Environmental Assessment

1. Date	July 21, 2021
2. Name of Applicant	Ecolab Inc.
3. Address	Agent for Notifier: Joan Sylvain Baughan, Partner Steptoe & Johnson LLP 1330 Connecticut Avenue, N.W. Washington, D.C. 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) as an antimicrobial agent in ice for contact with fish and seafood. The FCS solution is electrolytically generated at the Notifier's manufacturing facilities and will be shipped to retail food establishments and food processing facilities who will store and dilute the concentrate prior to use. The concentrated FCS solution will be stored for no more than six months before use. The FCS will be shipped in a concentrated solution, which will be diluted on site with tap water to an in-use solution containing up to 60 parts per million (ppm) available free chlorine (AFC).

b. Need for Action

The ice containing the FCS will be used to cool the fish and seafood while on display, to reduce or prevent the growth of spoilage organisms. The requested action would improve food safety by providing more options for efficacious antimicrobial interventions in direct-to-consumer stores, such as grocery stores and fishmongers.

c. Locations of Use/Disposal

The FCS is intended for use nationwide in grocery stores of various sizes and locations. After use, the dilute 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.

Information has been provided by the Notifier regarding the projected number of grocery store use sites, based on fifth-year sales estimates. These figures are confidential and are included in Confidential Attachment A.

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

Ecolab's hypochlorous acid solution delivers a maximum of 60 ppm of available free chlorine (AFC) at the pH of a weak acid. Relative proportions of the active chlorine species are determined by the pH of the solution. The concentrated solution is buffered to ensure hypochlorous acid is the dominant chlorine species present.

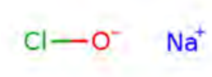
Identifying information is also provided for residual chemicals that may be present in the final solution, including degradation oxychloro species (chlorate and chlorite) and trihalomethane (THM) formation by-products (bromodichloromethane, chlorodibromomethane, bromoform, and chloroform).

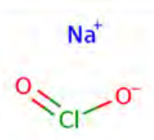
Table 1 - Chemical Identity of Substances of the Proposed Action

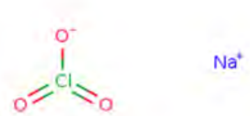
CAS Name	Hypochlorous acid
CAS Registry Number	7790-92-3
Formula	$HOCl$
Structure	Cl-OH
Molecular weight	52.46 g/mol
Comment	The primary active oxychloric species in the solution; present at not more than 60 ppm (as AFC) in the end-use product solutions; interchangeable chlorine species in the final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

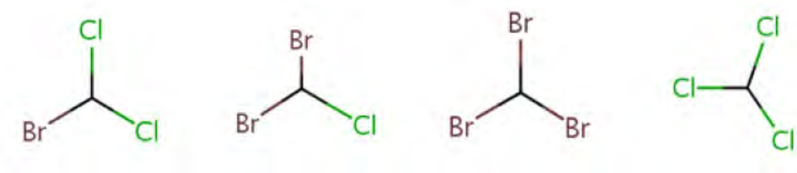
CAS Name	Hypochlorite
CAS Registry Number	7681-52-9
Formula	ClO^{-} ($NaClO$)

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

Levels of AFC and other residuals in the hypochlorous acid solution were measured as part of determining the stability of the concentrate over its 6-month shelf-life. Samples were packaged to simulate commercial packaging and storage conditions. Table 2 lists the concentrations measured in the hypochlorous acid solution generated from concentrate that had been stored for 6 months.

Table 2. Measurements of the FCS and Residual Chemical Species in Hypochlorous Acid Solution After Storage

Chemical Species	**Maximum Measured Hypochlorous Solution**[1]	
	ppm	**%**
Food Contact Substance		
Available free chlorine (primarily hypochlorous acid)	60[2]	0.006
Residuals		
Chlorate	2.38	0.000238
Chlorite	<0.5	<0.00005
Total trihalomethanes (THM)	0.0692	0.00000692

[1]Measurement of AFC and by-product concentration after storage of concentrate for 6 months and dilution to in-use concentration

[2]Nominal concentration of hypochlorous acid in Ecolab hypochlorous acid solution

AFC: At 185 days of storage, the level of free chlorine in the hypochlorous acid solution was 2,500 ppm, which equates to a diluted, in-use concentration of 25 ppm. To be conservative, the nominal concentration of AFC in the hypochlorous acid solution, 60 ppm, is used as a worst case estimate in the environmental exposure calculations.

Other Residuals: After at least 6 months of storage, the level of chlorate present in in-use solutions ranged from 1.84 to 2.38 ppm. Levels of chlorite also were measured for samples that were at least 6 months old and were less than the limit of quantification of 0.5 ppm. These values are used for the environmental assessment as a worst-case estimate of environmental exposure to the residuals that would be present at the end of the 6-month shelf-life. The concentrations of trihalomethanes (THMs) were measured in both the diluted, in-use solution and in the water used to dilute the hypochlorous acid solution concentrate. The level of THMs in the water sample was found to be 0.0569 ppm, whereas the level in the diluted hypochlorous acid solution was found to be 0.0692 ppm, indicating that the majority of THM residuals arise from the tap water used to dilute the concentrate, rather than from the concentrate itself.

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 EA 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 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) promulgated by 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 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

Use of the hypochlorous acid solution introduces AFC (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 use sites to POTWs for wastewater treatment and subsequent release to surface waters and POTW sludge. Therefore, the environmental introductions and impacts of AFC and the residual oxychloro and THM species noted are examined herein.

Treatment facilities use chlorine as part of the wastewater treatment process, as a disinfectant (EPA 2000).[1] 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.[2] 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.[3]

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 depends 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).[4] There is no evidence that active chlorine species accumulate in sediment (U.S. EPA, 1999). Again, 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). 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).[5] Oxychlorine species have low bioaccumulation potential, high mobility, and low volatility. They do not readily

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1 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. (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

2 *Ibid*, pg.1

3 U.S. Environmental Protection Agency. 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

4 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.

5 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.

biodegrade under aerobic conditions (EPA, 2006a[6] and 2006b). Upon reaching surface water, the THMs are expected to transition out of the aquatic environment within hours to days.[7] Based on the above, we conclude that the primary environmental exposure will be through the aquatic compartment.

1) Maximum market volume for proposed use

The maximum yearly market volume estimate for the proposed use at grocery stores is based on five-year sales projections (*see* Confidential Attachment A) for current and anticipated usage types (*i.e.*, cooling of whole and cut fish and seafood). Grocery store locations are anticipated to use 0.5 gallons of Ecolab's hypochlorous acid solution per day. The anticipated use of Ecolab's hypochlorous acid solution in ice for fresh whole and cut fish and seafood is limited to traditional grocery stores and is not expected to increase or expand to other grocery store formats (*e.g.*, warehouse).

Based on the use pattern outlined above, the worst-case scenario of 1:100 dilution to in-use solution, and the density of Ecolab's concentrated hypochlorous acid solution (4.05 kg/gallon), the maximum daily volume estimates for the diluted hypochlorous acid solution, on a per grocery store site basis, are as follows:

- Density of hypochlorous acid solution in 1:100 solution (given density of concentrate is 4.05 kg/gallon and density of water is 3.8 kg/gallon):

$$((4.05 \times 0.01) + (3.8 \times 0.99)) \div 1 = 3.8 \text{ kg/gallon}$$

- Maximum daily volume estimate of hypochlorous acid solution 1:100 solution per grocery site:

$$0.5 \text{ gallons } 1{:}100 \text{ solution} \times 3.8 \text{ kg/gallon} = 1.9 \text{ kg/site/day}$$

2) Estimate of Release of Substances to the environment

To estimate the down-the-drain release of the available free chlorine and residual chemicals from grocery store use sites, *i.e.*, the expected introduction concentrations (EICs), the percentage of each chemical species in the 1:100 solution (Table 2) is multiplied by the maximum daily volume estimate above.

Sample calculation: 60 ppm AFC × 1.9 kg/site/day = 114 mg/day = 0.000114 kg/day

Table 3 summarizes the resulting EICs, which represent chemical releases from grocery store use sites to POTWs via sanitary sewer systems. These EICs were calculated on a per site

[6] U.S. Environmental Protection Agency. (2006a). Chlorine Dioxide: Environmental Hazard and Risk Assessment Case 4023. EPA Docket No. EPA-HQ-2006-0328.

[7] *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.

per day basis in order to serve as appropriate input parameters for the environmental exposure model used to calculate estimated environmental concentrations (EECs), *i.e.*, levels of chlorine species and residual THM species in surface water.

Table 3. Daily Release Estimates of Free Chlorine and the Oxychloro and THM Residual Chemical Species from Grocery Store Use Site

<table>
<tr><th colspan="2">Chemical Species</th><th>Estimated per Site Release (EIC) (kg/day)</th></tr>
<tr><td rowspan="4">Chloro species</td><td>Available free chlorine (AFC) (60 ppm)</td><td>0.000114</td></tr>
<tr><td>Chlorate (2.38 ppm)</td><td>0.0000045</td></tr>
<tr><td>Chlorite (0.5 ppm)</td><td>0.000001</td></tr>
<tr><td>SUM</td><td>0.00012</td></tr>
<tr><td colspan="2">Trihalomethane species (0.0692 ppm)</td><td>0.00000013</td></tr>
</table>

3) The mode of chemical introduction into the environment

The hypochlorous acid solution is used intermittently, in batches/loads, at grocery stores as a 1:100 solution in ice, in accordance with demand at each retail outlet. For purposes of calculating high-end environmental exposure estimates, use is assumed to occur 365 days per year at a rate of one load per day; however, this does not consider site-specific demand or seasonality, which may contribute to lowered use rates at certain sites or certain times of the year.

4) Expected concentration of chemicals introduced into the environment

Surface Water: The chemical species in the hypochlorous acid solution are aqueous and will be introduced into the aquatic environment via down-the-drain movement from grocery store use sites via sanitary sewer systems into POTWs for standard treatment processes before movement into aquatic environments. This pathway to surface water represents the primary route of introduction of the FCS into the environment.

To estimate EECs, Ecolab elected to use the EPA screening-level exposure model, Exposure and Fate Assessment Screening Tool (E-FAST 2014) and the Probabilistic Dilution Model (PDM) contained within its General Population and Ecological Exposure module. The underlying principles, calculations, and units incorporated into this estimate are described in more detail in the E-FAST Documentation Manual (Versar, 2007). This module is intended to assess industrial and/or commercial releases of chemicals and is capable of estimating surface water concentrations resulting from indirect releases to POTWs (Versar, 2007). Additionally, it generally provides highly conservative assessments of environmental exposure (Versar, 2007).

Per the E-FAST Documentation Manual, inputs of releases into E-FAST for estimation of surface water concentrations represent the amount of chemical released, in kg chemical/site/day, not the total volume of dilute solution. Therefore, the bolded EICs shown in Table 3, which incorporate the percent of chemical species in the 1:100 in-use hypochlorous acid solution, were used in E-FAST to calculate EECs.

Another input into E-FAST is a Standard Industrial Classification (SIC) code, which allows for the use of appropriate stream flow distributions for calculating concentrations of chemicals in surface water. There are numerous SIC codes reflecting many industrial categories, but E-FAST only contains data for 36 common SIC codes. Although there is a SIC code representing grocery stores (5411), it is not one of the 36 that are available for use in E-FAST. Therefore, because the hypochlorous acid solution is disposed of down-the-drain at grocery stores and travels via sanitary sewer systems to POTWs, the Standard Industrial Classification (SIC) code representing industrial POTWs was selected. Use of the industrial POTW SIC code, which incorporates a relatively low stream flow distribution (*i.e.*, low level of dilution), should provide a conservative estimate of resulting surface water concentrations resulting from the release of chlorine and residual substances following down-the-drain disposal at grocery store use sites.

Other inputs into E-FAST include the number of sites, the number of days per year that the release occurs, and the rate of removal during wastewater treatment. Releases were assumed to occur at the maximum number of projected grocery store use sites (*see* Confidential Attachment A) for 365 days per year. These assumptions incorporate a high degree of conservatism into the resulting EEC estimates, as this use pattern does not account for site-specific demand or seasonality, which may contribute to lowered use rates at certain sites or certain times of the year. Related to the rate of removal during wastewater treatment, chlorine and oxychloro species are common sanitizers for potable water. Therefore, POTWs are designed to capture and minimize the impact of brines, sanitizers, and their residual products on aquatic environments. POTWs using chlorination disinfection employ dechlorination mechanisms such as sulfonation to remove chlorine compounds and the removal efficiency of chlorinated compounds during dechlorination processes range from 87% to 98% (U.S. EPA, 2000). Additionally, since oxychlorine species are strong oxidizers, they are expected to react readily with oxidizable compounds in the POTW before discharge to surface waters. Although it is likely that the active chlorine species will be removed and/or depleted during wastewater treatment at POTWs, wastewater treatment removal rates of 0% were employed to provide another layer of conservatism.

Additionally, since users are instructed to drain and dispose of the Ecolab hypochlorous acid solution when the concentration of AFC drops below 25 ppm, the level of AFC (primarily hypochlorous acid) disposed of down-the-drain is expected to be ≤ 25 ppm, rather than the nominal 60 ppm that was assumed as a worst-case scenario. Therefore, the use of the nominal 60 ppm concentration when calculating EICs incorporates further conservatism into resulting environmental exposure estimates.

Modeling results, *i.e.*, surface water concentrations, or EECs, are shared below (Table 4). The model output files are being held as confidential, as they incorporate the projected number of grocery store use sites and are included in Confidential Attachment B.

Table 4. Estimated Environmental Concentrations of Chloro and THM Species in Aquatic Environments After Release from POTWs

Chemical Species	E-FAST Data Input		Surface Water Concentration (EEC)[1]
	WWT removal (%)	Amount of Chemical Release (EIC) (kg/site/day)	(µg/L)
Sum of chloro species	0%	0.00012	0.00159
Sum of THMs	0%	0.00000013	0.0000132

[1]E-FAST Probabilistic Dilution Model, 10th percentile 1Q10 stream dilution descriptor, which provides the most conservative surface water concentration estimates for acute scenarios, as it is based on the single day of lowest flow in a receiving stream over a ten-year period. (Versar, 2007)

7. Fate of Emitted Substances in the Environment

For the primary pathway of hypochlorous acid solution into the environment, we have demonstrated that, using very conservative assumptions, a very low concentration of chloro species (EEC = 0.00159 µg/L) and a negligible concentration of THM species (EEC = 0.0000132 µg/L) are anticipated in the aquatic environment (Table 4).

The majority of environmental depletion mechanisms such as adsorption and oxidation-reduction reactions, will have occurred during processing through POTWs, before reaching the aquatic environment. For example, because oxychlorine species are strong oxidizers, they are expected to react readily with oxidizable compounds in the POTW before discharge to surface waters (ECHA 2007). However, available environmental fate properties for the discussed chemical species are included below (Table 5).

Table 5. Available Environmental Fate Properties

Fate Properties*	**Chlorine, Hypochlorous Acid, Hypochlorite** U.S. EPA, 2010; U.S. EPA, 1999	**Chlorite** U.S. EPA, 2006a	**Chlorate** U.S. EPA, 2006c
Water solubility mg/L at 25ºC	7,300	Highly soluble	Highly soluble
Vapor Pressure mm Hg @ 25ºC	5,830-5,850 (chlorine)	--	Negligible
Henry's Law Constant atm-cu m/mole	--	--	Negligible
Bioconcentration Factor (BCF)	3.16 (no potential for bioaccumulation)	Not likely to bioaccumulate	Low potential to bioaccumulate
Log octanol water partition coefficient (K_{ow})	0.85	-7.17	-7.08
Soil adsorption coefficient (K_{oc})	--	Likely to be mobile	Likely to be mobile

* "--" No data available

Fate Properties	**Bromodichloromethane** ATSDR, 2020	**Chlorodibromomethane** ATSDR, 2005	**Bromoform** ATSDR, 2005	**Chloroform** ATSDR, 1997
Water solubility mg/L at 25ºC	3,030	2,700	3,100	7,000-9,000
Vapor Pressure mm Hg @ 25ºC	50	76	5	160 (at 20ºC)
Henry's Law Constant atm-cu m/mole	2.21E-03	9.9E-04	5.6E-04	4.06E-03
Bioconcentration Factor (BCF)	7	2-10	2-10	6-14
Log octanol water partition coefficient (K_{ow})	2	2.16	2.40	1.97
Log soil adsorption coefficient (K_{oc})	1.8	1.92	2.06	1.65-2.40

As in solution, in aquatic environments, the available free chlorine species will exist in pH-dependent equilibrium between chlorine, hypochlorous acid, and hypochlorite. Decomposition of hypochlorous acid and hypochlorite ions 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 maximum decomposition rate of hypochlorous acid occurs at a pH of 6.89 (U.S. EPA, 1999). Effluents containing free residual chlorine appear to dissipate rapidly after release into receiving waters, which reduces the residence time of these species at the point of discharge (U.S. EPA, 1999). The half-life of free residual chlorine in natural freshwater systems is estimated to be between 1.3 and 5 hours (U.S. EPA, 1999). There is also no evidence that active chlorine species accumulate in sediment (U.S. EPA, 1999).

Oxychloro species are strong oxidizers and readily react with oxidizable organico compounds such as phenols, amino acids, proteins and inorganic compounds such as iron, manganese, sulfides, and progress to reduced chlorine species, *e.g.*, hypochlorite (ClO-, oxidation state I), chlorine dioxide (oxidation state IV), and the chloride anion (oxidation state -I) (EPA, 2006b). Chlorate does not bind readily to soil or sediment particulates and is expected to be very mobile and partition predominantly into the water (U.S. EPA, 2006b). However, extensive redox reactions are expected to occur in the environment, which would serve to reduce the concentration of chlorate in surface waters (U.S. EPA, 2006b). Little is reported on the fate properties of the oxychloro species, but it is assumed that they have low bioaccumulation potential, high mobility, and low volatility and they do not readily biodegrade under aerobic conditions (EPA, 2006a and 2006b).

Upon reaching surface water, the THMs are expected to transition out of the aquatic environment within hours to days. Volatilization from water surfaces is expected to be an important fate process for all THM species based upon Henry's Law constants which range from 5.6 E-04 to 2.12 E-03. All of the THM species have low likelihoods of bioaccumulating, based on their low K_{ow} and BCF values, but some THM species are likely to adsorb to suspended solids or sediment. Based upon measured or estimated K_{oc} values, THM species other than chlorodibromomethane are expected to adsorb to suspended solids or sediment in aquatic environments.

Estimated Environmental Concentration (EEC): For the purposes of this examination, the EECs presented in Item 6 (see Table 4) are considered without additional depletion or removal mechanisms applied. The EECs were calculated using a model (E-FAST) that incorporates a stream flow distribution in its estimate of surface water concentration, so an additional dilution factor is not employed.

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 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 6 and 7, respectively.

Effects on terrestrial organisms are not expected from the requested use of hypochlorous acid solution based on the primary route of environmental exposure. Therefore, environmental effects are evaluated by comparing the most sensitive aquatic toxicity endpoints against the EECs.

Table 6. 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
	Chlorate	>1,000	U.S. EPA, 2006c
	Chlorine (AFC)	0.045-0.71	U.S. EPA, 2010
Freshwater invertebrates	Chlorite	0.027-1.4	U.S. EPA, 2006a
	Chlorate	920	U.S. EPA, 2006c
	Chlorine (AFC)	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 (AFC)	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 (AFC)	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 (AFC)	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 highly-conservative EEC for oxychloro species (0.00159 µg/L) is four orders of magnitude lower than the most sensitive aquatic toxicity endpoint. Thus, adverse environmental effects are not indicated based on a comparison of the EECs against aquatic toxicity endpoints. Additionally, discharges of chlorine to ambient waters are regulated by the National Pollutant Discharge Elimination System (NPDES), under which discharge permit limits are established to meet state water quality standards, which reflect federal ambient water quality criteria (WQC) established for the protection of aquatic life and human health (U.S. EPA, 2015). The WQC include the Criteria Maximum Concentration (CMC), which is an estimate of the highest concentration of a material in surface water to which an aquatic community can be exposed briefly without resulting in an unacceptable effect, and the Criterion Continuous Concentration (CCC), which is an estimate of the highest concentration of a material in surface water to which an aquatic community can be exposed indefinitely without resulting in an unacceptable effect.

The CMC and CCC for chlorine in freshwater are 19 µg/L and 11 µg/L, respectively (U.S. EPA, 2015). The surface water concentrations of chlorine species, as estimated by EFAST's Probabilistic Dilution Model, are below these concentrations and therefore meet water quality standards.

Table 7. Environmental Toxicity for THM Species[8]

Aquatic Species	Chemical Species	Acute LC_{50} or EC_{50} (mg/L)[a]
Freshwater fish	Bromodichloromethane	--
	Chlorodibromomethane	34
	Bromoform	29
	Chloroform	0.185-133
Freshwater invertebrates	Bromodichloromethane	240
	Chlorodibromomethane	53
	Bromoform	46-56
	Chloroform	29-353
Estuarine/marine fish	Bromodichloromethane	--
	Chlorodibromomethane	--
	Bromoform	7.1-29
	Chloroform	--
Estuarine/marine invertebrates	Bromodichloromethane	--
	Chlorodibromomethane	--
	Bromoform[6]	1.0-24,400
	Chloroform[5]	81.5
Aquatic plants	Bromodichloromethane	--

8 *Id.*

	Chlorodibromomethane	--
	Bromoform	--
	Chloroform[5]	437-950

[a] "--" No data was listed

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 highly-conservative EEC for THM species (0.0000132 μg/L) is more than four orders of magnitude lower than the most sensitive aquatic toxicity endpoint.

Based on very conservative assumptions, the resulting EECs for chloro and THM species are still far less than the most sensitive aquatic endpoints examined. Therefore, adverse environmental effects are not anticipated based on the requested use.

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.

12. List of Preparers

Ms. Patricia Kinne, Steptoe & Johnson LLP 1330 Connecticut Avenue, N.W., Washington, D.C. 20036. Ms. Kinne has over 10 years of experience with food contact compliance matters, including FCN submissions and chemical registration submissions.

Ms. Deborah C. Attwood, Steptoe & Johnson LLP, 1330 Connecticut Avenue, N.W., Washington, DC 20036. Ms. Attwood has 11 years of experience preparing environmental submissions to FDA.

Joan Sylvain Baughan, Partner, Steptoe & Johnson LLP, 1330 Connecticut Avenue N.W., Washington, D.C. 20036. J.D. with 30 years of experience with Food Additive Petitions, FCN submissions, and environmental assessments.

13. Certification

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

Date: July 21, 2021

[redacted]

Joan Sylvain Baughan, Partner

14. References

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