# Environmental Assessment

1. **Date:** August 8th, 2017

2. **Name of Notifier:** Selective Micro Technologies, LLC

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## 4. Description of the Proposed Action

The action requested in this food contact notification (FCN or Notification) is to establish a modification of the approved uses of the food contact substance (FCS), chlorine dioxide ($ClO_2$), currently approved by the FDA for use as an antimicrobial agent during the processing of fruits and vegetables.

The Food and Drug Administration's (FDA) food additive regulations at 21 C.F.R. § 173.300 currently provide for three alternate methods of the generation of chlorine dioxide for these uses, and additional methods have been cleared via Notifications to the FDA. This Notification seeks to acquire the FDA's approval for the FCS to be used as an antimicrobial agent in water used to wash fruits and vegetables that are raw agricultural commodities (RAC). The FCS will be used in an amount not to exceed 3 ppm residual chlorine dioxide as determined by Method 4500-$ClO_2$-E. When used on fruits and vegetables that are RAC, the FCS will be applied 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)(1)(B)(i)(III). The application of the FCS to fruits or vegetables that are RAC will be followed by a potable water rinse and/or cooking, canning, blanching or packaging.

The FCS will be added to fruit and vegetable RAC processing and packaging operations throughout the United States in an amount not to exceed 3 ppm residual chlorine dioxide as determined by methods described in the regulations at 21 C.F.R. §173.300. The use of the FCS in this manner is regulated under 21 C.F.R. §173.325, based upon solutions of acidified sodium chlorite.

## 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. To generate chlorine dioxide gas, an SMT product-specific micro-reactor will either be added to a volume of water, or a volume of water will be added to a vessel containing this micro-reactor. Inside the micro-reactor, compartmentalized precursor chemicals react to generate nearly-pure chlorine dioxide gas into 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 and into the surrounding solution.

In order to sustain such a residual, it will be required to ensure that the FCS is generated in the solution at a concentration greater than 3 ppm, as ongoing chemical reactions with food and micro-organisms will ensue. Although the amount of chlorine dioxide used may vary between applications, we suggest no greater than a maximum 10 ppm feed rate be utilized for intended use applications of the FCS.

The FCS will act as an oxidizer and reduce levels of bacteria and other microbes on the surface of fruits and vegetables that are RAC. The $ClO_2$ gas concentration in-solution should be monitored using a product capable of reading the parts-per-million level of $ClO_2$ in a solution, such as *Selective Micro® Chlorine Dioxide Test Strips* or an equivalent measuring instrument. To obtain a greater concentration of $ClO_2$ gas in-solution, increase the volume of the FCS in-solution or decrease the volume of water in which SMT's chlorine dioxide is generated. To obtain a lower concentration of $ClO_2$ gas in-solution, decrease the volume of FCS in-solution or increase the volume of water in which the FCS is generated.

### c. Locations of use/disposal

The FCS is an antimicrobial wash which will treat fruits and vegetables that are RAC. The FCS will be added to process water used to treat fruits and vegetables that are RAC in plants, facilities, warehouses, and distribution centers using methods approved by the FD&C Act. The majority of this $ClO_2$ gas will be consumed in antibacterial reactions with organic matter in-solution while the remainder is to be released to a wastewater stream. 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).

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

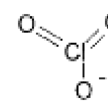
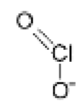
FCS Chemical Information

| | |
|---|---|
| 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)

| Substance Name | CAS Reg. Number | Structure |
|---|---|---|
| Chlorate Ion | 14866-68-3 |  |
| Chlorite Ion | 14998-27-7 |  |
| Chloride Ion | 7647-14-5 | $Cl^-$ |

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

| Substance Name | CAS Reg. Number | Structure |
|---|---|---|
| Chlorine | 7782-50-5 | Cl – Cl |
| Oxygen | 7782-44-7 | O = O |

## 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 of having adverse effects on the environment or posing an increased risk of introducing substances into the environment.

### b. As a Result of Use/Disposal

How To Use

The product is used by immersing a micro-reactor in water. Chlorine dioxide is generated upon immersion and diffuses into the surrounding water to form an aqueous antimicrobial solution. 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 functioning of a proprietary membrane on the outer surface of a Selective Micro Technologies micro-reactor. This membrane nearly purifies the product reaction by allowing only gases such as chlorine dioxide to diffuse into the surrounding water and keeping byproducts of the chlorine dioxide-generating reaction contained inside its selectively-permeable walls. Unreacted starting materials and reaction byproducts are contained within the selectively-permeable sachet. When the $ClO_2$ reaction is complete, food-grade citric acid is the only ingredient remaining inside the micro-reactor.

Due to the selective permeability of this membrane, only chlorine dioxide gas diffuses into the solution. Because no ionic compounds can diffuse across the membrane and into the solution, the chlorine dioxide solution generated in the water is extremely close to pure. Any scenario in which the chlorine dioxide-generating reaction results in a partial yield has no effect on the purity of the FCS: the micro-reactor envelope will retain any unreacted citric acid and will not release it into the final aqueous FCS solution.

Disposal – Air

As chlorine dioxide gas is intended only for the uses specified in this Environmental Assessment, air releases are expected to be negligible. Using SMT’s method of chlorine dioxide production, the only potential release of chlorine dioxide to the atmosphere is by off-gassing from process water. As a result, air releases from the use of chlorine dioxide as proposed in this FCN are expected to be far below the 3 ppm residual. Small amounts of the FCS which were to volatilize out of solution would rapidly decompose. 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 – 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 will be 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 this Environmental Assessment.

In accordance with 40 CFR 1508.27 the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context, 40 CFR 98.2(a)(3) requires stationary fuel combustion sources that emit 25,000 metric tons (mT) $CO_2$ equivalents (CO2-e) or more per year to report their GHG emissions to the U.S. Environmental Protection Agency (EPA). Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 CFR 98.30(a).

Municipal solid waste combustion facilities that emit 25,000 metric tons carbon dioxide equivalents[5] or more per year are required to report their GHG emissions per EPA's Greenhouse Gas Reporting Program.[6] 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

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[1] 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.

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

[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 land disposed and 19.6% is combusted.

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

[6] 40 CFR Part 98—Mandatory Greenhouse Gas Reporting

emissions are well below the 25,000 metric tons carbon dioxide equivalents threshold (again, as demonstrated in the Confidential Assessment to this Environmental Assessment).

Disposal – Water

After use, the FCS will be disposed with processing plant wastewater according to National Pollutant Discharge Elimination System (NPDES) regulations. For processing plants that hold a NPDES permit (*i.e.*, direct dischargers), the FCS-containing wastewater will be treated on-site before direct discharge to surface waters. For processing plants without such NPDES permits (*i.e.*, indirect dischargers), the FCS-containing wastewater will travel through the sanitary sewer system into publicly owned treatment works (POTWs) for standard wastewater treatment processes before movement into aquatic environments. Chlorine dioxide undergoes a reduction to chloride, chlorite, and chlorate ions as it is exposed to organic matter. Additionally, chlorine dioxide often reduces to chlorine and oxygen when exposed to ultraviolet radiation, and from there it is likely to degrade into chloride ions. Therefore, we consider 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.[7,8]

*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:

- The application rate used by the employer of the FCS is 10 ppm (The Notifier's highest suggested feed rate for intended use applications of the FCS)

- 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[9]

[7] 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.

[8] 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.

[9] 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.

- In calculating the maximum potential EIC, we assume a worst-case scenario in which the entirety of the FCS discharged at the suggested maximum application rate of 10 ppm 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 is:
10 ppm x 0.7 = 7 ppm

The maximum EIC for chlorate is:
10 ppm x 0.15 = 1.5 ppm

$$1.5 \text{ ppm } ClO_2 = \frac{1.5 \text{ g } ClO_2}{10^6 \text{g water}} * \frac{\text{mol } ClO_2}{67.45 \text{ g } ClO_2} * \frac{\text{mol } ClO_3^-}{\text{mol } ClO_2} * \frac{85.45 \text{ g } ClO_3^-}{\text{mol } ClO_3^-} = 1.9 \text{ ppm } ClO_3^-$$

And the maximum EIC for chloride is:

$$10 \text{ ppm } ClO_2 = \frac{10 \text{ g } ClO_2}{10^6 \text{ g } H_2O} * \frac{\text{mol } ClO_2}{67.45 \text{ g } ClO_2} * \frac{\text{mol } Cl^-}{\text{mol } ClO_2} * \frac{35.45 \text{ g } Cl^-}{\text{mol } Cl^-} = 5.3 \text{ ppm } Cl^-$$

*EEC's (Estimated Environmental Concentrations) For The Chlorite, Chlorate, Chloride Ions*

Concerning the EEC's 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 following assumptions about its chlorine dioxide upon its entrance to such bodies of water:

- Approximately 50% of the total water discharged from a fruit and vegetable RAC use center is to be treated with the FCS chlorine dioxide[10]

- The receiving stream dilution factor is 10[11]

[10] Fruit and Vegetable Processing. Food Processing Environmental Assistance Center, Purdue University.

[11] Rapaport, Robert A., 1988. Prediction of consumer product chemical concentrations as a function of publically owned treatment works treatment type and riverine dilution. Environmental Toxicology and Chemistry 7(2), 107-115.

- Chlorite destruction and removal by the wastewater treatment of the food processing plant is 99%[12]

Using these assumptions, we make the following estimate of the maximum EECs for the chlorite, chlorate, and chloride ions

The maximum EEC for chlorite ($ClO_2^-$) is:
7 ppm * 0.50 * (1-0.99) * 0.10 = 0.0035 ppm or mg/L

The maximum EEC for chlorate ($ClO_3^-$) is:
1.9 ppm * 0.50 * 0.10 = 0.095 ppm or mg/L

The maximum EEC for chloride ($Cl^-$) is:
5.3 ppm * 0.50 * 0.10 = .265 ppm or mg/L

## 7. Fate of Substances Released Into the Environment

### a. Wastewater Treatment

Upon its entrance into water, a solution of Selective Micro Technologies' chlorine dioxide will form the degredation ions described above (chlorate, chlorite, chloride). If used and disposed of according to the pathways above, the products of the generated FCS or any of its prepackaged ingredients should not be released into the environment in any substantial quantity.

### b. Air Releases

The use of the FCS according to the methods described in this FCN is not expected to contribute dangerous levels of hazardous pollutants into the atmosphere. 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 methods proposed in this FCN, trace amounts of chlorine dioxide in the generated FCS solution may volatize into the atmosphere. This volatized $ClO_2$ 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.

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[12] 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.

[13] 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.

Chlorine, however, will rapidly be broken down in reactions with ultraviolet light or other atmospheric particles to form the chloride particle.[14] Under the Clean Air Act, chlorine is 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.[15,16]

Because of the rapid degradation and dilution expected to occur immediately upon chlorine dioxide's entrance to the atmosphere, Selective Micro Technologies expects negligible contributions to background levels of chloride in the atmosphere as a result of these releases. Similarly, SMT does not expect entrances of chlorine dioxide into the atmosphere to result in increased exposures to chlorine dioxide or chlorine in the air because of their propensity to rapidly degrade and be diluted. The entrance of the FCS to the atmosphere 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 it is exposed to natural sunlight.

*Air*

On page 7 of its *Reregistration Eligibility Decision (RED) for Chlorine Dioxide and Sodium Chlorite (Case Number 4023)*, the EPA published the results of a toxicity study of chlorine dioxide in rats (including data on exposure through oral channels and inhalation). The results of the study are reproduced in a table below: [17]

[14] 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.

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

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

[17] Registration Eligibility Decision (RED) for Chlorine Dioxide and Sodium Chlorite (Case 4023); EPA 738-R-06-007; USEPA; Office of Pesticide Programs: Washington, DC, August 2006. Page 7.

| 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.

If the FCS is used and released to the environment as directed, exposure to SMT's chlorine dioxide will be well below these thresholds.

The lowest inhalation endpoint provided in the study is the $LC_{50}$ of 0.29 mg/L. As the maximum suggested feed rate of the FCS is 10 ppm, a worst-case scenario is the potential air release of chlorine dioxide by off-gassing from process water at a 10 ppm residual in-air. Chlorine dioxide at a 10 ppm residual is equal to: [18]

$$10\ \text{ppm ClO}_2 = \frac{10\ \text{mg ClO}_2}{1000\ \mu\text{g ClO}_2} * \frac{67.45\ \text{g ClO}_2}{\text{mol ClO}_2} * \frac{\text{mol ClO}_2}{24.45\ \text{L mol ClO}_2} = 2.76 \times 10^{-2}\ \text{mg/L ClO}_2$$

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 potential air release of chlorine dioxide by off-gassing from process water would have a negligible impact.

[18] 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*

On page 43 of its document *Chlorine Dioxide: Final Risk Assessment Case 4023*, the EPA published their final decision on whether chlorine dioxide was eligible to be registered as a pesticide. 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." The results of this study are reproduced in a table below:[19]

| 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 |

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 released to the environment, where it will ultimately degrade to the chlorite ion, then chloride ion.[20]

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: 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

[19] 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. Page 43

[20]The EEC for chloride is .265 ppm, lower than background levels, as discussed under Item 7b of this Environmental Assessment

chlorite calculated in Section 6 of this EA (0.0035 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. The manufacture of SMT's micro-reactor utilizes existing sources of natural resources and energy. Consequently, we do not anticipate any effect on the use of natural resources and energy upon the approval of this FCN.

## 10. Mitigation Measures

No adverse environmental effects are expected upon the use and/or the 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. He also authored FDA's Acknowledgement Letter (AL) regarding FCN 1764, intending use of chlorine dioxide as a fumigation agent to fruit and vegetables that are raw agricultural commodities.

## 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]

August 8th, 2017

**Kevin Dearwester**
VP of Business Development
Selective Micro Technologies
855-256-8299

## 14. References


1. Advancing Sustainable Materials Management: 2014 Fact Sheet. United States Environmental Protection Agency, 2016. Available online at http://www.epa.gov/wastes/nonhaz/municipal/msw99.htm

2. Toxicological Profile for Chlorine Dioxide and Chlorite. Sep. 2004. U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry. Available online at http://www.atsdr.cdc.gov/toxprofiles/tp160.pdf

3. Agency for Toxic Substances and Disease Registry (ATSDR). Nov. 2010. "Public Health Statement." Toxicological Profile for Chlorine. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service. Available online at https://www.atsdr.cdc.gov/phs/phs.asp?id=683&tid=36

4. Anderson, B.; Hetrick, J. A.; Nelson, H. Environmental Fate and Ecological Risk Assessment for the Reregistration of Sodium Chlorate as an Active Ingredient in Terrestrial Food/Feed and Non-food/Non-feed Uses. Reregistration Case Number 4049; Docket ID No. EPA-HQ-OPP-2005-0507; U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances: Washington, D.C., Jan 31, 2005.

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

6. 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.

7. Code of Federal Regulations, Standards of Performance for New Stationary Sources, title 40, sec. 60.

8. Code of Federal Regulations, Mandatory Greenhouse Gas Reporting, title 40, sec. 98.

9. Code of Federal Regulations, Criteria For Municipal Solid Waste Landfills, title 40, sec. 258.

10. Environmental, Health and Economic Impacts of Road Salt. New Hampshire Department of Environmental Services. State of New Hampshire, 2017. Available at http://www.des.nh.gov/organization/divisions/water/wmb/was/salt-reduction-initiative/impacts.htm

11. Fruit and Vegetable Processing. Food Processing Environmental Assistance Center, Purdue University. Available online at http://www.fpeac.org/fruit/fruitveg.html

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