


Hypochlorous Acid

Handling

Identification of Petitioned Substance

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2	Chemical Names: Hypochlorous acid,	CAS Numbers: 7790-92-3
3	hypochloric(I) acid, chloranol,	
4	hydroxidochlorine	10 Other Codes: European Community
5	Other Name: Hydrogen hypochlorite,	11 Number-22757, IUPAC-Hypochlorous acid
6	Chlorine hydroxide	List other codes: PubChem CID 24341
7	Trade Names: Bleach, Sodium hypochlorite,	InChI Key: QWPPOHNGKGFJK-
8	Calcium hypochlorite, Sterilox, hypochlorite,	UHFFFAOYSA-N
9	NVC-10	UNII: 712K4CDC10

Summary of Petitioned Use

A petition has been received from a stakeholder requesting that hypochlorous acid (also referred to as electrolyzed water (EW)) be added to the list of synthetic substances allowed for use in organic production and handling (7 CFR §§ 205.600-606). Specifically, the petition concerns the formation of hypochlorous acid at the anode of an electrolysis apparatus designed for its production from a brine solution. This active ingredient is aqueous hypochlorous acid which acts as an oxidizing agent. The petitioner plans use hypochlorous acid as a sanitizer and antimicrobial agent for the production and handling of organic products. The petition also requests to resolve a difference in interpretation of allowed substances for chlorine materials on the National List of Allowed and Prohibited Substances that contain the active ingredient hypochlorous acid ([NOP-PM 14-3 Electrolyzed water](#)) 

The NOP has issued [NOP 5026 "Guidance, the use of Chlorine Materials in Organic Production and Handling."](#) This guidance document clarifies the use of chlorine materials in organic production and handling to align the National List with the November, 1995 NOSB recommendation on chlorine materials which read:

"Allowed for disinfecting and sanitizing food contact surfaces. Residual chlorine levels for wash water in direct crop or food contact and in flush water from cleaning irrigation systems that is applied to crops or fields cannot exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (currently 4 ppm expressed as Cl₂)."

The recent policy memo, NOP PM-14-3, clarifies which synthetic chlorine compounds specified in the National List are allowed for use in organic production and handling. Although hypochlorous acid is an intermediate product produced when hypochlorite salts or chlorine are dissolved in water, purified or generated hypochlorous acid is not specifically included on the National List.

Characterization of Petitioned Substance

Composition of the Substance:

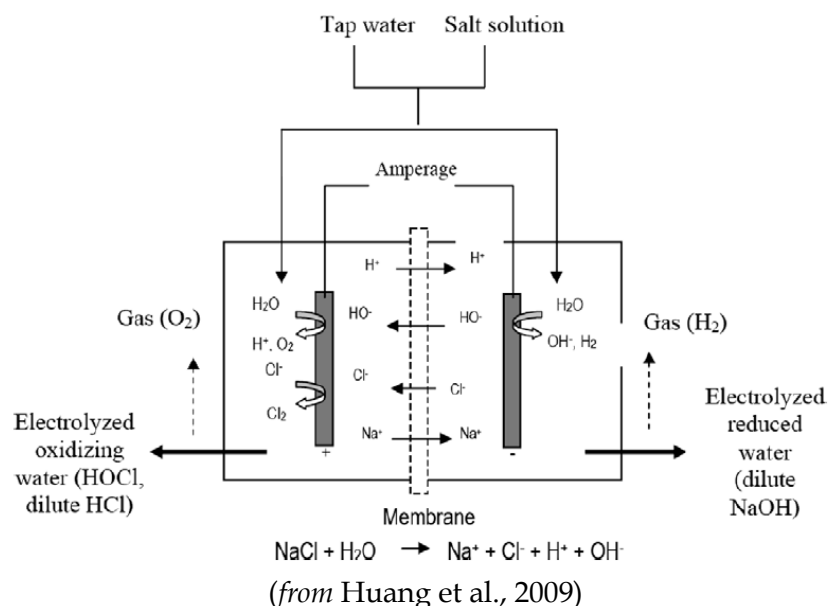
Hypochlorous acid (also referred to as electrolyzed water, EW) is an oxyacid of chlorine (with formula HClO) containing monovalent chlorine that acts as an oxidizing or reducing agent (NCBI, 2015; Su et al., 2007). It is a weak acid and highly unstable and can only exist in solution. The molecules are electron-accepting in oxidation-reduction reactions in which electrons are transferred from one molecule to another (NCBI, 2015).

43 Electrolyzed water ("electrolyzed water", EOW, ECA, electrolyzed oxidizing water, electro-activated
 44 water or electro-chemically activated water solution) is produced by the electrolysis of water-sodium
 45 chloride solution. The electrolysis of such salt solutions produces hypochlorous acid, hypochlorite, and
 46 free chlorine.

47 **Source or Origin of the Substance:**

48 As reported by Hricova et al., 2008 and Huang et al., 2009, EW is the product of the electrolysis of
 49 a dilute NaCl solution in an electrolysis cell, containing a semi-permeable membrane that
 50 physically separates the anode and cathode but permitting specific ions to pass through. The
 51 basic approach for producing EW is shown in Figure 1. The voltage between the electrodes is
 52 generally set at 9 to 10 volts (Al-Haq et al., 2005). During electrolysis, sodium chloride (NaCl)
 53 dissolved in deionized water (brine) dissociates into negatively charged chloride (Cl⁻) and
 54 positively charged sodium (Na⁺). At the same time, hydroxide (OH⁻) and hydrogen (H⁺) ions
 55 are formed. Negatively charged ions Cl⁻ and OH⁻ move to the anode to lose electrons and form
 56 oxygen gas (O₂), chlorine gas (Cl₂), hypochlorite ion (OCl⁻), hypochlorous acid (HOCl) and
 57 hydrochloric acid.

58 Fig. 1 Schematic of hypochlorous acid generator action



61 Positively charged ions such as H⁺ and Na⁺ move to the cathode to form hydrogen gas (H₂) and
 62 sodium hydroxide (NaOH). The solution separates into an acidic solution on the anode side of
 63 the membrane, with a pH of 2 to 6.0, an oxidation-reduction potential (ORP) of ≥1,000 mV, and a
 64 chlorine content of 10 to 90 ppm, and a basic solution on the cathode side of the membrane, with
 65 a pH of 7.5 to 13 and an ORP of ~-800 to -900 mV. The solution from the anode is called acidic
 66 electrolyzed water (EW), and the cathodic solution is known as basic EW. Neutral EW, with a
 67 pH of 6 to 7.5 and an ORP of 750 mV, is produced by mixing the anodic solution with OH⁻ ions
 68 or by using a single-cell chamber.

69 Basic chemical reactions at the anode (positive pole) and at the cathode (negative pole) are
 70 provided in Table 1. The solution from the anode is called acidic electrolyzed water, acid
 71 oxidizing water, or electrolyzed oxidizing water, and the cathodic solution is known as basic
 72 electrolyzed water, alkaline electrolyzed water, or electrolyzed reducing water. As reported by
 73 Al-Haq et al., 2005, there are a number of EW-producing instruments available in the
 74 marketplace. They can be divided into those that contain a membrane and produce acidic EW

75 and basic EW (two-cell chamber) and those that do not contain a membrane and therefore
 76 produce neutral EW (single-cell chamber).

Table 1 Formula Representation of Hypochlorous Acid Production*	
Anode (positive pole):	$2\text{H}_2\text{O} \rightarrow 4\text{H}^+ + \text{O}_2 \uparrow + 4\text{e}^-$ $2\text{NaCl} \rightarrow \text{Cl}_2 + 2\text{e}^- + 2\text{Na}^+$ $\text{Cl} + \text{H}_2\text{O} \rightarrow \text{HCl} + \text{HOCl}$
Cathode (negative pole):	$2\text{H}_2\text{O} + 2\text{e}^- \rightarrow 2\text{OH}^- + \text{H}_2 \uparrow$ $2\text{NaCl} + 2\text{OH}^- \rightarrow 2\text{NaOH} + \text{Cl}^-$
*H-hydrogen, O-oxygen, Na-sodium, Cl-chlorine, e-transfer electron	

77 **Properties of the Substance:**

78 The physical properties and chemical composition (Table 2) of hypochlorous acid (EW) will vary
 79 depending on the concentration of NaCl solution, amperage level, time of electrolysis,
 80 temperature and pH (Wiant, C., 2013, Eryilmaz et al., 2013, Al-Haq et al., 2005). These properties
 81 impact the antimicrobial/sanitizing effects of hypochlorous acid (EW). Sanitizing means
 82 reducing the microorganisms of public health importance to levels considered safe, without
 83 adversely affecting either the quality of the product or its safety (Pfundtner, 2011).

Table 2. Chemical and Physical Properties of Hypochlorous acid (NCBI, 2015)	
Chemical formula	HOCl
Molar mass	52.46 g/mol
Appearance	colorless aqueous solution
Solubility in water	soluble
Number of H ⁺ bond acceptors	1
Number of H ⁺ bond donors	1
Density	1.4±0.1 g/cm ³
Dissociation constant (pKa)	7.53

84 The effectiveness of hypochlorous acid as an active sanitizing agent is determined in large part by
 85 the pH, a measure of the acidity or hydrogen ion concentration of the solution. Hypochlorous
 86 acid exists interchangeably with other chlorine species, including chlorine, hydrogen chloride
 87 (aqueous and gaseous) and hypochlorite. This is supported by the equilibrium chemistry of
 88 active chlorine. In a controlled pH environment, hypochlorous acid will exist as the dominant
 89 chlorine species under pH conditions ranging from 2 to 7.5 (Figure 2).

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91 Specific Uses of the Substance:

92 Electrolyzed water (EW) is produced by electrolysis of a dilute water-sodium chloride solution
93 flowing through specialized equipment designed to separate alkaline and acidic products (Fig. 1).
94 This electrolytic process facilitates the conversion of chloride ions and water molecules into
95 chlorine oxidants (chlorine gas, hypochlorous acid, and hypochlorite ion) within the anode
96 chamber and sodium hydroxide in the cathode chamber of the production equipment. At an
97 acidic to neutral pH, the predominant chemical species is hypochlorous acid (HOCl) with a high
98 oxidation reduction potential (ORP) of $\geq 1,000$ mV (Guentzel et al., 2008).

99 EW has received recent attention as an alternative to other chlorine disinfectants and sanitizers. A
100 number of studies have demonstrated the strong antibacterial activity of EW water against
101 foodborne pathogens on raw agricultural products and food contact surfaces. Applications of EW
102 as a disinfectant for reducing microbial contamination have been reported for fresh fruits and
103 vegetables, poultry carcasses, shell eggs, cutting boards, and food processing surfaces. Some
104 advantages of using EW water are: 1) EW is as effective as any chlorine treatment, 2) it is not
105 necessary to handle potentially dangerous chemicals, e.g. chlorine gas, chlorine dioxide, bleach,
106 3) the apparatus to produce EW is relative inexpensive and easy to operate, 4) because only water
107 and sodium chloride are used EW production is environmentally friendly and 5) the properties of
108 the EW can be controlled at the preparation site (Su et al., 2007).

109 In addition to its microbiocidal action on actively growing bacteria, EW water is known to kill
110 bacterial spores by damaging their inner membrane rendering them unable to germinate.
111 However, spore killing by hypochlorous acid differs from the action of chlorine dioxide, where
112 the killing action resembles hydrogen peroxide (Young and Setlow, 2003).

113 In their review of the scientific literature, Keskinen et al., 2009 reported that sanitizing washes are
114 the most practical means of decontaminating raw produce. In commercial value added produce
115 operations, solutions that contained chlorine compounds (with concentrations varying from 50-
116 200 ppm) and with contact times of 2 minutes or greater showed a decrease in the bacterial load
117 by from <1 log colony forming units (CFU)/gram (g) to 3.15 log CFU/g.

118 At a pH of 6.0-7.5 (neutral), EW (ORP=750 mV) contains primarily hypochlorous acid,
119 hypochlorite ion and trace amounts of chlorine. The effectiveness of neutral EW as a sanitizer has
120 been demonstrated for reducing *Escherichia coli* O157:H7, *Salmonella enteritidis* and *Listeria*
121 *monocytogenes* biofilms on the surface of tomato (Deza et al., 2003) and also on plastic and
122 wooden cutting boards (Deza et al., 2007).

123 EW has been reported to have strong bactericidal effects on many pathogenic bacteria, such as
124 *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* species (Kim et al., 2000).
125 Suppression of fruit rot in pears caused by the fungus *Botryosphaeria berengeriana* was observed
126 after dipping fruit in an EW water solution for as little as 10 minutes (Al-Haq et al., 2002).

127 EW quickly kills a variety of fungi and shows promise as a broad-spectrum contact fungicide for
128 control of foliar diseases of greenhouse-grown ornamentals. One requirement for use in the
129 greenhouse is that EW will not cause excessive phytotoxic symptoms on a wide variety of
130 species. EW causes slight damage to some plant species but, in general, appears to be safe to use
131 as a foliar spray on a wide variety of bedding plants grown under greenhouse conditions. Such
132 applications may be useful in reducing bacterial contamination resulting from insect scale and
133 known arthropod plant disease vectors (Buck et al., 2003).

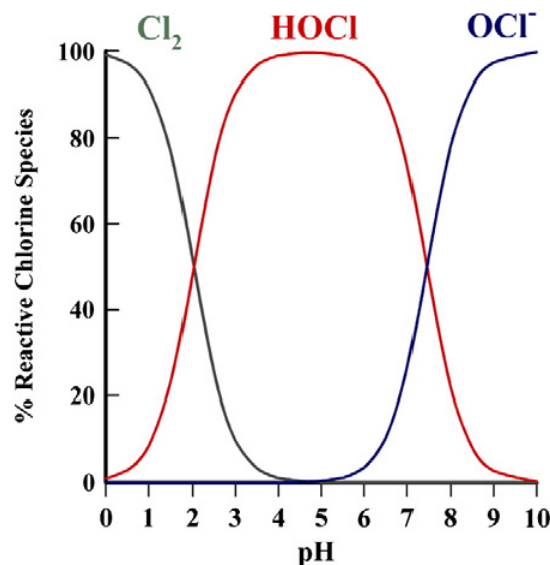
134 The practice of spraying or washing of eggshells with electrolyzed water has been found to both
135 reduce broiler mortality and microbial contaminations of shell eggs (Fasenko et al., 2009; Achiwa
136 and Nishio, 2002). Discoloration was not observed with the use of electrolyzed water.

137 The problem of corrosion to processing equipment or hand irritation is a lesser concern when
138 using neutral EW. Stainless steel is very resistant to chlorine products. The solution is stable and
139 chlorine loss is significantly reduced at pH 6–8 (Ayebah et al., 2005 and Len et al., 2002).

140 Chlorine compounds are widely used sanitizers. In some cases, there is a potential for chlorine
141 compounds used in sanitation to react with organic material (humic acid) which can lead to the
142 formation of potentially carcinogenic and teratogenic trihalomethanes and haloacetic acids. A
143 concern by the produce industry for the potential regulatory constraints on using chlorine in its
144 present form has increased efforts to identify and evaluate alternative sanitizing agents (Stevens,
145 1982). Although, most of the concern in this area refers to the use of chlorine gas in the sanitation
146 of drinking water, it is generally accepted that carcinogenic and teratogenic trihalomethanes and
147 haloacetic acids are not formed by the action of hypochlorous acid in neutral and near-neutral
148 solutions (Satyawli et al., 2007).

149 The use of chlorine products that form hypochlorous acid in solution at very low pH has limited
150 potential for long-term applications. At this pH <4.0, dissolved chlorine gas can be rapidly lost
151 due to volatilization, decreasing the biocidal effectiveness of the solution over time, but creating
152 human health and safety issues. The high acidity of the solution may adversely affect food
153 processing equipment and medical instruments surfaces by causing corrosion (Fisher, 2009).

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Fig. 2 The pH profile for reactive chlorine species

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The relative concentrations of molecular chlorine (Cl₂; green), hypochlorous acid (HOCl; red) and hypochlorite (OCl⁻; blue) were calculated at 140 mM chloride using $K = 1.3 \times 10^{-3} \text{ M}^2$ for reaction 1 and a pKa of 7.44 for the reaction $\text{HOCl} \rightarrow \text{OCl}^- + \text{H}^+$ (Kettle et al., 2014)

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Approved Legal Uses of the Substance:

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The Environmental Protection Agency (EPA, 2014) registers all sanitizers and disinfectants as pesticides. However, onsite EW devices (generators) that use sodium chloride and water to produce antimicrobial substances are not required to be registered as a pesticide. The manufacturer of the device must provide documentation that the device complies with 40 CFR 152.500 and the manufacturing establishment's registration number should be on the device.

169 Hypochlorous acid can be used as an ingredient in an antimicrobial pesticide formulation and
170 may be applied to dairy processing equipment, and food-processing equipment and utensils.
171 Hypochlorous acid is listed in 40 CFR §180.940, Tolerance exemptions for active and inert
172 ingredients for use in antimicrobial formulations (food-contact surface sanitizing solutions):

173 Pesticide Chemical: Hypochlorous acid

174 CAS No.: 7790-92-3

175 Limits: When ready for use, the end-use concentration of all
176 hypochlorous acid chemicals in the solution is not to
177 exceed 200 ppm determined as total available chlorine.

178 40 CFR 180.1054 provides an exemption from the requirement of a tolerance for calcium
179 hypochlorite:

180 (a) Calcium hypochlorite is exempted from the requirement of a tolerance when used
181 pre-harvest or postharvest in solution on all raw agricultural commodities.

182 (b) Calcium hypochlorite is exempted from the requirement of a tolerance in or on
183 grape when used as a fumigant postharvest by means of a chlorine generator pad.

184 The Food and Drug Administration (FDA) regulations (21 CFR Part 178) permit the use of
185 sanitizing solutions containing sodium hypochlorite on food processing equipment and food
186 contact surfaces. The active ingredients in these solutions are the chlorine oxidants hypochlorous
187 acid, hypochlorite ion and free chlorine:

188 The following provisions must be followed:

- 189 1) Equipment or articles sanitized with the solution must be allowed to drain
190 adequately before contact with food.
- 191 2) Solutions used for sanitizing equipment shall not exceed 200 parts per million
192 (ppm) of available chlorine.

193 In addition to sanitizing food contact surfaces, cleaning solutions containing the active ingredient
194 hypochlorous acid may be used for sanitizing raw fruits and vegetables during the washing or
195 peeling process. The federal regulations that apply differ slightly from those for sanitizing
196 solutions.

197 The regulations (21 CFR §173.315 - Chemicals used in washing or to assist in the peeling of fruits
198 and vegetables) specify two conditions for the permitted use of hypochlorite solutions in washing
199 produce:

- 200 1) The concentration of sanitizer in the wash water must not exceed 200 ppm
201 hypochlorite.
- 202 2) The produce must be rinsed with potable water following the chlorine treatment.
- 203 3) Contact times of one minute or greater are typically sufficient to achieve a
204 thorough kill.
- 205 4) Any chlorine ingredient that is used for making a sanitizing solution, whether for
206 equipment or raw produce, must be of sufficient purity to be categorized as a food
207 grade substance.

208 FDA's Food Code (FDA, 2013) states that chemical sanitizers, including chemical sanitizing
209 solutions generated on-site, and other chemical antimicrobials applied to food contact surfaces
210 shall (chapter 7-204.11 of the Food Code):

- 211 (A) Meet the requirements specified in 40 CFR 180.940 tolerance exemptions for active and
212 inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing
213 solutions) or

214 (B) Meet the requirements as specified in 40 CFR §180.2020 pesticide chemicals not
215 requiring a tolerance or exemption from tolerance-non-food determinations.

216 The criteria for chemicals for washing, treatment, storage and processing fruits and vegetable are
217 stated in chapter 7-204.12 of the Food Code:

218 (A) Chemicals*, including those generated on-site, used to wash or peel raw, whole fruits
219 and vegetables shall:

220 (2) Be generally recognized as safe (GRAS) for this intended use, or

221 (3) Be the subject of an effective food contact notification for this intended use
222 (only effective for the manufacturer or supplier identified in the notification),
223 and

224 (4) Meet the requirements in 40 CFR 156, Labeling Requirements for Pesticide and
225 Devices.

226 *Neither Hypochlorous acid nor EW is mentioned by name.

227 The USDA's Food Safety and Inspection Service Directive 7120.1 "Safe and Suitable Ingredients
228 Used in the Production of Meat and Poultry Products", has approved the use of electrolytically
229 generated hypochlorous acid as a food additive for use on meat and poultry products. It is
230 allowed for use on red meat carcasses down to a quarter of a carcass, whole or eviscerated
231 poultry carcasses, in water used in meat and poultry processing, in poultry chiller water, for
232 reprocessing contaminated poultry carcasses, on giblets and salvaged parts, and on beef primal
233 cuts of beef. Depending on the product sanitized from 5 to 50 ppm free available chlorine can be
234 used.

235 USDA's "Regulations Governing the Voluntary Grading of Shell Eggs" explains the minimum facility
236 and operating requirements for shell egg grading and packing plants regarding shell egg cleaning
237 operations. This includes specific temperature requirements for washing and rinsing eggs as well as
238 the chlorine sanitizer that will be used (USDA, 2008).

239 **Action of the Substance:**

240 This solution is generated by the electrolysis of a diluted water-sodium chloride solution passing
241 through on electrolysis chamber. This electrolytic process facilitates the conversion of chloride
242 ions and water molecules into chlorine oxidants (chlorine gas, hypochlorous acid, and
243 hypochlorite ion) within the anode chamber. At an acidic to neutral pH, the predominant
244 chemical species is hypochlorous acid (HOCl) with a high oxidation reduction potential (ORP) of
245 $\geq 1,000$ mV (Guentzel et al., 2008). The effectiveness of hypochlorous acid as an active sanitizing
246 agent is determined in large part by the pH. Hypochlorous acid exists interchangeably with other
247 chlorine species, including chlorine, hydrogen chloride (aqueous and gaseous) and hypochlorite
248 (Fig 2). The pH is believed to reduce bacterial growth and make the bacterial cells more sensitive
249 to active chlorine. Active chlorine compounds can destroy the membranes of microorganisms,
250 but other modes of chlorine action (e.g., decarboxylation of amino acids, reactions with nucleic
251 acids, and unbalanced metabolism after the destruction of key enzymes) have been reported as
252 well (Huang et al., 2008; Hricova et al., 2008; Guentzel et al., 2008; Young and Setlow, 2003).

253 In Huang's et al., 2008 review of the scientific literature, the authors suggested that hypochlorous
254 acid penetrates cell membranes and produces hydroxyl radicals, which exert their antimicrobial
255 activity through the oxidation of key metabolic systems. Hricova et al., 2008 reported that
256 researchers suggested that the high ORP is the determining factor for the antimicrobial activity of
257 acidic EW. The ORP of a solution is an indicator of its ability to oxidize or reduce, with higher
258 ORP values corresponding to greater oxidizing strength. The high ORP and low pH of acidic EW
259 seems to act synergistically with hypochlorous acid to inactivate microorganisms.

Combinations of the Substance:

Dilute mixtures of chlorine based compounds and water are very common and cost effective for use in methods for sanitizing equipment in food processing operations. Chlorine materials on the National Organic Program's (NOP) National List of Allowed and Prohibited Substances have been approved for a variety of uses as an algicide, disinfectant, sanitizer and others. Chlorine based methods are commonly used for equipment cleaning.

The chlorine containing substances are:

- Calcium hypochlorite, 7 CFR § 205.601(a)(2)(i), 205.603(a)(7)(i), and 205.605(b);
- Chlorine dioxide, 7 CFR § 205.601(a)(2)(ii), 205.603(a)(7)(ii), and 205.605(b);
- Sodium hypochlorite, 7 CFR §205.601(a)(2)(iii), 205.603(a)(7)(iii), and 205.605(b); and
- Acidified sodium chlorite, 7 CFR§ 205.605(b).

When water is added to these chlorine compounds the resulting reaction produces hypochlorous acid, hypochlorite ion and chlorine (Fig 2). At a pH of 6.5, 95% of the chlorine is in the hypochlorous acid form; maintaining the water pH at this range provides the greatest sanitizing effect. In a processing plant environment, sanitizers are used in the presence of organic matter, such as debris, soils and microorganisms present, all of which reduce the sanitizer efficacy. The solutions need to be monitored and refreshed to maintain desired bactericidal activity. Also, NOP regulations restrict the residual chlorine levels in the water at the discharge or effluent point to the maximum residual disinfectant limit under the Safe Drinking Water Act, (40 CFR Part 142) currently established by the Environmental Protection Agency (EPA) at 4 mg/L (ppm) for chlorine (NOP 5026-The use of Chlorine Materials in Organic Production and Handling).

Status

Historic Use:

In their review of the scientific literature, Hricova et al., 2008 reported that EW was originally developed in Russia, where it has been used for water decontamination, water regeneration, and disinfection in medical institutions. Since the 1980s, EW also has been used in Japan. One of the first applications of EW was the sterilization of medical instruments in hospitals. In the late 1990s, food safety concerns regarding foodborne pathogens found raw produce have caused researchers to look at and evaluate alternative sanitizers such as EW. With recent improvements in technology and the availability of better equipment, EW has gained popularity as an effective and environmentally friendly sanitizer for the food industry.

Acidic EW is generally recognized as safe and reported effective against pathogens on produce. It has been shown to be an economically favorable alternative to chlorinated water. Other advantages include: (1) EW is produced on site by the electrolysis of sodium chloride solution with the help of an electrolysis flow generator, and 2) there is no need for handling or storage of potentially dangerous chlorine materials in liquid or solid form (Stopforth et al., 2008).

Organic Foods Production Act, USDA Final Rule:

Known as electrolyzed water, hypochlorous acid is a synthetic substance not found on the National List of Allowed and Prohibited Substances (§7 CFR 205.600-606) for production and handling of organic products. This solution is generated by the electrolysis of a diluted water-sodium chloride solution passing through an electrolysis chamber (Fig 1). This electrolytic process facilitates the conversion of chloride ions and water molecules into chlorine oxidants (chlorine gas, hypochlorous acid, and hypochlorite ion). When used in accordance with good agricultural practice, electrolyzed water can be used as an effective and environmentally friendly sanitizing solution.

305 International

306 • Canada - Canadian General Standards Board Permitted Substances List – CAN/CGSB-32.311-
307 2006 Amended June 2011

308 <http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/bio-org/permises-permitted-eng.html>
309

310 Neither Hypochlorous acid (Sanitizer) nor Electrolyzed water is on the permitted substance list
311 for processing and handling of organic food.

312 • CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and
313 Marketing of Organically Produced Foods (GL 32-1999)

314 Neither Hypochlorous acid (Sanitizer) nor Electrolyzed water is on the permitted substance list
315 for processing and handling of organic food.

316 • European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008

317 Neither Hypochlorous acid (Sanitizer) nor Electrolyzed water is on the permitted substance list
318 for processing and handling of organic food.

319 • Japan Agricultural Standard (JAS) for Organic Production –

320 Japanese Agricultural Standard for Organic Processed Foods (Notification No. 1606 of the
321 Ministry of Agriculture, Forestry and Fisheries of October 27, 2005).

322 Foods additive list for processing and handling of organic food.

323 Hypochlorous acid water- Limited to be used for processed foods of plant origin (limited to those
324 made by electrolysis of saltwater), animal intestine as disinfection, or egg as cleansing

325 • The International Federation of Organic Agriculture Movements (IFOAM)
326 <http://www.organic-standards.info/en/documents>

327 Organic processing restricts disinfecting and sanitizing substances that may come in contact with
328 organic products to water and substances that are on (a) list(s) referenced by the standard. Such
329 lists are based on lists and/or criteria in international organic standards. In cases where these
330 substances are ineffective and others must be used, organic processing ensures that these other
331 substances do not come into contact with any organic products.

332 Neither Hypochlorous acid (Sanitizer) nor Electrolyzed water is on the permitted substance list
333 for processing and handling of organic food.

334 Evaluation Questions for Substances to be used in Organic Handling

335 **Evaluation Question #1: Describe the most prevalent processes used to manufacture or**
336 **formulate the petitioned substance. Further, describe any chemical change that may occur**
337 **during manufacture or formulation of the petitioned substance when this substance is**
338 **extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).**

339 Chlorine gas dissolves in water to form a mixture of hypochlorous acid (HOCl) and hydrochloric
340 acid (HCl). In aqueous solution, hypochlorous acid partially dissociates to form hypochlorite ions
341 (OCl⁻). An ion is an atom or molecule with an unequal number of protons and electrons giving
342 the atom or molecule a net positive or negative electrical charge. Chloric acid (HClO₃) also forms
343 from hypochlorous acid, but rapidly dissociates to chlorite ions (ClO₃⁻). Salt formation
344 (neutralization of an acid and a base) stabilizes ions and acids. Salts of hypochlorous acid are
345 called hypochlorites. Salts of chlorous acid are called chlorites.

346 Sodium hypochlorite and calcium hypochlorite are hypochlorous acid salts approved for use as
347 algaecides, disinfectants and sanitizers in organic production and handling. However, for pre-

348 harvest use (food sanitation) and uses where food may contact a disinfected or sanitized surface
349 the total combined concentration of hypochlorous acid and hypochlorite ions permitted for
350 organic production and handling may not exceed 4 ppm ([NOP 5026 “Guidance, the use of](#)
351 [Chlorine Materials in Organic Production and Handling.”](#)). Both calcium and sodium
352 hypochlorite may be used in the treatment of seeds for organic edible sprout production at the
353 level indicated on an environmental protection agency approved label for this application, which
354 is generally 20,000 ppm (§205.601(a)(2)(i and iii), §205.603(a)(7)(i and iii), (§205.605(b)). Two other
355 chlorine containing compounds, acidified sodium chlorite and chlorine dioxide are also approved
356 for disinfection and sanitation purposes in organic food production and handling. Hypochlorous
357 acid has not been reviewed by the NOSB for use in organic production and handling (NOP,
358 2014).

359 Sodium chloride (Salt—table salt) is an abundant mineral. Salt comes from mines or is processed
360 from ocean or mineral rich spring water. Salt (NaCl) occurs naturally in foods. In moderate
361 amounts it is necessary to support the metabolisms of all living organisms. When sodium
362 chloride is dissolved in water, it chemically separates into positively charged sodium ions (Na⁺)
363 and negatively charged chloride ions (Cl⁻). The separation is particularly easy because water has
364 a very high dielectric constant. The hydration numbers for Na⁺ and Cl⁻ respectively are 3 and 2.
365 The hydration number of an ion is the number of water molecules that have lost their
366 translational freedom because of their association with the ion. With a direct electric current
367 imposed on the brine solution, positive ions migrate toward the negative pole (commonly called
368 the cathode—cathodic pole) of a power source and negative ions migrate toward the positive pole
369 (commonly called the anode—anodic pole). This process is called electrolysis. Electrolysis is
370 simply a chemical method using electric current to drive an otherwise non-spontaneous reaction.
371 Electrolysis produces much higher concentrations of hypochlorite ions (hypochlorous acid) in the
372 solution.

373 The chlorine industry which produced over 72.8 million tons of chlorine in 2014 commonly uses
374 the electrolytic properties of sodium chloride (NaCl) in solution (brine) to manufacture chlorine
375 (European Commission, 2014). Brine electrolysis produces chlorine gas which both bubbles from
376 the brine solution when the pH is low and dissolves in water rapidly forming hypochlorous acid
377 when the pH is high. Inserting a semi-permeable membrane (perfluoracetate film) between the
378 two electrodes of an electrolysis device permits further concentration of the products of this
379 reaction. During membrane mediated electrolysis of brine at pH 4-7, hypochlorous acid
380 (electrolyzed water) forms at the anode (negatively charged hypochlorite ions in aqueous
381 solution) and sodium hydroxide forms at the cathode. Once concentrated hypochlorous acid and
382 sodium hydroxide solutions may be removed from the electrolysis system for use and replaced
383 by fresh brine (Fig 1).

384 **Evaluation Question #2: Discuss whether the petitioned substance is formulated or**
385 **manufactured by a chemical process, or created by naturally occurring biological processes (7**
386 **U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural**
387 **source.**

388 Hypochlorous acid as described for the petitioned use is a synthetic substance. The chemical
389 process that is used to produce hypochlorous acid from brine is called electrolysis. Salt (Sodium
390 chloride) and water used to make brine both occur naturally. Electrolysis is the use of direct
391 electric current to drive a chemical reaction that would not otherwise occur naturally or
392 spontaneously. A schematic apparatus for the production of electrolyzed water is provided (Fig
393 1). The formula based depiction of hypochlorous acid production that is demonstrated by this
394 apparatus is provided in Table 1 (Huang et al., 2008).

395 **Evaluation Question #3: If the substance is a synthetic substance, provide a list of**
396 **nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).**

397 There are no commercially available sources of natural hypochlorous acid. However, many
398 animals have a set of phagocytic cells that are protective against invasion of pathogenic bacteria
399 and employ various enzymatically mediated mechanisms including hypochlorous acid to
400 accomplish bacterial killing (Nakayasu et al., 2005). An example of an enzymatically mediated
401 adaptive immune response is the myeloperoxidase secreted by human neutrophils.
402 Myeloperoxidase which appears to be conserved and present in other animal species uses
403 hydrogen peroxide and chloride present during the adaptive immune response to produce
404 hypochlorous acid. Hypochlorous acid binds to bacterial membranes, modifying their proteins,
405 increasing their permeability and subsequently killing the bacteria (Prokopowicz et al., 2010). It
406 has also been shown that purified human myeloperoxidase is effective *in vitro* in killing bacteria
407 at neutral pH by catalyzing the production hypochlorous acid in the presence of hydrogen
408 peroxide and chloride (Sips and Hamers, 1981).

409 It was first shown that synthetically produced hypochlorous acid contained in electrolyzed water
410 with a free chlorine concentration of 10 to 80 ppm was effective in killing *Staphylococcus aureus*,
411 *Escherichia coli* and *Salmonella spp.* on laboratory and kitchen surfaces (Shimizu and Hurusawa,
412 1992; Venkitanarayanan et al., 1999).

413 **Evaluation Question #4: Specify whether the petitioned substance is categorized as generally**
414 **recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7**
415 **CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.**

416 Hypochlorous acid is not currently listed in 21 CFR 184, 184 or 186 as generally recognized as
417 safe. However, only two entries for hypochlorous acid are listed in the US Food and Drug
418 Administration's (FDA) [inventory of effective food contact substance \(FCS\) notifications](#). This
419 database lists effective premarket notifications in the United States for food contact substances
420 database that have been demonstrated to be safe for their intended use. Under section
421 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348 (h)(2)(C)) a food contact
422 substance notification (FCN) is only effective for the manufacturer or supplier identified in the
423 notification. Persons who market a FCS based on an effective notification must be able to
424 demonstrate that the notification is effective for their food contact substance. All persons who
425 purchase a food contact substance manufactured or supplied by a manufacturer or supplier
426 identified in an effective notification may rely on that notification to legally market or use the
427 food contact substance for the use that is the subject of the notification, consistent with any
428 limitations in that notification.

429 1) [FCN No. 1176](#)

430 [HSP USA, LLC](#) (According to Section 409(h)(1)(C) of the Federal Food, Drug, and
431 Cosmetic Act, food contact substance notifications (FCNs) are effective only for the
432 listed manufacturer and its customers. Other manufacturers must submit their
433 own FCN for the same food contact substance and intended use.)

434 Food Contact Substance: Hypochlorous acid (CAS Reg. No. 7790-92-3)

435 Notifier: HSP USA, LLC, Manufacturer: HSP USA, LLC

436 Intended Use: For use as an antimicrobial agent in a solution for the re-hydrating
437 of fresh fruits and vegetables including leafy green vegetables.

438 Limitations/Specifications*: The concentration of available free chlorine will be
439 limited to 60 ppm, and the food contact substance (FCS) will be replaced after use
440 if the concentration falls below 25 ppm available free chlorine. Leafy greens or
441 other uncut fruits and vegetables will be soaked in a 20 gallon solution of the FCS

442 in five pound loads for a minimum of five minutes and a maximum of ten
443 minutes. The FCS solution will drain off of the fresh produce for a minimum of ten
444 minutes before the produce is used for display or prepared for consumption.

445 FDA Decision: Finding of No Significant Impact (FONSI)

446 Effective Date: Aug 15, 2012

447 2) [FCN No. 1470](#)

448 [Sterilox Food Safety/Div. of PuriCore](#) (According to Section 409(h)(1)(C) of the
449 Federal Food, Drug, and Cosmetic Act, food contact substance notifications
450 (FCNs) are effective only for the listed manufacturer and its customers. Other
451 manufacturers must submit their own FCN for the same food contact substance
452 and intended use.)

453 Food Contact Substance: Hypochlorous acid (CAS Reg. No. 7790-92-3)
454 electrolytically generated in dilute solution.

455 REPLACES FCN 692

456 Notifier: Sterilox Food Safety/Div. of PuriCore, Manufacturer: Sterilox Food
457 Safety/Div. of PuriCore

458 Intended Use: For use as an antimicrobial agent in solutions used to re-hydrate
459 fresh and fresh-cut fruits and vegetables.

460 Limitations/Specifications*: On-site generation of the FCS solution will occur at
461 least every 24 hours. The concentration of available free chlorine will not exceed 60
462 ppm, and the FCS solution will be replaced if the concentration falls below 25 ppm
463 available free chlorine. Fresh and fresh-cut produce may be treated with the FCS
464 solution by soaking for 90 seconds to 10 minutes or by spraying. After treatment,
465 the produce will be allowed to drain for no less than 10 minutes before it is placed
466 on display or prepared for consumption.

467 FDA Decision: [Finding of No Significant Impact \(FONSI\)](#)

468 Effective Date: Jan 1, 2015

469 The FDA Food Code describes the generation of hypochlorous acid (electrolyzed water, electro
470 chemically activated water, elector activated water) through on-site technology and refers the
471 user of these technologies to seek efficacy data from the equipment manufacturers, since the EPA
472 does not require registration for this type of equipment (FDA, 2013).

473 **Evaluation Question #5: Describe whether the primary technical function or purpose of the**
474 **petitioned substance is a preservative. If so, provide a detailed description of its mechanism**
475 **as a preservative (7 CFR § 205.600 (b)(4)).**

476 The primary technical function of hypochlorous acid is disinfection of food and food contact
477 surfaces used in the production and handling of food. A disinfectant is a chemical agent that
478 helps eliminate undesirable microorganisms from inanimate environmental surfaces. It is similar
479 to an antiseptic, except that antiseptics are used on living tissue. A sanitizer is a chemical or
480 physical agent that reduces microorganism contamination levels on inanimate environmental
481 surfaces (Martinez, 2009). Hypochlorous acid is also used for disinfecting foods such as meat,
482 eggs or fresh produce preventing bacterial and fungal growth and extending shelf life. A biostatic
483 agent inhibits the growth of microorganisms (Martinez, 2009). The desirable effect of
484 disinfectants on the sensory properties of fresh-cut vegetables is preserving quality and slowing
485 down deterioration. Hypochlorous acid at a concentration of 50 ppm did not significantly affect
486 quality characteristics such as color and general appearance as well as visual quality of fresh-cut

487 lettuce and carrots. However, when the concentration was increased to 240 ppm, it caused
488 detrimental effects on fresh-cut lettuce resembling leaf burn despite showing a significantly
489 higher reduction of *E. coli* O157:H7 (Gil et al., 2015). A study of California consumers' attitudes
490 toward organically grown lettuce indicated that the most desirable quality attributes irrespective
491 of production and handling methods are freshness, value, free of insects, and safe for workers
492 (Wolf et al., 2002).

493 **Evaluation Question #6: Describe whether the petitioned substance will be used primarily to**
494 **recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when**
495 **required by law) and how the substance recreates or improves any of these food/feed**
496 **characteristics (7 CFR § 205.600 (b)(4)).**

497 Hypochlorous acid is not a flavoring agent, a colorant, a texturizer or a nutritional supplement.
498 Its technical function is primarily as a disinfectant of food and food contact surfaces. It can be
499 added to solutions used for washing or spraying food products to reduce microbial
500 contamination consisting of bacteria and fungi that cause spoilage.

501 **Evaluation Question #7: Describe any effect or potential effect on the nutritional quality of**
502 **the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).**

503 Red radish seeds infected with *Listeria monocytogenes* responded differently to decontamination
504 treatment with 20,000 ppm calcium hypochlorite, 50 and 100 ppm chlorinated water, acidic
505 electrolyzed water (60-80 ppm hypochlorous acid), low-alkaline electrolyzed water (60-80 ppm
506 hypochlorous acid), and ozonated water compared to distilled water treated control seeds.
507 Treatments with 20,000 ppm calcium hypochlorite, acidic and low-alkaline electrolyzed water
508 were more effective than treatments with chlorinated water and ozonated water. Immersion in
509 20,000 ppm calcium hypochlorite resulted in a 1000 fold microbial reduction, while treatments
510 with acidic and low-alkaline electrolyzed water reduced aerobic plate count (APC) by 1000 fold
511 and *L. monocytogenes* counts by 100 fold. After sprouting, APC and *L. monocytogenes* counts on
512 seeds treated with 20,000 ppm calcium hypochlorite, acidic and low-alkaline electrolyzed water
513 were significantly lower than the control. The germination rate ranged from 93.5% to 97.7%
514 except for 20,000 ppm calcium hypochlorite (from 82.3% to 84.8%) after 48 hours (Kim et al.,
515 2010).

516 Naturally contaminated shelled peanuts with aflatoxin B1 levels greater than 34.8 parts per
517 billion (ppb) treated with hypochlorous acid at pH 3.0 showed a significant reduction in aflatoxin
518 level after treatment (>5 ppb): an 85% decrease. Aflatoxin B1 is a powerful toxin produced by
519 *Aspergillus spp.* mold. It is known to contaminate peanuts and is potentially carcinogenic. Protein,
520 lipid and carbohydrate levels did not significantly leading to the conclusions that treatment with
521 hypochlorous acid reduced aflatoxin B1 levels but did not affect peanut nutrition (Zhang et al.,
522 2012).

523 Drying is traditionally used to preserve fish. However, bacteria present during the drying process
524 can affect both nutrition and organoleptic properties of the dried products. Drying carp filets
525 with thymol and carvacrol (oil of oregano) after treatment with electrolyzed water significantly
526 reduced fat oxidation, protein degradation and improved the overall organoleptic and flavor
527 profile of the product when compared to no treatment. This process had a greater antimicrobial
528 and antioxidant effect than other treatments, and resulted in good preservation of carp fillets
529 during the drying process. (Mahmoud et al., 2006). However, National Organic Program
530 regulations do not currently allow for the certification of fish (7 CFR Part 205).

531 The pesticides acephate, omethoate and dimethyl dichlorovinyl phosphate are commonly used as
532 broad-spectrum insecticides in pest control for conventional agriculture and high-residual levels
533 are frequently detected in vegetables. The use of these pesticides is prohibited in organic
534 production and handling. Electrolyzed water (70 ppm chlorine) can effectively reduce the

535 concentration of acephate, omethoate and dimethyl dichlorovinyl phosphate residues on fresh
536 spinach, cabbage and leek more effectively than tap water alone. Reduction ranged from 46% to
537 74%. It may be possible to mask the use of some pesticides in organic production with the use of
538 electrolyzed water. In addition, electrolyzed water did not affect the contents of ascorbic acid
539 (vitamin C) suggesting that using electrolyzed water to wash vegetables would not result in loss
540 of nutrition (Hao et al., 2011).

541 **Evaluation Question #8: List any reported residues of heavy metals or other contaminants in**
542 **excess of FDA tolerances that are present or have been reported in the petitioned substance (7**
543 **CFR § 205.600 (b)(5)).**

544 It is well known that chlorine rapidly hydrolyzes to near completion in water forming
545 hypochlorous acid (HOCl), hypochlorite (OCl-) and Cl₂. The relative concentration of these
546 species is pH dependent. At pH 6-7, hypochlorous acid is the dominant species at 90%. At pH 8,
547 hypochlorite is the major species. Since it is produced at pH 6-7 and concentrated by membrane
548 mediate electrolysis of brine, electrolyzed water contains mostly hydrochlorous acid at
549 concentrations 60-80 ppm (Fukayama et al., 1986). Furthermore, of the three aqueous species,
550 hypochlorous acid is the primary bactericidal agent in aqueous chlorine, possessing
551 approximately 80% of the germicidal potency of hypochlorite (White, 1972). Thus, higher level
552 total chlorine requirements for the use of sodium or calcium hypochlorite in disinfection or
553 sanitation may not be applicable to the use of hypochlorous acid since its germicidal capacity is
554 greater at a lower total chlorine concentration.

555 Hypochlorous acid at low pH and high concentration is unstable and decomposes to halogenated
556 chemical species: chlorine, chlorite, chlorate and trihalomethanes (THMs) including:
557 bromodichloromethane, dibromochloromethane and bromoform) and oxygen (EPA, 2014).

558 Hypochlorous acid is electrophilic and can react with organic compounds such as those present
559 in agricultural commodities and products. Chlorine in hypochlorous acid is likely to combine
560 with an electron pair in ammonia, amines, phenols and other aromatics present in organic
561 substrates. Substrates can include carbohydrates, lipids and proteins. Radiolabeled chlorine was
562 followed in during an immersion process for shrimp in 150 ppm hypochlorous acid. It was found
563 that 1.5% (2.25 ppm) of the labeled chlorine was found in the edible portion of the shrimp.
564 Chlorine from hypochlorous acid, usually at concentrations at or above 200 ppm has been found
565 to bind to lipid, proteins and carbohydrates of immersed meat, poultry and fish although at low
566 levels. At higher chlorine treatment levels (>200 ppm) there is potential for the formation of
567 chloroform at very low levels in meat products (Fukayama et al., 1986).

568 Contaminants listed in the [US Food and Drug Administration's Guidance for Industry: Action](#)
569 [Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed](#) are unlikely to
570 be found in hypochlorous acid since it is the electrolysis product of two generally recognized as
571 safe materials, salt and water.

572 **Evaluation Question #9: Discuss and summarize findings on whether the manufacture and**
573 **use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. §**
574 **6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).**

575 Chlorine is widely used to disinfect drinking water and wastewater prior to discharge, and when
576 used appropriately, its role in preventing the spread of waterborne infectious diseases is well
577 established. Low levels of residual chlorine, however, can be harmful to aquatic life if drinking
578 water or heavily chlorinated waste-water is discharged into the environment. Australian
579 cladocerans are small crustaceans similar to North American daphnia. They are particularly
580 sensitive to chlorine in their environment. At pH 7.5-8.3 where a high proportion of aqueous
581 chlorine is expected to be hypochlorite, the lowest concentration of total chlorine in a one hour
582 exposure to have an effect on them was 0.28 ppm. The eastern king prawn is endemic to

583 Australia coastal waters. In similar chlorine toxicity studies on these crustaceans in saltwater the
584 lowest effective concentration was 0.12 ppm (Manning et al., 1996). Although hypochlorous acid
585 would be more reactive for crustaceans at pH below 7.0, the molecular form of aqueous chlorine
586 in their native condition is hypochlorite.

587 Chlorine gas was first registered in the US in 1948, as a disinfectant for swimming pool, drinking
588 water, cooling towers and sewage systems. In 1991, it was declared exempt from the requirement
589 for a tolerance except for use on raw agricultural commodities because measurable residues were
590 not expected. Hypochlorous acid, one of the two chlorine hydrolysis products is an oxidizing
591 agent having a sanitizing effect on organic and inorganic contaminants. When treated effluent is
592 released into receiving waters, free residual chlorine dissipates rapidly with a half-life of 1.3 to 5
593 hours. The ultimate fate of chlorine containing effluent is site specific and depends on factors
594 such as the chemical constituents of their receiving waters, their temperature, the dilution ratio
595 and the intensity of sunlight (EPA, 1999).

596 In studies with lithium chloride, which forms hypochlorous acid in aqueous solutions at pH <
597 7.0, toxicity to birds was minimal on a sub-acute dietary basis. However, hypochlorous acid was
598 found to be very toxic to fish and freshwater invertebrates. Levels of concern were 0.009 ppm for
599 aquatic invertebrates, 0.023 ppm for freshwater fish and 0.013 ppm for estuarine organisms.
600 Levels for endangered species were 0.00085 ppm for aquatic invertebrates, 0.0023 ppm for
601 freshwater fish and 0.0013 for estuarine invertebrates (EPA, 1999).

602 Diluted aqueous solution of hypochlorous acid decomposes very slowly in the dark but more
603 rapidly in the presence of light, particularly rapidly in full sun light, by producing hydrogen
604 chloride and oxygen. Some chlorine and chloric acid may also develop. Chlorine released into the
605 environment is distributed into water and preferably air. In water and in atmosphere
606 chlorine/hypochlorite undergoes photolysis with an estimated half-life of 1-4 hours, depending
607 on the time of the day. In natural water, in the presence of organic or inorganic compounds, the
608 free available chlorine immediately reacts forming various chlorinated by-products e.g.
609 chloramines and chloromethanes which are mainly distributed to the hydrosphere, but are also
610 able to transfer to some extent to the atmosphere depending on their intrinsic properties. A
611 potential for bioaccumulation or bioconcentration of active chlorine species can be disregarded,
612 because of their water solubility and their high reactivity.

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

616 In general, hypochlorous acid at pH 6.5-7.5 is safer to use than other chlorine containing
617 disinfectants. The concentration of chlorine present in electrolyzed water is usually over ten
618 thousand times less than household bleach. There is also the advantage of its production on site,
619 alleviating the need to transport dangerous material. Chlorine in the form of hypochlorous acid is
620 one of the most effective disinfectant and sanitizer for reduction and removal of foodborne
621 pathogens.

622 Chlorine bleach, or hypochlorous acid, is the most reactive two-electron oxidant produced in
623 appreciable amounts in our bodies. It is very toxic and oxidizes cell membranes. Neutrophils are
624 the main source of hypochlorous acid. The human innate immune system uses hypochlorous acid
625 to fight infection but also directs it against host tissue in inflammatory diseases (Kettle et al.,
626 2013). Hungarian obstetrician Dr Ignaz Phillip Semmelweis (July 1, 1818–August 13, 1865) is
627 attributed with recognizing the cause of puerperal sepsis (child bed fever) and introducing
628 chlorine handwashing for the first time to prevent this disease. The medical term used to describe
629 the chlorine hand microbicide developed by Semmelweis was *chlorina liquida* (Noakes et al.,

2007). It was hypochlorous acid. Hypochlorous acid is reactive with a wide variety of organic substances including proteins, carbohydrates and lipid (Deborde and Gunten, 2008).

Neutrophils are highly specialized for their primary function, the phagocytosis and destruction of microorganisms. Microorganisms in blood or tissue are coated with opsonins (generally complement and/or antibody). The coated microorganisms bind to specific receptors on the surface of the neutrophils, phagocytized incorporating the microorganism into an intracellular vesicle (phagocytosis). Hydrogen peroxide is first secreted from membrane bound respiratory enzymes and floods the vesicle. A neutrophil enzyme, myeloperoxidase (MPO) is also released into the vesicle with the hydrogen peroxide (H_2O_2), as well as a halide, particularly chloride. The primary product of the MPO- H_2O_2 -chloride system is hypochlorous acid. Subsequent formation of chlorine, chloramines, hydroxyl radicals, singlet oxygen, and ozone has also been proposed. These same toxic agents can be released to the outside of the cell, where they may attack normal tissue and thus contribute to the pathogenesis of disease, e.g. atherosclerosis, renal injury, carcinogenesis, lung injury, multiple sclerosis, cystic fibrosis, Alzheimer's disease, brain infarction and Parkinson's disease. The MPO system, *vis à vis* hypochlorous acid plays an important role in the microbiocidal activity of phagocytes including monocytes and neutrophils (Sips and Hamers, 1981; Klebanoff, 2005). Antigens are label by the action of hypochlorous acid, making them better substrates for immune presentation and ultimately for the production of antibodies in the antibody mediated immune response (Prokopowicz et al., 2012).

Although the ingestion of chlorine gas is unlikely, solutions of chlorine may pose hazard by this route of exposure (OECD, 2003). Poisoning incidents involving accidental ingestion of household bleach, chlorine has caused a burning sensation in the mouth and throat, irritation to the digestive tract and stomach, and vomiting. Exposure to chlorine gas causes effects ranging from bronchitis, asthma and swelling of the lungs, to headaches, heart disease and meningitis. Acute exposure causes more severe respiratory and lung effects, and can result in fatalities. (EPA, 1999). Available chlorine is readily absorbed via oral route and distributed into plasma, bone marrow, testis, skin, kidney and lung. Only ca. 50% is excreted mainly with the urine followed by excretion with feces. HOCl is not enzymatically metabolized and its (bio) transformation readily occurs through direct reactions with organic compounds or with other chemicals present in the cellular environment, leading to the formation of chlorinated organic compounds possessing their own inherent toxicity (OECD, 2003). More often, however, the effects are not permanent; complete and rapid recovery generally occurs with treatment (EPA, 1999).

Chlorine disinfectants have been shown to cause occupational dermatitis or irritation of the skin. People who are asthmatic or allergic to chlorine may be at high risk for adverse reactions after inhaling or ingesting chlorine, for example, after drinking treated water (EPA, 1999). No information is available on any potential systemic toxicity that can be caused by dermal route as no dermal acute toxicity studies are available for both chlorine or hypochlorite salts solutions. It can be expected to be low considering the low acute systemic toxicity by the oral route (OECD, 2003).

Pursuant to 40 CFR §180.1095, Chlorine gas is exempt from the requirement of a tolerance when used pre- or postharvest on all raw agricultural commodities. Use of chlorine in food processing water systems to prevent decay of raw agricultural commodities may result in residues on treated produce; however, finite residues or residues above naturally occurring background levels are not expected. Similarly, if livestock ingest chlorine treated water, finite residues or residues above background levels are not expected to occur in meat, milk or eggs. Chlorine gas used as a food contact surface sanitizer on food, meat or poultry processing premises and equipment is under FDA's regulatory purview. EPA regulates contaminants in drinking water under the Safe Drinking Water Act (SDWA). The Office of Drinking Water has established a

678 Maximum Residual Disinfectant Level (MRDL) of 4 mg/L for chlorine. An MRDL is an
 679 enforceable Federal Standard (EPA, 1999).

680 Risk to the public is not anticipated from consuming food or water treated with chlorine.
 681 Although residues may remain on fruits and vegetables as a result of their treatment with
 682 chlorine solution, these residues are exempt from tolerance requirements and are not believed to
 683 pose risks. Residues above background levels are not expected in meat, milk or eggs as a result of
 684 chlorine use in drinking water. Use of chlorine to sanitize food contact surfaces and food
 685 processing equipment presumably does not result in residue of concern in foods (this use is
 686 under FDA's jurisdiction). EPA's Office of Drinking Water regulates chlorine in drinking water
 687 supplies under the SDWA (EPA, 1999).

Table 3. Disinfection methods with their advantages and disadvantages

Treatment	Advantages	Disadvantages
Sodium hypochlorite Calcium hypochlorite Chlorine dioxide Acidified Sodium Chlorite	Chlorine based disinfectants, very effective at killing most microorganisms including spores. Liquids best used at pH 6.5-7.5.	After use concentration must be less than 4 ppm. Can damage products at high concentrations. Issues with humic acids.
Ozone	Effective disinfectant kills rapidly.	Must be produced on site, harmful to humans. Not approved for organic production and handling.
Irradiation	Very effective disinfectant.	May affect sensory qualities of products, harmful to humans. Ionizing radiation is not permitted in organic production.
Hydrogen Peroxide (H ₂ O ₂)	Potential as disinfectant.	Affects sensory qualities of some products, harmful to humans and not applicable to all products.
Organic Acids	Effective alone or in combination with other sanitizers, simple products such as lemon juice, or vinegar may be used.	Not useful for all products, may have adverse effects on sensory qualities, may lead to loss of germination percentage when used on seeds.
Essential Oils	Most effective for gram positive bacteria.	Gram negative bacteria are more resistant, adverse sensory effects.
High Temperatures	Successful disinfection method.	Not applicable to all products consumed raw.
Biocontrol and non-thermal process	Not well tested in fruit and vegetable products.	High cost, not enough research.

Cooper et al., 2007

688 A no-observed-adverse-effect level (NOAEL) of 950 ppm available chlorine (59.5 milligram
 689 (mg)/kilogram (kg) body weight (bw)/day) can be derived from a 13-week rat study with
 690 sodium hypochlorite in drinking water. A NOAEL of 14 mg/kg bw/day for rats and a NOAEL

691 of 22.5 mg/kg bw/day for mice can be derived from a two year study with sodium hypochlorite
692 in drinking water. No evidence of treatment related carcinogenicity was observed in mice and
693 rats exposed by inhalation to chlorine and orally to sodium hypochlorite, but some equivocal
694 results were reported for female rats by oral route. For human cancer no association between
695 chlorine exposure and tumor incidence was observed (OECD, 2003).

696 **Evaluation Question #11: Describe any alternative practices that would make the use of the**
697 **petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).**

698 Chlorine in different forms has been traditionally preferred for disinfection. There are a few
699 alternatives such as ozone or other gas treatments, UV irradiation, different organic acids,
700 essential oils and mild heating (Cooper et al., 2007). Heat is a reliable method eliminating
701 contamination for some products, e.g. after washing the article can be dried at 80°C or higher for
702 2 hours or more to remove contamination. Microwave treatment or infrared radiation can also be
703 used to heat the material. Ultraviolet light produces a maximum bactericidal effect at 240-280 nm.
704 It is useful for non-porous surface, but has limited use for porous surfaces and is potentially
705 destructive to produce, meat or fish. Pasteurization kills microorganisms, but does not kill
706 bacterial spores (CDC, 2008). Water can be pasteurized prior to use in crisping greens. Some
707 advantages and disadvantages are provided in Table 3. A handler is prohibited from using
708 ionizing radiation in or on agricultural products intended to be sold as “organic.” Ionizing
709 radiation cannot be used in or on any ingredients labeled “organic” (7 CFR 205.105; 21 CFR
710 179.26). Radiation sources such as radiofrequency (microwave) used for heating food (21 CFR
711 179.30) and ultraviolet for food processing and treatment (21 CFR 179.39) are not ionizing
712 radiation per the US Food and Drug administration definition (21 CFR 176.26).

713 The safe drinking water act requires that drinking water depending on its source meets specific
714 criteria determining the need for a combination of filtration and treatment with chlorine to
715 remove pathogenic organisms. Chlorine is described in the [Safe Drinking Water](#) act as an
716 alternative to filtration. Water can also be filtered through a 0.22 micron or less filter to remove
717 bacteria (CDC, 2008).

718 **Evaluation Question #12: Describe all natural (non-synthetic) substances or products which**
719 **may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of**
720 **allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m)**
721 **(6)).**

722 Isopropanol (CAS No. 67-63-0) and ethanol (CAS No. 64-17-5) are aliphatic alcohols both
723 permitted substances in organic crop and livestock production. Respectively, as synthetic
724 substances allowed for use as algicides, disinfectants, and sanitizers §205.601(a)(1)(ii) and
725 §205.601(a)(1)(i) in organic crop production and §205.603(a)(1)(ii) and §205.603(a)(1)(i) as in
726 organic livestock production (USDA, 2014a; 2014b). Organically produced ethanol is marketed
727 and available commercially for organic handling. Isopropanol is only available in synthetic form
728 and is not allowed in organic handling. Isopropanol is a high production volume chemical used
729 in many industrial and consumer products as a disinfectant. It does not persist in the
730 environment and has been well characterized in mammalian/human toxicological studies
731 (OECD, 1997).

732 Sodium and calcium hypochlorite, better known as bleach, are widely used compounds whose
733 chemical and toxicological properties are extensively documented in published literature. These
734 chemicals were first registered for use as pesticides in 1957. Sodium and calcium hypochlorite are
735 chlorinated inorganic disinfectants used to control bacteria, fungi, and slime-forming algae that
736 can cause diseases in people and animals (EPA, 1991, 1992; USDA, 2006a, Ricke et al., 2012).
737 These disinfectants also are used in cleaning irrigation, drinking water, and other water and
738 wastewater systems.

739 Chlorine dioxide is an antimicrobial disinfectant and pesticide used to control harmful
740 microorganisms including bacteria, viruses, and fungi on inanimate objects and surfaces
741 primarily in indoor environments. It is used as a food disinfectant (e.g., for fruit, vegetables,
742 meat, and poultry), for disinfecting food processing equipment, and treating medical wastes,
743 (EPA, 2003; USDA, 2006a).

744 Copper sulfate is used as a fungicide and algicide for organic production (USDA, 2011; 2015a).
745 Ethanol is used for disinfection of production tools and surfaces, plant regulation (ripening) and
746 topical disinfection (USDA, 2014b). Hydrogen peroxide is used as an algicide and fungicide in
747 greenhouses and horticultural settings, applied to greenhouse structures and surfaces as well as
748 greenhouse seeds, soils and plants (USDA, 2015b). Ozone gas has been for the treatment of
749 drinking water, as a disinfectant and sanitizer (USDA, 1995; 2002). Peracetic acid is used in food
750 processing and handling is as a sanitizer for food contact surfaces and as a disinfectant for fruits,
751 vegetables, meat, and eggs (USDA, 2000). Phosphoric acid is used in food processing and
752 handling is as a sanitizer for food contact surfaces and as a disinfectant (USDA, 2003). Soaps are
753 used as algicides and demossers in organic crop production (USDA, 2015c).

754 Sodium carbonate peroxyhydrate is used applications where the use of liquid hydrogen peroxide
755 is impractical. Sodium carbonate peroxyhydrate provides the same oxidative/reductive action of
756 hydrogen peroxide in a solid form making it an easy to use source of hydrogen peroxide for
757 environmental control. Hydrogen peroxide acts as both a chemical oxidant and reducing agent,
758 as a supplier of molecular oxygen (USDA, 2014c).

759 **Evaluation Information #13: Provide a list of organic agricultural products that could be**
760 **alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).**

761 Sodium chloride can be used to disinfect surfaces and water at concentrations greater than 10%
762 (Somani et al., 2011). The antimicrobial efficacy of citric acid has been documented against
763 foodborne microorganisms in fluid medium (Ricke et al., 2012). Organic Acids (e.g., acetic acids,
764 ascorbic acid, citric acid, lactic acid, lactates, tartaric acid, malic acid and vinegar) and essential
765 oils have been used as disinfectants (Table 3) with varying amounts off success (Cooper, 2007;
766 Ricke et al., 2012).

767 Nisin and the bacteriocins are bacterial polypeptides produced by the bacterium, *Streptomyces*
768 *lactis* with antimicrobial properties (Ricke et al., 2012). Although they can be naturally produced,
769 many are produced via recombinant technology. They are prohibited from use in organic
770 production and handling. Nisin was reviewed by the NOSB in 1995 (USDA, 1995).

771 Egg white lysozyme has also been used as an antimicrobial (Ricke, 2012). Biopreservation with
772 protective bacterial cultures known as spoilers can also be used (Ricke, 2012). Water can be used
773 to rinse surfaces and food. Hot water, near 100°C will reduce microbial contamination.

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