H. Environmental Assessment

1. **Date:**
October 1, 2003

2. **Name of Petitioner:**
Vulcan Chemicals

3. **Address:**
P O Box 385015
Birmingham, AL 35238-5015

4. **Description of Proposed Action:**

This petition requests that FDA amend 21 CFR § 173.300 to approve electrochemical generator systems for the production of chlorine dioxide for disinfection of fruits and vegetables and poultry.

Section 173.300 already approves chlorine dioxide for these uses when it is generated by treating an aqueous solution of sodium chlorite with either chlorine gas or a mixture of sodium hypochlorite and hydrochloric acid.

The electrochemical generation methods produce a high purity chlorine dioxide product that meets the 90% minimum purity requirement in section 173.300. These systems do not require the use of any chemical activators, and do not generate any unique impurities or byproducts that have not already been addressed in previous petitions.

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 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	ClO_2 and O=Cl=O
Molecular weight	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)

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(b) Use Rates

A maximum residual chlorine dioxide concentration level of 3 ppm is specified by Section 173.300 for use on fruits and vegetables and for use in poultry processing. These approved levels established for previously approved generators are equally appropriate for electrochemical generators since the same food additive is generated.

(c) Impurities

Depending on the generation system employed, the chlorine dioxide effluent can contain small quantities of chlorine, chlorite and chlorate.

6. Introduction of Substances into the Environment

(a) Production Releases

The chlorine dioxide is produced on site within a closed reactor. Therefore, production releases and use releases occur at the same site.

Chlorine dioxide is generated by the electrolysis of a solution of sodium chlorite according to the following half-cell reactions:

Anode: $2Na^+ + 2ClO_2^- \rightarrow 2Na^+ + 2ClO_2 + 2e^-$ (1)

Cathode: $2H_2O + 2e^- \rightarrow 2OH^- + H_2$ (2)

The starting chemicals are fed into the reactor and the finished aqueous solution is metered into the stream of process water. The products entering the process water stream consist of essentially pure chlorine dioxide. The representative analyses from commercially available technologies are shown in Table 1.

Table 1 – ClO_2 Composition

Parameter	PureLine PureStrip	ERCO R 101	Halox H 2000
ClO_2 Production Rate	7-30 lb/day	22 lb/day	5.5 lb/day
ClO_2 Concentration	Variable	1200 ppm	550 ppm
ClO_2 Purity	>99%	98.8 ± 0.3%,	92.4 %
Chlorine in ClO_2	<0.5%	0.3 - 0.7%	0
Other contaminants in ClO_2	Not observed	Chlorite: 0.1% Chlorate: 0.7%	Chlorite: 4.2% Chlorate: 3.3%

In addition, depending on the specific electrochemical technology being used, there is a potential to produce the following additional effluent streams:

Table 2 Anode (Anolyte) Effluent

Parameter	PureLine PureStrip	ERCO R 101	Halox H 2000
ClO_2 Production Rate	30 lb/day	22 lb/day	5.5 lb/day
Effluent Composition (Typical)	$NaClO_2$: 0.15 - 0.20 wt% $NaClO_3$: 0.60 - 0.80 wt% ClO_2: 0.005 - 0.015 wt% PH: 5.0 – 5.5	$NaClO_2$: 0.8 - 0.9 wt% $NaClO_3$: 8.2 – 9.4 wt% ClO_2: 0.13 - 0.15 wt% PH: 5.0 – 7.0	N/A
Effluent Components Rate (Typical)	$NaClO_2$: 2.2 lb/day $NaClO_3$: 9 lb/day ClO_2: 0.1 lb/day	$NaClO_2$: 0.17 lb/day $NaClO_3$: 1.7 lb/day ClO_2: 0.03 lb/day	N/A
Effluent Volume	16 gal/day	1.9 gal/d	None

Table 3 Cathode (Catholyte) Effluent

Parameter	PureLine PureStrip	ERCO R 101	Halox H 2000
ClO_2 Production Rate	30 lb/day	22 lb/day	5.5 lb/day
Effluent Composition (Typical)	NaOH: 10 - 20 wt%	NaOH: 0.15-0.2 wt%	NaOH: 0.0022 wt% PH: 10.5
Effluent Components Rate (Typical)	NaOH: 24 lb/day H_2: 0.36 lb/day	NaOH: 13.7 lb/day H_2: 0.34 lb/day	NaOH: 3.5 lb/day H_2: 0.085 lb/day
Effluent Volume	20-30 gal/day	570 gal/day	38 gal/day

All of these systems also co-produce of hydrogen gas from electrolytic reaction at the cathode at amounts proportional to the ClO_2 production rate. This hydrogen gas exists as small bubbles in the catholyte stream and is either dissolved in the effluent stream (the amount of hydrogen is generally an order of magnitude below its solubility limit in the waste water) or safely vented to the atmosphere.

(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 was 0.03 ppm. This level would soon decrease further 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 are similar and the air releases of ClO_2 will be similarly negligible.

Water Releases – In previously-approved generation technologies, both unreacted feedstock and reaction byproducts formed in the process of ClO_2 generation are carried with it onto the food. As can be seen from the tables above, electrochemical generation technologies offer the advantage of segregating these components from the ClO_2 produced.

(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. Electrochemically 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 petition 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 but both substances will eventually be reduced to chloride.

8. Environmental effects of Released Substances

We incorporate by reference the studies used in the Amended EA of FAP No. 4A4408 to support the use of chlorine dioxide. These include (1) Aquatic studies; (2) Terrestrial Organism Studies; and (3) Environmental Benefits.

Chlorine dioxide is an alternative to chlorine for disinfection in the poultry, industry and in the fruit and vegetable industries. Replacement of chlorine with chlorine dioxide has already occurred. We anticipate that the proposed method of chlorine dioxide generation will encourage additional replacement of chlorine in smaller size systems where lower usage rates would not support the costs associated with installation of conventional chlorine dioxide generators.

9. Mitigation measures

No adverse environmental effects are anticipated if this petition is approved. 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 Roger E. Etherington of Vulcan Chemicals. Mr. Etherington is a chemical engineer with over 20 years of experience in preparing submissions to government agencies.

12. Certification

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

Name: Roger E. Etherington

Title: Manager, Product Regulatory Support, Vulcan Chemicals

Signature 

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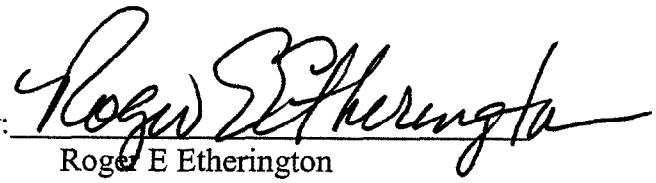
The foregoing and all appendices to this Petition considered, it is respectfully requested that the Food and Drug Administration promulgate an order amending Section 173,300 of the Food additive regulations in substantially the form proposed in Appendix I of this Petition to permit the use of chlorine dioxide produced by electrochemical generation.

Respectfully Submitted,
Vulcan Chemicals

By: 
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