An EA Revision Sheet has been prepared for this Environmental Assessment – See the FONSI for this Food Contact Notification

Environmental Assessment

1. **Date:** April 4th, 2017
2. **Name of Notifier:** Selective Micro Technologies
3. **Address:** 6200 Avery. Rd., Suite A, Dublin, OH 43016, 855-256-8299

4. Description of the Proposed Action

a. Requested action

This Food Contact Notification (FCN or Notification) is to approve the use of the food contact substance (FCS), chlorine dioxide (ClO_2), as a gaseous antimicrobial agent for fumigating fruits and vegetables, including fruits and vegetables that are raw agricultural commodities. The FCS will be used as a gaseous antimicrobial agent for fumigating raw agricultural commodities in the preparing, packaging or holding of food for commercial purposes consistent with the FD&C Act section 201(q)(1)(B)(i) but not applied for use under 201(q)(1)(B)(i)(I), (q)(1)(B)(i)(II) or (q)(I)(B)(i)(III) of the FD&C Act. The FCS will be applied only in unlit areas and is generated in a solution yielding 3 ppm residual (or less) in the surrounding atmosphere. All treated fruits or vegetables will be further processed by blanching, cooking, canning, or an air flush. The FCS is not for use in contact with infant formula and human milk.

b. Need for action

This Environmental Assessment (EA) is intended to demonstrate that the proposed use of this FCS will not cause significant effects to the environment. The Notifier—Selective Micro Technologies (or SMT)—has a patented technology which ensures the controlled generation of chlorine dioxide gas upon the addition of water. Chlorine dioxide gas is generated through the use of our patented, specially-manufactured micro-reactor membrane technology. Inside this micro-reactor, compartmentalized precursor chemicals react to generate nearly-pure chlorine dioxide gas into a surrounding vessel of water. Nearly all the impurities resulting from the generation of the gas are retained safely inside the Selective Micro Technologies micro-reactor, meaning that a safe, uniform flow of chlorine dioxide gas is generated from the reaction inside the micro-reactor.

To generate chlorine dioxide gas, an SMT product-specific micro-reactor will either be immersed in a vessel of water or will be inside a dry, empty vessel to which water is to be added. Chlorine dioxide gas will generate according to the methods described in Section 4(c) of this document. Once the gas is generated into the water immersing the SMT micro-reactor, that gas will immediately begin to volatize into the surrounding air. Chlorine dioxide gas will be generated according to directions on the product label at a 3 ppm in-air residual. The chlorine dioxide gas will act as an oxidizer and reduce levels of bacteria and other microbes on the surface of fruits, vegetables, and RACs.

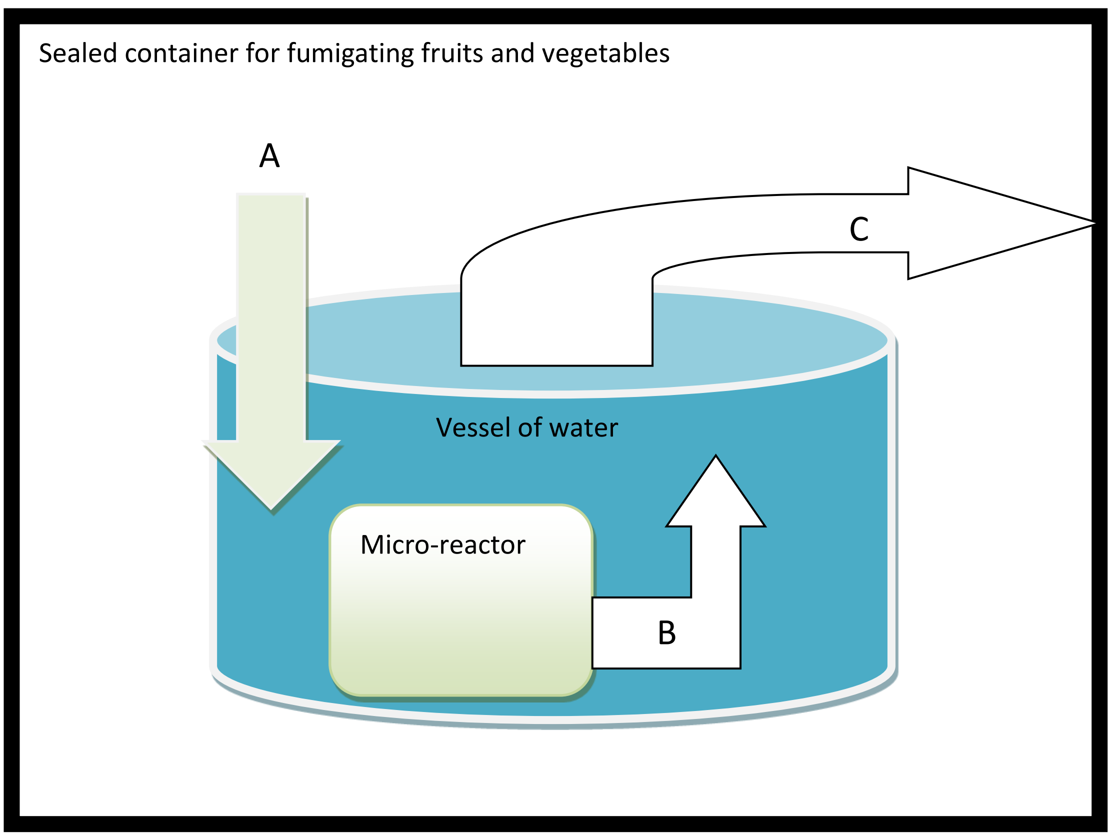
In-air levels of ClO_2 gas should be monitored using a Model C16 PortaSens II chlorine dioxide gas leak detector (or an equivalent measuring instrument). The reaction should be constantly monitored until the ClO_2 gas generates at a 3 ppm residual in-air. To obtain higher ClO_2 gas residuals, increase the concentration of the liquid ClO_2 solution generated in the reaction vessel or decrease the area that the gas is to treat. To generate lower ClO_2 gas residuals, dilute the liquid ClO_2 solution generated in the reaction vessel or increase the area that the gas is to treat. Once the generation reaction yields ClO_2 gas at a constant 3 ppm residual in-air, use the ClO_2 gas for fumigation applications as described on the product label. Check levels of ClO_2 gas at every fifteen minutes to ensure that the reaction maintains its 3 ppm in-air residual.

c. Locations of use/disposal

The FCS will treat fruits and vegetables in darkened, oxidation-resistant, sealed containers. This treatment will occur at plants, food processing facilities, warehouses, and distribution centers. The majority of this ClO_2 gas will be consumed in antibacterial fumigation reactions with organic matter. The remainder will be released to the atmosphere upon completion of the treatment.

There are two ways to use a Selective Micro Technologies micro-reactor to generate ClO_2 gas:

1. Place the micro-reactor in a vessel of water. Water vapor will then enter the micro-reactor. Through osmotic force, chlorine dioxide gas is released from the micro-reactor into the vessel of water. The resulting chlorine dioxide solution is sparged, atomized or used as a fumigant to apply gaseous ClO_2 to fruits and vegetables inside a darkened, UV and oxidation-resistant, sealed container.

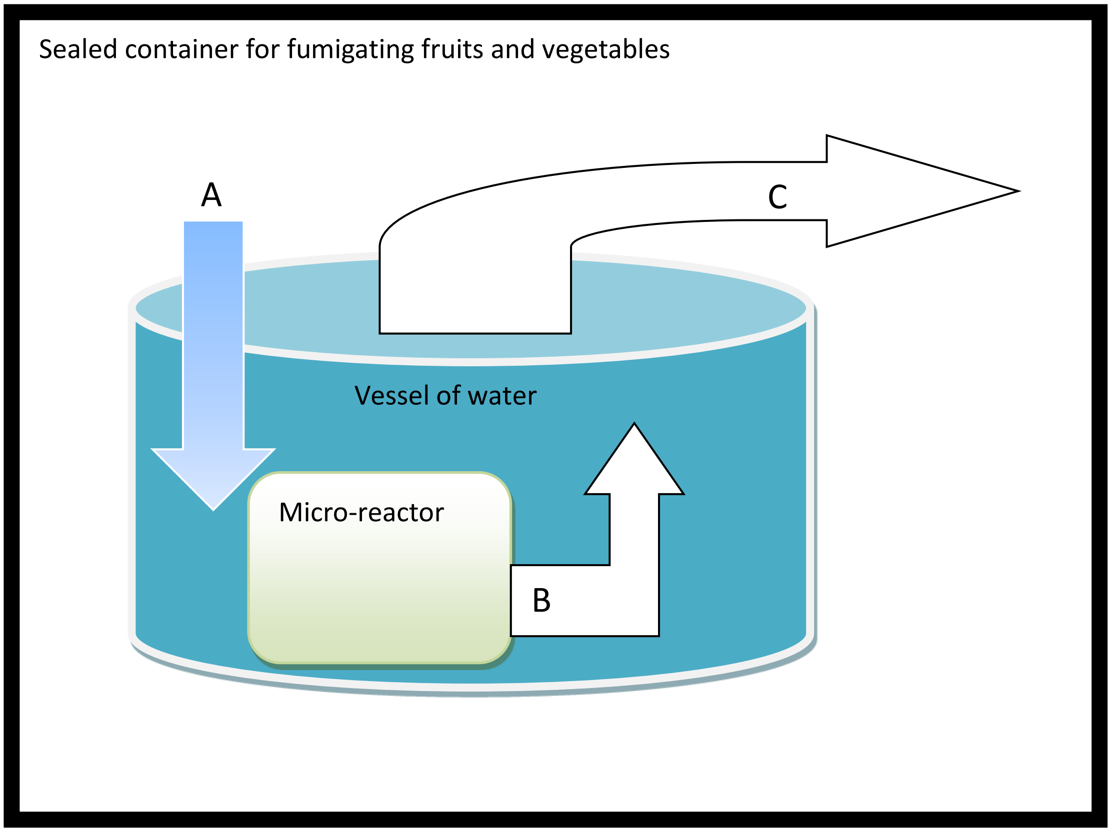


A - Selective Micro Technologies micro-reactor is placed in solution

B - ClO_2 is generated into solution

C - ClO_2 is released as a gas from the agitated solution

2. Alternatively, tap water can be added to a vessel of water with the micro-reactor already placed inside. Through osmotic force, only chlorine dioxide gas will be released from the micro-reactor into the water. The resulting chlorine dioxide solution is sparged, atomized or used as a fumigant to apply chlorine dioxide gas to fruits and vegetables inside a darkened, UV and oxidation-resistant, sealed container.



A - Tap water is added to vessel containing Selective Micro Technologies micro-reactor

B - ClO_2 is generated into solution

C - ClO_2 is released as a gas from the agitated solution

Regardless of the method used to generate ClO_2 gas, the micro-reactor will be disposed of after use according to directions on the label. The chlorine dioxide solution generated in the reaction vessel is to be diluted to a concentration of no more than 0.25 ppm ClO_2 and released to a wastewater stream.

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

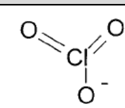
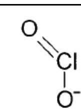
FCS Chemical Information

Chemical Name(s)	Chlorine Dioxide, Chlorine (IV) Oxide
CAS Registry	10049-04-4
Chemical Formula	ClO_2

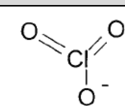
Structure

FCS Degradation Products

Chlorine Dioxide Degradation Products (In Water)

Chlorate Ion	14866-68-3	
Chlorite Ion	14998-27-7	
Chloride Ion	7647-14-5	Cl^-

Chlorine Dioxide Degradation Products (Gas Applications On Food)*

Chlorate Ion	14866-68-3	
Chloride Ion	7647-14-5	Cl^-

Chlorine Dioxide Degradation Products (Gas Upon Reaction to Ultraviolet Light)

Chlorine	7782-50-5	Cl – Cl
Oxygen	7782-44-7	O = O

* Selective Micro Technologies' treatment of fruit and vegetables with gaseous ClO_2 is not expected to result in the formation of the perchlorate ion. Though the perchlorate ion has been identified as a degradation product in the treatment of fruits and vegetables with gaseous ClO_2, *Smith et al.* (2015) confirmed that "in the presence of a chlorine dioxide sink and in the absence of light, perchlorate formation from chlorine dioxide is nil" (Pg. 7) and "the formation of chlorate and perchlorate can be minimized or essentially eliminated … if chlorine dioxide sanitation processes are protected from light" (Pg.2).

6. Introduction of Substances into the Environment

a. As a Result of Manufacturing Process

Selective Micro Technologies does not believe that the manufacturing of the FCS precursor materials will result in any adverse environmental impact. Under 21 C.F.R. § 25.40(a), an Environmental Assessment should ordinarily focus on relevant environmental issues relating to the use and disposal from use of FDA-regulated substances rather than their production. SMT maintains that the manufacturing process of the FCS has no indications which would otherwise present adverse effects to the environment or pose increased risks for introduction of substances into the environment.

b. As a Result of Use/Disposal

How to use

The principal feature that distinguishes the generation of ClO_2 using a Selective Micro Technologies micro-reactor from similar methods of ClO_2 generation is the use of a proprietary membrane on the outer surface of the micro-reactor. This membrane contains the product reaction by allowing only gases such as chlorine dioxide to diffuse into surrounding water and trapping reaction byproducts inside its selectively-permeable walls. As discussed in Section 4 of this document, chlorine dioxide gas can be produced two ways using SMT's micro-reactor:

1. The micro-reactor is immersed in a vessel containing a prescribed amount of water. Chlorine dioxide gas diffuses into water solution, which is then sparged, atomized, or fumigated into a darkened, UV and oxidation-resistant, and sealed treatment container for fumigating fruits and vegetables.

2. Tap water is added to the vessel with the micro-reactor already placed inside. Chlorine dioxide gas diffuses into water solution, which is then sparged, atomized, or fumigated into a darkened, UV and oxidation-resistant, and sealed treatment container for fumigating fruits and vegetables.

Regardless of which method is employed, when the ClO_2 generation reaction is complete, food-grade citric acid is the only ingredient remaining inside the micro-reactor. As it comes into contact with food surfaces, chlorine dioxide gas will be consumed by the oxidation of organic matter and micro-organisms present on food. Unlike chlorine dioxide gas in-solution, which decomposes into various oxychloro species upon its exposure to water, gaseous chlorine dioxide will decompose into only chlorine and oxygen when released to the atmosphere.[1] [2]

Disposal - Air

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[1] Toxicological profile for Chlorine Dioxide and Chlorite.Agency for Toxic Substances and Disease Registry (ATSDR). 2004.

[2] Dobson, Stuart and Cary, Richard. Concise International Chemical Assessment Document: Chlorine Dioxide (Gas). World Health Organization Geneva, 2002.

The generated chlorine dioxide gas is meant to fumigate fruits and vegetables in darkened, oxidation-resistant, sealed containers at a residual of 3 ppm. When treatment of the fruits and vegetables is complete, any remaining levels of chlorine dioxide can be released into the atmosphere via a controlled air flush.

Disposal – Municipal Solid Waste

Disposal of articles containing the FCS is not expected to result in significant introductions of substances at landfill sites because EPA regulations at 40 CFR Part 258 that were published in the Federal Register of October 9, 1991 (56 FR 50978) require new and expanded landfills to have leachate collection systems and liners to prevent leachate from entering surfacewater or groundwater. Although operators of existing landfills are not required to retrofit liner systems, they are required to monitor groundwater adjacent to existing landfills and to take corrective action as appropriate.[3] Assuming that 19.6% of used SMT micro-reactors are combusted at an MSW combustion facility, the Notifier does not anticipate a violation of the standards of municipal solid waste landfills.[4] This is further supported by information provided in the Confidential Attachment to the Environmental Assessment.

On August 1, 2016, the Council on Environmental Quality issued a final guidance to agencies regarding greenhouse gas (GHG) emissions and climate change impacts. As page three of the document asserts, the guidance is "intended to help federal agencies ensure their analysis of potential GHG emissions and effects of climate change in an EA or EIS is commensurate with the extent of the effects of the proposed action."[5]

Municipal solid waste combustion facilities that emit 25,000 metric tons carbon dioxide equivalents[6] or more per year are required to report their GHG emissions per the EPA's Greenhouse Gas Reporting Program.[7] We use this threshold to evaluate the significance of GHG emissions associated with this FCN. We have estimated the metric tons of carbon dioxide equivalents that the disposal of our micro-reactors is expected to produce in the Confidential Attachment to this Environmental Assessment. Selective Micro Technologies does not anticipate any significant environmental impacts as a result of the combustion of used micro-reactors in MSW combustion facilities, as estimated GHG emissions are well below the 25,000 metric tons carbon dioxide equivalents threshold (again, as demonstrated in the Confidential Assessment to the Environmental Assessment).

Disposal - Water

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[3] As outlined in 40 CFR 258

[4] Municipal solid waste combustion facilities are regulated at 40 CFR 60. Also, according to the US Environmental Protection Agency (EPA)'s 2016 update regarding municipal solid waste (MSW) in the United States as of 2014, 65.4% of MSW was not recycled or composted, of which 52.6% of MSW was disposed of in landfills and 12.8% was combusted. Thus, based on the above numbers, 80.4% of the material not recycled is disposed of in landfills and 19.6% is combusted.. Please see Advancing Sustainable Materials Management: Fact Sheet 2014. US EPA, 2016.

[5] Memorandum For Heads Of Federal Departments And Agencies. Executive Office of the President Council on Environmental Quality, August 1, 2016.

[6] Carbon dioxide equivalents (CO_2-e) is common metric for evaluating the environmental effects of various greenhouse gasses in terms of levels of atmospheric CO_2

[7] 40 CFR Part 98—Mandatory Greenhouse Gas Reporting

Upon completion of use, the solution is to be diluted until its concentration is at or less than 0.25 ppm chlorine dioxide in-solution. The concentration of the chlorine dioxide molecule can be measured with *Selective Micro® Chlorine Dioxide Test Strips* or an equivalent tool that is able to accurately measure levels of chlorine dioxide in a solution. Once the solution has been diluted to a concentration of 0.25 ppm, the expected route of disposal for process water from these facilities is via discharge to a local Publicly-Owned Treatment Works (POTW), an on-site wastewater treatment system, or directly into a natural body of water or a man-made depository channeling into a natural body of water (if the depositor has an NPDES permit for point-source discharge into open water).

a) Wastewater Treatment of Discharged Process Water

The potential releases of chlorite, chlorate, and chloride in process water discharged either to a POTW, directly into a natural body of water, or to a man-made depository channeling into a natural body of water are estimated below. All processors expected to employ FCS for the intended uses described in this document are subject to discharge regulations outlined in 40 C.F.R. 403 and are required by federal law either to:

1. Meet mandatory wastewater pretreatment requirements through on-site wastewater treatment facilities or alternative methods of effective treatment

   or

2. Conform to the prerequisites necessary to obtain an NPDES permit for point-source discharge into open water.[8]

Upon the FCS's discharge directly into a natural body of water or man-made depository channeling into a natural body of water, chlorine dioxide undergoes a reduction to chloride, chlorite, and chlorate ions upon exposure to organic matter. Additionally, chlorine dioxide often reduces to chlorine and oxygen when exposed to ultraviolet radiation and that it from there is likely to degrade into chloride ions. Therefore, the Notifier considers a release of the FCS into an aquatic environment in any significant concentration extraordinarily unlikely due to its probable removal from the wastewater pathway either through reactions resulting from the FCS's contact with organic matter, exposure to ultraviolet radiation, or removal by a POTW or processor's wastewater treatment method prior to its issuance into the environment.[9] [10]

EICs (Environmental Introduction Concentrations) For The Chlorite, Chlorate, and Chloride Ions

In estimating the maximum potential EIC levels for chlorite, chlorate, and chloride ions upon their entrance into wastewater, the Notifier makes the following assumptions:

[8] Please refer to http://water.epa.gov/polwaste/npdes/index.cfm

[9] Gordon, et al. 1990. Minimizing chlorite ion and chlorate ion in water treated with chlorine dioxide. Research and Technology: Journal of the American Water Works Association. April, p. 160-165.

[10] Toxicological Profile for Chlorine Dioxide and Chlorite. U.S. Department Of Health And Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. Sep. 2004.

- A solution of Selective Micro Technologies' chlorine dioxide is diluted to a concentration at or below 0.25 ppm chlorine dioxide in-solution before entry into wastewater

- In-line with the results of Lee et al. (2004), we conservatively estimate that the residual chlorite concentration is approximately 70% of chlorine dioxide consumed in-reaction and that residual chlorate concentration is approximately 15% of chlorine dioxide consumed in-reaction. The reaction's remaining 15% can be categorized as minor reaction products.[11]

- In conservatively calculating the maximum potential EIC, we assume a worst-case scenario in which the entirety of the FCS discharged at a concentration of 0.25 is converted to chloride.

- There are no chlorite impurities in the FCS.

According to these assumptions, we make the following estimates for the EICs of the chlorite, chlorate, and chloride ions:

The maximum EIC for chlorite would be:
0.25 ppm x 0.7 = 0.175 ppm

The maximum EIC for chlorate would be:
0.25 ppm x 0.15 = 0.0375 ppm

$$0.0375 \text{ ppm } ClO_2 = \frac{0.0375 \text{ g } ClO_2}{10^6 \text{g water}} * \frac{\text{mol } ClO_2}{67.45 \text{ g } ClO_2} * \frac{\text{mol } ClO_3^-}{\text{mol } ClO_2} * \frac{83.45 \text{ g } ClO_3^-}{\text{mol } ClO_3^-} = 0.0464 \text{ ppm } ClO_3^-$$

And the maximum EIC for chloride would be:

$$0.25 \text{ ppm } ClO_2 = \frac{0.25 \text{ g } ClO_2}{10^6 \text{g water}} * \frac{\text{mol } ClO_2}{67.45 \text{ g } ClO_2} * \frac{\text{mol } Cl^-}{\text{mol } ClO_2} * \frac{35.45 \text{ g } Cl^-}{\text{mol } Cl^-} = 0.13 \text{ ppm } Cl^-$$

EECs (Estimated Environmental Concentrations) For The Chlorite, Chlorate, and Chloride Ions

Concerning the EECs for the chlorite, chlorate, and chloride ions in the wastewater of fruit and vegetable/RAC processors utilizing the FCS and discharging wastewater directly into an aquatic body or man-made depository channeling into a natural body of water, Selective Micro Technologies makes the assumption that the receiving stream dilution factor is 10.[12]

[11] Lee, Yoon-jin, Hea-tae Kim, and Un-gi Lee. (2004). Formation of Chlorite and Chlorate from Chlorine Dioxide with Han River Water. Korean J. Chem. Eng., 21(3): 647-653.

[12] Please see Rapaport, Robert A., 1988. Prediction of consumer product chemical concentrations as a function of publically owned treatment works

Using this assumption, we make the following estimate of the maximum EEC's for the chlorite, chlorate, and chloride ions:

The maximum EEC for chlorite (ClO_2^-) is:
0.175 ppm * 0.10 = 0.0175 ppm or mg/L

The maximum EEC for chlorate (ClO_3^-) is:
0.0464 ppm * 0.10 = 0.00464 ppm or mg/L

The maximum EEC for chloride (Cl^-) is:
.13 ppm * 0.10 = .013 ppm or mg/L

SMT does not foresee any degradants of gaseous chlorine dioxide migrating into wastewater in any significant quantity as a result of the FCS's use. Similarly, degradants that may form within the micro-reactor as a result of ClO_2 generation are to remain inside the micro-reactor and be disposed of in a landfill.

7. Fate of Substances Released Into the Environment

a. Wastewater Treatment

A solution of Selective Micro Technologies' chlorine dioxide that is used to generate the FCS will form the degredation ions described above (chlorate, chlorite, chloride).

b. Air Releases

According to the ATSDR Toxicological Profile on Chlorine Dioxide and Chlorite, "chlorine dioxide is an unstable gas that rapidly decomposes in air." [13] When the FCS is used in the manner described by this FCN, any residual chlorine dioxide released to the atmosphere is expected to immediately decompose to chlorine and oxygen upon its exposure to ultraviolet light. (*e.g.*, upon interaction with natural sunlight).

As oxygen is an element already abundant in the earth's atmosphere, the release of oxygen to the atmosphere from uses of the FCS is not expected to have any appreciable impact on the environment. Chlorine, however, will rapidly be broken down in reactions with ultraviolet light or other atmospheric particles to form the chloride particle.[14] [15] Under the Clean Air Act, chlorine is

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treatment type and riverine dilution. Environmental Toxicology and Chemistry 7(2), 107-115.

[13] Agency for Toxic Substances and Disease Registry (ATSDR). 2004. Toxicological profile for Chlorine Dioxide and Chlorite. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

[14] Agency for Toxic Substances and Disease Registry (ATSDR). 2004. Toxicological profile for Chlorine Dioxide and Chlorite. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

considered a Hazardous Air Pollutant by the Environmental Protection Agency, and existing background levels of chloride in the environment range from 1-10 mg/L.[16] [17]

Because of the rapid degradation and dilution expected to occur immediately upon the FCS's release to the atmosphere, Selective Micro Technologies expects releases of the FCS to contribute to background levels of chloride in the atmosphere at negligible levels. Similarly, SMT does not expect releases of the FCS to the atmosphere to result in exposures to chlorine dioxide or chlorine in the air because of their propensity to rapidly degrade and be diluted. The release of the FCS to the atmosphere via air flush is not expected to increase atmospheric exposures to chlorine dioxide, chlorine, or the chloride ion.

8. Environmental Effects of Released Substances

There are no anticipated environmental effects of released substances into the environment. Upon its release to the environment, the FCS will decompose when exposed to natural sunlight.

[15] Chlorine Dioxide: Final Risk Assessment Case 4023; Docket ID No. EPA-HQ-OPP-2006-0328; U.S. Environmental Protection Agency, Antimicrobials Division: Washington D.C., Aug 2, 2006.

[16] Please see https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-modifications

[17] Environmental, Health and Economic Impacts of Road Salt. New Hampshire Department of Environmental Services. State of New Hampshire, 2017.

Air

In its 2006 Chlorine Dioxide: Final Risk Assessment Case 4023, the EPA published the results of a toxicity study of chlorine dioxide in rats (including data on exposure through oral channels and inhalation).[18] If the product is used and released to the environment as directed, exposure to SMT's chlorine dioxide will be well below these thresholds:

Table 1. Acute Toxicity Profile for Chlorine Dioxide/ Sodium Chlorite				
Guideline Number	Study Type[a] / Test substance (% a.i.)	MRID Number/ Citation	Results	Toxicity Category
870.1100 (§81-1)	Acute oral (79% chlorine dioxide)	43558601	LD_{50} = 292 mg/kg (males) LD_{50} = 340 mg/kg (females)	II
870.1200 (§81-2)	Acute dermal (80% sodium chlorite)	40168704	LD_{50} > 2000 mg/kg	III
870.1300 (§81-3)	Acute inhalation (80.6% sodium chlorite)	42484101	LC_{50} = 0.29 mg/L	II
870.2400 (§81-4)	Primary eye irritation (2% chlorine dioxide)	43441903	Mild irritant	III
870.2500 (§81-5)	Primary dermal irritation (80% sodium chlorite)	40168704	Primary irritant	II
870.2600 (§81-6)	Dermal sensitization	No acceptable sensitization study available.		

[a] The available acute studies are all graded as acceptable. An acceptable dermal sensitization study is not available in the database.

The lowest inhalation endpoint provided in the study is the LC_{50} of 0.29 mg/L. Selective Micro Technologies' chlorine dioxide is to be generated at a 3 parts per million residual in-air. Chlorine dioxide at a 3 ppm residual is equal to: [19]

$$3 \text{ ppm } ClO_2 = \frac{3 \text{ mg } ClO_2}{1000 \text{ µg } ClO_2} * \frac{67.45 \text{ g } ClO_2}{\text{mol } ClO_2} * \frac{\text{mol } ClO_2}{24.45 \text{ L mol } ClO_2} = 8.28 \times 10^{-3} \text{ mg/L } ClO_2$$

Selective Micro Technologies' chlorine dioxide is to be generated at a residual of 3 ppm or 8.28 x 10^{-3} mg/L ClO_2 in-air. Because this concentration is significantly less than the inhalation toxicity endpoint of 0.29 mg/L provided in the EPA's RED (Case 4023), Selective Micro Technologies maintains that air releases of the FCS will have a negligible impact.

[18] Chlorine Dioxide: Final Risk Assessment Case 4023; Docket ID No. EPA-HQ-OPP-2006-0328; U.S. Environmental Protection Agency, Antimicrobials Division: Washington D.C., Aug 2, 2006.

[19] 24.45 is the volume (in liters) of a mole of a gas at 1 atmosphere and at 25°C and 67.5 is the molecular weight of chlorine dioxide.

Water

In 2006, the EPA published their final decision on whether chlorine dioxide was eligible to be registered as a pesticide (the decision is captured in "Chlorine Dioxide: Final Risk Assessment Case 4023").[20] One of the analyses conducted to support the EPA decision on chlorine dioxide was the ecological hazard and risk assessment for chlorine dioxide. This ecological analysis explains that the ecological risk assessment relies on chlorite endpoints to be protective of chlorine dioxide and its degredates "because under environmental conditions, chlorine dioxide converts mostly into chlorite ions." [21] While this Environmental Assessment has calculated EECs for chlorite, chlorate, and chloride, we follow the EPA's approach and rely upon chlorite endpoints in our analysis. After use, Selective Micro Technologies' chlorine dioxide will be diluted to a concentration of 0.25 ppm and released to the environment, where it will ultimately degrade to the chlorite ion (and the EEC for chloride is 0.013 ppm, lower than background levels, as discussed under Item 7b of this Environmental Assessment). Formations of the chlorite ion as a result of the disposal of a solution of Selective Micro Technologies' chlorine dioxide will be well below chlorite ecological endpoints:

Table 18. Acute Ecotoxicity of Chlorine Dioxide and Sodium Chlorite

Substance/% Active Ingredient (AI)	Organism	Endpoints/Results (ppm) (95% conf. interval)	Reference	Study Classification
Freshwater Invertebrates				
Sodium Chlorite/80%	*Daphnia magna*	EC50 = 0.027 (0.021-0.031) NOEC = 0.003	Barrows, 1984 MRID # 146162	acceptable
Sodium Chlorite/80%	*Daphnia magna*	EC50 = 0.39 (0.32-0.54) NOEC =N.R.	Hoberg and Surprenant, 1984 MRID # 141149	acceptable
Sodium Chlorite/79%	*Daphnia magna*	LC50 = 0.29 (0.25-0.33) NOEC = 0.10	Vilkas, 1976 MRID # 131350	acceptable
Sodium Chlorite/80%	*Daphnia magna*	LC50 = 0.08 (0.06-0.10) NOEC = 0.06	Larkin, 1984 ACC # 254182	acceptable
Sodium Chlorite/80%	*Daphnia magna*	LC50 = 0.146 (0.12 - 0.18) NOEC = 0.06	Nachrord, 1984 MRID # 94068009	acceptable
Sodium Chlorite/25%	*Daphnia magna*	LC50 = 1.4 (1.0-1.9) NOEC = 0.4	MBA Laboratories, 1984 ACC # 252854	supplemental

[20] Chlorine Dioxide: Final Risk Assessment Case 4023; Docket ID No. EPA-HQ-OPP-2006-0328; U.S. Environmental Protection Agency, Antimicrobials Division: Washington D.C., Aug 2, 2006.

[21] Chlorine Dioxide Environmental Hazard and Risk Assessment. Case 4023; U.S Environmental Protection Agency, July 13, 2006. P. 2 https://www.regulations.gov/document?D=EPA-HQ-OPP-2006-0328-0020

The lowest ecotoxicity endpoint provided in the study is the EC_{50} of 0.027 ppm. Because this concentration is greater than the EEC for chlorite provided in Section 6 of this EA (0.0175 ppm), Selective Micro Technologies maintains that the release of solutions of Selective Micro Technologies' chlorine dioxide to the natural bodies of water will have a negligible impact.

Based upon these toxicity endpoints and the information provided in above sections, Selective Micro Technologies foresees no adverse effects on the environment as a result of the release of its chlorine dioxide to environmental channels.

9. Use of Resources and Energy

This FCS will replace existing methods of generation, and is not expected to result in an increased use of natural resources. The use of the FCS will replace other sources of chlorine dioxide, and is not expected to require additional natural resources during its use or disposal. Manufacture of SMT's micro-reactor utilizes existing sources of natural resources and energy; consequently, there is no increase with anticipated effect on the use of natural resources and energy with effective FCN.

10. Mitigation Measures

No adverse environmental effects are expected upon use and/or disposal of the FCS per the specifications of this FCN. The use of the FCS as proposed is not reasonably expected to result in environmental problems requiring mitigation measures. There will be no significant impact to the environment though GHG emissions.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified that would necessitate alternative actions to that which is proposed in this Environmental Assessment. The decision to not approve this proposed FCS would result in the continued use of chlorine dioxide produced by other methods of generation. No identifiable or significant environmental impact is expected as a result from its use.

12. List of Preparers

This assessment was prepared by Mr. Kevin Dearwester, VP of Business Operations for Selective Micro Technologies and reviewed by Mr. Jeff Thomas, President and CEO of Selective Micro Technologies. Together, Jeff and Kevin have nearly 15 years of experience working with chlorine dioxide, most notably in food safety and water system technologies. The assessment preparer, Mr. Dearwester, holds a Bachelor of Arts (BA) double major in Spanish and Psychology (concentration in Neuroscience). He earned an MBA from Ohio University in May, 2013. His business curriculum was supplemented at the International Study Program (ISP) via Ohio University's School of Business in Managua, Nicaragua, which Mr. Dearwester successfully completed for a Certification of Excellence in International Business in January 2014. Kevin also has several years of research and teaching experience with emphasis in multiple sclerosis, general oncology, and cerebral hemispheric processing. Kevin spent time at Kent State University, where he was First Author of three professionally published pharmacology journals via NEOUCOM and Elsevier and instructed Anatomy and Physiology laboratories for pre-med students. Recently, he authored FCN 1578, a newly-approved Food Contact Notification allowing for the use of Selective Micro Technologies' chlorine dioxide products in antimicrobial washes used to treat red meat, pork, and seafood products.

13. Certification

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

[redacted]

April 4th, 2017

14. References

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