of the soil, potentially resulting in physiological effects on soil organisms. Further, release of
427 hydrogen peroxide, an antimicrobial oxidizing agent and chemical reagent used in the synthesis of sodium
428 chlorite, to the agro-ecosystem could prove deleterious to the health of soil-dwelling microorganism
429 populations.

430 Technical information regarding potential impacts of ASC on endangered species, populations, viability or
431 reproduction of non-target organisms and the potential for measurable reductions in genetic, species or
432 eco-system biodiversity, is lacking.

433 **Evaluation Question #9: Discuss and summarize findings on whether the use of the petitioned**
434 **substance may be harmful to the environment (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A)**
435 **(i)).**

436 When used as petitioned, acidified sodium chlorite (ASC) and its component chemicals exhibit minimal
437 likelihood of persistence or accumulation in the environment. The active ingredient, chlorous acid, is
438 consumed through redox (i.e., oxidation/reduction) interactions with microorganisms and other organic
439 matter present on contaminated surfaces. Chlorine dioxide, chlorite, and chlorate are the predominant
440 chemical residues from ASC solutions due to the breakdown of reactive chlorous acid. If soils are
441 contaminated with a spill, chlorate may remain in soil for 0.5–5 years, depending upon a number of
442 variables (i.e., rate of application, soil type, fertility, organic matter content, and weather conditions) and is
443 readily mobile in soils. Likewise, the water solubility of chlorite is also high and therefore is likely to leach
444 from soils during significant rain events. The estimated log K_{ow} (octanol–water partition coefficient) values
445 of chlorine dioxide (–3.22) and sodium chlorite (–7.17) suggest that neither are likely to bioaccumulate in
446 aquatic organisms.

447 ASC, its breakdown products, and the chemicals used in related manufacturing processes may pose
448 significant risks to the agro-ecosystem and the environment as a whole. For example, strong acids, bases,
449 and oxidizing agents used in the preparation of feedstock chemicals sodium chlorite and chlorine dioxide
450 could lead to ecological impairment if accidentally released. Improper use or disposal of acidic and basic
451 reagents during the production of trace minerals could affect both the pH and chemical composition of the
452 soil, potentially resulting in physiological effects on soil organisms. Further, release of hydrogen peroxide,
453 an antimicrobial oxidizing agent and chemical reagent used in the synthesis of sodium chlorite, to the agro-
454 ecosystem could negatively impact the health of beneficial soil-dwelling microorganisms. Laboratory
455 studies of rainbow trout indicated that the risk of sodium chlorite toxicity is minimal even at reasonably
456 high concentrations. Overall, the risk of environmental impairment related to ASC production and use is
457 low when responsible manufacturing and disposal practices are exercised. Microbial resistance and toxic
458 trihalomethane formation has not been attributed to ASC or its breakdown products.

459 Regarding animal toxicity, the strongest correlations were observed between oral exposure to oxy-chlorine
460 compound (i.e., chlorine dioxide, chlorite) and the incidence of reproductive and developmental effects. A
461 number of studies on laboratory animals have consistently demonstrated developmental effects following
462 in utero exposure or postnatal gavage administration of 14 mg/kg-day chlorine dioxide. Reduced rabbit
463 pup weights were observed at higher dietary sodium chlorite concentrations (i.e., 19–28 mg/kg-day), while
464 a two-generation study found no alterations in reproductive performance in rats exposed to 22.7 mg/kg-
465 day in drinking water. Allowed and petitioned uses of ASC should lead to significantly lower levels of
466 chlorite and chlorine dioxide exposure than the above LOAELs (lowest observed adverse effect levels). The
467 ultimate metabolite of the ASC components chlorine dioxide (ClO₂) and chlorite (ClO₂⁻) is chloride (Cl⁻), a
468 required macromineral naturally observed in water and foods.

469 **Evaluation Question #10: Describe and summarize any reported effects upon human health from use of**
470 **the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i) and 7 U.S.C. § 6518**
471 **(m) (4)).**

472 Any adverse effects upon human health caused by acidified sodium chlorite (ASC) would likely result
473 from the feedstock chemicals and breakdown products as well as the inherent acidity of in situ generated
474 chlorous acid. Acidification of sodium chlorite results in conversion of chlorite to chemically unstable
475 chlorous acid, which breaks down to chlorite and chlorine dioxide and is reduced to chloride following the
476 oxidation of organic matter. According to the material safety data sheets (MSDS), lactic acid is an irritant of
477 the skin, eyes, and respiratory tract, and may be harmful if swallowed in sufficient quantities (Sigma
478 Aldrich, 2013). Sodium chlorite is extremely destructive to the tissues of the mucous membranes and upper
479 respiratory tract, will burn the skin upon dermal exposure, and may be toxic if swallowed (Sigma Aldrich,
480 2013). Likewise, gaseous chlorine dioxide is highly irritating to skin and mucous membranes of the
481 respiratory tract (Merck, 2006). The California Pesticide Illness Surveillance Program indicates that between
482 1992 and 2010, 122 incidents of poisoning from use of sodium chlorite were reported, primarily from
483 splashes of rinse water containing sodium chlorite. Symptoms included skin, eye and respiratory irritation
484 (DPR, 2013).

485 Human studies, including short-term toxicity studies and retrospective developmental and reproductive
486 studies, have provided differing insights regarding the potential for human toxicity from exposure to
487 chlorine dioxide and chlorite. No physiologically relevant alterations in general health, vital signs, serum
488 clinical chemistry parameters or hematologic parameters were observed in a 12 week study of adult males
489 administered drinking water containing varying amounts of chlorine dioxide or chlorite (U.S. EPA, 2000).
490 The authors of a retrospective developmental and reproductive study asserted that the incidence of
491 newborns judged premature by physician assessment was significantly higher in the community with
492 chlorine dioxide treated drinking water. In a review of this study, EPA determined there was no increase in
493 the proportion of premature infants when the mother's age was controlled and that greater postnatal
494 weight loss occurred in infants of mothers exposed to chlorine dioxide (U.S. EPA, 2000). Developmental
495 effects such as neonatal jaundice, reduced infant cranial circumference and reduced body length were also
496 observed following maternal exposure to chlorine dioxide treated drinking water. Interpretability of these
497 results is limited due to the lack of consideration of exposure and potential confounding factors (U.S. EPA,
498 2000).

499 **Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be**
500 **used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed**
501 **substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).**

502 Information regarding the availability of natural, non-synthetic agricultural commodities or products that
503 could substitute for the petitioned substance, ASC solutions, is limited. Nisin, a naturally occurring
504 antimicrobial protein known as a bacteriocin, has been incorporated into pre- and postmilking teat dips
505 and is highly effective against Gram-positive as well as Gram-negative bacteria (Nickerson, 2001).
506 Formulated products containing nisin, such as Wipe Out® Dairy Wipes, are currently available for mastitis
507 prevention (Jeffers Livestock, 2013). Nisin naturally present in milk is also instrumental in preventing milk
508 spoilage due to bacterial contamination (Ahlberg, 2012). The antimicrobial mode of action for nisin
509 involves lysis of the cytoplasmic membrane phospholipid components (Nickerson, 2001).

510 The status of nisin for use as a topical treatment in organic livestock production is somewhat unclear.
511 Nisin, generally considered a natural product, is not listed as a prohibited non-synthetic substance in
512 organic livestock production (7 CFR 205.604). However, the NOSB classified nisin as synthetic during their
513 1995 review of the substance for organic processing (USDA, 1995c). Nisin was ultimately prohibited for use
514 in the processing of food labeled as “organic” and “made with organic ingredients” (USDA, 1995d).

515 Small-scale milk producers frequently use homemade udder washes containing lavender essential oil,
516 water, and apple cider vinegar (i.e., acetic acid) as the active antimicrobial agent (Weaver, 2012). Other
517 procedures for pre- and postmilking treatments have been disclosed, including an udder wash (warm
518 water or warm water with a splash of vinegar) in combination with a teat dip (1 part vinegar, 1 part water,
519 plus 3–4 drops Tea Tree oil per ounce). Organic acids (e.g., lactic acid) may be used as standalone
520 germicides or further activated through the synergistic interaction with hydrogen peroxide to provide a
521 bactericidal teat cleansing treatment (Belsito, 2012). In addition to the natural substances mentioned above,
522 a small number of synthetic substances are allowed as disinfectants, topical treatments, and external
523 parasiticides in organic livestock production (7 CFR 205.603 (a) and (b)):

- 524 • **Iodine:** Disinfectant, topical treatment, and/or parasiticide. A broad spectrum germicide, which is
525 fast acting and effective against all mastitis-causing bacteria as well as fungi, viruses, and bacterial
526 spores. It is microbicidal due to the oxidizing reaction between iodine and organic matter.
527 Iodophor is produced when iodine is dissolved in water through its complexation with water-
528 soluble detergents or surfactants (Nickerson, 2001).
- 529 • **Ethanol:** Disinfectant and sanitizer only, prohibited as a feed additive.
- 530 • **Isopropanol:** Disinfectant only.
- 531 • **Sodium hypochlorite:** Commonly referred to as commercial bleach. On the National List as a
532 disinfectant, not a topical treatment option. It has been noted that such solutions are not marketed
533 as teat dips and their use violates federal regulations; however, its use has continued for both pre-
534 and postmilking teat dips at a 4.0% hypochlorite concentration (Nickerson, 2001).
- 535 • **Hydrogen peroxide:** On the National List as a disinfectant, not a topical treatment option. Provides a
536 wide spectrum of control against most mastitis-causing bacteria through its oxidizing action.
- 537 • **Chlorhexidine:** Allowed synthetic on the National List for surgical procedures conducted by a
538 veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical
539 barriers have lost their effectiveness.

540 The available information suggests that commercial antimicrobial products containing oxidizing chemicals
541 (e.g., sodium chlorite, hypochlorite, iodophor), natural products composed of organic acids (e.g., lactic
542 acid), and homemade products using vinegar (i.e., acetic acid) as the active ingredient may all be equally
543 effective teat dip treatments. However, peer-reviewed literature and information from agricultural
544 extensions regarding the relative efficacy of organic acids as teat dips are unavailable. Although numerous
545 active ingredients are commercially available for the cleansing of animal teats prior to and following
546 milking, ASC solutions represent an effective alternative for maintaining the health and productivity of
547 milk-producing animals.

548 **Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned**
549 **substance unnecessary (7 U.S.C. § 6518 (m) (6)).**

550 A number of control measures for contagious mastitis pathogens have been developed and successfully
551 implemented in the dairy industry. Mastitis, an inflammation of the breast tissue, is typically caused by
552 environmental pathogens, such as Gram-negative bacteria *Serratia spp.* (Pettersson-Wolfe, 2011). Since these
553 pathogens are commonly found in soil and plant matter, cows on pasture or housed on organic bedding
554 experience heightened exposure to mastitis-causing pathogens. Damage of the teat ends and poor udder
555 cleanliness may also increase the risk of spreading the pathogens throughout the herd. The risk of mastitis
556 incidents is significantly reduced when producers maintain a clean and dry environment for the animals.
557 Frequently changing the animal's bedding material and/or using inorganic bedding (i.e., sand) may also
558 reduce environmental contamination with these bacteria (Pettersson-Wolfe, 2011). In addition, providing a
559 healthy, balanced diet to the animal and ensuring the cleanliness of milking implements are important
560 steps for maintaining health udders.

561 Teat dips and udder washes are critical for preventing incidents of mastitis and virtually all milk producers
562 apply some form of teat disinfectant post milking. Any mastitis control program will incorporate
563 disinfecting teat dips at milking to prevent new infections and reduce the duration of existing infections.
564 Cessation of hygienic milking practices, and particularly teat dipping, will allow bacterial populations on
565 teat skin to propagate, thus increasing the risk of infection (Poock, 2011). While pre-dipping can be
566 beneficial to animal health, post-dipping with an effective sanitizer is essential for both removing milk
567 residue left on the teat and killing harmful microorganisms (Bray, 2012). Overall, dairy professionals agree
568 that teat dipping using a safe and effective disinfectant is vital to maintaining the health and productivity
569 of milk-producing animals.

570 Alternative practices to teat dipping/spraying or udder washing are not advised, as the exclusion of a
571 disinfecting step from a mastitis control program would significantly increase the likelihood of infection.
572 Although alternative practices are not available, a number of alternative substances are presented in
573 Evaluation Question #11.

574

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