Environmental Assessment

1. Date: January 14, 2007

2. Name of Applicant/Petitioner:

Bio-Cide International, Inc.

3. Address:

P.O. Box 722170
Norman, OK 73070-8644

4. ***Description of the proposed action:***

a. ***Requested action***. Existing regulations permit the use of the food additive as a sanitizing solution for use on food-processing equipment and utensils, and on other food contact articles as described in 21 CFR 178.1010(b)(34), which reads as:

(34) An aqueous solution of an equilibrium mixture of oxychloro species (predominantly chlorite, chlorate, and chlorine dioxide) generated either (i) by directly metering a concentrated chlorine dioxide solution, prepared just prior to use, into potable water to provide the concentration of available chlorine dioxide stated in paragraph (c) (29) of this section, or (ii) by acidification of an aqueous solution of oxychloro species (predominantly chlorite and chlorate) followed by dilution with potable water to provide the concentration of available chlorine dioxide described in paragraph (c) (29) of this section.

The requested action of this Food Contact Notification is to allow the use of the food additive as a sanitizing solution for treating beverage containers. The food contact substance is activated with a GRAS acid and subsequently diluted in accordance with the requirements of 21 CFR 178.1010(b)(34) prior to the intended use as a sanitizing solution on beverage containers at concentrations from 50 to 200 ppm available chlorine dioxide as determined by methods provided in 21 CFR 178.1010(c)(29). Treated containers are allowed to adequately drain before filling. Beverage container materials may include glass, polyethylene teraphthalate (PET), polycarbonate resins and other common materials of beverage container construction.

b. ***Need for action***. The proposed action is needed to allow the permitted use of the food contact substance as a sanitizing solution for the safe and effective antimicrobial treatment of beverage containers prior to filling.

c. ***Locations of use/disposal***. The food contact substance is intended for use in food beverage bottling facilities. Beverages which are foods may include, but are not limited to, bottled water, beer, soft drinks, fruit drinks, and energy drinks. Beverage bottling facilities are located at numerous sites and are found in all states.

5. ***Identification of chemical substances that are the subject of the proposed action:***

The proposed food contact substance is an aqueous solution consisting primarily of sodium chlorite, chlorine dioxide, and sodium chloride. The solution is prepared in accordance with the requirements of 21 CFR 178.1010(b)(34) and is intended for use at concentrations of available chlorine dioxide from 50 – 250 ppm quantifiable by iodometric titration methods described in 21 CFR 178.1010(c)(29).

Identity of Sodium Chlorite:

Nomenclature: Sodium chlorite; chlorous acid, sodium salt

Chemical Abstract Service Registry Number (CAS): 7758-19-2

Empirical Formula: $NaClO_2$

Formula Weight: 90.45

Method of Production:

The method for production of the sodium chlorite precursor product is considered to be confidential business information. A description of the manufacturing process is enclosed at Item 16 as a **CONFIDENTIAL** attachment.

The permitted usage as a beverage container sanitizer will be added to the EPA master label for Oxine® and other products registered with EPA as antimicrobial pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act. The EPA product master label for Oxine® is available at: http://oaspub.epa.gov/pestlabl/Ppls.getimage?imgid=189489

Identity of Chlorine Dioxide:

Nomenclature: Chlorine dioxide; Chlorine (IV) oxide

Chemical Abstracts Service Registry Number (CAS): 10049-04-4

Empirical Formula: ClO_2

Formula Weight: 67.45

Source: Chlorine dioxide in the proposed food contact substance is produced by acidification of sodium chlorite present in the precursor solution. The generalized reaction for the generation of chlorine dioxide by acidification of sodium chlorite is as follows:

$$5NaClO_2 + 4H^+ \rightarrow 4ClO_2 + NaCl + 4Na^+$$

Identity of GRAS Acids:

Examples of GRAS acids that may be used as acidifiers of the sodium chlorite solutions include:

Citric acid	CAS No. 77-92-9 (anhydrous)
$HOC(CH_2CO_2)2CO_2H$	CAS No. 5949-29-1 (monohydrate)
	Conforms to 21 CFR 184.1033. Citric acid.
Phosphoric acid	CAS Reg. No. 7664-38-2
H_3PO_4	Conforms to 21 CFR 182.1073. Phosphoric acid.

6. Introduction of substances into the environment:

a. ***Introduction of substances into the environment as a result of manufacture***. Releases of substances into the environment are not anticipated under normal manufacturing conditions. To the best of our knowledge, no extraordinary circumstances pertain to the manufacture of the food contact substance precursor products.

b. ***Emission substances from the use of the Food Contact Substance***. The food contact substance use solutions which are the subject of this environmental assessment will be produced on site immediately prior to use in beverage bottling facilities. The potential for introduction into the environment for chemical species of concern, such as chlorine dioxide, chlorite, chlorate and acids are expected to be essentially identical to that associated with currently permitted usages as a sanitizing solution for food processing equipment, utensils, etc. The Environmental Assessment for Food Additive Petition, 5H3889, originally addressed environmental considerations associated with the usage of the food additive as a food contact surface sanitizer. FAP 5H3889 is cited by reference.

The potential for air and water releases of chemically similar, or identical, food contact substances and its effects on on-site wastewater treatment plants and on publicly owned treatment works (POTWs) has been thoroughly described in the Environmental Assessments for the following Food Additive Petitions, hereby incorporated by reference: FAP 7A4532, FAP 9A4692, and FAP 0A4724. Additionally, the Environmental Assessments for Food Contact Notifications FCN 445 and FCN 450 similarly address these issues.

The environmental assessment (EA) and finding of no significant impact (FONSI) for FAP 7A3532 are available through a freedom of information (FOI) request. Information on obtaining information through a FOI request is available at http://www.fda.gov/foi/foia2.htm.

The EA for FAP 9A4692 is available at http://www.fda.gov/OHRMS/DOCKETS/98fr?992907e2.pdf and the FONSI is at http://www.fda.gov/OHRMS/DOCKETS/98fr/992907fn.pdf.

The EA for FAP 0A4724 is available at http://www.fda.gov/OHRMS/DOCKETS/98fr/001488ea.pdf and the FONSI is at http://www.fda.gov/OHRMS/DOCKETS/98fr/001488fn.pdf.

The EA for FCN 445 is available at
http://www.cfsan.fda.gov/~acrobat2/fnea0445.pdf

The EA for FCN 450 is available at
http://www.cfsan.fda.gov/~acrobat2/fnea0450.pdf

When used in accordance with label instructions, the oxychlorine species associated with FCS would undergo conversion to the chloride, Cl^-, prior to release into the environment.

> The oxidation-reduction reactions of chlorine dioxide in water result in the formation of the chlorite ion according to the following reaction:
>
> $$ClO_2 + e^- \rightarrow ClO_2^-$$
>
> The chlorite ion is also an effective oxidizing agent and will be consumed through oxidation-reduction reactions with oxidizable material. These occur as follows:
>
> $$ClO_2^- + 4\,H^+ + 4e^- \rightarrow Cl^- + 2\,H_2O$$

It is reported in the literature that under municipal drinking water treatment conditions, approximately 50 -70 percent of the chlorine dioxide reacted will immediately appear as chlorite and the remainder as chloride. The residual chlorite continues to degrade in reactions with oxidizable material in the water distribution system under these conditions.

Under wastewater treatment conditions, the amount of oxidizable material present would greatly exceed that present under drinking water treatment conditions and would insure the conversion of oxychloro species to chloride. Thus, chloride is the substance of eventual release into the environment from the proposed usage.

7. Fate of emitted substances in the environment:

Sodium chlorite, sodium chlorate, and chlorine dioxide released into the environment will likely undergo reduction in contact with organic matter, inorganic chemical reactions. Ultimately these oxychlorine species will be reduced to the chloride ion.

a. ***Air***. When performed in accordance with label instructions, the acid activation of the FCS will produce some free chlorine dioxide from the sodium chlorite solution. This may result in the volatilization of, at most, trace amounts of ClO_2 into the air. In a worst case scenario resulting from over-acidification or other misuse, a small release might occur. Chlorine dioxide in air readily undergoes photochemical decomposition. (1, 2)

b. ***Freshwater, marine and estuarine ecosystems***. Chlorine dioxide and chlorite are the substances of environmental concern which might be released into aquatic environments. If used in accordance with the labeled instructions for the proposed use, the possibility of the release of toxic substances into aquatic environments in harmful quantities is remote. Discharges from a beverage bottling operation would go to either the plant wastewater facility or to a municipal sewer for treatment prior to release. Chlorine dioxide and chlorite would both be eliminated through reactions with inorganic and organic compounds. The predominant chlorine form expected to eventually result from the various reactions is the chloride ion, Cl^-. Additionally, photochemical decomposition of ClO_2 and biodegradation of ClO_2 and chlorite would be expected. Various reactions of ClO_2 and chlorite which are documented in the scientific literature are presented below

(i) Reactions of ClO_2 and ClO_2^- with inorganic compounds:

(a) Reactions with ferrous iron and manganese: In aqueous solutions with pH at or below neutrality ClO_2 reacts with Fe^{+2} and Mn^{+2} with the oxidation of the divalent cation and reduction of ClO_2 to chloride. These reactions occur when iron and manganese are present in a reduced state. Stoichiometrically, the reaction of ClO_2 with ferrous iron is: (3)

$$ClO_2 + 4\,H^+ + 5\,Fe^{+2} \rightarrow 5\,Fe^{+3} + Cl^- + 4\,H_2O$$

Under alkaline conditions, where the chlorite ion might predominate, salts of ferrous iron and manganese are oxidized quantitatively by sodium chlorite. (4)

$$ClO_2^- + 4 FeO \rightarrow 2 Fe_2O_3 + Cl^-$$

(b) Reactions with sulfides: The formation and control of sulfides are common problems in wastewater treatment. Sulfides readily react with ClO_2 and ClO_2^-. The exact reactions which would occur are dependent upon pH and other factors. The expected reactions are listed below:

$$2 ClO_2 + 5 H_2S \rightarrow 5 S + 4 H_2O + 2 H^+ + 2 Cl^-$$

$$ClO_2^- + H_2S \rightarrow SO_4^{+2} + 2 H^+ + Cl^-$$

(c) Reactions with ammonia and amines: In wastewater containing ammonia and primary amines, no residual oxidants corresponding to chloramines are formed since ClO_2 does not react with ammonia and primary amines. (5)

(ii) Reactions with organic compounds:

In general, chlorine dioxide reacts with organic compounds by the addition of oxygen rather than by the addition of chlorine. This preference for the addition of oxygen to organic compounds is the principle reason that chlorine dioxide has become the disinfectant of choice for some drinking water and wastewater treatment facilities. For these uses, the formation of trihalomethanes and other toxic or carcinogenic chlorinated organic compounds is significantly reduced or eliminated by the use of ClO_2 instead of $C1_2$. The reactions of organic compounds in red meat, with ClO_2 from acidification of sodium chlorite are expected to be the same as those which occur from the ClO_2 treatment of drinking water and wastewater.

Chlorine dioxide readily reacts with phenols and phenolic compounds by the addition of oxygen and the breaking of the ring structure. Chlorine dioxide has been used for many years to control phenolic tastes and odors in drinking water. The use of ClO_2 for this purpose is widely published. (6)

The reactions of chlorine dioxide and chlorite with phenols and phenolic derivatives are numerous and complex due to the large number of phenolic compounds and due to the numerous mechanisms of oxidation. Masschelein presents a good and readily available review of the reactions of ClO_2 and ClO_2^- with phenols and phenolic acid derivatives. (7)

The U.S. E.P.A. has reviewed a large body of literature concerning the reaction products of ClO_2 and ClO_2^- with organic compounds in the treatment of drinking water. They concluded that halogenation of organic compounds can occur with the use of chlorine dioxide, but at rates considerably lower than for chlorine. (8)

Stevens concluded that organic halogen concentrations are significantly lower when ClO_2 is used as the disinfectant rather than Cl_2 when used to treat waters with naturally occurring organic compounds. Non-chlorinated products may also occur, such as quinones and epoxides. Inorganic compounds associated with the use of ClO_2 are chlorite, chlorate and chloride. (9)

Chlorine dioxide has been shown to react with and eliminate various pesticides, including products highly toxic to fish such as rotenone. (10) Chlorine dioxide has been shown to be the oxidant of choice for the removal of phenylamide pesticides from water. (11) Other pesticides which can be eliminated by reaction with ClO_2 are methoxychlor (DMDT) and aldrin. (12) Herbicides such as paraquat and diquat are oxidized by chlorine dioxide. (13)

The photolytic decomposition of chlorine dioxide also occurs in aqueous systems. The principle decomposition products are expected to be chlorate and chloride. (14)

Finally, enzymatic mechanisms for the bio-degradation of chlorite and chlorine dioxide have been shown to exist in eukaryotic systems. (15) Chloroperoxidase enzymes have been isolated which catalyze the dismutation of both chlorine dioxide and chlorite. The following molar ratios were observed for the reactions:

1 mole chlorine dioxide	0.3 mole chloride, 0.7 mole chlorate, and 0.17 mole oxygen (O_2)
1 mole chlorite	0.4 mole chloride, 0.6 mole chlorate, and 0.13 mole oxygen (O_2)

Other similar antioxidant mechanisms are known to exist which could provide a similar system for the biodegradation of chlorine dioxide and chlorite.

c. ***Terrestrial Ecosystems***: The fate of the FCS released into a terrestrial ecosystem would be the rapid decomposition by the oxidation of organic material in the manner presented in (B) of this section.

8. Environmental effects of released substances:

For purposes of the Registration, Data Call-in and Re-registration programs for pesticide products regulated under the Federal Insecticide, Fungicide and Rodentcide Act, the US EPA has determined that the potential health and environmental effects for chlorine dioxide and chlorite are essentially identical.

a. ***Air***. It is believed that no significant impact on the health of human beings or other organisms would occur by approval of the proposed usage. This is due to the extremely low potential for the release of significant quantities of ClO_2 into the air and due to the expected photochemical decomposition of ClO_2 in air.

b. ***Aquatic and Terrestrial Ecosystems***.

The toxic effects of chorine dioxide, chlorite, and chlorate on aquatic organisms have been studied and numerous reports are available in the literature. The EPA re-registration eligibility decisions (REDS) for chlorine dioxide, chlorite, and inorganic chlorates provide a complete discussion of the available data. The REDs and database listings for the toxicology literature are available on the web at:

Reregistration Eligibility Decision (RED) for Chlorine Dioxide and Sodium Chlorite (CASE 4023); EPA 738-R-06-007; U.S. Environmental Protection Agency; Prevention, Pesticides and Toxic Substances: Washington, D.C., Aug. 2006. http://www.epa.gov/pesticides/reregistration/REDs/chlorine dioxide_red.pdf.

Reregistration Eligibility Decision (RED) for Inorganic Chlorates; EPA 738-R-06-014; U.S. Environmental Agency: Washington, D.C., July, 2006. http://epa.gov/pesticides;reregistration/REDs/inorganicchlorates_red.pdf.

FDA has produced tables summarizing the environmental toxicity for chlorites and chlorates as shown below.

Table 1. Summary of environmental toxicity endpoints for chlorite.[ab]

Species	**LC50 or EC50 (mg/L)**	**NOEC (mg/L)**
Freshwater Fish	50.6 - 420	32 - 216
Freshwater Invertebrates	0.027 - 1.4	0.003 - 0.4
Estuarine/Marine Fish	75	13.9
Estuarine/Marine Invertebrates	0.576 - 21.4	14.3
Aquatic Plants	1.32	<0.62

[a] The substance tested was sodium chlorite with approximately 80% active ingredient.
[b] All data from: 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.

Table 2. Summary of environmental toxicity endpoints for chlorate.[a]

Species	LC50 or EC50 (mg/L)	NOEC (mg/L)
Freshwater Fish	7.3 - 1100	600 - 1000
Freshwater Invertebrates	2100 - 4100	52 - 1000
Aquatic Plants	133 - 444	50 - 3137

[a] All data from: 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.

The acute oral LD50 of sodium chlorite to bobwhite quail is reported in," Acute Oral Toxicity Study with Sodium Chlorite in Bobwhite Quail". The reported LD50 of $NaClO_2$ in quail was 660 mg/kg. (16)

Calandra reported the LD50 of sodium chlorite in mallard ducks to be 1000 mg/kg in, "Acute Oral Toxicity Study with Sodium Chlorite in Mallard Ducks". (17)

The toxic effects of a stabilized chlorine dioxide solution on honey bees were reported by Lackett in, "Oxodene: Longevity of Honey Bees". It was found that concentrations of 10 and 100 ppm chlorine dioxide in sucrose significantly lengthened the life times of the tested honey bees. Higher concentrations reduced longevity with all test bees fed 10,000 ppm ClO_2 dying within a week. (18)

The Pesticide Information Profile on sodium chlorate available from the Extension Toxicology Network indicates a relatively low mammalian toxicity for sodium chlorate. The possible 48 hour LC50 for sodium chlorate for various fish species was 10,000 mg/l with a verbal description as considered non-toxic to fish. Additionally, sodium chlorate is considered non-toxic to bees. The long term toxicity to birds resulted in reduced egg production and fertility. The EXTONET Pesticide Information Profile is available at: http://extoxnet.orst.edu/pips/sodiumch.htm

The United States Environmental Protection Agency (EPA) recently published the "Reregistration Eligibility Decision (RED) for Inorganic Chlorates (Case No. 4049). The RED gives a comprehensive review of the uses of sodium chlorate, its toxicity, environmental fate, ecological exposure and risk. This document is available on the web as previously cited in this section.

EPA maintains an extensive database on the chemical toxicity for aquatic and terrestrial life in the ECOTOX Database. The ECOTOX Database is accessible on the web at http://www.epa.gov/ecotox_home.htm. Sodium chlorate is a listed chemical in the ECOTOX Database.

The release of the FCS into terrestrial ecosystems would have minimal effects. Chlorine dioxide reaching the ground would quickly react and degrade to chloride according to the chemical reactions and physical mechanisms which have been previously discussed. No threats to groundwater would be anticipated. Bio-accumulation would not occur in either plants or animals.

The data available strongly suggests that the amounts of the oxychlorine species which would be expected to be released into the environment through use and disposal would be so low as to pose no threat to either aquatic or terrestrial ecosystems.

9. Uses of Resources and Energy:

a. ***Use of Natural Resources and Energy***.

The food contact substance will replace currently permitted uses, such that there is essentially no net effect on the use of natural resources and energy,

b. ***Endangered and Threatened Species***.

There are no anticipated effects on endangered or threatened species from either the production or use of food contact substance. The whooping crane and bald eagle, as rare transients, would be expected to range in the vicinity of the production facility. Use of the FCS would replace currently permitted food additive uses and, as such, would have essentially no effect on the endangered or threatened species. Similarly, disposal of FCS and would present no anticipated effects on any threatened or endangered species. A listing of Oklahoma endangered and threatened species is available at:
http://www.wildlifedepartment.com/endanger2.htm

c. ***Historical Sites***.

There are no anticipated effects on any sites listed or eligible for listing in the National Register of Historic Places from the production of the food contact substance precursor. The National Register of Historic Places, for Cleveland County, Oklahoma contains a list of all county sites listed in the National Register of Historic Places. The nearest site to the Bio-Cide production facility is the Norman Historic District, located at 105 W. Main and 100 to 232 E. Main. This site is approximately four (4) miles from the production facility and would be unaffected by the proposed action. There are no anticipated impacts on historic sites from either the use or disposal of the FCS. The National Register of Historic Places for Cleveland County is available at:
http://www.nationalregisterofhistoricplaces.com/OK/Cleveland/state.html

10. Mitigation Measures:

No adverse effects associated with the proposed usage of the food contact substance requiring mitigation have been identified.

11. Alternatives to the Proposed Action:

Alternatives to the proposed action need not be considered because no potentially adverse effects have been identified.

12. Preparer:

This Environmental Assessment was prepared by James P. Ringo, M.S., Director of Regulatory Affairs for Bio-Cide International, Inc. His educational background is in zoology, microbiology, chemistry, and environmental sciences with professional experience in microbiology, oxychlorine chemistry, environmental regulatory affairs, and has previously served as an Environmental Planner for the Oklahoma Department of Pollutions Control.

13. Certification:

The undersigned official certifies that the information presented is true, accurate, and complete to the best knowledge of Bio-Cide International, Inc.

Date: January 14, 2007

Signature: ________________________________

Name: James P. Ringo
Title: Director of Regulatory Affairs

14. References

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2. Spinks, J.W.T., and Porter, J.M., "Photodecomposition of Chlorine Dioxide", J. Am. Chem. Soc., 56, p. 264 (1934).

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5. White, G.C., Handbook of Chlorination, p. 603, Van Nostrand Rheinhold Co. (1972).

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8. Miller, G.W., "An Assessment of Ozone and Chlorine Dioxide Technologies for Treatment of Municipal Water Supplies", USEPA, EP A-600 / 8-78-018, (October, 1978).

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10. Op cit., Masschelein. p. 162.

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15. Shahangian, S., and Hager, L.P., "The Reaction of Chloroperoxidase with Chlorite and Chlorine Dioxide", Journal of Biological Chemistry, 256 (12) p.6034 (1981).

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17. Calandra, J.C., "Acute Oral Toxicity Study With Sodium Chlorite In Mallard Ducks", Report No.1 IBT 0 J2118 to Olin Corporation, New Haven, CT. (Jan. 9, 1973).

18. Lackett, J., "Oxodene: Longevity of Honey Bees", Journal of Economic Entomology, 65 (1), p. 19 (1972).

15. Appendices

16. Confidential Attachments

1. Description of the Manufacturing Process and Process Controls