Environmental Assessment
of Ultra-Lyte® Hypochlorous Acid Solution

1. Date:	September 20, 2023
2. Name of Applicant:	Clarentis Technologies, LLC
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4. Description of the 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 Substance Substance (FCS) hypochlorous acid (CAS Reg. No. 7790-92-3).

Intended Use:
For use as an antimicrobial agent in an aqueous solution in the production and preparation of fish and seafood, fruits and vegetables, and shell eggs, except in contact with infant formula and human milk (see Limitations/Specifications).

Limitations/Specifications:
The FCS solutions will be stored for no more than six months before use. The concentration of available free chlorine in the diluted solution will not exceed 60 parts per million (ppm), and the FCS solution will be replaced if the concentration falls below 25 ppm available free chlorine. The diluted solution containing the FCS may be used in processing facilities and retail food establishments as follows:

1. in process water or ice for washing, rinsing, rehydrating, cooling, or spraying fruits, and 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 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 no-pathogenic microorganisms that may be present in the food or in the process water or ice used during production. In summary, the requested action to expand the currently approved uses of the FCS is needed to address current and future needs of food processors and governmental agencies to improve food safety. Use of the FCS provides more options for efficacious antimicrobial interventions in processing facilities and retail food establishments as follows:

c. Location of Use/Disposal

The antimicrobial agent is intended for use in fruit and vegetable, fish and seafood, and egg processing plants and food establishments throughout the United States. It may also be used aboard fishing vessels during initial evisceration and cleaning of 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), for this assessment we will evaluate for evaluate facilities who 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. Wastewater from fishing vessels expected to be disposed in the ocean.

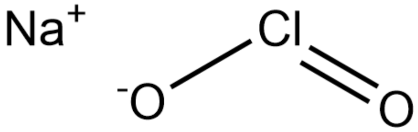
5. Identification of Substances that are Subject of Proposed Action

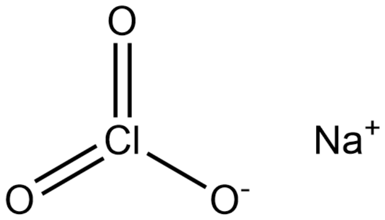
The FCS, Clarentis's Ultra-Lyte® antimicrobial hypochlorous acid solution, will be generated at up to 60 ppm of free available chlorine (FAC) at a pH of 5.8 to 6.2. Relative proportions of the active chlorine species are determined by the pH of the solutions.

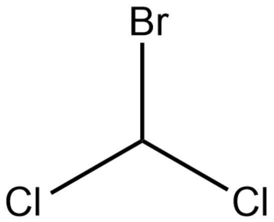
The identities are provided for the residual chemicals that may be generated in the final solution, including degradation of oxychlorine species (chlorate and chlorite) and trihalomethane (THM)formation by-products (bromodichloromethane, chlorodibromomethane, bromoform, and chloroform).

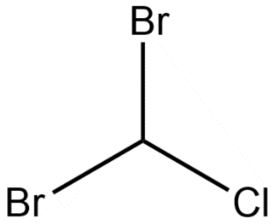
Table 1: Chemical Identity of Substances of the Proposed Action

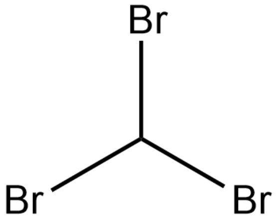
Parameter	*Specification*
CAS Name:	**Hypochlorous Acid**
CAS Registry Number:	7790-92-3
Formula:	HOCl
Structure:	HO—Cl
Molecular weight:	52.46 g/mol
Water solubility:	Soluble
Comment:	The primary active species in solution. Present at not more than 60 ppm.

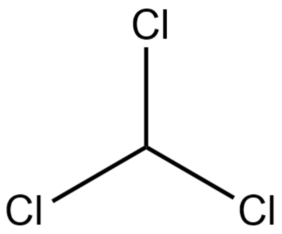
CAS Name:	**Chlorite**
CAS Registry Number:	7758-19-2 (Sodium chlorite)
Formula:	$ClO2^{-}$ (NaClO2)
Structure:	
Molecular weight:	90.44 g/mol (NaClO2)
Water solubility:	Soluble
Comment:	By-product from Ultra-Lyte® hypochlorous acid solution

CAS Name:	**Chlorate**
CAS Registry Number:	7775-09-9 (Sodium chlorate)
Formula:	$ClO3^{-}$ (NaClO3)
Structure:	
Molecular weight:	106.44 g/mol (NaClO3)
Water solubility:	Soluble
Comment:	By-product from Ultra-Lyte® hypochlorous acid solution, mineralized under controlled pH environment

CAS Name:	**Bromodichloromethane**
CAS Registry Number:	75-27-4
Formula:	CHBrCl2
Structure:	
Molecular weight:	163.83 g/mol
Water solubility:	Soluble
Comment:	By-product formed in final solution

CAS Name:	**Chlorodibromomethane**
CAS Registry Number:	124-48-1
Formula:	CHBr2Cl
Structure:	
Molecular weight:	208.28 g/mol
Water solubility:	Soluble
Comment:	By-product formed in final solution

CAS Name:	**Bromoform**
CAS Registry Number:	75-25-2
Formula:	CHBr3
Structure:	
Molecular weight:	252.73 g/mol
Water solubility:	Soluble
Comment:	By-product formed in final solution

CAS Name:	**Chloroform**
CAS Registry Number:	67-66-3
Formula:	CHCl3
Structure:	
Molecular weight:	119.38 g/mol
Water solubility:	Soluble
Comment:	By-product formed in final solution

6. Introduction of Substances into the Environment

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

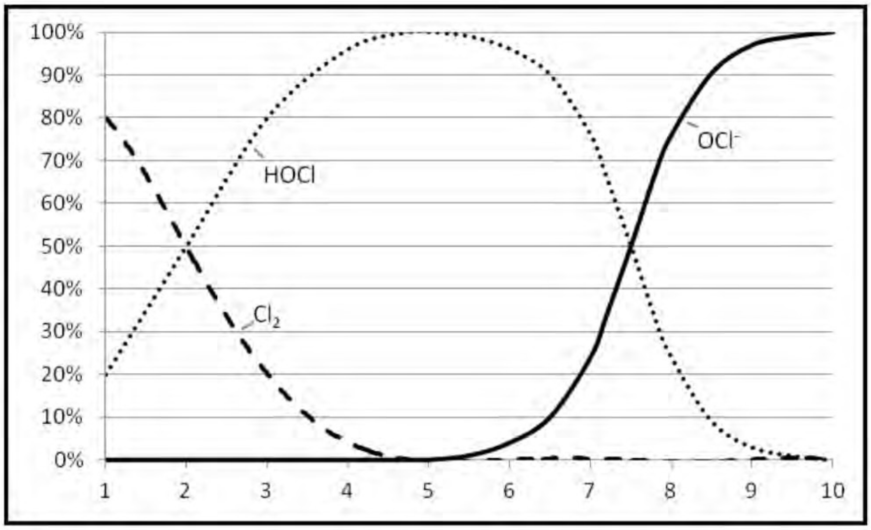
Under 21 C.F.R. § 25.40(a), an environmental assessment should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS is manufactured in plants which meet all applicable Federal, State, and local environmental regulations. The notifier asserts 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) promulgated by the Federal, State, or local environmental agencies and that may harm the environment; 2) the 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 orthreatened, 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 products 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 the use of the product as an antimicrobial agent in processing water for the foods identified above, and the subsequent disposal of such water in accordance with an NPDES permit. Most of the requested applications of the FCS will involve treatmentin 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. To be conservative, 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 controlled pH environment in the range of 3.4 to 7.4, 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 the surface waters. Because the pH of Ultra-Lyte® antimicrobial hypochlorous acid 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 Clarentis's operational parameters include operation between pH 5.8 and 6.2 to maximize available HOCl 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 and 7 the predominant reactions will be:

1. $2HClO \rightarrow 2HCl + O_2$
2. $3NaClO \rightarrow NaClO_3 + 2NaCl$ [2]

The second reaction will be favored at higher pH but both reactions will tend to decrease overall by pH increasing H+ concentrations through production of HCl or through dissociation of HOCl to form OCL^- to maintain 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.

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

[2] Ibid.

In addition, we note that only one chlorate ion is produced for every three hypochlorite ions in reaction toabove. 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 dichlorination 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 Systems (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]

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

i. Fruit and Vegetable Processing

Water is used extensively in almost all aspects of processing fruits and vegetables, including during cooling, washing, and conveying 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 fruits and vegetable processing water and the subsequent disposal of 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 the 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 facility) would be expected to include significant amounts of organic matter including produce processing waste and removed soil.

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[3] 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:Regulations.gov - Supporting & Related Material Document

[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, pg. 11, https://archive.epa.gov/pesticides/reregistration/web/pdf/inorganicchlorates_red.pdf.

[6] Ibid EPA 2000, pg. 1

[7] 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.

[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: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-cut-fruits-and-vegetables.

ii. Fish and Seafood Processing

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 the use aboard fishing vessels during the initial evisceration and cleaning of fresh-caught seafood. The wastewater from such a use will be discharged directly into the 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 use are difficult to compare, with reported values including 4.4 gal/min (16.6 L/min) of fresh water during washing, 2.8 gal/case (360 eggs) of eggs (10.6 L/case), and 2.5 billion gal (9.46 billion L) of wastewater each year (Northcutt 2005).[10] 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 a typical shell egg processing plant. The U.S. Department of Agriculture has developed regulations governing the voluntary grading of shell eggs.[11] This program requires shell eggs to be washed with 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]

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

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

[11] 7 C.F.R. Part 56, available at 2019-20123.pdf (govinfo.gov)

[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 http://handle.nal.usda.gov/10113/3896

[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)

Water is also used for general plant operations. Effluent for such facilities going to on-site treatment facilities (or 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 the above processes, and soil will be present as all of the above uses are primarily intended to wash way 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 European 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 reaction among hypochlorites, hypochlorous acid, other oxychloro compounds, and organic matter including food, 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 $4x\ 10^{-27}$ 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 regarding environmental introductions. We consider the estimate of the production of these compounds relative to available chlorine conservative for our intended use because the EU report also shows that uses including larger amounts of available organic material will reduce the residual oxidative species significantly.[22]

Thus, conservatively we estimate a maximum combined concentration of trihalomethanes and other trichloroacetic and other haloacetic acids as 60 ppm X 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 speciesafter treatment. Thus we estimate the concentrations of trihalomethanes, trichloroacetic acid and other chloroacetic acids prior to treatment to be not more 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. EECs for compounds for the aqueous compartment are: 4×10^{-27} ppb for HOCl-, ClO2- and ClO3-; 1×10^{-10} ppb for chloramines; [23] 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, incorporating only the 10% reduction for dilution in surface waters.

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[20] Op Cite EU Appendix

[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 free chlorine species. Decomposition of free chlorine species depends on several factors such as pH, concentration, nature of inorganic or organic matter in the 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 organic compounds. Chlorate does not bind readily to soil or sediment particulates and is expected to be very mobile and partition predominately into the water (EPA, 2006b). However, extensive redox reactions are expected to occur in the environment, which would serve to reduce the concentration of chlorate in surface water (EPA 2006b).[25] Oxychlorine species have low bioaccumulation potential, high mobility, and low volatility. They do not readily biodegrade under aerobic conditions (EPA, 2006a [26] an 2006b). Upon reaching surface water, the THMs are expected to transition out of the aquatic environment with hours to days [27] (HSDB, 2009c-e; HSDB 2006).

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

8. Environmental Effects of Released Substances

Free or reduced chlorine species including chlorine, hypochlorous acid, hypochlorite, chlorite, or chlorate, and THM species, may be released down the drain through POTWs into aquatic environments during use of the hypochlorous acid solution. Aquatic toxicity is summarized in the following tables:

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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. 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-OPP-2006-0328.

[27] See attached extracts from the Hazardous Substance Database regarding environmental fate information for Bromoform, Chloroform, Bromodichloromethane and Chlorodibromomethane.

Table 2. Environmental Toxicity for Chlorine Species

Aquatic Species	Chemical Species	Acute LC50 or EC50 (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

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[28] Op cite EPA 2006a, see p. 5-11

[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 Users. Reregistration Case Number 4049, Docket No. EPA-HQ-OPP-2005-0507.

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

In Table 2, the most sensitive value for environmental toxicity for oxychloro species is that for freshwater invertebrate at 17 μg/L. The EIC based on the EU risk assessment is 4 x 10^{-27}μg/L for HOCl, OCl^-, $ClO2^-$ and $ClO3^-$. Thus, the EEC for oxychlorospecies is more than 25 orders of magnitude lower than the EIC.

Table 3. Environmental Toxicity for THM Species[31]

Aquatic Species	**Chemical Species**	**Acute LC50 or EC50 (mg/L)**[a]	**Source**
Freshwater fish	Bromodichloromethane	--	HSDB, 2009c
	Chlorodibromomethane	53 – 250[b]	HSDB, 2006
	Bromoform	29	HSDB, 2009d
	Chloroform	0.185[b] – 133	HSDB, 2009e
Freshwater invertebrates	Bromodichloromethane	--	HSDB, 2009c
	Chlorodibromomethane	--	HSDB, 2006
	Bromoform	46 – 56[b]	HSDB, 2009d
	Chloroform	29 – 353	HSDB, 2009e
Estuarine/marine fish	Bromodichloromethane	--	HSDB, 2009c
	Chlorodibromomethane	--	HSDB, 2006
	Bromoform	7.1 – 29	HSDB, 2009d
	Chloroform	--	HSDB, 2009e
Estuarine/marine invertebrates	Bromodichloromethane	--	HSDB, 2009c
	Chlorodibromomethane	--	HSDB, 2006
	Bromoform	1.0 – 24.4	HSDB, 2009d
	Chloroform	81.5	HSDB, 2009e
Aquatic plants	Bromodichloromethane	--	HSDB, 2009c
	Chlorodibromomethane	--	HSDB, 2006
	Bromoform	--	HSDB, 2009d
	Chloroform	437 – 950	HSDB, 2009e

a “—” No data was listed
b Non-standard test duration

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[31] See attached HSDB extracts for each THM.

The volatility of halomethanes will mean that most will evaporate from surface waters in a matter of hours.[32] In Table 3, the most sensitive value for environmental toxicity for THM species is thatfor freshwater fish at 185 µg/L. The EIC estimated above of 8.6 µg/L is well below the most sensitive endpoint for aquatic toxicity.

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

Monochloroacetic acid is produced in the disinfection of drinking water and are 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.[33] In addition, OECD SIDS has assessed the environmental safety of trichloroacetic acid.[34] OECD SIDS identified the alga *Chlorella pyrenoidosa* as the most sensitive species with a NOEC of 10 µg/L. OurEIC 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 EEC for chloride of 6 ppm. A review of the ecotoxicology data on chloride ion indicates that the most sensitive species based on LC_{50} and EC50 is *Cladoceron* with an EC50 of 735 ppm (mg/L).[35]

9. Use of Resources and Energy

The use of the FCS will not require additional energy resources for treatment and disposal of waste solution, as the wastewater system already is designed to treat the substances produced from the intended use of the FCS. 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 effects are identified herein that would require mitigation in this Food Contact Notification.

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[32] Ibid.

[33] World Heath Organization, *Monochloroacetic Acid in Drinking-water, Background Document for development of WHO Guidelines for Drinking-water Quality* (2004). Available at: http://www.who.int/water_sanitation_health/dwq/chemicals/monochloroaceticacid.pdf.

[34] See Attachment: EA Reference_OECD_trichloroacetic acid.pdf

[35] 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).

11. Alternatives to the Proposed Action

No potential 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 thesubject FCS would replace. Such action would have no significant environmental impact. The addition of hypochlorous acid to the options available to food processors is not expected to increase the use of antimicrobial products.

12. Summary:

In summary, the food contact substance and all of its reaction and breakdown products will ultimately be reduced to chloride at a concentration of 6.0 ppm after a 10% reduction for dilution in surface waters. In addition, the EIC of the total organohalogens was calculated to be 900 ppb. The EIC and EECof the individual organohalogens can be seen in the table below.

Table 4 Summary of Environmental Concentrations

Organohalogen	% of total Organohalogen	EIC Calculation (ppb)	EEC (ppb)
Trihalomethanes	9.6	0.096 x 900 ppb = 86.4	8.64
Trichloroacetic acid	3.5	0.035 x 900 ppb = 31.4	3.14
Other trichloroacetic acids	4.0	0.040 x 900 ppb = 36.0	3.60

EEC = EIC / 10 for dilution factor after release to surface water

In addition to the information listed in the table above, the EU risk assessment model (discussed in Section 6, subsection vii of this EA) predicts the EIC of sodium hypochlorite will decay to less than $4x10^{-27}$ ppb active chlorine in approximately 9 hours. This EIC includes all breakdown products, including hypochlorite, chlorate, and chlorite. The lowest endpoint is 17 ppb (Chlorine-FAC, *Daphnia magna*, LC_{50}). The EIC of $4x10^{-27}$ ppb is far below this endpoint. The concentration of chloride will be reduced to 6 ppm when discharged into the environment. This concentration is much lower than the endpoint of the most sensitive species (735 ppm, *Cladoceron sp.*, EC50). According to the calculations, any chloramines produced during the process will decay to $1x10^{-10}$ ppb, well below the lowest ecotoxicity endpoint of 0.016 ppm (*Daphnia magna*, LC_{50}).

13. Preparer

Duke van Kalken. Mr. van Kalken has a Law Degree of the University of Amsterdam and is the author/ inventor of numerous patents regarding the electrochemical activation of water, issued in the United States, Canada, and Singapore. Mr. van Kalken has been involved with the design and development of electrolytic cells and the manufacturing of ECA equipment, since 2003 and was the preparer of FCN 2186 and FCN 2188.

14. Certification

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

[redacted]

Duke van Kalken
President
Clarentis Technologies, LLC

Date: September 20, 2023

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