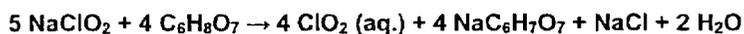


5. Identification of Chemical Substances that are the Subject of the Proposed Action

(a) Chemical Information for the Subject Additive, Precursor Chemicals and Impurities

The SMT product produces chlorine dioxide based on the following general chemical equation:



In addition to the chlorine dioxide and its oxidation products, the process generates sodium citrate. The most advanced features of this generator are the selectively permeable membranes that control output. The amount of product produced is constrained because the sachets are designed to limit the quantities of reagents available for reaction. As a worst-case, we have employed a 90% conversion level in our exposure calculations for possible contaminants, as this is the minimum reaction efficiency for chlorine dioxide specified in Section 173.300.

In summary, citric acid and its salts are the only new contaminants produced by SMT's process that are not also produced by the currently approved ClO₂ generators. The subject additive of this petition, chlorine dioxide, is presented below.

1. Chemical Name	Chlorine Dioxide
2. Synonyms	Chlorine Oxide, Chlorine (IV) Oxide
3. CAS Registry Number	10049-04-4
4. Formula and Structure Molecular weight	ClO ₂ and O=Cl=O 67.45 g/mole
5. Properties	
Melting point	-59 °C
Boiling point	11 °C
Solubility	3.01 g/l (@ 25°C and 34.5 mm Hg)
6. Purity	Consistent with the regulatory specifications set out in Section 173.300, we have assumed a worst case minimum 90% conversion efficiency in our calculations of impurities.

(b) Use Rates

The FCN seeks to permit use of the subject additive so as to allow a maximum residual chlorine dioxide concentration level of 3 ppm in water used during the processing of fruits and vegetables and poultry. Consequently, this entails a production rate as high as ppm.

(c) Impurities

The configuration of the sachets and the packaging, as well as the semipermeable nature of the membranes limit the potential for release of impurities. The impurities generated by this application are ClO_3^- , ClO_2^- , Cl^- , H^+ , as well as citric acid and its sodium salts.

6. Introduction of Substances into the Environment

Use of chlorine dioxide generated in this manner yields no new or significantly different releases with respect to the currently approved uses. The only minor differences are related to the impurities inherent to the generation chemistry. In this case, citric acid and its sodium salts may be produced, rather than peroxide, sulfate, and dissolved chlorine, which are unique to the approved chemistries noted in Section 173.300. In any event, the packaging arrangement limits the potential for non-use release, and the spent chlorine dioxide generator apparatus can simply be land-filled according to the label directions.

(a) Production Releases

The chlorine dioxide is produced on-site within a closed reactor. Therefore, production releases and non-use releases amount to very little, and occur at the site of use. This chlorine dioxide generator is based on the reaction of sodium chlorite and citric acid. The stoichiometric chemical equation is:



The starting chemicals are held in selectively permeable membrane sachets within the water-containing reactor. The finished aqueous solution is diluted appropriately before use. The products entering the process water stream consist of chlorine dioxide and water. In addition, there may be small amounts of citric acid or sodium citrate, although the citric acid is contained within a sachet that precludes its release. The rate of production of the ClO_2 is controlled by the stoichiometry of the reaction with respect to the amount of available reactants.

To the best of our knowledge, no extraordinary circumstances pertain to the manufacture of the FCS.

(b) Use Releases

Air Releases - Air releases from the approved uses of chlorine dioxide are negligible. Since the production of chlorine dioxide is confined to a closed system, the only potential release of ClO_2 is by evaporation from the process water. The EA from FAP No. 4A4408 (poultry) showed that the maximum possible air concentration of ClO_2 from a ClO_2 aqueous solution of chiller water is 0.03 ppm. This level would rapidly decrease by decomposition processes active in the outside environment. Appendix 4 of FAP No. 4A4408 provides the complete calculation for estimating air concentration of chlorine dioxide. The generation system for fruit and vegetable processing is similar; consequently, the air releases of ClO_2 will be similarly negligible. The information presented in these FAPs is incorporated herein by reference.

Water Releases - According to the stoichiometric equation above, one mole of sodium citrate is produced for every mole of chlorine dioxide formed. Sodium citrate is, therefore, the principal impurity formed in the process of ClO₂ generation; however, the selectively permeable nature of the membrane is expected to preclude introduction of anything but gases into the process water stream. In any event, sodium citrate is GRAS.

In addition to these primary products, it is assumed that approximately 10% of the unreacted starting ingredients may be carried over into the process water stream (based on 90% reaction efficiency). While it is anticipated that the selectively permeable nature of the sachets will preclude introduction of any citric acid and sodium chlorite into the process water, the chlorite rapidly decomposes to chlorate and chloride.

To maintain a chlorine dioxide residual level of 3 ppm in the process water, more than 3 ppm must be generated to allow for the ongoing reaction with food and food microorganisms. The precise amount of excess chlorine dioxide depends on the demand of the process and the degree of decontamination desired; in any case, it should not be any higher than 5-10 ppm. Upon reaction with food or food microorganisms, chlorine dioxide immediately forms chlorite and some chlorate. Data developed by Werdenoff and Singer, 1987, and from several other studies, show that residual chlorite concentration is about 70% of chlorine dioxide consumed, with chlorate likely accounting for most of the remainder. We have used this 30/70 ratio to calculate the residual chlorate/chlorite concentrations.¹

The information presented in the following table provides the calculated concentration of the unreacted starting materials and the products produced by the generating reaction. If it is assumed that 50% of the total water discharged from a food processing plant is treated with chlorine dioxide,² then the concentration of effluent from such a plant would be one-half of the concentration of the process water. Further, if a worst-case estimate of the flow percentage that is contributed by a food processing plant is 27% of the total, then the average POTW contribution would be only 27% of the waste water concentration. We note that the values reported for Environmental Introduction Concentrations (EICs) for the poultry and fruit and vegetable petitions are all in the 0.1 ppm to 3.0 ppm range.³

¹ See FAP Nos. 4A4408, 4A4414, and 0A4716.

² FDA accepted the use of this assumption in issuing a Finding of No Significant Impact (FONSI) in response to the EA for the fruit and vegetable petition (FAP No. 4A4415).

³ See FAP No. 4A4408.

Concentration of Components in the Process Water Stream, the Waste Water Stream and the Average Concentration distributed to POTW's per 10 ppm of ClO ₂ Produced				
Compound	Conc (M) (Process water)	PPM (Process water)	PPM (Waste water)	Avg PPM (Distribution water)
ClO ₂	4.45 x 10 ⁻⁵	3.0	1.5	0.4
ClO ₂ ⁻	8.91 x 10 ⁻⁵	6.0	3.0	0.8
ClO ₃ ⁻	3.12 x 10 ⁻⁵	2.6	1.3	0.4
Na ⁺	1.65 x 10 ⁻⁵	0.4	0.2	0.1

Based on the assumption that the reaction goes 90% to completion. The amounts include (1) the yield pertaining to 10 ppm ClO₂, (2) the unreacted starting material passing over into the process water representing 10% (on a Molar basis) of the products, and (3) the decomposition of 7.0 ppm of ClO₂ back to chlorite and chlorate in a 7:3 ratio

These effluents are comparatively low strength wastes, which are well within the capacity of POTW's. None of these calculated concentrations reflect the fact that most of the chlorine-containing substances would be reduced to chloride before completing its circulation within the distribution system. EPA's, September 1987, *Guidance Manual for Preventing Interference at POTW's* (NTIS No. PB92-117969), provides a published a list of substances known to cause interference with POTW's. Neither chlorite, chlorate, nor chlorine dioxide are on the list.

As indicated by the table above, the input of chlorine dioxide oxidation products to POTW's from food processing plants is small and well below levels added by POTW's, themselves, to treat water for purification. The purity of the treated water from POTW's will not be affected by the low levels of chlorine dioxide products coming from food processing plants. Also, as indicated above, the pH of waters entering POTW's is naturally variable within a wide range, and the small contribution of acidified water from food processing plants is well within normal variation.

Irrigation Systems - Use of fruit and vegetable process water as irrigation water is anticipated to have a negligible environmental impact since extensive efforts are made, particularly in California, to conserve irrigation water. Accordingly, runoff of irrigation water to aquatic bodies is expected to be limited.

Indoor air releases - The air concentration of chlorine dioxide from its use in disinfecting processed fruits and vegetables and from poultry is expected to be below the U.S. Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) of 0.1 ppm (0.3 mg/m³).⁴

⁴ See FAP Nos. 4A4408, 4A4415, and 0A4716.

(c) Compliance status

Chlorine dioxide generated by the processes prescribed at Section 173.300 is cleared for use in the processing of poultry and fruits and vegetables. SMT generated chlorine dioxide is intended to replace that which is now produced and used in compliance with the existing provisions of Section 173.300. Accordingly, approval of the subject notification should not affect compliance with current regulations.

7. Fate of Emitted Substances in the Environment

As discussed above in Section 6 of this EA, the previous petitions demonstrate that chlorine dioxide will be rapidly converted in the environment to chlorite and chlorate. These are moderately stable in water; however, both substances will eventually be reduced to chloride.

8. Environmental Effects of Released Substances

We incorporate by reference the studies used in the Revised EA of FAP No. 4A4408 and the Amended EA of FAP No. 4A4415 to support the use of chlorine dioxide from chlorite-generation. These studies are summarized below.

Organism	Test	ClO ₂ ⁵	ClO ₂ ⁻⁶	ClO ₃ ⁻⁷
Bluegill sunfish	LC ₅₀ (96 hr.)	0.15 ppm	100 ppm	> 1000 ppm
Rainbow trout	LC ₅₀ (96 hr.)		41 ppm	> 1000 ppm
<i>Daphnia magna</i>	LC ₅₀ (48 hr.)		161 ppb	> 1000 ppm
Mysid shrimp	LC ₅₀ (96 hr.)		650 ppb	> 1000 ppm
Eastern Oyster	LC ₅₀ (96 hr.)		129 ppm	> 1000 ppm
Sheepshead minnow	LC ₅₀ (96 hr.)	Juvenile: 0.02 ppm	105 ppm	> 1000 ppm
		Adult: 0.17 ppm		
Rat	LD ₅₀ (acute oral)		~260 mg/kg	> 5000 mg/kg
Mallard duck	LD ₅₀ (acute oral)		706 mg/kg	> 2500 mg/kg
Mallard duck	LD ₅₀ (avian dietary)		> 5000 ppm	> 5000 mg/kg
Bobwhite quail	LD ₅₀ (avian dietary)		>5000 ppm	> 5000 mg/kg

Chlorine dioxide is an alternative to chlorine for disinfection in the poultry industry and in the fruit and vegetable industries. Widespread replacement of chlorine with chlorine dioxide has already occurred. EPA has recently conclude that chlorine dioxide is significantly less toxic to aquatic organisms than chlorine:⁸

⁵ FAP No. 4A4408, EA Tables 1 and 2.

⁶ FAP No. 4A4415, EA Table 1.

⁷ *Id.*

⁸ See "Reregistration Eligibility Document for Sodium and Calcium Hypochlorite Salts," February 1992; NTIS Report No. 540/RS-92-193. Because hypochlorite salts, as well as chlorine, form hypochlorous acid upon aqueous dissolution, these aquatic toxicology parameters are applicable to these three sources of hypochlorous acid.

Organism	Test	Cl ₂
Cold water fish	LC ₅₀ (96 hr.)	0.1 – 1.4 ppm
Warm water fish	LC ₅₀ (96 hr.)	0.3 – 2.1 ppm
<i>Daphnia magna</i>	LC ₅₀ (48 hr.)	0.04 – 2.1 ppm

The physical form of chlorine dioxide precludes the acute toxicity to terrestrial organisms caused by chlorine gas exposure.

We anticipate that the proposed method of chlorine dioxide generation, with its economic advantages, will encourage the substitution of chlorine based systems, as well as replacement of currently approved chlorite-generation processes. The energy trade off is negligible; the energy required to manufacture chlorine dioxide is offset by a decrease in the energy required for chlorine manufacture.

9. Mitigation measures

No adverse environmental effects are anticipated if this Notification becomes effective; therefore, mitigation measures are not required.

10. Alternatives to Proposed Action

No alternative actions are necessary.

11. List of Preparers

This assessment was prepared by Jeffrey S. Eberhard, Ph.D, and Holly H. Foley.

12. Certification

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

Name: George G. Misko, Esq.
Title: Counsel for the Notifier

Signature:

Date: July 27, 2004

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