

**Environmental Assessment of
Ultra-Lyte® Hypochlorous Acid Solution from Concentrate**

1. **Date:** December 23, 2021
2. **Name of Applicant:** Clarentis Technologies, LLC
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4. **Description of the Proposed Action**

a) **Requested action.**

The action requested in this submission is the use of the food contact substance (FCS), hypochlorous acid, electrolytically generated and diluted to generate a hypochlorous acid solution for re-crisping whole and cut produce, that delivers 25-60 ppm of free available chlorine (FAC).

Ultra-Lyte® hypochlorous acid concentrate is generated at a Clarentis Technologies, LLC designated manufacturing facility, through the electrochemical processing of sodium chloride, in the same manner as Ultra-Lyte®, disinfectant, EPA Reg. No. 86854-1.
(https://www3.epa.gov/pesticides/chem_search/ppls/08654-00001-20201222.pdf, accessed 12-14-2021).

Ultra-Lyte® concentrate is diluted at grocery use sites with tap water. The appropriate dilution is ensured through the use of the installed diluter device. The fruit or vegetable may be cut prior to submerging in the solution or cut after the fresh fruits and vegetables have been soaked in the diluted Ultra-Lyte® hypochlorous acid solution.

The use conditions for the Ultra-Lyte® hypochlorous acid solution are as follows: The concentrated FCS solution will be stored for no more than 6 months before use. In the diluted solution, the concentration of free available chlorine will not exceed 60 ppm, and the FCS solution will be replaced if the diluted solution falls below 25 ppm free available chlorine.

Produce is placed into a sink containing diluted Ultra-Lyte® hypochlorous acid solution and soaked for a minimum of 90 seconds. The produce is removed from the hypochlorous acid solution and set aside to drain for at least 10 minutes, to remove to the extent possible, residues of the FCS.

Alternatively, diluted Ultra-Lyte® hypochlorous acid solution can be introduced by spraying the solution onto fresh produce and allowing the solution to drain from the produce for 10 minutes. The Ultra-Lyte® hypochlorous acid solution application process continues until all

the produce requiring hydrating and crisping is complete. Produce may be used for display in the store or consumed. The FCS is not for use in contact with infant formula and human milk.

b) Need for Action.

The FCS is intended for use as an antimicrobial agent in solutions used to re-hydrate fresh and fresh-cut fruits and vegetables.

c) Locations of Use / Disposal.

The FCS is intended for use in grocery stores and commercial kitchens of various sizes and locations. After use, the Ultra-Lyte® hypochlorous acid solution will be drained from the sink via down-the-drain movement through the sanitary sewer system into Publicly Owned Treatment Works (POTWs) for standard wastewater treatment processes before movement into aquatic environments.

At this time, notifier has not been able to determine the projected number of grocery store and commercial kitchen use sites.

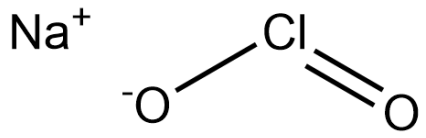
5. Identification of the Food Contact Substance

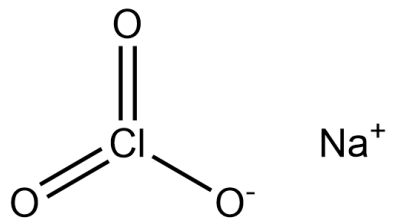
Ultra-Lyte® hypochlorous acid solution after dilution delivers 25 to 60 ppm of FAC.

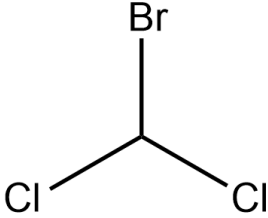
The identities are provided for the residual chemicals that may be present in the final solution, including degradation of oxychlorine species (chlorate and chlorite) and trihalomethane (THM) formation by-products (bromodichloromethane, chlorodibromomethane, bromoform, and chloroform).

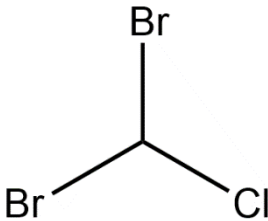
Table 1: Chemical Identify of Substances of the Proposed Action

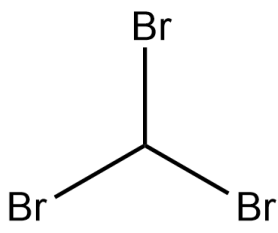
<i>Parameter</i>	<i>Specification</i>
CAS Name:	Hypochlorous Acid
CAS Registry Number:	7790-92-3
Formula:	HOCl
Structure:	HO — Cl
Molecular weight:	52.46 g/mol
Water solubility:	Soluble
Comment:	The primary active species in solution. Present at not more than 60 ppm.

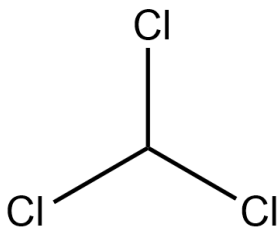
CAS Name:	Chlorite
CAS Registry Number:	7758-19-2 (Sodium chlorite)
Formula:	ClO ₂ ⁻ (NaClO ₂)
Structure:	
Molecular weight:	90.44 g/mol (NaClO ₂)
Water solubility:	Soluble
Comment:	By-product from Ultra-Lyte® hypochlorous acid solution

CAS Name:	Chlorate
CAS Registry Number:	7775-09-9 (Sodium chlorate)
Formula:	ClO ₃ ⁻ (NaClO ₃)
Structure:	
Molecular weight:	106.44 g/mol (NaClO ₃)
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:	CHBrCl ₂
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:	CHBr ₂ Cl
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:	CHBr ₃
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:	CHCl ₃
Structure:	
Molecular weight:	119.38 g/mol
Water solubility:	Soluble
Comment:	By-product formed in final solution

Levels of FAC in Ultra-Lyte[®] hypochlorous acid solution were measured in a 6-month GLP Storage Stability study, a Confidential Attachment 10, to the EA - GLP Storage Stability Study.

6. Introduction of Substances into the Environment

a) As a Result of Manufacture

Ultra-Lyte® hypochlorous acid is generated at a Clarentis® Technologies designated manufacturing site and bottled as a 550 ppm FAC concentrate. Ultra-Lyte®'s proprietary manufacturing process is described in the following Clarentis® issued patents: US 7,374,645, US 7,691,249, US 8,002,955, US9,347,140, and US 9,777,383.

Ultra-Lyte® generates besides hypochlorous acid, sodium hydroxide, hydrogen, and oxygen gas due to the hydrolysis of water in the electrochemical cell, but because of control of pH during production, only trace amounts of hydrogen, oxygen and diatomic chloride gas are generated. Therefore, release of these gases into the atmosphere at the site of production is negligible.

Under 21 Code of Federal Regulations (CFR) § 25.40(a), an EA should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Information available suggests no extraordinary circumstances suggesting an adverse environmental impact as a result of manufacturing.

b) As a Result of Use / Disposal

Using Ultra-Lyte® hypochlorous acid solution introduces FAC (primarily hypochlorous acid), and residual amounts of degradation oxychloro species (chlorite and chlorate) and THM by-products into the environment via down-the-drain transport from grocery store and commercial kitchen use sites to POTWs for wastewater treatment and subsequent release to surface waters. Therefore, the environmental introductions and impacts of FAC and the residual oxychloro and THM species noted are examined herein.

The yearly market volume estimate for the proposed use at grocery stores and commercial kitchens is impossible to calculate at this time, as Ultra-Lyte® is a new product that will directly compete with "Produce Fresh", an established product that is distributed by KAY Chemical Company.

Ultra-Lyte®'s manufacturing process generates a concentrate of 550 ppm of FAC. After dilution the FCN delivers a 25-60 ppm hypochlorous acid solution.

Hypochlorous acid (HOCl) breaks down readily upon exposure to any of the following conditions, 1) when exposed to strong acids, alkalis, oxidizing agents, organic and soil materials, and 2) when exposed to direct light exposure, freezing and high temperatures. HOCl is also known to participate in numerous reactions with organic matter. Deborde, et al., has done a study characterizing the reactions and reaction mechanisms of HOCl with various organic compounds and micropollutants.

In either case, the reactions involve the rapid utilization of HOCl, forming a dilute saline solution as a harmless decomposition product. Its decomposition product, dilute saline

solution, is harmless to practically all terrestrial and aquatic organisms. As discussed above, even if any residual HOCl were to persist for a short amount of time in the environment, it does not have any acute or chronic effects to the living macro-organisms at the concentration in this product.

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 hypochlorite, 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. This kinetic model predicts that even concentrations as high as 75 ppm, substantially higher than the FCN at 25-60 ppm FAC, 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} 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. 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.

Thus, conservatively we estimate a maximum combined concentration of trihalomethanes and other trichloroacetic and other haloacetic acids as $60 \text{ ppm} \times 1.5\% = 900 \text{ ppb}$. 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 after 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, chlorite (ClO_2^-) and chlorate (ClO_3^-); 1×10^{-10} ppb for chloramines; 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.

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, 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).¹ 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).² Oxychlorine species have low bio-accumulation potential, high mobility, and low volatility. They do not readily biodegrade under aerobic conditions (EPA, 2006a³ and 2006b). Upon reaching surface water, the THMs are expected to transition out of the aquatic environment with hours to days⁴ (HSDB, 2009c-e; HSDB 2006).

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

¹ 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>

² 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

³ U.S. Environmental Protection Agency. (2006a) *Chlorine Dioxide: Environmental Hazard and Risk Assessment, Case 4023*. EPA Docket No. EPA-HQ-OPP-2006-0328.

⁴ See attached extracts from the Hazardous Substance Database regarding environmental fate information for Bromoform, Chloroform, Bromodichloromethane and Chlorodibromomethane.

8. Environmental Effects of Released Substances

Aquatic toxicity is summarized in the following tables:

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 ⁵
	Chlorate	> 1,000	U.S. EPA, 2006c ⁶
	Chlorine (FAC)	0.045 – 0.71	U.S. EPA, 2010 ⁷
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

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 4×10^{-27} µg/L for HOCl, OCl⁻, ClO₂⁻ and ClO₃⁻. Thus, the EIC for oxychloro species is more than 25 orders of magnitude lower than the EIC.

⁵ Op cite EPA 2006a, see p. 5-11

⁶ 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.

⁷ 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.

Table 3: Environmental Toxicity for THM Species ⁸

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; see 3 attached PubChem references for toxicity

^b Non-standard test duration

The volatility of halomethanes will mean that most will evaporate from surface waters in a matter of hours.⁹ In Table 3, the most sensitive value for environmental toxicity for THM species is that for 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 LC50 of 0.016 mg/L. It is expected that the chloramines 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 LC50.

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

⁸ See attached HSDB extracts for each THM (Section 14 – References)

⁹ Ibid.

includes a 100-fold safety factor, and which is still more than 60-fold larger than our EIC of 3.6 µg/l.¹⁰ In addition, OECD SIDS has assessed the environmental safety of trichloroacetic acid.¹¹ OECD SIDS identified the alga *Chlorella pyrenoidosa* as the most sensitive species with a NOEC of 10 µg/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 the ecotoxicology data on chloride ion indicates that the most sensitive species based on LC50 and EC50 is *Cladoceron* with an EC50 of 735 ppm (mg/L).¹² Thus, the EIC is over two orders of magnitude below the lowest measure of aquatic toxicity.

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 impacts are expected to result from the use and disposal of the dilutions of antimicrobial product. Therefore, the mixture is not reasonably expected to result in any new environmental issues that require mitigation measures of any kind.

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 this 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. The addition of hypochlorous acid to the options available to food processors is not expected to increase the use of antimicrobial products.

12. Preparer

Duke van Kalken. Mr. van Kalken has a law degree of the University of Amsterdam and is the author/inventor of several 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 manufacturing of ECA equipment, since 2003.

¹⁰ World Health 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/dwg/chemicals/monochloroaceticacid.pdf.

¹¹ <http://www.inchem.org/documents/sids/sids/76039.pdf>

¹² 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).

13. Certification

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



Duke van Kalken
President
Clarentis Technologies, LLC

Date: December 23, 2021

14. References

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- U.S. FDA (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/ucm0644>
- European Union Risk Assessment Report Sodium Hypochlorite, Final Report, 23/11/2007, EINECS No: 231-668-3.
- ECHA 2021 List no.: 232-232-5 CAS no.: 7790-92-3, (EU) 2021/347.

Petition to Include Hypochlorous Acid (generated by Electrolyzed Water) onto National List 7
CFR § 205.603 –

https://www.ams.usda.gov/sites/default/files/media/Petition%20to%20include%20HOCl%20on%20to%20205.603_combined.pdf. Pages 28-35 and Appendix V: Literature research about Hypochlorous Acid

- a) Environmental Assessment of Hypochlorous Acid Solution from HSP USA, LLC, to Food Contact Notification FCN No. 001176
- b) Environmental Decision Memo for Food Contact Notification No. 001176
- c) Environmental Assessment of Hypochlorous Acid Solution from Sterilox Food Safety/Div. Puricore for Food Contact No. 001470
- d) Environmental Decision Memo for Food Contact Notification No. 001470

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