



Environmental Assessment

1. **Date:** August 18, 2006
2. **Name of Notifier:** Selective Micro Technologies, LLP
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4. **Description of Proposed Action:**

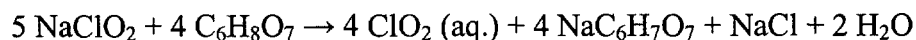
The action requested in this food contact notification (FCN or Notification) is to establish the clearance of the food contact substance (FCS), chlorine dioxide, that is intended for use as an antimicrobial agent during processing of poultry and fruits and vegetables. The Food and Drug Administration's (FDA) food additive regulations at 21 C.F.R. § 173.300 currently provide for three alternate methods of generation of chlorine dioxide for these uses, and additional methods have been cleared via Notifications to FDA. This Notification seeks to modify the use of the FCS, as currently cleared for use on poultry, fruits and vegetables, to remove the requirement for a potable water rinse for fruits and vegetables that are not further processed by blanching, cooking or canning.

Because the Agency is interested in consolidating the FCN No. 445 with the subject FCN, an analysis of the poultry application is included in this assessment. This assessment varies from that submitted with FCN No. 445 in that it assumes a greater percentage of the poultry process water is treated with the FCS. The FCS is to be used as an antimicrobial agent in water used in poultry processing and to wash fruits and vegetables that are not raw agricultural commodities 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 FCS will be added to process water used in poultry and fruit and vegetable plants throughout the United States. The chlorine

dioxide will be consumed by the oxidation of organic matter and microorganisms present in food and/or process water, or during wastewater treatment. Chlorine dioxide is reduced primarily to chlorite and eventually to chloride, with low levels of chlorate produced during the chlorine dioxide generation process. As discussed below, neither chlorite nor chlorate are expected to be released into the environment in significant quantities. The expected route of disposal for process water from these facilities is via discharge to a local Publicly-Owned Treatment Works (POTWs) or to on-site wastewater treatment systems. Accordingly, the use of chlorine dioxide produced with this technology to control microbial growth may result in small amounts of chloride, chlorite and chlorate being discharged to POTW's or on-site wastewater treatment systems.

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

Production of the FCS, using the SMT products, is based on the following general chemical equation:



The principal feature that distinguishes the generation of ClO_2 using one of SMT's products is its use of a proprietary membrane to contain the reactants. The membrane is selectively permeable, allowing only gases (*i.e.*, chlorine dioxide) to diffuse out into the surrounding water, trapping the reaction byproducts inside a sealed reaction envelope. To produce chlorine dioxide, tap water is added to a pouch that contains the dry ingredients inside an envelope, the exterior of which is constructed with the selective membrane (alternatively, the envelope is removed from packaging, and immersed in a vessel containing a prescribed amount of water). Only chlorine dioxide gas diffuses into solution and unreacted starting materials and reaction byproducts are contained within the selectively permeable sachet. Because no ionic compounds can diffuse across the membrane into solution, the resultant chlorine dioxide solution is nearly pure (greater than 99% of the total oxychloro species). The degree to which the reaction reaches completion is not relevant to the purity of the FCS due to the non-permeability of the reaction envelope's membrane to liquid water and ionic constituents—only true gases can diffuse through into the final aqueous FCS solution.

The composition of a concentrated solution of the FCS is provided in the Confidential Attachment to this EA. The analysis demonstrates that the concentrated aqueous solution of the FCS is 99% or greater in purity. This information is incorporated below into our discussion of the estimated maximum concentration of the FCS and its degradates in the discharge streams.

6. Introduction of Substances into the Environment

a. Introduction of substances into the environment as a result of manufacture:

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated substances. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS precursor materials. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b. Introduction of substances into the environment as a result of use and disposal:

The FCS, *i.e.*, chlorine dioxide, will be produced on site either within a closed product pouch, or within a closed container of water. Potential releases to environmental media, including air, water and soil, are discussed in more detail below.

Air releases from the approved uses of chlorine dioxide are expected to be negligible. Since the production of chlorine dioxide is in a closed system, the only potential air release of chlorine dioxide is by off-gassing from process water. Further, chlorine dioxide will undergo rapid photochemical decomposition in the air. As a result, while air releases from the use of chlorine dioxide as described is expected to be negligible, if small amounts of the FCS were to volatilize out of solution it would rapidly decompose.

If the product is used as intended, it is not expected that at the proposed maximum application rate, safe exposure limits will be exceeded, including those established by NIOSH (Short Term Exposure Limit (STEL) of 0.3 ppm (0.9 mg/m³) during any 15-minute period of a 10-hour workday), or by OSHA (Permissible Exposure Limit (PEL) of 0.1 ppm (0.3 mg/m³ time-weighted average over an 8-hour shift)).¹ The Material Safety Data Sheets (MSDS) for SMT's

¹ See <http://www.cdc.gov/niosh/npg/npgd0116.html>

products identifies the potential hazards associated with chlorine dioxide, and provides the inhalation limits for the workplace established by OSHA. Workers handling the FCS are instructed to wear a respirator if exposure limits are exceeded. The Notifier understands that the USDA and OSHA have in place a memorandum of understanding (1994) that established a process and a framework for worker protection.

The potential loads of chlorite, chlorate and chloride introduced into wastewater streams are estimated below. Importantly, it is expected that the organic loading of the wastewater streams present in an on-site wastewater treatment facility or POTW would cause any trace levels of chlorine dioxide and chlorite in the process water to undergo reduction to chloride ions. Unreacted starting materials and reaction byproducts are contained within the reaction envelope an arrangement that limits the potential for non-use release. The spent chlorine dioxide pouch and sachet(s) can be landfilled according to the label directions.

c. Wastewater Treatment of Discharged Process Water

Based on the calculations in the Confidential Attachment to this Environmental Assessment, and conservatively assuming that no reduction in chlorite or chlorate has occurred during use of the process water, estimates of the maximum chlorate and chlorite levels in water entering wastewater treatment from each type of processing are provided below:

Poultry:	8.5 mg ClO ₂ ⁻ /L
	0.1 mg ClO ₃ ⁻ /L
Fruit and Vegetables:	3.6 mg ClO ₂ ⁻ /L
	0.05 mg ClO ₃ ⁻ /L

The process water discharged to the local POTW will undergo further dilution. Although the exact dilution factor will be dependent on the average daily influent volume to the POTW, we reference as the percentage of total POTW influent contributed by either a poultry or food processing facility those values identified in FAPs 4A4408 and 4A4415. Specifically, the Environmental Assessments for Food Additive Petitions 4A4408 and 4A4415 indicate that the average poultry, fruit or vegetable processing facility is expected to contribute 13.5% of the influent to a POTW. Based on this information, residues of the FCS in the process water will be diluted as shown in the calculations below.

Poultry:

$$(8.5 \text{ mg ClO}_2^-/\text{L}) \times (0.135) = 1.15 \text{ mg ClO}_2^-/\text{L}$$

$$(0.1 \text{ mg ClO}_3^-/\text{L}) \times (0.135) = 0.014 \text{ mg ClO}_3^-/\text{L}$$

Fruit and Vegetable Processing:

$$(3.6 \text{ mg ClO}_2^-/\text{L}) \times (0.135) = 0.49 \text{ mg ClO}_2^-/\text{L}$$

$$(0.05 \text{ mg ClO}_3^-/\text{L}) \times (0.135) = 6.8 \times 10^{-3} \text{ mg ClO}_3^-/\text{L}$$

Releases to surface water from a POTW or onsite treatment system would be subject to the terms and conditions of a National Pollution Discharge Elimination System (NPDES) permit.

7. Fate of Emitted Substances in the Environment

a. Wastewater Treatment

Chlorine dioxide is reduced primarily to chlorite and chloride, with the potential for introduction of low levels of chlorate during generation of the FCS.² Both chlorite and chlorate are further reduced to chloride in the environment. The reduction of chlorite to chloride is enhanced in the presence of ferrous iron (Fe^{2+}), and when Fe^{2+} is in excess, total reduction may be achieved in minutes.³ Gordon et al. (1990) also report that sulfite (SO_3^{-2}) reduces chlorite to chloride in minutes to a few days, depending on the pH and sulfite concentration.⁴ Reduced forms of sulfur compounds, such as sulfite, are present under anoxic conditions (*e.g.*, in wastewater treatment plants using anaerobic digestion or in aquatic sediments).

Several journal articles describe the reduction reactions of chlorite and chlorate to chloride during wastewater treatment, and there have been investigations into the most efficient means of reducing these compounds to chloride in drinking water disinfected with chlorine dioxide. Gordon et al. (1990) report that treatment of wastewater or drinking water with sulfur dioxide-sulfite ion removes up to 99 percent of chlorite ion in 0.34 minutes at pH 5.0 and within 15.6 minutes at pH 7.5. Only when the pH was at 8.5 was there a significant increase in the time

² As noted above, the selective permeability of the membrane used in the envelope in which the chlorine dioxide is made is such that no chlorate should be present in the solution. Thus, the estimates presented here are all conservative in nature.

³ Werdehoff and Singer, 1987 Chlorine dioxide effects on the formation of THMFP, TOXFP and inorganic byproducts. Research and Technology: Journal AWWA. September, pp. 107-113.

⁴ 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.

required to reduce chlorite to chloride (3.2 days).⁵ Griese also reported that sodium thiosulfate and ferrous chloride achieve greater than 80% reduction of chlorite within 60 minutes.⁶ Two commonly used chemicals to aid flocculation of suspended solids in wastewater treatment are ferrous chloride (FeCl_2) and ferrous sulfate ($\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$).⁷

Chlorite is also reduced to chloride when exposed to light, with an increase in rate of reduction as the pH of the solution decreases.⁸ Gordon et al. stated that 100% of a chlorous acid (HClO_2) solution decomposed to chloride and oxygen in one hour.

Under anaerobic conditions, as would be present during anaerobic wastewater treatment or in aquatic sediments, a stoichiometric reduction of chlorate occurs in approximately 10 days, producing oxygen and chloride.⁹ Chlorate undergoes biological reduction to chloride under anaerobic conditions by denitrifying microorganisms.¹⁰ Nearly 100% of the chlorate introduced into an activated sludge mixture was reduced to chlorite in 10 days. In sediment and water collected from various sites, chlorate was also reduced to chlorite within 10 days when oxygen was excluded. During anaerobic digestion of wastewater, populations of denitrifying microorganisms are deliberately enhanced in order to prevent the release of nitrates into the environment. As nitrate is depleted as an electron acceptor, chlorate will be reduced to chloride. Anaerobic treatment processes in wastewater treatment plants range from a few hours to two days, depending on the system installed.¹¹ However, once discharged, chlorate that is trapped in anaerobic sediments or anoxic water columns will undergo reduction to chloride, and thus will persist for only short periods of time following release, if any is extant.

Based on the above information, it is not expected that chlorite or chlorate will be present as such in the water discharged following treatment. Therefore, we have assumed that 100% of

⁵ Griese, et al. 1998. Combining methods for the reduction of oxychlorine residuals in drinking water. *Journal AWWA*, November, p. 69.

⁶ Griese, et al. 1991 Using reducing agents to eliminate chlorine dioxide and chlorite ion residuals in drinking water. *Research and Technology: Journal of the AWWA*. September. P. 107-113.

⁷ *Wastewater Engineering: Treatment, Disposal, and Reuse*. Third Edition, p. 488. Metcalf and Eddy, Inc. Tchobanoglous and Burton (ed.) McGraw-Hill, Inc. 1991.

⁸ Gordon, G., Kieffer, R.G., and Rosenblatt, D.H. 1972. The chemistry of chlorine dioxide. *In Progress in Inorganic Chemistry*, Vol. 15, p. 224-225. S.J. Lippard (ed.). Wiley-Interscience, New York, NY.

⁹ Van Ginkel, C.G., C.M. Plugge and C.A. Stroo. 1995. Reduction of chlorate with various energy substrates and inocula under anaerobic conditions. *Chemosphere*, 31(9): 4057-4066.

¹⁰ See van Ginkel, *et al.*, *id* at Footnote 10.

¹¹ See *Wastewater Engineering*, *id* at Footnote 8, p. 428.

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the chlorite load will be reduced to chloride, and that 50% of the chlorate is reduced to chloride following typical wastewater treatments. These estimates also incorporate a 10-fold dilution of the water upon release into the environment. Therefore, chlorate levels are calculated to be a maximum of 7.0×10^{-4} from poultry process water and 3.4×10^{-4} from fruit and vegetable process water.

b. Discharge as Irrigation Water

Use of fruit and vegetable process water for irrigation of crops is employed as a method of final treatment to remove excess organic material and nutrients (notably nitrogen), and as a beneficial recycling of a scarce resource. Some fruit and vegetable processors may dispose of up to 100% of the process water by irrigation, once primary on-site treatment is completed. The volume of water used for irrigation on a daily basis, and number of acres on which it is applied are quite variable, depending on the soil texture, depth to groundwater, crops grown, and climate. However, groundwater protection regulations do not permit a processor to apply more nutrients to irrigated crop than they are capable of using during the growing season.¹² Assuming 100% of the treated process water is used for irrigation, a maximum daily load of chlorite and chlorate is 4.8×10^{-8} mg/L and 1.3×10^{-8} mg/L, respectively (assuming a 50% reduction of chlorite to chloride following on-site treatment, but no dilution as would occur in surface water releases). It is not expected that irrigation water would be applied at rates that result in significant or frequent introduction of process water into natural bodies of water by runoff, as the intent is to maximize an available resource. Chlorite in the process water is expected to undergo decomposition upon exposure to sunlight, forming oxygen and chloride ion. Chlorate, as discussed above, is stable under aerobic conditions, but will be reduced to chloride in anaerobic sediments. Therefore, neither degradates of chlorine dioxide is expected to persist in the environment and accumulate in soil or the irrigated crops.

c. Air Releases

With respect to air releases, chlorine dioxide in air will undergo rapid photochemical decomposition. As a result, while air releases from the use of chlorine dioxide as described is expected to be negligible, even if a small amount of chlorine dioxide were to volatilize out of solution, it would decompose and dissipate rapidly.

¹² See, for example, http://www.swrcb.ca.gov/rwqcb5/available_documents/waste_to_land/FoodProcessingInfoItem/

8. Environmental Effects of Released Substances

The U.S. Environmental Protection Agency recently released its draft environmental risk assessment for chlorine dioxide and chlorite, and for sodium chlorate. In these drafts, the following endpoints for aquatic and terrestrial toxicity were summarized.

Organism	Test	ClO ₂ ⁻	ClO ₃ ⁻
Bluegill sunfish	LC ₅₀	244-420 ppm	> 1000 ppm
Rainbow trout	LC ₅₀	203-360 ppm	> 1000 ppm
<i>Daphnia magna</i>	EC ₅₀ (48 hr.)	27 - 390 ppb	920 ppm
Mysid shrimp	EC ₅₀ (96 hr.)	576 ppb	> 1000 ppm
Eastern Oyster	EC ₅₀ (96 hr.)	21.4 ppm	> 1000 ppm
Aquatic plants (green algae)	EC ₅₀	1.32 ppm	133 ppm
Northern bobwhite quail	LC ₅₀	> 5000 ppm	> 5000 ppm
Northern bobwhite quail	LD ₅₀	390 - 797 mg/kg	No data
Mallard duck	LC ₅₀	> 5000 ppm	> 5000 ppm
Mallard duck	LD ₅₀	>31 mg/kg	>2510 mg/kg

Based on the levels of chlorite and chlorate conservatively estimated to be released into aquatic or terrestrial environments, no adverse effects to aquatic organisms, including fish and invertebrates, are anticipated from the proposed use of the FCS.

9. Use of Resources and Energy

The production of the FCS using the method described in the Confidential Attachment to this Environmental Assessment will replace existing methods of generation, and is not expected to result in 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 of wastes containing the FCS or its degradates. Deletion of the rinse requirement for fresh-cut fruits and vegetables is expected to reduce the demand on water resources, to reduce the volume of wastewater from fruit and vegetable processing facilities, and ultimately to reduce costs to both food processors and consumers.

10. Mitigation Measures

No significant adverse environmental effects are expected to result from the use and disposal of food-contact materials containing the FCS. This is due to the similarity of the FCS to other sources of chlorine dioxide that it is intended to replace, and the very low levels of degradates of the FCS that may persist following wastewater treatment. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to Proposed Action

No potential adverse environmental effects are identified herein which 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 chlorine dioxide produced through other methods of generation. In view of the absence of any significant environmental impact that would result from its use, the establishment of an effective FCN to permit the use of the FCS as described herein is environmentally safe in every respect.

12. List of Preparers

Elizabeth A. Heger, Staff Scientist, Keller and Heckman LLP

13. Certification

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

Date: August 18, 2006



George G. Misko

Counsel for Selective Micro Technologies, LLP

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