

Environmental Assessment

1. Date:

October 28, 2024 *

2. Name of Notifier:

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4. Description of Proposed Action

(a) Requested Action and Need for Action

This action requests inclusion of the Energis Solutions chlorine dioxide manufacturing method (also referred to as the Electro-BioCide manufacturing method), an electrolytic method for generating chlorine dioxide from a brine solution containing sodium chloride salts, as an allowed method of generating chlorine dioxide. Electro-BioCide will be used in similar ways and in accordance with current use/use level regulations for which chlorine dioxide is already approved. The chlorine dioxide antimicrobial agent reduces or inhibits the growth of pathogenic and non- pathogenic microorganisms that may be present on and in food to provide safer food for consumers. The Electro- Biocide method of chlorine dioxide generation provides an additional resource to food processors so they may better respond to microbial pressures present in their processing systems.

(b) Location(s) of Use/ Disposal

The Electro-BioCide method will be used to generate high purity (i.e., > 90%) chlorine dioxide for use in the preparation of aqueous chlorine dioxide solutions for use as an antimicrobial agent intended for treatment of raw agricultural grains, fruits, vegetables, meat (including poultry), flour, seeds, and seafood consistent with currently permitted uses of chlorine dioxide under 21 CFR § 173.300 and 21 CFR § 173.325. Electro-BioCide will be generated as a 0.08% solution and subsequently packaged for sale as a ready to use product that can be used later at the point of application. It is intended for use in processing plants and facilities throughout the United States. It may also be used aboard fishing vessels to cool and process fresh-caught seafood. The Electro-BioCide method produces no traditional effluent as the chlorine dioxide and other chlorinated products formed during the manufacturing procedure are reincorporated to enhance and stabilize the resulting aqueous chlorine dioxide solution. Following use, it is expected that these facilities will discharge remaining treated water to publicly owned treatment works (POTWs) or following on-site water treatment to discharge directly to surface waters in accordance with a permit issued under the National Pollutant Discharge Elimination System (NPDES). Wastewater

*Subsequent to this date, this EA was edited using the Adobe text editor tool to make several minor corrections of an editorial nature to correct typographical errors and to remove outdated or extraneous language.

from fishing vessels is expected to be disposed into the ocean.

Intended use:

As an antimicrobial agent:

1. in water used in the processing of poultry, red meat, fish, and seafood.
2. in water used to wash fruits and vegetables that are raw agricultural commodities (RAC), and to wash fruits and vegetables that are not RAC.
3. as a spray on grains (wheat, barley, oats, rice, rye, corn, millet, sorghum, spelt, triticale), pulses (peas, beans, chickpeas, soybeans), edible seeds (amaranth, chia, flax, quinoa, sesame, buckwheat), and nuts (peanuts, almonds, cashews, chestnuts, Brazil nuts, hazelnuts, pecans, macadamia, pistachio, walnuts), except for use in contact with infant formula or infant formula ingredients and human milk (see Limitations/Specifications).

Limitations and specifications

1. The FCS will be used in an amount not to exceed 3 ppm residual chlorine dioxide as determined by Method 4500-CLO₂-D.
2. When used on fruits and vegetables that are raw agricultural commodities (RAC), the FCS will be applied in the preparing, packing, or holding of food for commercial purposes, consistent with the FD&C Act section 201(q)(1)(B)(i), but not applied for use under 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II), or (q)(1)(B)(i)(III). Treatment of all fruits and vegetables shall be followed by a potable water rinse, blanching, cooking, or canning.
3. When used on grains (wheat, barley, oats, rice, rye, corn, millet, sorghum, spelt, triticale), pulses (peas, beans, chickpeas, soybeans), edible seeds (amaranth, chia, flax, quinoa, sesame, buckwheat), and nuts (peanuts, almonds, cashews, chestnuts, Brazil nuts, hazelnuts, pecans, macadamia, pistachio, walnuts), the FCS will be applied in the preparing, packing, or holding of the food for commercial purposes, consistent with the FD&C Act section 201(q)(1)(B)(i). Treatment of all grains, pulses, edible seeds, and nuts shall be followed by a potable water rinse, blanching, cooking, or canning.

5. Identification of Chemical Substances that are the Subject of the Proposed Action

(a) Chemical Information for the Subject Food Contact Substance (FCS), Precursor chemicals and Impurities

The subject FCS of this notification, chlorine dioxide, is presented below.

1. Chemical Name	Chlorine Dioxide
2. Synonyms	Chlorine Oxide, Chlorine (IV) Oxide
3. CAS Registry Number	10049-04-04
4. Formula and Structure Molecular Weight	ClO ₂ and O=Cl=O 67.45 g/mole
5. Properties	
Melting point	-59 °C
Boiling point	11 °C
Solubility	3.01 g/l (@25 °C and 34.5 mm Hg)

{b) Use Rates

Electro-BioCide is a method to electrolytically generate chlorine dioxide by electrolysis of a brine solution containing chloride salts. Chlorine dioxide is added at a maximum treatment level in food at 0.08% (800 ppm). A maximum residual chlorine dioxide concentration level of 3 ppm is specified by Section 173.300 for use on fruits and vegetables and for use in poultry processing. These approved levels established for previously approved generators are equally appropriate for electrolytic methods of chlorine dioxide generation since the same food

contact substance, chlorine dioxide, is generated. Residual analysis has demonstrated that the residual levels of chlorine dioxide generated by Electro-BioCide range from 0.084 mg/kg (ppm) to below the limit of detection. The methods used to analyze residual levels were the TK00C-Total Residual Chlorine (DPD) method for chlorine (which measures chlorine dioxide) (reference SM4500Cl-G 2000), the TK05S-Chlorite by IC method (reference EPA 300.0) for chlorite, and TK05R-Chlorate by IC method (reference EPA 300.0) for chlorate. Details of these methods are provided in APPENDIX II. The limit of quantification (LOQ) for chlorine was 0.0992 mg/L, and 0.16 mg/L for both chlorite and chlorate. These LOQ values correspond to 0.0053 mg/kg, 0.00848 mg/kg and 0.015 mg/kg for chlorine, chlorite, and chlorate, respectively, for a 60 kg person. As any use rate will be limited to that which is currently regulated, the inclusion of the Electro- BioCide method to produce chlorine dioxide as an antimicrobial agent is not expected to increase the amount of chlorine dioxide released into the environment.

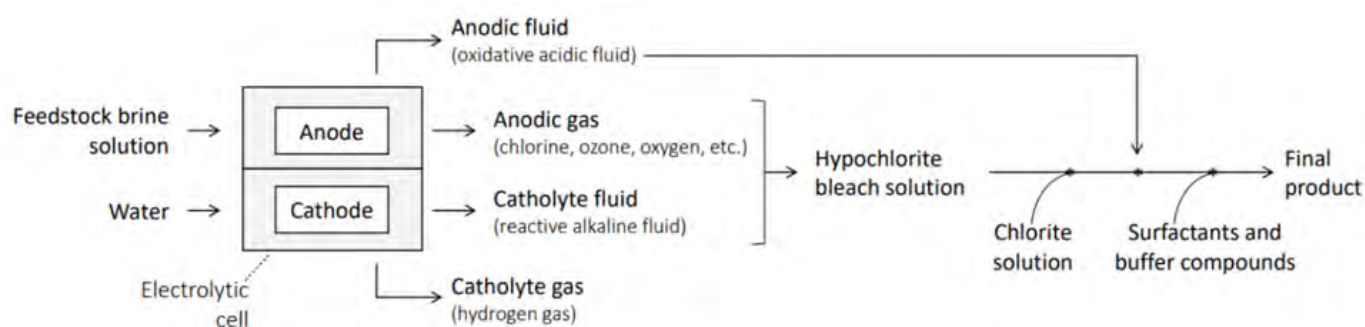
(c) Impurities

The electrolytic system of chlorine dioxide used by Electro-BioCide, may contain small quantities of chlorine, chlorite, and chlorate and are elaborated in Table 1 (in EA Section 6.a.). The presence of other mixed oxides that can be generated in small quantities include ozone, hydrogen peroxide, and hypochlorous acid. However, any of these species formed during the manufacturing procedure are reincorporated to enhance and stabilize the aqueous chlorine dioxide solution. Ozone is approved as an antimicrobial agent for bottled water (21 CFR §184.1563) and meat, poultry, and raw agricultural commodities (21 CFR § 173.368). Hydrogen peroxide is authorized for use n over 100 effective food contact notifications¹ and has a tolerance exemption (40 CFR § 180.1197). Hypochlorous acid is the subject of four effective food contact notifications (1176, 1470, 1606, and 1811)², all of which concluded "Finding of No Significant Impact" (FONSI). Therefore, as no significant environmental release is expected, no significant environmental impacts are anticipated from these impurities. Therefore, these will not have further analysis in this EA.

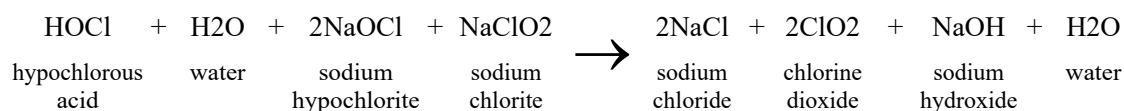
6. Introduction of Substances into the Environment

(a) Introduction of substances into the environment as a result of manufacture

The generation of the chlorine dioxide final product in the Electro-Biocide generator is shown graphically as follows:



The feedstock brine solution is comprised of sodium chloride which is passed through the anode of the Electro-Biocide system. The overall production of chlorine dioxide generated by the electrolysis of the brine solution is conducted by the following stoichiometric equation:



¹ U.S. Food and Drug Administration Inventory of Effective Food Contact Substance (FCS) Notifications, search term hydrogen peroxide, <https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=FCN>

² Ibid

The specifications for Electro-BioCide, which elaborate the chlorinated products that could be released as a result of this process, the minimum detection limit (MDL) and test method utilized are provided in Table 1.

Table 1. Chlorinated Products of the Electro-Biocide Method

Parameter	MDL	Specification	Method	Lot Number (230320-#)					Average
				001	002	003	004	005	
Chlorine dioxide (ppm)	0.020	N/A	Optek-Colorimetric for ClO ₂ ³	786	806	792	814	826	804.8 ± 16.22
Chlorine dioxide purity (%)	N/A	≥ 90%	Calculation	N/A	N/A	N/A	N/A	N/A	92.84% ± 0.13
Free chlorine (mg/L)	0.006	N/A	SM4500-Cl G	ND	ND	ND	ND	ND 38.4	ND ± 0

MDL= Method Detection Limit

N/A = not applicable

ND = not detected

³ Method ASTM 4500-ClO₂B is a Confirmatory Method for Optek

We note that these specifications are in conformance with those of 21 CFR §173.300 (2), which states:

"The generator effluent contains at least 90 percent (by weight) of chlorine dioxide with respect to all chlorine species as determined by Method 4500-ClO₂ E in the "Standard Methods for the Examination of Water and Wastewater," 20th ed., 1998, or an equivalent method. Method 4500-ClO₂ E ("Amperometric Method II") is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Treatment of the fruits and vegetables with chlorine dioxide shall be followed by a potable water rinse or by blanching, cooking, or canning."

Further, the levels of chlorite and chlorate are very low, yielding a chlorine dioxide purity greater than 92% across all five lots.

Electro-BioCide does not produce the traditional effluents seen in the other currently authorized chlorine dioxide generation methods as the chlorine dioxide and other chlorinated products formed during the manufacturing procedure are reincorporated to enhance and stabilize the final aqueous chlorine dioxide solution. Therefore, the necessity to determine the chlorine dioxide purity in the generator effluent is not applicable.

Extraordinary Circumstances: The above-described manufacturing process for chlorine dioxide has no indications which would otherwise present significant adverse effects to the environment or pose increased risks for introduction of substances into the environment. The notifier asserts that there are no extraordinary circumstances that would indicate the potential for significant adverse environmental impacts resulting from the manufacture of chlorine dioxide such as those listed in 21 CFR 25.21. Consequently, information on the manufacturing site and compliance with relevant emissions is not provided here.

(b) Introduction of substances into the environment as a result of Use of the Produced Antimicrobial Solution

Air Releases

Air releases from the approved uses of chlorine dioxide are negligible. Since the production of chlorine dioxide is confined to a closed system, the only potential release of chlorine dioxide is by evaporation from the process water. Other systems of chlorine dioxide production contain an effluent which must contain 90%/w chlorine dioxide. However, the chlorine dioxide and other products generated by Electro-BioCide are reincorporated back into the product medium; therefore, the levels of gaseous chlorine dioxide and other products released into the air will be negligible. Further, assuming that the maximum residual level of chlorine dioxide after use is limited to 3 ppm per 21 CFR 173.300, the maximum possible air concentration of chlorine dioxide from chlorine dioxide treated water is as calculated in Appendix 1 of this EA at 0.04 ppm. This amount would subsequently decrease further by decomposition processes active in the environment. Chlorine dioxide is an unstable gas that rapidly decomposes in air and will decompose when exposed to mild heat or exposure to sunlight. Unlike chlorine dioxide gas in-solution, which decomposes into various oxychloro species upon its exposure to water, gaseous chlorine dioxide will decompose into only chlorine and oxygen when released to the atmosphere.^{4 5}

Water Releases

⁴ Toxicological Profile for Chlorine Dioxide and Chlorite. U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. Sep. 2004.

⁵ Dobson, Stuart and Cary, Richard. Concise International Chemical Assessment Document: Chlorine Dioxide (Gas). World Health Organization Geneva, 2002.

The introduction of chlorine dioxide and its subsequent breakdown products (i.e., chlorite, chlorate) into the environment through use and disposal of treated water in poultry processing, and fruit and vegetable processing facilities has been previously addressed. It is not expected that the approval of this proposed alternative method to produce chlorine dioxide will result in the introduction of new substances into the environment, or an increase in the level of known substances introduced into the environment as the result of chlorine dioxide production. The FCS in this notification is intended to substitute for currently regulated methods of production and will not significantly affect the overall market for chlorine dioxide. In previously approved generation technologies, both unreacted feedstocks and reaction byproducts formed in the process of chlorine dioxide generation are present in the chlorine dioxide product stream. As stated above, the products produced by Electro-BioCide are reincorporated back into the production medium and therefore a traditional effluent is not generated. Therefore, since no wastewater or discharged processing water will be involved with the use of Electro-BioCide, chlorine dioxide nor its degradation byproducts will be present in either water source. To estimate the maximum environmental introduction concentration (EIC) of chlorine dioxide, the average residue concentration of chlorine dioxide, chlorite, and chlorate can be used to estimate the potential amount that could be released into water. Even though the use of Electro-BioCide does not necessitate a rinse step, in the event Electro-BioCide treated foods are rinsed with water, the average residue values can be used to estimate maximum potential releases of chlorine dioxide, chlorite, and chlorate into water. Based on the average residue data of Electro-BioCide treated foods the EIC for chlorine dioxide, chlorite, and chlorate, and chlorine released into water would be at most 0.0529, 0.078, and 1.92 respectively (Table 2). To determine the maximum EIC for free chlorine, the MDL of 0.006 can be utilized, as free chlorine was not detected in Electro-BioCide (Table 1).

Table 2. Residual analysis of foods treated with chlorine dioxide Electro-BioCide

Sample Reference	Chlorine dioxide Residue (measured as chlorine; mg/kg)	Chlorite residue (mg/kg)	Chlorate residue (mg/kg)
Seeds	0.0840	<0.1	3.10
5 Apples	0.0520	<0.05	1.40
2 Packages of Ground Beef	<0.03	<0.05	0.200
(5) 10 oz Raw Shrimp	<0.03	0.200	0.500
2 Packages of Boneless Chicken Breasts	<0.03	<0.05	0.200
5 Bags of Dole Spinach	0.0380	<0.05	4.40
Average residue concentration (mg/kg)	0.0529	0.078	1.92

Quantitative limits: Chlorine= 0.03 ppm; Chlorite = 0.05 ppm (0.01 in seeds); Chlorate= No limit stated in regulations

Based on the EIC for chlorine dioxide, chlorite, chlorate, the estimated environmental concentration (EEC) can be derived for each of these species. Chlorine dioxide converts to chlorite and chlorate at a ratio of 70:15, with the other 15% forming other minor products (Lee et al., 2004). For entrance into wastewater, the following assumptions are made when calculating the EEC for chlorine, chlorite, and chlorate exposure: (1) approximately 50% of water discharged from a vegetable, fruit, and raw agricultural commodity processing plant is treated with chlorine dioxide (EPA, 2006), (2) the receiving stream dilution factor is 10 (Rapaport, 1988), and (3) chlorite removal by the wastewater treatment at the vegetable, fruit, raw agricultural commodity, and poultry processing facility is 99% (ATSDR, 2004).

For fruits and vegetables, the EEC for chlorite for fruit, vegetable, and raw agricultural commodity processing facilities:

$$0.078 \text{ ppm} \times 0.5 \times (1 - 0.99) \times 0.1 = 0.000039 \text{ ppm} (0.000039 \text{ mg/L})$$

The EEC for chlorate would yield the following:

$$1.92 \text{ ppm} \times 0.5 \times 0.1 = 0.096 \text{ ppm} (0.096 \text{ mg/L})$$

The EEC for free chlorine would yield the following:

$$0.006 \text{ ppm} \times 0.5 \times 0.1 = 0.0003 \text{ ppm} (0.0003 \text{ mg/L})$$

Approximately 43% of water discharged from a poultry processing plant is treated with chlorine dioxide (Northcutt and Jones, 2004). Therefore, to calculate the EEC for chlorite in a poultry processing facility would be determined as follows:

$$0.078 \text{ ppm} \times 0.43 \times (1 - 0.99) \times 0.1 = 0.000034 \text{ ppm} (0.000034 \text{ mg/L})$$

The EEC for chlorate would be:

$$1.92 \text{ ppm} \times 0.43 \times 0.1 = 0.0826 \text{ ppm} (0.0826 \text{ mg/L})$$

The EEC for free chlorine would yield the following:

$$0.006 \text{ ppm} \times 0.43 \times 0.1 = 0.00027 \text{ ppm} (0.00027 \text{ mg/L})$$

To assume the maximum exposure, it is assumed that all the chlorite, chlorate, and free chlorine would be converted into chloride. Therefore, this would result in a chloride EEC value of 0.09634 ppm for vegetables, fruit, and raw agricultural commodities, and 0.08294 ppm for poultry processing.

(c) Compliance Status

Chlorine dioxide generated by the processes prescribed under 21 CFR §173.300 and 21 CFR §173.325 is cleared for use as an antimicrobial agent for water used in poultry processing, wash for fruits and vegetables, the processing of red meat, red meat parts, and organs, in water and ice that are used to rinse, wash, thaw, transport, or store seafood, and to processed fruits and processed root, tuber, bulb, legume, fruiting (i.e., eggplant, groundcherry, pepino, pepper, tomatillo, and tomato), and cucurbit vegetables. The electrolytic generation of chlorine dioxide from a brine solution is intended to replace that which is now produced and used in compliance with the existing provisions of Sections 173.300 and 173.325. Therefore, approval of the subject notification should not affect compliance with current regulations.

7. Fate of Emitted Substances in the Environment

The environmental fate of chlorine dioxide has been comprehensively evaluated (EPA, 2000, 2004, 2006) and demonstrates that chlorine dioxide rapidly converts into chlorite, chlorate, and chloride in the environment. According to the USEPA Reregistration Eligibility Decision (RED) for Chlorine Dioxide and Sodium Chlorite case 4023, the chlorite ion is the major degradation product when chlorine dioxide interacts with organic and inorganic molecules and compounds in water. Moreover, chlorine dioxide has a short half-life, breaking down into chloride and chlorite ions in the presence of direct sunlight. When chlorite dissolves in water, it produces chloride and chlorate. Chlorite and chlorate can migrate from the surface to groundwater readily. Biodegradation of chlorate and chlorite under anaerobic and anoxic conditions occurs in ground water, sediments, and soils,

with the endpoints being chloride and oxygen. People are exposed to chlorine dioxide in drinking water, which is rapidly converted to chlorite when consumed. The EPA has set the maximum concentration (the maximum residual disinfectant level (MRDL) of chlorine dioxide in drinking water at 0.8 mg/L and the maximum concentration level of its oxidation product, chlorite, is 1.0 mg/L (EPA, 2000). In a twelve-week epidemiology study, the levels of chlorine dioxide, chlorite and chlorate in water were 0.3 - 1.1, 3.2 - 7.0, and 0.3 - 1.1 mg/L, respectively (Quentel *et al.*, 1994). The levels of chlorite and chlorate in water treatment facilities ranged from 15 - 740 and 21 - 330 µg/L respectively (Bolyard *et al.*, 1993). Chlorite and chlorate are moderately stable in water but both substances will eventually be reduced to chloride. The Occupational Safety and Health Administration (OSHA) has set a Permissible Exposure Limit (PEL) for chlorine dioxide for general industry and construction industry at 0.1 ppm (0.3 mg/m³) (OSHA, 2020). The American Conference of Governmental Industrial Hygienists set a threshold limit value of 0.1 ppm (0.28 mg/m³).

Chlorine dioxide is not naturally produced, nor does it persist in the environment, as it quickly breaks down when in contact with organic matter (Gomez-Lopez, 2014). Chlorinated compounds can form disinfection by-products (Parveen *et al.*, 2022; Aieta and Berg 1986; Chang 1982; Stevens 1982), including chlorite and chlorate and halogenated organic compounds; however, it does not form trihalomethanes (Parveen *et al.*, 2022). The presence of hypochlorous acid and chlorine dioxide in specific ratios inhibits the formation of haloform products. In the air chlorine dioxide decomposes in response to heat or pressure, but when reduced to less than 15% by volume it is stable in the dark (Vogt *et al.*, 1986). The photochemical reaction of chlorine dioxide as a gas corresponds to the homolytic cleavage of one of the chlorine-oxygen bonds, which produce doublet oxygen, chlorine gas, and chlorine trioxide (Griese *et al.* 1992; Zika *et al.* 1984). In the air the measured levels of chlorine dioxide range from <1 - 60 ppb in steam and power generation plants, nondetectable - 3ppb in effluent water-treatment plants, nondetectable - 5.8 ppb in maintenance work areas, < 10 ppb in a pulp mill factory, and < 10- 300 ppb in the bleach/chemical preparation areas (Kauppinen *et al.*, 1997; Teschke *et al.*, 1999, Kennedy *et al.*, 1991). The residual chlorine species that are generated from Electro-BioCide use range from 0.0840 mg/kg to undetectable, which are gone within minutes after Electro-BioCide use. Therefore, chlorine dioxide, or any other chlorinated species, are not going to the consumer or into the environment. Therefore, the above information indicates that the potential level of chlorine dioxide released from the use of electro-BioCide is not of a sufficient quantity to affect the amount of chlorine dioxide currently found in the environment.

8. Environmental effects of Released Substances

We incorporate by reference the studies used in the Amended EA of FAP No. 4A4408 to support the use of chlorine dioxide. These are included as Appendix (2) Aquatic studies; and (3) Terrestrial Organism Studies. Chlorine dioxide is an alternative to chlorine for disinfection in the poultry, industry and in the fruit and vegetable industries. Replacement of chlorine with chlorine dioxide has already occurred. Electro-BioCide is already an EPA registered disinfectant that has been rated as a "Practically Non-Toxic" substance (EPA category IV). We anticipate that the proposed method of chlorine dioxide generation will not enhance the environmental effects of chlorine dioxide that are currently found in the environment from other sources. Chlorine dioxide can be separated from water and possesses a partition coefficient as a gas of 21.5 at 35°C and 70.0 at 0°C (Aieta and Berg 1986; Kaczur and Cawfield 1993; Stevens 1982). The estimated log *K_{ow}* of chlorine dioxide is -3.22 and for sodium chlorite is -7.17, and current studies do not predict either would bioaccumulate in aquatic organisms (EPA RED, 2006a).

Utilizing EPA published document Chlorine Dioxide: Final Risk Assessment Case 4023 the ecological risk assessment relies on chlorite endpoints to be protective of chlorine dioxide "because under environmental conditions, chlorine dioxide converts mostly into chlorite ions" (EPA, 2006). Tables 3-7 below describe aquatic toxicity study endpoints of chlorine dioxide and chlorite. According to the Reregistration Eligibility Decision (RED) for chlorine Dioxide and Sodium chlorite (EPA RED, 2006a) chlorine dioxide is slightly toxic to practically non-toxic for freshwater fish (Table 3) and from non-toxic to very highly toxic for certain aquatic invertebrates (Table 4). At the highest doses, there is risk to freshwater and marine/estuarine fish and invertebrates (Table 5) and aquatic plants, and at the lowest doses there is risk only to freshwater invertebrates (EPA RED, 2006a).

According to the Reregistration Eligibility Decision (RED) for Inorganic Chlorates (EPA RED, 2006b), chlorate is "practically non-toxic" for both freshwater and marine/estuarine fish. Chlorate was below the EPAs Level of Concern (LOC) for aquatic invertebrates and plants. Toxicity studies for chlorate are summarized in Tables 8-11. Other studies that were located from other sources are also included in the table utilizing the EPA EcoTox database. The EEC of chlorine dioxide, chlorite, and chlorate are 0.00265, 0.000073, and 0.1786 mg/L, which are all orders of magnitude below the lowest concentrations that achieved toxicity in all terrestrial and aquatic organisms. Even if the maximum EEC is assumed (*i.e.*, all the chlorite, chlorate, and free chlorine would be converted into chloride, yielding EEC values of 0.09634 ppm for vegetables, fruit, and raw agricultural commodities, and 0.08294 ppm for poultry processing), the maximum EEC values are still well below the concentrations that yielded toxicity. Therefore, the levels of chlorine dioxide, chlorite, and chlorate produced by Electro-BioCide are well below the threshold for these risks and are not a concern for terrestrial or aquatic flora and/or fauna.

Table 3. Acute Toxicity of Chlorine Dioxide and Sodium Chlorite to Freshwater Fish ⁷

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Sodium chlorite, analytical grade	Colorado Pikeminnow (<i>Ptychocheilus lucius</i>) (juvenile)	LC50 (96-hr), 0.464 (0.42-0.53) mg/L, mortality observed	Beleau, 1982	Ecotox database ⁸	n/a
Sodium chlorite, 80%	Bluegill (<i>Lepomis macrochirus</i>)	LC50 (96-hr) = 420 (220-600) mg/L LC50 (72-hr) = 222 (207-237) mg/L LC50 (10 days) = 208 (165-262) mg/L	EPA, 1992	Ecotox database	n/a
Sodium chlorite, 80%	Rainbow trout (<i>Oncorhynchus mykiss</i>)	LC50 (96-hr) = 244 (196-304) mg/L LC50 (13 days) = 50.6 (38-65.8) mg/L	EPA, 1992	Ecotox database	n/a
Sodium chlorite, 79%	Sheepshead minnow (<i>Cyprinodon variegatus</i>)	LC50 (96-hr) = 75 (62-90) mg/L	EPA, 1992	Ecotox database	n/a
Sodium chlorite, 80%	Rainbow trout (<i>Oncorhynchus mykiss</i>)	LC50 (96-hr), larvae = 2.2 ppm LC50 (96-hr), adult = 8.3 ppm LC50 (20-day), larvae = 1.6 ppm NOAEC = N.R.	SeceVICIUS <i>et al.</i> (2005) ⁹	n/a	n/a
Chlorine dioxide, 80%	Rainbow trout (<i>Oncorhynchus mykiss</i>)	LC50 = 360 (216-600) NOAEC = 216	Barrows, 1984 MRID # 94068007	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Bluegill (<i>Lepomis macrochirus</i>)	LC50 = 244 (196-304) ppm NOAEC = 108 ppm	Larkin, 1984 ACC # 254181	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Rainbow trout (<i>Oncorhynchus mykiss</i>)	LC50 = 360 (216-600) ppm NOAEC = 216 ppm	Larkin, 1984 ACC # 254180	EPA, 2006a	Acceptable
Sodium chlorite, 80.25%	Bluegill (<i>Lepomis macrochirus</i>)	LC50 = 265 (231-309) NOAEC = 130	EG&G Bionomics, 1978 ACC# 69809	EPA, 2006a	Supplemental

⁷ Chlorine Dioxide Environmental Hazard and Risk Assessment (2006) Docket: EPA-HQ-OPP-2006_0328; <https://www.regulations.gov/document/EPA-HQ-OPP-2006-0328-0020>; site last visited on August 31st 2023.

⁸ <https://cfpub.epa.gov/ecotox/search.cfm> ; site last visited on September 14th 2023.

⁹ SeceVICIUS, G.; Syvokiene, J.; Stasiunaite, P ; Mickeniene, L. (2005) Acute and chronic toxicity of chlorine dioxide (ClO₂) and chlorite (ClO₂⁻) to rainbow trout (*Oncorhynchus mykiss*). Environmental Science and Pollution Research International. 12(5):302--305.

Table 3, continued

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Sodium chlorite, 79%	Bluegill (<i>Lepomis macrochirus</i>)	LC50 = 208 (165-262) NOAEC = N.R.	Sleight III, 1971 MRID # 131351	EPA, 2006a	Supplemental
Sodium chlorite, 79%	Rainbow trout (<i>Oncorhynchus mykiss</i>)	LC50 = 50.6 (38.8-65.8) NOAEC = N.R.	Sleight III, 1971 MRID # 131351	EPA, 2006a	Supplemental
Sodium chlorite, 80%	Rainbow trout (<i>Oncorhynchus mykiss</i>)	LC50 = > 100 NOAEC = N.R.	McMillen, 1985 ACC # 253743	EPA, 2006a	Supplemental
Sodium chlorite, 80%	Bluegill (<i>Lepomis macrochirus</i>)	LC50 = >100 NOAEC = N.R.	McMillen, 1985 ACC # 253743	EPA, 2006a	Supplemental
Sodium chlorite, 25%	Rainbow trout (<i>Oncorhynchus mykiss</i>)	LC50 = 203 (175-236) NOAEC = 100	MBA Laboratories, 1984 ACC # 252854	EPA, 2006a	Acceptable
Sodium chlorite, 25%	Bluegill (<i>Lepomis macrochirus</i>)	LC50 = 222 (207-237) NOAEC = 186	MBA Laboratories, 1983 ACC # 252854	EPA, 2006a	Supplemental
Sodium chlorite, 81.5%	Bluegill (<i>Lepomis macrochirus</i>)	LC50 = 310 (270-350) NOAEC = 220	Sousa, 1981 ACC # 245697	EPA, 2006a	Acceptable
Sodium chlorite, 80.25%	Rainbow trout (<i>Oncorhynchus mykiss</i>)	LC50 = 290 (250-340) NOAEC = < 70	EG&G Bionomics, 1979 ACC # 69810	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Rainbow trout (<i>Oncorhynchus mykiss</i>)	LC50 = 340 (220-600) NOAEC = 130	Sousa and Surprenant, 1984 ACC # 253379	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Bluegill (<i>Lepomis macrochirus</i>)	LC50 = 420 (220-600) NOAEC = 220	Sousa and Surprenant, 1984 MRID # 94068006	EPA, 2006a	Acceptable

Table 4. Acute Toxicity of Chlorine Dioxide and Sodium Chlorite to Freshwater Invertebrates

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Sodium chlorite, 25%	Water flea (<i>Daphnia magna</i>)	EC50 (48-hr) = 1.4 (1-1.9) mg/L, immobility observed	EPA, 1992	n/a	n/a
Sodium chlorite, 80%	Water flea (<i>Daphnia magna</i>)	EC50 (48-hr) = 0.39 (0.32-0.54) mg/L, immobility observed	EPA, 1992	n/a	n/a
Sodium chlorite, 79%	American or Virginia Oyster (<i>Crassostrea virginica</i>)	EC50 (48-hr) = 0.29 (0.25-0.33) mg/L, immobility observed EC50 (96-hr) = 21.4 (14.3-27.1) mg/L, immobility observed	EPA, 1992	n/a	n/a
Sodium chlorite, 79%	Opossum Shrimp (<i>Americamysis bahia</i>)	EC50 (96-hr) = 0.576 (0.44-0.75) mg/L, mortality observed	EPA, 1992	n/a	n/a
Chlorine dioxide	Fouling Barnacle (<i>Amphibalanus reticulatus</i>)	<u>N-II larvae</u> : 0.1 mg/L, survival significantly ($p < 0.05$) reduced to 51, 43 and 40% at contact times of 3, 10 and 20 min, respectively <u>N-IV nauplii</u> : 0.1, 0.2 and 0.5 mg/L, survival ($p < 0.05$) 55, 30 and 15%, respectively, at the end of Day 3 for 20-minute exposure. <u>N-VI larvae</u> : 0.1, 0.2, and 0.5 mg/L, survival ($p < 0.05$) 67, 62, and 43%, respectively, for 20-minute exposure <u>Stage IV-VI cypris larvae</u> : 0.1 mg/L, > 50% inhibited; 0.1, 0.2 and 0.5 mg/L, significant decrease in the settlement, attachment, and metamorphosis rates. NOAEC = N.R.	Venkatnarayanan <i>et al.</i> (2017) ¹⁰	n/a	n/a
Sodium chlorite, 80%	Water flea (<i>Daphnia magna</i>)	EC50 = 0.027 (0.021- 0.031) NOAEC = 0.003	Barrows, 1984 MRID # 146162	EPA, 2006a	Acceptable

¹⁰ Venkatnarayanan, S.; Murthy, P. S.; Kirubakaran, R.; Venugopalan, V. P. (2017) Chlorine dioxide as an alternative antifouling biocide for cooling water systems: Toxicity to larval barnacle *Amphibalanus reticulatus* (Utinomi). Marine Pollution Bulletin. 124(2):803-810.

Table 4, continued

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Chlorine dioxide, 80%	Water flea (<i>Daphnia magna</i>)	LC50 = 360 (216-600) NOAEC=216	Barrows, 1984 MRID # 94068007	EPA, 2006a	Acceptable
Sodium chlorite, 79%	Water flea (<i>Daphnia magna</i>)	LC50 = 244 (196-304) ppm NOAEC = 108 ppm	Larkin, 1984 ACC # 254181	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Water flea (<i>Daphnia magna</i>)	LC50 = 360 (216-600) NOAEC = 216	Larkin, 1984 ACC # 254180	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Water flea (<i>Daphnia magna</i>)	LC50 = 265 (231-309) NOAEC = 130	EG&G Bionomics, 1978 ACC # 69809	EPA, 2006a	Acceptable
Sodium chlorite, 25%	Water flea (<i>Daphnia magna</i>)	LC50 = 208 (165-262) NOAEC = N.R.	Sleight III, 1971 MRID # 131351	EPA, 2006a	Supplemental

Table 5. Acute Toxicity of Chlorine Dioxide and Sodium Chlorite to Estuarine / Marine Fish and Invertebrates

Substance % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Sodium chlorite, 25%	Fish: Sheepshead minnow (<i>Cyprinodon variegatus</i>)	EC50 (96-hr) = 75 (62.6-89.8) ppm NOAEC = 13.9 ppm	Yurk and Overman, 1994 MRID # 43259401	EPA, 2006a	Acceptable
Sodium chlorite, 79%	Invertebrates: Eastern oyster (<i>Crassostrea virginica</i>)	EC50 (96-hr) = 21.4 (14.3-27.1) ppm NOAEC = 14.3 ppm	Yurk and Overman, 1994 MRID # 43259403	EPA, 2006a	Acceptable
Sodium chlorite, 79%	Mysid shrimp (<i>Mysidopsis bahia</i>)	EC50 (96-hr) = 0.576 (0.44-0.75) ppm NOAEC = N.R.	Yurk and Overman, 1994 MRID # 43259402	EPA, 2006a	Acceptable

Table 6. Avian Acute and Subacute Dietary Toxicity of Chlorine Dioxide and Sodium Chlorite

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Sodium chlorite, 80%	Northern bobwhite (<i>Colinus virginianus</i>)	Acute oral toxicity: LD50 = 382 (300-520) NOAEL = 175	Robaidek, 1985 ACC # 259373	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Northern bobwhite (<i>Colinus virginianus</i>)	LD50 = 390 (310-490) NOAEL = N.R.	Robaidek and Johnson, 1985 ACC#257341	EPA, 2006a	Acceptable
Chlorine dioxide, 80%	Northern bobwhite (<i>Colinus virginianus</i>)	LD50 = 395 (272-573) NOAEL = N.R.	Fletcher, 1984 ACC #253378	EPA, 2006a	Acceptable
Sodium chlorite, 83 %	Northern bobwhite (<i>Colinus virginianus</i>)	LD50 = 660 (540-810) NOAEL = N.R.	Fletcher, 1973 MRID # 31610	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Northern bobwhite (<i>Colinus virginianus</i>)	LD50 = 467 (372-585) NOAEL = N.R.	Beavers, 1984 ACC#254177	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Mallard duck (<i>Anas platyrhynchos</i>)	LD50 = > 31.25 NOAEL = N.R.	Beavers, 1984 ACC#254176	EPA, 2006a	Supplemental
Sodium chlorite, 25%	Northern bobwhite (<i>Colinus virginianus</i>)	LD50 = 797(420-2594) NOAEL = 125	MBA Laboratories, 1984 ACC#252854	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Mallard duck (<i>Anas platyrhynchos</i>)	Subacute oral toxicity: LC50 = > 5000 ppm NOAEC = 5000 ppm	Johnson, 1984 MRID # 94068008	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Northern bobwhite (<i>Colinus virginianus</i>)	LC50 = > 5000 ppm NOAEC = N.R.	Fletcher, 1984 ACC#253378	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Mallard duck (<i>Anas platyrhynchos</i>)	LC50 = > 5000 ppm NOAEC = N.R.	Fletcher, 1984 ACC # 253378	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Northern bobwhite (<i>Colinus virginianus</i>)	LC50 = > 5000 ppm NOAEC = N.R.	Johnson, 1984 MRID # 94068005	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Mallard duck (<i>Anas platyrhynchos</i>)	LC50 = > 5620 ppm NOAEC = N.R.	Beavers, 1984 ACC#254178	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Northern bobwhite (<i>Colinus virginianus</i>)	LC50 = > 5620 ppm NOAEC = N.R.	Beavers, 1984 ACC#254179	EPA, 2006a	Acceptable

Table 6, continued

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Sodium chlorite, 80%	Northern bobwhite (<i>Colinus virginianus</i>)	LC50 = > 10000 ppm NOAEC = N.R.	Fink, 1977 MRID # 130649	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Mallard duck (<i>Anas platyrhynchos</i>)	LC50 = > 10000 ppm NOAEC = N.R.	Fink, 1977 MRID # 130650	EPA, 2006a	Acceptable
Sodium chlorite, 25%	Mallard duck (<i>Anas platyrhynchos</i>)	LC50 = 18686 (8186-109184) ppm NOAEC = N.R.	MBA Laboratories, 1983 ACC#252854	EPA, 2006a	Acceptable
Sodium chlorite, 25%	Northern bobwhite (<i>Colinus virginianus</i>)	LC50 = 2031 (1226-3903) ppm NOAEC = 417	MBA Laboratories, 1984 ACC #252854	EPA, 2006a	Acceptable

Table 7. Toxicity of Chlorine Dioxide/Sodium Chlorite to Terrestrial, Semi-aquatic and Aquatic Plants

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Sodium chlorite, 80%	Terrestrial and Semi-aquatic Plants: Monocots & Dicots (10 Species)	EC25 = > 3.5 ppm	Backus <i>et al.</i> , 1990 MRJD # 41843101	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Monocots & Dicots (9 Species)	EC25 = > 3.5 ppm	Backus <i>et al.</i> , 1990 MRJD # 41843102	EPA, 2006a	Acceptable
Sodium chlorite, 80%	Buckwheat (<i>Polygonum convolvulus</i>)	EC25 = < 3.5 ppm	Backus <i>et al.</i> , 1990 MRJD # 41843102	EPA, 2006a	Acceptable
Sodium chlorite, 79%	Aquatic plants: Green algae (<i>Selenastrum capricornutum</i>)	EC50 (96-hr) = 1.32 (1.18-1.47) ppm NOAEC = < 0.62 ppm	Ward and Boeri, 1991 MRID # 41880403	EPA, 2006a	Supplemental

Table 8. Acute Toxicity of Chlorate to Freshwater Fish

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Sodium chlorate (not specified)	Harlequinfish, Red Rasbora (<i>Rasbora heteromorpha</i>)	LC50 = 8600 mg/L	Alabaster, 1969	EcoTox Database	<i>In vivo</i>
Sodium chlorate (not specified)	Fathead Minnow (<i>Pimephales promelas</i>)	LC50 (96-hr) = 13500-13800 (12750-14520) mg/L	Shifrer <i>et al.</i> , 1974	EcoTox Database	<i>In vivo</i>
Sodium chlorate (not specified)	Brown trout (<i>Salmo trutta</i>)	LC50 (96-hr) = 7.3 mg/L	Woodiwiss <i>et al.</i> , 1974	EcoTox Database	<i>In vivo</i>
Sodium chlorate (50%)	Japanese Barbel (<i>Tribolodon hakonensis</i>)	LC50 (6-hr) = 4900 mg/L LC50 (12-hr) = 4700 mg/L LC50 (24-hr) = 4200 mg/L LC50 (48-hr) = 3800 mg/L LC50 (96-hr) = 3800 mg/L	Matida <i>et al.</i> , 1976	EcoTox Database	<i>In vivo</i>
Sodium chlorate (not specified)	Japanese Barbel (<i>Tribolodon hakonensis</i>)	LC50 (24-hr) = 4000 mg/L LC50 (48-hr) = 3800 mg/L LC50 (96-hr) = 3300 mg/L LC50 (240-hr) = 2000 mg/L	Matida <i>et al.</i> , 1976	EcoTox Database	<i>In vivo</i>
Sodium chlorate, 50%	Cherry Salmon (<i>Oncorhynchus masou</i>)	LC50 (24-hr) = 4000 mg/L LC50 (48-hr) = 3300 mg/L LC50 (96-hr) = 1100 mg/L	Matida <i>et al.</i> , 1976	EcoTox Database	<i>In vivo</i>
Sodium chlorate, 99%	Sheepshead minnow (<i>Cyprinodon variegatus</i>)	LC50 (96-hr) = > 1000 mg/L	EPA, 1992	EcoTox Database	<i>In vivo</i> , Fish; Standard Test Species
Sodium chlorate, 99%	Bluegill (<i>Lepomis variegatus</i>)	LC50 (96-hr) = > 1000 mg/L	EPA, 1992	EcoTox Database	<i>In vivo</i> , Fish; Standard Test Species
Sodium chlorate, 99%	Rainbow Trout (<i>Oncorhynchus mykiss</i>)	LC50 (48-hr) = > 1000 mg/L LC50 (96-hr) = > 1000 mg/L	EPA, 1992	EcoTox Database	<i>In vivo</i> , Fish; Standard; Test Species; U.S. Threatened and Endangered Species

Table 8, continued

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Potassium chlorate	Fathead Minnow (<i>Pimephales promelas</i>)	LC50 (48-hr) = 4230 mg/L NI50 ¹¹ = 17432 mg/L	Brandao <i>et al.</i> , 1992	EcoTox Database	<i>In vitro</i>
Potassium chlorate	Fathead Minnow (<i>Pimephales promelas</i>)	LC50 (48-hr) = 4230 mg/L Piso ¹² = 13727 mg/L	Dierickx, 1993	EcoTox Database	<i>In vitro</i>
Sodium chlorate (not specified)	Japanese Medaka (<i>Oryzias latipes</i>)	LC50 (96-hr) = 2585 (1925-3487) mg/L	Toussaint <i>et al.</i> , 2001	EcoTox Database	<i>In vivo</i> , Fish; Standard Test Species

¹¹ The concentration of test compound required to induce a 50% reduction in neutral red uptake in cultured FHM fish cells.

¹² The concentration of test compound that induces a 50% decrease in cell proteins.

Table 9. Acute Toxicity of Chlorate to Freshwater Invertebrates and vertebrates

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Sodium chlorate (not specified)	Invertebrates: Water flea (<i>Daphnia magna</i>)	Toxicity threshold of immobilization = 4240 mg/L	Anderson, 1946	EcoTox Database	<i>In vivo</i>
Sodium chlorate	Scud, Amphipod (<i>Gammarus sp.</i>)	Mortality reported at 57 mg/L	Matida <i>et al.</i> , 1975	EcoTox Database	<i>In vivo</i>
Sodium chlorate, 50%	Aquatic Sowbug (<i>Asellus hilgendorffii</i>)	LC50 (24-hr) = 4100 mg/L LC50 (48-hr) = 3400 mg/L LC50 (96-hr) = 2800 mg/L	Matida <i>et al.</i> , 1976	EcoTox Database	<i>In vivo</i>
Sodium chlorate (not specified)	Aquatic Sowbug (<i>Asellus hilgendorffii</i>)	LC50 (48-hr) = 3100 mg/L LC50 (96-hr) = 2100 mg/L	Matida <i>et al.</i> , 1976	EcoTox Database	<i>In vivo</i>
Potassium chlorate (not specified)	Water flea (<i>Daphnia magna</i>)	NOAEL = 600 mg/L LC50 (24-hr) = 880 mg/L LC100 (24-hr) = 1310 mg/L	Bringmann and Kuhn, 1977	EcoTox Database	<i>In vivo</i>
Potassium chlorate (not specified)	Ciliate (<i>Uronema carducci</i>)	LC50 (20-hr) = 1092 mg/L	Bringmann and Kuhn, 1980	EcoTox Database	<i>In vivo</i>
Sodium chlorate (not specified)	Ciliate (<i>Colpoda cucullus</i>)	LC50 (9-hr) = 320 mg/L, reduced population growth rate LC10 (9-hr) = 110 mg/L, reduced population growth rate	Schreiber and Brink, 1989	EcoTox Database	<i>In vivo</i>
Sodium chlorate, > 99%	Water flea (<i>Daphnia magna</i>)	EC50 (48-hr) = 919.3 (612.28-1380.3) mg/L, immobility LOAEC (21-day) = > 526 mg/L NOAEC = 526 mg/L NOAEL (48-hr) = 1000 mg/L NOAEL (48-hr; age < 24 hours) = 405 mg/L LC50 (96-hr) = > 1000 mg/L	EPA, 1992	EcoTox Database	<i>In vivo</i>
Sodium chlorate, 99%	American or Virginia Oyster (<i>Crassostrea virginica</i>)	LC50 (96-hr) = > 1000 mg/L NOAEL = < 500 mg/L	EPA, 1992	EcoTox Database	<i>In vivo</i>

Table 9, continued

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Sodium chlorate, 99%	Opossum Shrimp (<i>Americamysis bahia</i>)	NOAEL (96-hr) = 360 mg/L	EPA, 1992	EcoTox Database	<i>In vivo</i>
Sodium chlorate (not specified)	Water flea (<i>Daphnia magna</i>)	LC50 (48-hr) = 3162 mg/L	Dosdall <i>et al.</i> , 1997	EcoTox Database	<i>In vivo</i>
Sodium chlorate (not specified)	Vertebrates: African Clawed Frog (<i>Xenopus laevis</i>) (embryo)	LC50 (96-hr) = 5225-6475 mg/L, mortality EC50 (96-hr) = 4170-5362 mg/L	Brennan <i>et al.</i> , 2005	EcoTox Database	<i>In vitro</i> culture

Table 10. Acute and chronic toxicity of sodium chlorate to mammals and birds

Substance, % AI	Organism	Endpoints/Results (95% CI)	Effect	Referenced In	Study Classification
Sodium chlorate	Rat (<i>Rattus norvegicus</i>)	Acute oral toxicity: LD50 = > 5000 mg/kg-bw	At 5000 mg/kg-bw, 1/10 animals died.	EPA RED, 2006b	<i>n/a</i>
Sodium chlorate	Mallard duck (<i>Anas platyrhynchos</i>)	LD50 = > 2510 mg/kg-bw	No mortality and no clinical signs of toxicity were observed.	EPA RED, 2006b	<i>n/a</i>
Sodium chlorate	Rat (<i>Rattus norvegicus</i>)	LD50 = 2 ≥ 5000 mg/kg-bw	Oral Toxicity Category: IV (practically non-toxic and not an irritant)	EPARED, 2006b (for inorganic chlorates)	<i>n/a</i>
Sodium chlorite	Rat (<i>Rattus norvegicus</i>)	Chronic oral toxicity: NOAEC = 500 mg/kg-bw, highest dose tested approx. 10000 mg/kg-bw	No reproductive effects	EPARED, 2006b	<i>n/a</i>
Sodium chlorate	Northern Bobwhite (<i>Colinus virginianus</i>)	NOAEC = 271 ppm LOAEC = 964 ppm	The LOAEC was 964 ppm based on effects on egg production and thickness, embryonic survival, and hatchling body weight.	EPA RED, 2006b	<i>n/a</i>

Table 11. Toxicity of chlorate to Terrestrial, Semi-aquatic and Aquatic plants

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Chlorate/Pro analysis grade, pro analysis quality, p.a. grade	Lesser Duckweed (<i>Lemna aequinoctialis</i>)	Terrestrial and Semi-aquatic Plants: EC50 (96-hr) = 100 mg/L, reduction in population abundance EC50 (96-hr) = 37-43 mg/L, reduction in biomass	Bengtsson <i>et al.</i> , 1999	EcoTox Database	<i>n/a</i>
Sodium chlorate (not specified)	American Frog's-Bit (<i>Egeria densa</i>)	EC50 = 1037 mg/L, reduction in growth after 28 days	Palma <i>et al.</i> , 2013	EcoTox Database	<i>n/a</i>
Sodium chlorate (not specified)	Golden-Brown Algae (<i>Oikomonas termo</i>)	Aquatic Plants: EC10 (9-hr) = 1000 mg/L, reduced population growth rate EC50 (9-hr) = 40000 mg/L, reduced population growth rate	Schreiber and Brink, 1989	EcoTox Database	<i>n/a</i>
Potassium chlorate (not specified)	Green Algae Order (<i>Chlorococcales sp.</i>)	EC10 (24-hr) = 18 mg/L, reduced assimilation efficiency EC50 (24-hr) = 210 mg/L, reduced assimilation efficiency	Krebs, 1991	EcoTox Database	<i>n/a</i>
Sodium chlorate, 99%	Green Algae (<i>Raphidocelis subcapitata</i>)	EC50 = 133 (122-144) mg/L, reduction in population abundance after 5 days	EPA, 1992	EcoTox Database	<i>n/a</i>
Sodium chlorate, 99.66%	Inflated Duckweed (<i>Lemna gibba</i>)	EC50 = 43 (30-62) mg/L, reduction in population abundance after 7 days	EPA, 1992	EcoTox Database	<i>n/a</i>
Chlorate (not specified)	Bladder Wrack (<i>Fucus vesiculosus</i>)	EC50 = 0.08 mg/L, reduction in biomass after 182.64 days	Rosemarin <i>et al.</i> , 1994	EcoTox Database	<i>n/a</i>
Chlorate (not specified)	Toothed Wrack (<i>Fucus serratus</i>)	EC50 = 0.13 mg/L, reduction in growth after 1095 days	Rosemarin <i>et al.</i> , 1994	EcoTox Database	<i>n/a</i>
Chlorate (not specified)	Brown Algae (<i>Fucus sp.</i>)	EC50 = 0.08 mg/L, population changes observed after 182.64 days	Rosemarin <i>et al.</i> , 1994	EcoTox Database	<i>n/a</i>
Chlorate (not specified)	Green Algae (<i>Chlorella protothecoides</i>)	EC50 (72-hr) = 1200 µM (0.100 mg/L)	Stauber, 1995	EcoTox Database	<i>n/a</i>
Chlorate (not specified)	Green Algae (<i>Raphidocelis subcapitata</i>)	EC50 (72-hr) = 730 (470-1000) µM [0.6083 (0.392-0.833) mg/L]	Stauber, 1995	EcoTox Database	<i>n/a</i>

Table 11, continued

Substance, % AI	Organism	Endpoints/Results (95% CI)	Reference	Referenced In	Study Classification
Sodium chlorate, > 99.0%	Diatom (<i>Phaeodactylum tricornutum</i>)	EC50 (72-hr) = 298 (177-468) mg/L, reduction in biomass EC50 (72-hr) = 444 (274-719) mg/L, reduction in population growth rate	Brixham Environmental Laboratory, 1995	EcoTox Database	n/a
Sodium chlorate (not specified)	Brown Algae (<i>Ectocarpus variabilis</i>)	EC50 = 15.04 mg/L, reduced population growth rate after 14 days LOAEC = 6.26 mg/L NOAEC = < 6.26 mg/L	Van Wijk <i>et al.</i> , 1998	EcoTox Database	n/a
Sodium chlorate (not specified)	Green Algae (<i>Selenastrum capricornutum</i>)	LOAEC = 77.7 mg/L NOAEC = 62.66 mg/L	Van Wijk <i>et al.</i> , 1998	EcoTox Database	n/a
Potassium chlorate (not specified)	Diatom (<i>Nitzschia closterium</i>)	EC50 (72-hr) = 1.9 (1.6-2.3) mg/L, general population changes	Stauber, 1998	EcoTox Database	n/a
Potassium chlorate (not specified)	Green Algae (<i>Dunaliella tertiolecta</i>)	EC50 (72-hr) = 11 (9-12) mg/L, general population changes	Stauber, 1998	EcoTox Database	n/a

9. Use of Energy and Resources

The manufacture and use of the chlorine dioxide generated using the Electro-Biocide method is not expected to result in a net increase in the use of energy and resources because the subject FCS is intended to be used in place of similar systems on the market (i.e., existing methods and other sources of chlorine dioxide generation). The partial replacement is not expected to have any significant adverse impact on the use of natural resources and energy and resources.

10. Mitigation measures

As discussed above, no significant adverse environmental impacts are expected to result from the use of the FCS in this notification. The use of the FCS as proposed is not expected to result in significant adverse environmental impacts requiring mitigations measures.

11. Alternatives to Proposed Action

No significant adverse environmental effects are identified herein that would necessitate alternatives actions to those proposed in this notification. The alternative of not approving the proposed herein would simply result in the continued use of the currently marketed antimicrobial materials, including chlorine dioxide, that the FCS would replace. Such action would have no significant impact.

12. List of Preparers

This initial assessment was prepared by Erik Hedrick of Burdock Group Consultants. Dr. Hedrick is an associate scientist with over 9 years of toxicology experience and over 15 years of molecular biology and biochemistry experience and updated by Darin Jensen, Vice President of Quality and Food Safety of Energis Solutions

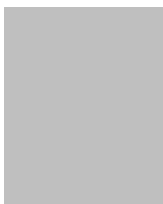
13. Certification

The undersigned certifies that the information presented is true, accurate and complete to the best knowledge of previously Burdock Group Consultants and currently Energis Solutions.

Name: Darin Jensen

Title: Vice President Quality and Food Safety

Signature



14. References

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15. Attachments

- 1) Air Concentration of Chlorine Dioxide
- 2) Appendix 2 - Screenshot of FAP 4A4408 EA page 000014: Environmental Effects of Released Substances: Aquatic Studies
- 3) Appendix 3 - Screenshot of FAP 4A4408 EA page 000015: Environmental Effects of Released Substances: Terrestrial Organism Studies
- 4) Appendix 3 - Screenshot of FAP 4A4408 EA page 000016: Environmental Effects of Released Substances: Terrestrial Organism Studies

Appendix 1: - Air Concentration of Chlorine Dioxide

The air concentration of chlorine dioxide, from its use to disinfect food products, can be calculated by using Henry's Law. The calculation assumes a "worst-case" concentration of residual chlorine dioxide of 3 ppm (= 0.003 g/L).

Henry's Law states that the equilibrium concentration of a dissolved gas [A] is proportional to its partial pressure, or:

$$[A] = K_H P_A$$

For chlorine dioxide, the Henry's Law constant value is $K_H = 55.6 \text{ atm} / (\text{mol ClO}_2 / \text{mol H}_2\text{O})$.

The partial pressure due to an 800 ppm chlorine dioxide solution is calculated as the ratio of mole fractions of chlorine dioxide to water multiplied by the Henry's constant:

$$X_{\text{ClO}_2} = \frac{(0.003 \text{ g/L}) / (67.45 \text{ g/mol ClO}_2)}{(1000 \text{ g/L}) / (18.02 \text{ g/mol H}_2\text{O})} = 8.015 \times 10^{-7} \frac{\text{mol ClO}_2}{\text{mol H}_2\text{O}}$$

$$P_{\text{ClO}_2} = 55.6 \text{ atm} / (\text{mol ClO}_2 / \text{mol H}_2\text{O}) \times (8.015 \times 10^{-7} \text{ mol ClO}_2 / \text{mol H}_2\text{O})$$

Therefore $P_{\text{ClO}_2} = 4.456 \times 10^{-5} \text{ atm}$

From the Ideal Gas Law ($PV = nRT$):

$$\frac{n_{\text{ClO}_2}}{V} = \frac{P_{\text{ClO}_2}}{RT} = \frac{4.456 \times 10^{-5} \text{ atm}}{(0.082057 \text{ L-atm} / \text{K-mol}) \times (298 \text{ K})} = 1.82 \times 10^{-6} \text{ mol/L}$$

$$(1.82 \times 10^{-6} \text{ mol/L}) (67450 \text{ mg ClO}_2/\text{mol}) = 0.123 \text{ mg/L} \times 1000 \text{ l/m}^3 = 0.0018 \text{ mg/m}^3$$

Converting this to ppm in air using the standard molar volume coefficient...

$$0.0018 \text{ mg/m}^3 \times 24.45 = 0.04 \text{ ppm}$$

8. Environmental Effects of Released Substances:

a) Aquatic Studies

USEPA's base set of freshwater and marine aquatic toxicity studies have been conducted with technical sodium chlorite and chlorate. Table 1 summarizes the results of these tests. The aquatic toxicity of both sodium chlorite and chlorate has been reviewed, under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), by USEPA's Office of Pesticide Programs. Due to the toxicity of chlorite to *Daphnia magna*, USEPA has determined that sodium chlorite is toxic to fish. Rio Linda is not aware of any USEPA evaluation of chlorine dioxide. As noted above, chlorine dioxide released into the environment will be converted to chlorite and chlorate.

TABLE 1

Aquatic Toxicity of Sodium Chlorite and Chlorate

Test	Sodium Chlorite	Sodium Chlorate
Bluegill sunfish	100 ppm (96-hr LC ₅₀)	> 1000 ppm (96-hr LC ₅₀)
Rainbow trout	41 ppm (96-hr LC ₅₀)	> 1000 ppm (96-hr LC ₅₀)
<i>Daphnia magna</i>	161 ppb (48-hr LC ₅₀)	> 1000 ppm (48-hr LC ₅₀)
Mysid shrimp	650 ppb (96-hr LC ₅₀)	> 1000 ppm (96-hr LC ₅₀)
Eastern Oyster	129 ppm (96-hr LC ₅₀)	> 1000 ppm (96-hr LC ₅₀)
Sheepshead Minnow	105 ppm (96-hr LC ₅₀)	> 1000 ppm (96-hr LC ₅₀)

b) Terrestrial Organism Studies

The toxicity of sodium chlorite and chlorate to terrestrial organisms has been evaluated in several studies. Study results are summarized in Table 2.

TABLE 2

**Toxicity of Sodium Chlorite and Chlorate
to Terrestrial Organisms**

Test	Sodium Chlorite	Sodium Chlorate
Acute Oral LD ₅₀ (rat)	~260 mg/kg	> 5 g/kg
Acute Oral LD ₅₀ (mallard)	706 mg/kg	> 2.5 g/kg
Avian Dietary LC ₅₀ (mallard)	> 5000 ppm	> 5000 ppm
Avian Dietary LC ₅₀ (bobwhite)	> 5000 ppm	> 5000 ppm

Copies of all the above studies are being submitted to FDA for incorporation into Food Additive Master File (FAMF) No. 510.

c) Environmental Benefits

The use of chlorine dioxide instead of chlorine for disinfecting meat and poultry process water offers two environmental benefits:

1) Reduction in Aquatic Toxicity

According to a recent USEPA document for hypochlorite salts¹, the following aquatic toxicity values were reported².

- Coldwater Fish: 0.132-1.35 ppm (96-hr LC₅₀)
- Warm water fish: 0.28-2.1 ppm (96-hr. LC₅₀)
- *Daphnia magna*: 0.037-2.1 ppm (48-hr. LC₅₀)

¹Reregistration Eligibility Document for Sodium and Calcium Hypochlorite Salts, February, 1992. NTIS Report No. 540/RS-92-193.

²Since both the hypochlorite salts and chlorine form hypochlorous acid upon aqueous dilution the data for hypochlorite salts should be representative of chlorine.

The data indicate that chlorine is much more toxic to freshwater fish (cold and warm water) than sodium chlorite or chlorate and is slightly more toxic to the freshwater invertebrate, *Daphnia magna*. Since data collected by Rio Linda suggests that lower doses of chlorine dioxide will accomplish the same level of disinfection as chlorine the use of chlorine dioxide instead of chlorine significantly decrease the likelihood of aquatic risks resulting from disinfection of poultry and meat chiller water.

2) Trihalomethane Formation

Unlike chlorine, chlorine dioxide does not form trihalomethanes (THMs)¹. Four of the THMs - chloroform, bromodichloromethane, dibromochloromethane, and bromoform - are carcinogenic in animal bioassays².

¹ Aleta, M.E., Berg, J.D. *A Review of Chlorine Dioxide in Drinking Water Treatment*, 78(6), 1986. pgs. 62-72.

² Refer to USEPA's Proposed Rule for Disinfectants and Disinfectant By-Products: 58 *Fed. Reg.* pgs. 38668-38829, July 29, 1994.