Environmental Assessment

1.	**Date**	January 3, 2023
2.	**Name of Applicant**	Seriously Clean Ltd.
3.	**Address**	Agent for Notifier: Joan Sylvain Baughan, Partner Steptoe & Johnson LLP 1330 Connecticut Avenue, NW Washington, DC 20036

4. Description of Proposed Action

a. Requested Action

The action identified in this Food Contact Notification (FCN) is to provide for the use of the Food Contact Substance (FCS) hypochlorous acid (CAS Reg. No. 7790-92-3). The FCS will be shipped as a concentrate or as a pre-diluted, ready-to-use solution, and will be stored for no more than 6 months before use.

The FCS is intended for use as an antimicrobial agent in the production and preparation of fish and seafood; fruits and vegetables; and shell eggs, as follows:

(1) in process water or ice for washing, rinsing, rehydrating or cooling fruits, vegetables;

(2) in ice for cooling whole or cut fish and seafood; and

(3) in process water for washing or rinsing shell eggs;

When used to process fruits, vegetables, and fish and seafood products intended to be consumed raw, the treatment will be followed by either a 10-minute drain step or a potable water rinse to remove, to the extent possible, residues of the FCS. The free available chlorine (FAC) content of the solution placed into contact with food shall not exceed 60 parts per million (ppm). The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

b. Need for Action

The antimicrobial agent reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present on the food or in the process water or ice used during production.

c. Locations of Use/Disposal

The antimicrobial agent is intended for use in fruit and vegetable, fish and seafood, and egg processing plants and facilities, restaurants, and grocery stores throughout the United States. It may also be used aboard fishing vessels during initial to cool fresh-caught seafood. It is expected that most of these facilities – for example, restaurants and grocery stores – will discharge to publicly owned treatment works (POTW). However, as some facilities will discharge directly to surface waters after on-site pre-treatment in accordance with a permit issued under the National Pollutant Discharge Elimination System (NPDES), and for this assessment, we will evaluate facilities that will discharge directly to surface waters in accordance with NPDES regulations. During the on-site treatment process, very minor quantities of the solution are lost to evaporation. Waste water from fishing vessels is expected to be disposed in the ocean.

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

Seriously Clean's hypochlorous acid solution delivers a maximum of 60 ppm of free available chlorine (FAC) at the pH of a weak acid. Relative proportions of the active chlorine species are determined by the pH of the solution.

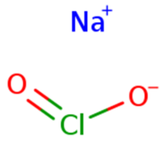
Identifying information is also provided for residual chemicals that may be present in the final solution, including degradation oxychloro species (chlorate and chlorite) and trihalomethane (THM) formation by-products (bromodichloromethane, chlorodibromomethane, bromoform, and chloroform).

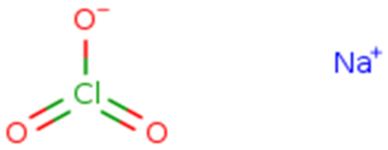
Table 1 - Chemical Identity of Substances of the Proposed Action

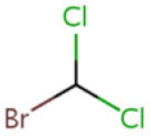
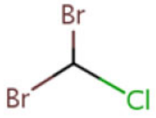
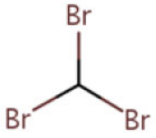
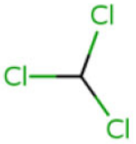
CAS Name	Hypochlorous acid
CAS Registry Number	7790-92-3
Formula	HOCl
Structure	HO—Cl
Molecular weight	52.46 g/mol
Comment	The primary active oxychloric species in the solution; present at not more than 60 ppm (as FAC) in the end-use product solutions; interchangeable chlorine species in the final solution.

CAS Name	Chlorine
CAS Registry Number	7782-50-5
Formula	Cl_2
Structure	Cl—Cl
Molecular weight	70.91 g/mol
Comment	Minimized under controlled pH environment; chlorine species in final solution.

CAS Name	Hypochlorite
CAS Registry Number	7681-52-9
Formula	ClO^- ($NaClO$)
Structure	
Molecular weight	74.4 g/mol
Comment	Minimized under controlled pH environment; interchangeable chlorine species in final solution

CAS Name	Chlorite
CAS Registry Number	7758-19-2 (Sodium chlorite)
Formula	ClO_2^- (ion form) ($NaClO_2$ salt)
Structure	
Molecular weight	90.44 g/mol ($NaClO_2$)
Comment	By-product of the hypochlorous acid solution, minimized under controlled pH environment.

CAS Name	Chlorate
CAS Registry Number	7775-09-9 (Sodium chlorate)
Formula	ClO_3^- (ion form) ($NaClO_3$ salt)
Structure	
Molecular weight	106.44 g/mol ($NaClO_3$)
Comment	By-product of the hypochlorous acid solution, minimized under controlled pH environment.

Name	Trihalomethanes (THMs)
CASRN	Bromodichloromethane: 75-27-4 Chlorodibromomethane: 124-48-1 Bromoform: 75-25-2 Chloroform: 67-66-3
Formula	Bromodichloromethane: $CHBrCl_2$ Chlorodibromomethane: $CHBr_2Cl$ Bromoform: $CHBr_3$ Chloroform: $CHCl_3$
Structure	 75-27-4  124-48-1  75-25-2  67-66-3
Molecular weight	119.38 to 252.73 g/mol
Comment	By-products formed in concentrate or final solution

6. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

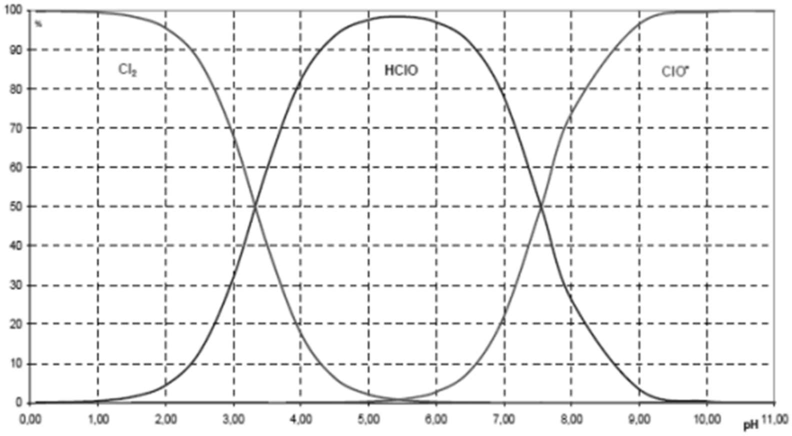
Under 21 Code of Federal Regulations (CFR) § 25.40(a), an Environmental Assessment (EA) should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of U.S. Food and Drug Administration (FDA)-regulated articles. The FCS is manufactured in plants that meet all applicable federal, state, and local environmental regulations. The Notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS, such as: 1) unique emission circumstances that are not adequately addressed by general or specific emission requirements (including occupational requirements) promulgated by Federal, State or local environmental agencies and that may harm the environment; 2) any action threatening a violation of Federal, State or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with the proposed action that may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law.

b. Introduction of Substances into the Environment as a Result of Use/Disposal

Introduction of very dilute solutions of the product into the environment will take place primarily via release from wastewater treatment systems. Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in processing water for the foods identified above, and the subsequent disposal of such water into surface waters in accordance with an NPDES permit. Most of the requested applications of the FCS will involve treatment in onsite facilities but some applications may involve drainage into POTWs. As a worst case, we will consider only on-site treatment prior to disposal to surface waters. We expect that large processing facilities may utilize a wastewater recovery system, however, as a conservativism, we have not assumed any water reuse in the assessment.

Hypochlorous acid exists interchangeably with other chlorine species. This is supported by the equilibrium chemistry of active chlorine. In a controlled pH environment in the range of 5.0 to 5.9, hypochlorous acid will exist as the dominant chlorine species.

Figure 1. Equilibrium Chemistry of Active Chlorine



The chemical species in the hypochlorous acid solution are aqueous and will be introduced into the aquatic environment via discharge to surface waters. Because the pH of Seriously Clean's hypochlorous acid solution is a weak acid, the dominant oxychlorine species is hypochlorous acid. It is well understood that the primary antimicrobial activity for hypochlorous acid and hypochlorite solutions is due to the activity of the acid component, and so Seriously Clean's operational parameters include operation between pH 5.0 and 5.9 to maximize available acid and the resulting antimicrobial efficacy. As we see in Figure 1, at pH 6 the solution is approximately 94% HOCl and 6% ClO-. Additionally, because oxychlorine species are strong oxidizers, they are expected to react readily with oxidizable compounds in the waste stream and be rapidly reduced to other chlorine species, primarily chlorides (ECHA 2007).[1] At a pH between 5.0 and 5.9 the predominant reactions will be:

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[1] European Union Risk Assessment Report Sodium Hypochlorite, Final Report, November 2007, pg. 21, *available at:* https://echa.europa.eu/documents/10162/330fee6d-3220-4db1-add3-3df9bbc2e5e5

1. $2HClO \rightarrow 2HCl + O_2$

2. $3NaClO \rightarrow NaClO_3 + 2NaCl$[2]

The second reaction will be favored at higher pHs, but both reactions will tend to decrease the overall pH by increasing H^+ concentrations through production of HCl or through dissociation of HOCl to form OCl^- to maintain the equilibrium between those two species. Thus, although reaction 2 may occur at the operational pH range, it should not predominate, as pH will be reduced through both reactions. In addition, we note that only one chlorate ion is produced for every three hypochlorite ions in reaction 2 above. Finally, chlorate ion is expected to be a strong oxidizer and to react with organic matter and/or metal ions in water to produce chlorite ion and ultimately chloride ion.[3,4]

Treatment facilities use chlorine as part of the wastewater treatment process, as a disinfectant (EPA 2000).[5] Because it is known that discharge of too much chlorine can have an adverse effect on aquatic life in receiving waters, prior to discharge of treated wastewater treatment facilities use dechlorination mechanisms such as sulfonation to remove chlorine compounds.[6] The levels of chlorine that may be discharged from treatment facilities are tightly regulated under National Pollutant Discharge Elimination System (NPDES) permits to meet established water quality standards which reflect EPA's water quality criteria for chlorine, including the Criteria Maximum Concentrations (CMCs) for acute effects and the Criterion Continuous Concentrations (CCCs) for chronic effects.[7]

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[2] *Ibid.*

[3] U.S. Environmental Protection Agency (EPA), *Product Chemistry, Environmental Fate, and Ecological Effects Scoping Document of Registration Review of Sodium and Calcium Hypochlorite Salts* (March 22, 2012), pg. 6, *available at:* www.regulations.gov, docket no. EPA-HQ-OPP-2012-0004, document no. 0003.

[4] Op Cite EU 2007.

[5] U.S. Environmental Protection Agency. (2000). *Wastewater Technology Fact Sheet: Dechlorination*. Washington, D.C.: Office of Water, EPA 832-F-00-022, *available at:* https://www3.epa.gov/npdes/pubs/dechlorination.pdf; U.S. Environmental Protection Agency. (2006b). *Reregistration Eligibility Decision (RED) for Inorganic Chlorates*, Washington, D.C.: Office of Prevention, Pesticides and Toxic Substances, EPA 738-R-06-014, p. 11, *available at:* https://archive.epa.gov/pesticides/reregistration/web/pdf/inorganicchlorates_red.pdf

[6] Ibid EPA 2000, pg. 1

[7] U.S. Environmental Protection Agency. (2015). *National Recommended Water Quality Criteria – Aquatic Life Criteria Table*, available at: https://www.epa.gov/wqc/national-recommended-water-quality-criteria-aquatic-lifecriteria-table.

Water containing hypochlorous acid may be used in the following manners:

i. Fruit and Vegetable Processing Facilities

Water is used extensively in almost all aspects of processing fruits and vegetables, including during cooling, washing, and conveying of produce (FDA 2008).[8] Different methods may be used to wash different types of produce, including submersion, spray, or both (FDA 2008). Introduction of the components of the product into the environment will result from use of the product as an antimicrobial agent in the fruit and vegetable processing water and the subsequent disposal of the water. Water is used in produce processing, in both commercial and retail settings, for a variety of applications that will not utilize the FCS, including blanching, filling, cleaning and sanitizing of plant equipment and facilities, and for processed product cooling, resulting in significant dilution of the FCS into the total water effluent. Effluent for such facilities going to on site treatment facilities (or any other treatment facilities) would be expected to include significant amounts of organic matter including produce processing waste and removed soil.

ii. Fish and Seafood Cooling

The FCS is intended for use in ice to cool whole or cut fish and seafood. Water is used during many steps of seafood processing, including preparation (*e.g.*, scaling, filleting, skinning, evisceration), inspection and trimming, product processing (*e.g.*, pickling and brining), and further processing (*e.g.*, freezing, canning, and bottling) (Tay 2006).[9] There are also a number of water uses in seafood processing plants that would not utilize the FCS, including equipment sprays, offal transport, cooling water, steam generation, and equipment and food cleaning (Tay 2006). The proposed use in seafood and fish processing also includes use aboard fishing vessels to cool fresh-caught seafood. The wastewater from such use will be discharged directly into ocean water. The resulting dilution would make any introduction from fishing vessels negligible.

iii. Shell Egg Wash

The FCS is intended for use as an antimicrobial rinse for shell eggs. Commercial washing of shell eggs is typically performed in a mechanical washer in which a series of spray nozzles mist an alkaline detergent over the eggs as flat brushes move side to side across the shells' surfaces (Northcutt 2005).[10] After washing, the final antimicrobial spray rinse is used. As with many food processing applications, estimates of water usage are difficult to compare,

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[8] U.S. Food and Drug Administration. (2008, February). *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008, *available at:* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm#ch4.

[9] Tay, J-H., Show, K-Y., and Hung, Y-T. (2006). *Seafood Processing Wastewater Treatment*, in Wang, L.K. et al. eds., *Waste Treatment in the Food Processing Industry*.

[10] Northcutt, J.K., Musgrove, M.T., and Jones, D.R. (2005). *Chemical Analyses of Commercial Shell Egg Wash Water*, Journal of Applied Poultry Research, 14: 289-295, *available at:* http://naldc.nal.usda.gov/download/38830/PDF.

with reported values including 4.4 gal/min (16.6 L/min) of fresh water during washing, 2.8 gal per case (360 eggs) of eggs (10.6 L/case), and 2.5 billion gal (9.46 billion L) of wastewater each year (Northcutt 2005). No data is reported on the water usage specifically during the antimicrobial rinse. More recent water usage values have not been located, however, it is possible to estimate a dilution factor based on total water usage in typical shell egg processing plants. The U.S. Department of Agriculture (USDA) has developed regulations governing the voluntary grading of shell eggs.[11] This program requires shell eggs to be washed using potable water and approved cleaning compounds.[12] This wash water must be changed at least every four hours, and replacement water is continually added.[13] In some facilities, multiple washing steps are used (Musgrove 2006).[14] There may also be a prewetting step prior to washing, which involves spraying a continuous flow of water over the eggs.[15] The antimicrobial spray rinse occurs after the various washing steps. The USDA program also requires a processing plant to clean the egg grading and packing rooms,[16] grading and candling equipment,[17] oil application equipment,[18] and cleaning equipment.[19] Water also is used for general plant operations. Effluent for such facilities going to on site treatment facilities (or any other treatment facilities) would be expected to include significant amounts of organic matter including removed soil.

iv. Introduction of Substances

All of the above intended uses of the FCS result in wastewater containing substantial amounts of soil and other organic matter before, during, and after treatment. For example, significant amounts of food particles will be included in the wastewater for nearly all of the above processes, and soil will be present in all as all of the above uses are primarily intended to wash away soil and other materials from processed food. In addition to oxidizable organic matter, numerous inorganic metal ions will also be present which may also be oxidized (*e.g.*, $Fe^{+2} \rightarrow Fe^{+3}$). The recent European Union (EU) risk assessment (EU 2007) for sodium hypochlorite emphasizes the reactivity of hypochlorous acid, hypochlorite ion and other associated oxychloro compounds. Because of the complexity of the potential reactions among hypochlorite, hypochlorous acid, other oxychloro compounds and organic matter including food,

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[11] 7 C.F.R. Part 56, *available at:* https://www.govinfo.gov/content/pkg/FR-2019-09-23/pdf/2019-20123.pdf

[12] 7 C.F.R. § 56.76(f).

[13] *Ibid*.

[14] Musgrove, M.T., *et al.* (2006). *Antimicrobial Resistance in Salmonella and Escherichia coli Isolated from Commercial Shell Eggs*, Poultry Science, 85: 1665-1669, *available at:* https://pubag.nal.usda.gov/catalog/3896

[15] 7 C.F.R. § 56.76(f).

[16] 7 C.F.R. § 56.76(b)(4).

[17] 7 C.F.R. § 56.76(c)(3).

[18] 7 C.F.R. § 56.76(e)(5).

[19] 7 C.F.R. § 56.76(f)(1).

soil and other oxidizable matter, the EU risk assessment has relied on kinetic modeling of the reduction of the various oxychloro compounds to chloride.[20] This kinetic model predicts that even concentrations as high as 75 ppm active chlorine result in near complete reduction of available chlorine to chloride in a matter of hours during transport, treatment and introduction into surface waters.

The rigor of the model has been tested and accepted as conservative for the EU risk assessment. The model predicts that at initial concentrations of 75 ppm sodium hypochlorite will decay to less than 4×10^{-27} parts per billion (ppb) active chlorine in the approximately 9 hours window for use and treatment and discharge of the chemical (including 10 minutes after discharge into surface waters). In addition, the model predicts decay of any chloramines that may be produced to concentrations of 1×10^{-10} ppb as well.

With respect to halomethanes and associated compounds, the EU risk assessment estimates an overall production rate for uses of hypochlorite disinfectants of about 1.5% of total available chlorine.[21] The EU risk assessment focuses on halomethanes, and chlorinated acetic acids with regard to environmental introductions. We consider the estimate of the production of these compounds relative to available chlorine to be conservative compared to the intended uses discussed herein, because the EU report also shows that uses including larger amounts of available organic material will reduce the residual oxidative species significantly.[22] Thus, we conservatively estimate a maximum combined concentration of trihalomethanes and other trichloroacetic and other haloacetic acids as 60 ppm × 1.5% = 900 ppb. However, the EU risk assessment estimates that trihalomethanes constitute no more than 9.6%; trichloroacetic acid constitutes no more than 3.49%; and other chlorinated acetic acids constitute no more than 4% of the total oxidizable species before treatment. Thus, we estimate the concentrations of trihalomethanes, trichloroacetic acid and other chloroacetic acids prior to treatment to be no greater than 86.4 ppb, 31.4 ppb, and 36 ppb, respectively. These concentrations would be reduced 10-fold upon dilution in surface waters. The EU assessment estimates that other species would be expected to be present at less than an order of magnitude lower than the substances of primary concern; trihalomethanes, trichloroacetic acid and other chloroacetic acids.[23] expected introduction concentrations (EICs) for compounds for the aqueous compartment are: 4×10^{-27} ppb for HOCl, OCL^-, ClO_2^- and ClO_3^-; 1×10^{-10} ppb for chloroamines; 8.64 ppb for trihalomethanes; 3.14 ppb for trichloroacetic acid and 3.6 ppb for other chloroacetic acids. Finally, because the hypochlorous acid and its reaction and breakdown products will be ultimately reduced to chlorides, we will assume a chloride concentration of 6 ppm (mg/L), incorporating only the 10% reduction for dilution in surface waters.

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[20] Op Cite EU Appendix 2.

[21] *Ibid* pg. 52.

[22] *Ibid.*

[23] *Ibid.* pg. 54.

7. Fate of Emitted Substances in the Environment

Adsorption and oxidation-reduction reactions will have occurred during wastewater treatment, before reaching the aquatic environment. Since oxychlorine species are strong oxidizers, they are expected to react readily with oxidizable compounds in the wastewater treatment process before discharge to surface waters. Though many of these species will have been depleted by the above-stated mechanisms, some potential for exposure through air may exist.

A pH-mediated equilibrium exists between the free chlorine species. Decomposition of free chlorine species depend on a number of factors such as pH, concentration, nature of inorganic and organic matter in aquatic environment, exposure to sunlight, and temperature. The half-life of free residual chlorine in natural freshwater systems is approximately 1.3 to 5 hours (U.S. EPA, 1999).[24] There is no evidence that active chlorine species accumulate in sediment (U.S. EPA, 1999). Oxychlorine species are strong oxidizers and readily react with oxidizable organic compounds. Chlorate does not bind readily to soil or sediment particulates and is expected to be very mobile and partition predominantly into the water (EPA, 2006b).[25] However, extensive redox reactions are expected to occur in the environment, which would serve to reduce the concentration of chlorate in surface waters (EPA, 2006b). Oxychlorine species have low bioaccumulation potential, high mobility, and low volatility. They do not readily biodegrade under aerobic conditions (EPA, 2006a[26] and 2006b). Upon reaching surface water, the THMs are expected to transition out of the aquatic environment within hours to days.[27]

Based on the above, we conclude that the primary environmental exposure will be through the aquatic compartment.

8. Environmental Effects of Released Substances

Any number of free or reduced chlorine species, possibly including chlorine, hypochlorous acid, hypochlorite, chlorite, or chlorate, as well as THM species, including bromodichloromethane, chlorodibromomethane, bromoform, and chloroform may be released

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[24] U.S. Environmental Protection Agency. (1999). *Registration Eligibility Decision (RED) for Chlorine Gas*. Washington, D.C.: Office of Prevention, Pesticides and Toxic Substances, EPA 738-R-99-001, *available at:* http://archive.epa.gov/pesticides/reregistration/web/pdf/4022red.pdf.

[25] U.S. Environmental Protection Agency. (2006b). *Reregistration Eligibility Decision (RED) for Inorganic Chlorates*. Washington, D.C.: Office of Prevention, Pesticides and Toxic Substances, EPA 738-R-06-014. *See* https://archive.epa.gov/pesticides/reregistration/web/pdf/inorganicchlorates_red.pdf.

[26] U.S. Environmental Protection Agency. (2006a). *Chlorine Dioxide: Environmental Hazard and Risk Assessment Case 4023*. EPA Docket No. EPA-HQ-2006-0328, *available at:* www.regulations.gov.

[27] *See* PubChem entries for the THM species: Chlorodibromomethane, https://pubchem.ncbi.nlm.nih.gov/compound/31296#section=Ecotoxicity-Excerpts; Bromoform, https://pubchem.ncbi.nlm.nih.gov/source/hsdb/2517#section=Ecotoxicity-Values; Chloroform, https://pubchem.ncbi.nlm.nih.gov/compound/6212#section=Ecotoxicity-Values&fullscreen=true; Bromodichloromethane, https://pubchem.ncbi.nlm.nih.gov/compound/bromodichloromethane#section=Ecotoxicity-Values.

down-the-drain through POTWs into aquatic environments during intermittent use of the hypochlorous acid solution. The available ecotoxicity endpoint ranges for chlorinated and THM species are summarized in Tables 2 and 3, respectively.

Table 2. Environmental Toxicity for Chlorine Species

Aquatic Species	**Chemical Species**	**Acute LC_{50} or EC_{50} (mg/L)**	**Source**
Freshwater fish	Chlorite	50.6-420	U.S. EPA, 2006a[28]
	Chlorate	>1,000	U.S. EPA, 2006c[29]
	Chlorine (FAC)	0.045-0.71	U.S. EPA, 2010[30]
Freshwater invertebrates	Chlorite	0.027-1.4	U.S. EPA, 2006a
	Chlorate	920	U.S. EPA, 2006c
	Chlorine (FAC)	0.017-0.673	U.S. EPA, 2010
Estuarine/marine fish	Chlorite	75	U.S. EPA, 2006a
	Chlorate	>1,000	U.S. EPA, 2006c
	Chlorine (FAC)	0.71	U.S. EPA, 2010
Estuarine/marine invertebrates	Chlorite	0.576-21.4	U.S. EPA, 2006a
	Chlorate	>1,000	U.S. EPA, 2006c
	Chlorine (FAC)	0.026-1.42	U.S. EPA, 2010
Aquatic plants	Chlorite	1.32	U.S. EPA, 2006a
	Chlorate	43-133	U.S. EPA, 2006c
	Chlorine (FAC)	None reported	U.S. EPA, 2010

The most sensitive endpoint for the chloro species is the freshwater invertebrate LC_{50} for chlorine (primarily hypochlorous acid in water), which is 0.017 mg/L, or 17 µg/L. The EIC based on the EU risk assessment is 4×10^{-27} µg/l for HOCl, OCL^-, $ClO2^-$ and $ClO3^-$. Thus, the EIC for oxychlorospecies is more than 25 orders of magnitude lower than the EIC.

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[28] U.S. Environmental Protection Agency. (2006a). *Chlorine Dioxide: Environmental Hazard and Risk Assessment Case 4023*. EPA Docket No. EPA-HQ-2006-0328, available at: www.regulations.gov.

[29] U.S. Environmental Protection Agency. (2006c). *Environmental Fate and Ecological Risk Assessment for the Reregistration of Sodium Chlorate as an Active Ingredient in Terrestrial Food/Feed and Non-food/Non-feed Uses*. Reregistration Case Number 4049, Docket No. EPA-HQ-OPP-2005-0507, *available at:* www.regulations.gov.

[30] U.S. Environmental Protection Agency. (2010). *Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Chlorine Registration Review Decision Document*, Case No. 4022, EPA Docket No. EPA-HQ-OPP-2010-0242, available at www.regulations.gov.

Table 3. Environmental Toxicity for THM Species[31]

Aquatic Species	**Chemical Species**	**Acute LC_{50} or EC_{50} (mg/L)[a]**
Freshwater fish	Bromodichloromethane	--
	Chlorodibromomethane	53-250 [b]
	Bromoform	29
	Chloroform	0.185 [b] -133
Freshwater invertebrates	Bromodichloromethane	--
	Chlorodibromomethane	--
	Bromoform	46-56 [b]
	Chloroform	29-353
Estuarine/ marine fish	Bromodichloromethane	--
	Chlorodibromomethane	--
	Bromoform	7.1-29
	Chloroform	--
Estuarine/marine invertebrates	Bromodichloromethane	--
	Chlorodibromomethane	--
	Bromoform[6]	1.0-24
	Chloroform[5]	81.5
Aquatic plants	Bromodichloromethane	--
	Chlorodibromomethane	--
	Bromoform	--
	Chloroform[5]	437-950

[a] "--" No data was listed

[b] Non-standard test duration

The most sensitive acute endpoint for THM species is the EC_{50} of 0.185 mg/L for freshwater fish, which is associated with exposure to chloroform. The volatility of halomethanes will mean that most will evaporate from surface waters in a matter of hours. The EIC of 8.6 µg/l estimated above is well below the most sensitive endpoint for aquatic toxicity.

Chloramines are chemicals commonly used in the disinfection of drinking water. We have attached records from EPA's Ecotox database. These data records show that the most sensitive aquatic species in the water flea with an LC_{50} of 0.016 mg/L. It is expected that chloroamines will be reduced so that the EIC will be no more than 1 x 10^{-10} ppb (µg/l). Thus, the EIC is over 11 orders of magnitude below the lowest LC_{50}.

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[31] *See* PubChem entries for the THM species: Chlorodibromomethane, https://pubchem.ncbi.nlm.nih.gov/compound/31296#section=Ecotoxicity-Excerpts; Bromoform, https://pubchem.ncbi.nlm.nih.gov/source/hsdb/2517#section=Ecotoxicity-Values; Chloroform, https://pubchem.ncbi.nlm.nih.gov/compound/6212#section=Ecotoxicity-Values&fullscreen=true; Bromodichloromethane, https://pubchem.ncbi.nlm.nih.gov/compound/bromodichloromethane#section=Ecotoxicity-Values.

Monochloracetic acid is produced in the disinfection of drinking water and is present in drinking water at levels between 2 and 82 µg/l. WHO has performed a risk assessment of monochloramine in drinking water and estimated a tolerable daily intake for humans of 210 µg/p/d, a level which includes a 100-fold safety factor and which is still more than 60-fold larger than our EIC of 3.6 µg/l. In addition, the Organisation for Economic Co-operation and Development (OECD) Screening Information Dataset (SIDS) has assessed the environmental safety of trichloracetic acid. OECD SIDS identified the alga *Chlorella pyrenoidosa* as the most sensitive species with a no observed effect concentration (NOEC) of 10µg/l. Our EIC of 3.14 µg/l for trichloroacetic acid is 3-fold below the referenced no effect concentration.

Finally, as noted in section 6 above we have estimated an EIC for chloride of 6 ppm. A review of ecotoxicology data on the chloride ion indicates that the most sensitive species based on LC_{50}s and EC_{50}s is Cladoceron with an EC_{50} of 735 mg/L (735 ppm).[32] Thus, the EIC is over two orders of magnitude below the lowest measure of aquatic toxicity.

9. Use of Resources and Energy

The notified use of the FCS will not require additional energy resources for treatment and disposal of waste solution, as the FCS is expected to compete with, and to some degree, replace similar products already on the market. The raw materials that are used in production of the mixture are commercially-manufactured materials that are produced for use in a variety of chemical reactions and production processes. Energy used specifically for the production of the mixture components is not significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the food contact substance. Therefore, no mitigation measures are required.

11. Alternatives to the Proposed Action

No significant adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. If the proposed action is not approved, the result would be the continued use of the currently marketed antimicrobial agents that the subject FCS would replace. Such action would have no significant environmental impact.

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[32] Siegel, Lori; Hazard Identification for Human and Ecological Effects of Sodium Chloride Road Salt (6 July, 2007), State of New Hampshire, Department of Environmental services Table 4 (pp. 8-9).

12. List of Preparers

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13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of her knowledge.

Date: January 3, 2023

[redacted]

Joan Sylvain Baughan, Partner

14. References

European Union Risk Assessment Report, *Sodium Hypochlorite Final Report*, November 2007, *available at:*https://echa.europa.eu/documents/10162/330fee6d-3220-4db1-add3-3df9bbc2e5e5

Musgrove, M.T., *et al.* (2006). *Antimicrobial Resistance in Salmonella and Escherichia coli Isolated from Commercial Shell Eggs*, Poultry Science, 85: 1665-1669, *available at:* https://pubag.nal.usda.gov/catalog/3896.

Northcutt, J.K., Musgrove, M.T., and Jones, D.R. (2005). *Chemical Analyses of Commercial Shell Egg Wash Water*, Journal of Applied Poultry Research, 14: 289-295, *available at:* http://naldc.nal.usda.gov/download/38830/PDF.

PubChem entries for Chlorodibromomethane, Bromoform, Chloroform, Bromodichloromethanes, *available at:* https://pubchem.ncbi.nlm.nih.gov/.

Siegel, Lori; Hazard Identification for Human and Ecological Effects of Sodium Chloride Road Salt (6 July, 2007), State of New Hampshire, Department of Environmental Services; Table 4 (pp. 8-9).

Tay, J-H., Show, K-Y., and Hung, Y-T. (2006). *Seafood Processing Wastewater Treatment*, in Wang, L.K. et al. eds., Waste Treatment in the Food Processing Industry.

U.S. Environmental Protection Agency. (2015). *National Recommended Water Quality Criteria – Aquatic Life Criteria Table, available at:* https://www.epa.gov/wqc/national-recommended-water-quality-criteria-aquatic-life-criteria-table

U.S. Environmental Protection Agency. (2010). *Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Chlorine Registration Review Decision Document*, Case No. 4022, EPA Docket No. EPA-HQ-OPP-2010-0242, *available at:* www.regulations.gov.

U.S. Environmental Protection Agency. (2006a). *Chlorine Dioxide: Environmental Hazard and Risk Assessment Case 4023*. EPA Docket No. EPA-HQ-2006-0328, *available at:* www.regulations.gov.

U.S. Environmental Protection Agency. (2006b). *Reregistration Eligibility Decision (RED) for Inorganic Chlorates.* Washington, D.C.: Office of Prevention, Pesticides and Toxic Substances, EPA 738-R-06-014, *available at:* https://archive.epa.gov/pesticides/reregistration/web/pdf/inorganicchlorates_red.pdf

U.S. Environmental Protection Agency. (2006c*). Environmental Fate and Ecological Risk Assessment for the Reregistration of Sodium Chlorate as an Active Ingredient in Terrestrial Food/Feed and Non-food/Non-feed Uses*. Reregistration Case Number 4049, Docket No. EPA-HQ-OPP-2005-0507, *available at:* www.regulations.gov.

U. S. Environmental Protection Agency, *Product Chemistry, Environmental Fate, and Ecological Effects Scoping Document of Registration Review of Sodium and Calcium Hypochlorite Salts* (March 22, 2012), pg. 6, *available at:* www.regulations.gov, docket no. EPA-HQ-OPP-2012-0004, document no. 0003.

U.S. Environmental Protection Agency. (2000). *Wastewater Technology Fact Sheet: Dechlorination*. Washington, D.C.: Office of Water, EPA 832-F-00-022, *available at:* https://permanent.fdlp.gov/websites/epagov/www.epa.gov/OWM/mtb/dechlorination.pdf

U.S. Environmental Protection Agency. (1999). *Registration Eligibility Decision (RED) for Chlorine Gas*. Washington, D.C.: Office of Prevention, Pesticides and Toxic Substances, EPA 738-R-99-001, *available at:* https://archive.epa.gov/pesticides/reregistration/web/pdf/4022red.pdf

U.S. Food and Drug Administration. (2008, February). *Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables*, February 2008, *available at:* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm#ch4.