Environmental Assessment of

ProduceFresh™ Hypochlorous Acid Solution from Concentrate

1. **Date:** December 18, 2015

2. **Name of Applicant:** PuriCore, Inc.

3. **Address:**

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All communication regarding this food contact notification (FCN) environmental assessment (EA) should be sent to the attention of the authorized representative:

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4. **Description of 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 from concentrate to generate a hypochlorous acid solution for re-crisping whole and cut produce that delivers 25 to 60 ppm of available free chlorine (AFC).

ProduceFresh hypochlorous acid concentrate is generated at a PuriCore manufacturing site through the electrochemical processing of a sodium chloride brine buffered to ensure hypochlorous acid is the dominant chlorine species present. This concentrate is then diluted 1:100 at grocery store use sites with tap water and appropriate dilution is ensured through the use of the installed, automatic diluter units.

ProduceFresh hypochlorous acid solution is intended to be used on fresh cut fruits and vegetables. The fruit or vegetable may be cut prior to submerging in the solution or cut after the fresh fruits and vegetables have soaked in the ProduceFresh hypochlorous acid solution. The use conditions for ProduceFresh hypochlorous acid solution are as follows:

i. ProduceFresh hypochlorous acid concentrate is diluted to a 1:100 solution at the site of use using a diluter unit and tap water, thus providing a 25-60 ppm in-use hypochlorous acid solution.
ii. The hypochlorous acid solution must be between 25 and 60 ppm and concentrations are measured at grocery store use sites with test strips manufactured by Serim Research. If AFC is below 25 ppm, the sink is drained and re-filled with fresh ProduceFresh hypochlorous acid solution.
iii. Fresh produce is placed into a sink containing ProduceFresh hypochlorous acid solution and soaked for a minimum of 90 seconds. The produce is removed from the solution and set aside to drain.
iv. Alternatively, ProduceFresh hypochlorous acid solution can be introduced by spraying the solution onto the fresh produce and allowing the solution to drain from the produce.
v. The ProduceFresh hypochlorous acid solution application process continues until all the produce requiring hydrating or crisping is complete.
vi. Produce may be used for display in the store or consumed (*e.g.*, made-to-order salad) after draining.

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 nationwide in grocery stores of various sizes and locations. After use, the ProduceFresh 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. This figure is being held as confidential and is included in Confidential Attachment A.

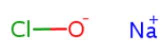
5. Identification of the Food Contact Substance

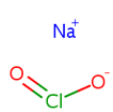
ProduceFresh hypochlorous acid solution delivers 25 to 60 ppm of AFC. Relative proportions of the active chlorine species are determined by pH control of the ProduceFresh solution. ProduceFresh concentrate is buffered to ensure hypochlorous acid is the dominant chlorine species present.

Identifying information is also provided for the other active chlorine species that can exist in equilibrium with hypochlorous acid (diatomic chlorine and sodium hypochlorite/hypochlorite ion), as well as 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).

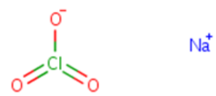
Name	Hypochlorous acid	Source
CASRN	7790-92-3	ChemID*plus*
Formula	HOCl	
Structure		
Molecular weight	52.46 g/mol	
Appearance	Greenish-yellow in solution	
Comment	The primary active oxychloric species in the solution; present at not more than 60 ppm in the end-use product solutions; interchangeable chlorine species in final solution	

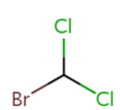
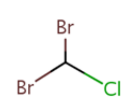
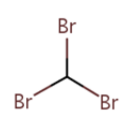
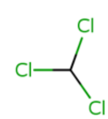
Name	Chlorine	Source
CASRN	7782-50-5	HSDB, 2008
Formula	Cl_2	
Structure		
Molecular weight	70.91 g/mol	
Appearance	Yellowish-green gas	
Comment	Minimized under controlled pH environment; interchangeable chlorine species in final solution	

Name	Hypochlorite	Source
CASRN	7681-52-9	HSDB, 2003
Formula	ClO^- (NaClO)	
Structure		
Molecular weight	74.44 g/mol	
Appearance	Greenish yellow liquid	
Comment	Minimized under controlled pH environment; interchangeable chlorine species in final solution	

Name	Chlorite	Source
CASRN	7758-19-2 (sodium chlorite)	HSDB, 2009a
Formula	ClO_2^- (ion form) ($NaClO_2$ salt)	
Structure		
Molecular weight	90.44 g/mol ($NaClO_2$)	

Name	Chlorite	Source
Appearance	White crystals or crystalline powder	
Comment	By-product from ProduceFresh hypochlorous acid solution, minimized under controlled pH environment	

Name	Chlorate	Source
CASRN	7775-09-9 (sodium chlorate)	
Formula	ClO_3^- (ion form) ($NaClO_3$ salt)	
Structure		HSDB, 2009b
Molecular weight	106.44 g/mol ($NaClO_3$)	
Appearance	Colorless cubic crystals	
Comment	By-product from ProduceFresh hypochlorous acid solution, minimized under controlled pH environment	

Name	Trihalomethanes (THMs)	Source
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: $CHCl_3$	HSDB, 2009c; HSDB, 2006; HSDB 2009d; HSDB 2009e
Structure	 75-27-4  124-48-1  75-25-2  67-66-3	
Molecular weight	119.38 to 252.73 g/mol	
Appearance	Ranges from clear, colorless liquid to colorless heavy liquid	
Comment	By-products formed in concentrate or final solution	

Levels of AFC and other residuals in ProduceFresh hypochlorous acid solution were measured as part of determining the stability of the concentrate over its 6 month shelf-life. Samples were packaged in 2.5-gallon jugs to simulate commercial packaging and storage conditions. Table 1 lists the concentrations measured in ProduceFresh hypochlorous acid solution generated from concentrate that had been stored for 6 months.

Table 1. Measurements of the FCS and Residual Chemical Species in Hypochlorous Acid Solution After Storage

Chemical Species	Maximum Measured Hypochlorous Acid 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 ProduceFresh 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 ProduceFresh 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 were also measured for samples that were at least 6 months old and found to be < 0.5 ppm. These values are used for the environmental assessment as a worst-case estimate of environmental exposure for 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) As a result of Manufacture

ProduceFresh hypochlorous acid concentrate is generated at a PuriCore manufacturing site by electrochemical processing of a sodium chloride solution, buffered to ensure hypochlorous acid is the dominant chlorine species present. The generation process generates sodium hydroxide, hydrogen, and oxygen gas due to the hydrolysis of water in the electrochemical cell, but due to the control of pH during production of the concentrate, 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. The manufacturing process is very efficient at solubilizing chlorine into solution and generates no chlorine waste. The concentrate is then sold to grocery stores, where it will be diluted 1:100 with tap water, under the control of an automatic diluter unit, to generate the 25-60 ppm hypochlorous acid solution.

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 ProduceFresh 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. Therefore, the environmental introductions and impacts of AFC and the residual oxychloro and THM species noted are examined herein.

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.*, soaking and misting of fresh whole and cut fruits and vegetables). Grocery store locations are anticipated to use three, 20-gallon loads of ProduceFresh hypochlorous acid solution per day. The anticipated use of ProduceFresh hypochlorous acid solution to mist fresh whole and cut fruits and vegetables is limited to traditional grocery stores and is not expected to increase or expand to other grocery store formats (*e.g.*, warehouse) because of the cost associated with installing and maintaining misting systems. The use of misting is included in the sales projections.

Based on the use pattern outlined above, the 1:100 dilution to in-use solution, and density of the ProduceFresh hypochlorous acid solution (3.8 kg/gallon), maximum daily volume estimates for the diluted hypochlorous acid solution are shown in Table 2, on a per grocery store site basis.

Table 2. Daily Volume Estimate of Diluted Hypochlorous Acid Solution

Density of ProduceFresh in 1:100 solution (given density of concentrate is 4.05 kg/gallon and density of water is 3.8 kg/gallon): ((4.05*0.01)+(3.8*0.99))/1 = 3.8 kg/gallon **Maximum daily volume estimate of ProduceFresh 1:100 solution per grocery site:** 20 gallons 1:100 solution x 3.8 kg/gallon x 3 loads/day x = 228 kg/site/day

2) Percent of market volume that will enter 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 1) is multiplied by the maximum daily volume estimate above (Table 2). 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 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

Chemical Species		Estimated per Site Release (EIC) (kg/day)
Chloro species	Available free chlorine (AFC) (60 ppm)	0.0137
	Chlorate (2.38 ppm)	0.0005
	Chlorite (0.5 ppm)	0.0001
	SUM	**0.0143**
Trihalomethane species (0.0692 ppm)		**0.000016**

3) The mode of chemical introduction into the environment

The ProduceFresh hypochlorous acid solution is used intermittently, in batches/loads, at grocery stores as a 1:100 solution in water, 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 three loads per day; however, this does not take into account 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, after use at grocery stores, 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, we elected to use the EPA screening-level exposure model, Exposure and Fate Assessment Screening Tool (EFAST 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 EFAST 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). PDM was applied similarly by EPA in its 2006 environmental exposure assessment of chlorine dioxide from cooling tower uses (U.S. EPA, 2006a).

Per the EFAST Documentation Manual, inputs of releases into EFAST 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 EFAST to calculate EECs for chloro and THM species.

Another input into EFAST 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 EFAST only contains data for 36 common SIC codes. Although there is an SIC code representing grocery stores (5411), it is not one of the 36 that are available for use in EFAST. Further, 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. Therefore, the use of the industrial POTW SIC code, which incorporates a relatively low stream flow distribution, should provide a conservative estimate of resulting surface water concentrations resulting from the release of chlorine and residual oxychloro and THM species following down-the-drain disposal at grocery store use sites.

Other inputs into EFAST 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 for the chloro and THM species to provide another layer of conservatism.

Additionally, since users are instructed to drain and dispose of the ProduceFresh 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	EFAST Data Input		Surface Water Concentration (EEC)[1]
	WWT removal (%)	Amount of Chemical Release (EIC) (kg/site/day)	(µg/L)
Sum of chloro species	0%	0.0143	1.89
Sum of THMs	0%	0.000016	0.00211

[1] EFAST 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)

As noted, the above EECs for the chloro and THM species in surface water are highly conservative, as they were calculated assuming no removal during wastewater treatment and assuming a worst-case concentration of 60 ppm AFC in the used solution disposed of down-the-drain.

The potential for unintentional releases (*i.e.*, spills) of the ProduceFresh hypochlorous acid concentrate was also considered. The 2.5-gallon jugs containing the ProduceFresh hypochlorous acid concentrate are equipped with a spill-proof insert manufactured by RD Industries, which is designed to prevent leaks and spills throughout the product life cycle (RD Industries, 2015). Based on this control, this pathway was not further considered.

7. Fate of Substances Released into 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 = 1.89 µg/L) and a negligible concentration of THM species (EEC = 0.00211 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, *e.g.*, since oxychlorine species are strong oxidizers, they are expected to react readily with oxidizable compounds in the POTW before discharge to surface waters. However, available environmental fate properties for the discussed chemical species are included below (Table 5).

Table 5. Available Environmental Fate Properties

Fate Properties[1]	**Chlorine, Hypochlorous Acid, Hypochlorite** U.S. EPA, 2010; U.S. EPA, 1999		**Chlorite** U.S. EPA, 2006a	**Chlorate** U.S. EPA, 2006b; U.S. EPA, 2005
Water solubility mg/L at 25^{o}C	7,300		Highly soluble	Highly soluble
Vapor Pressure mm Hg @ 25^{o}C	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
Fate Properties	**Bromodichloromethane** HSDB, 2009c	**Chlorodibromomethane** HSDB, 2006	**Bromoform** HSDB, 2009d	**Chloroform** HSDB, 2009e
Water solubility mg/L at 25^{o}C	3,968	2,700	3,100	7,950
Vapor Pressure mm Hg @ 25^{o}C	50	5.5	5.40	197
Henry's Law Constant atm-cu m/mole	2.12E-03	7.83E-04	05.35E-04	3.67E-03

Fate Properties	**Bromodichloromethane** HSDB, 2009c	**Chlorodibromomethane** HSDB, 2006	**Bromoform** HSDB, 2009d	**Chloroform** HSDB, 2009e
Bioconcentration Factor (BCF)	7	9	14	2.9-10.35
Log octanol water partition coefficient (K_{ow})	2	2.16	2.40	1.97
Soil adsorption coefficient (K_{oc})	53-251	84	116-126	34-196

[1] "--" No data available

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 organic 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 (HSDB, 2009c-e; HSDB 2006). 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 7.83 E-04 to 2.12 E-03 (HSDB, 2009c-e; HSDB 2006). 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 (HSDB, 2009c-e; HSDB 2006). Based upon measured or estimated Koc values, THM species other than chlorodibromomethane are expected to adsorb to suspended solids or sediment in aquatic environments (HSDB, 2009c-e; HSDB 2006).

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 (EFAST) that incorporates a stream flow distribution in its estimate of surface water concentration, so an additional dilution factor is not employed.

8. Environmental Effect 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 ProduceFresh 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. Summary of Environmental Toxicity Endpoints for Chlorine Chemical Species

Aquatic Species	Chemical species	Acute LC_{50} or EC_{50} (mg/L)[1]	Source
Freshwater fish	Chlorite	50.6-420	U.S. EPA, 2006a
	Chlorate	>1,000	U.S. EPA 2009
	Chlorine (AFC)[2]	0.045-0.71	U.S. EPA, 1999 and 2010
Freshwater invertebrates	Chlorite	0.027-1.4	U.S. EPA, 2006a
	Chlorate	920	U.S. EPA 2009
	Chlorine (AFC)[2]	0.017-0.673	U.S. EPA, 1999 and 2010
Estuarine/marine fish	Chlorite	75	U.S. EPA, 2006a
	Chlorate	>1,000	U.S. EPA 2009
	Chlorine (AFC)[2]	0.71	U.S. EPA, 1999 and 2010
Estuarine/marine invertebrates	Chlorite	0.576-21.4	U.S. EPA, 2006a
	Chlorate	>1,000	U.S. EPA 2009
	Chlorine (AFC)[2]	0.026-1.42	U.S. EPA, 1999
Aquatic plants	Chlorite	1.32	U.S. EPA, 2006a
	Chlorate	43-133	U.S. EPA 2009
	Chlorine (AFC)	---	U.S. EPA, 1999 and 2010

[1] "--" No data was listed for this endpoint

[2]Endpoints provided in U.S. EPA, 1999 and U.S. EPA, 2010 may reflect studies for lithium hypochlorite, which was deemed appropriate for satisfying all ecological effects data requirements for chlorine when used as an industrial microbicide. Additionally, the listed EPA sources reference Ambient Water Quality Criteria for Chlorine, 1984, EPA 440/5-84-030 as the original source for some of the endpoints provided for chlorine.

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 (1.89 µg/L) is roughly one order or 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.

Furthermore, the CMC and CCC for chlorine in freshwater is 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. Summary of Environmental Toxicity Endpoints for THM Chemical Species

Species	Chemical species	Acute LC50 or EC50 (mg/L)[1, 2]	Source
Freshwater fish	bromodichloromethane	--	HSDB, 2009c
	chlorodibromomethane	53-250[3]	HSBD, 2006
	bromoform	29	HSDB, 2009d
	chloroform	0.185[3]-133	HSDB, 2009e
Freshwater invertebrates	bromodichloromethane	--	HSDB, 2009c
	chlorodibromomethane	--	HSBD, 2006
	bromoform	46-56[3]	HSDB, 2009d
	chloroform	29-353	HSDB, 2009e
Estuarine/marine fish	bromodichloromethane	--	HSDB, 2009c
	chlorodibromomethane	--	HSBD, 2006
	bromoform	7.1-29	Ward et al. 1981; HSDB, 2009d[4]
	chloroform	--	HSDB, 2009e
Estuarine/marine invertebrates	bromodichloromethane	--	HSDB, 2009c
	chlorodibromomethane	--	HSBD, 2006
	bromoform	1.0 – 24.4	HSDB, 2009d[4]
	chloroform	81.5	HSDB, 2009e
Aquatic Plants	bromodichloromethane	--	HSDB, 2009c
	chlorodibromomethane	--	HSBD, 2006
	bromoform		HSDB, 2009d
	chloroform	437-950	HSDB, 2009e

[1] "--" No data was listed for this endpoint
[2] Endpoints reflecting EPA standard test durations were selected, where available
[3] Non-standard test duration
[4] Reviewed original source listed in HSDB to confirm units, as some units were shown in HSDB in mg/L, when the original source listed units as µg/L (values in above table still reported in mg/L)

The most sensitive acute endpoint for THM species is the EC_{50} of 0.185 mg/L, or 185µg/L, for freshwater fish, which is associated with exposure to chloroform. The highly-conservative EEC for THM species (0.00211 µg/L) is several 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 requested use will be competing with and/or replacing other antimicrobial agents in solution used to hydrate and/or wash fresh fruits and vegetables at grocery stores. Use of the FCS is therefore anticipated to have no net effect on resources or energy associated with typical use of such antimicrobial agents in solution for fresh fruit and vegetable wash and/or hydration processes. The use of ProduceFresh hypochlorous acid solution will remove the need for a potable water rinse, but this is expected to provide a minor reduction in overall water use.

10. Mitigation Measures

No potential adverse environmental effects are identified herein that would necessitate the proposal of mitigation measures.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this notification. The alternative of not approving the action proposed herein would simply result in the continued use of the FCS produced through other methods of generation.

12. List of Preparers

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Dr. Treble has more than thirty years of experience in the chemical industry with expertise in FDA compliance relating to food contact materials, excipients, and drug actives. Dr. Treble also has extensive experience with industrial chemical compliance and assessment under TSCA, as well as analytical chemistry.

13. Certification

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

December 18, 2015

Date

[redacted]

Imogene Treble, Ph.D.
Authorized Representative of PuriCore, Inc.

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15. Attachments

CONFIDENTIAL Attachment A: Fifth-Year Sales Projections for Grocery Store Use Site Number (Separate Enclosure)

CONFIDENTIAL Attachment B: EFAST 2014 Output Reports (Separate Enclosure)