EN

Environmental Assessment

1. ***Date of Revision:*** June 25, 2007

2. ***Name of Applicant/Petitioner:***

   Bio-Cide International, Inc

3. ***Address:***

   2845 Broce Drive
   Norman. OK 73072

4. Description of the proposed action:

Existing regulations permit the usage of the food additive, acidified sodium chlorite solutions, as an antimicrobial agent in poultry processing water in accordance with the provisions of 21 CFR 173.325, which reads as

> Acidified sodium chlorite solutions may be safely used in accordance with the following prescribed conditions
>
> (a) The additive is produced by mixing an aqueous solution of sodium chlorite (CAS Reg No. 7758-19-2) with any generally recognized as safe (GRAS) acid.
>
> (b) (1) The additive is used as an antimicrobial agent in poultry processing water in accordance with current industry practice under the following conditions
>
> (i) As a component of a carcass spray or dip solution prior to immersion of the intact carcass in a prechiller or chiller tank,
>
> (ii) In a prechiller or chiller solution for application to the intact carcass;
>
> (iii) As a component of a spray or dip solutions for application to poultry carcass parts,
>
> (iv) In a prechiller or chiller solution for application to poultry carcass parts, or
>
> (v) As a component of a post-chill carcass spray or dip solution when applied to poultry meat, organs, or related parts or trim.
>
> (2) When used in a spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm) in combination with any GRAS acid at a level sufficient to achieve a solution pH of 2.3 to 2.9
>
> (3) When used in a prechiller or chiller solution, the additive is used at levels that result in sodium chlorite concentrations between 50 and 150 ppm, in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2 8 to 3.2

The proposed action of this Food Contact Notification is to allow a modification of the existing permitted usages of acidified sodium chlorite solutions for use as an antimicrobial in poultry process water as follows:

> (1) Identity of the Food Contact Substance: Under the intended conditions of use the proposed FCS is an aqueous solution of primarily sodium chlorite and chlorine dioxide containing up to 1,200 mg/kg sodium chlorite and up to 30 mg/kg chlorine dioxide The pH of the solution is between 5.0 and 7.5.
>
> (2) Intended Use: As an antimicrobial agent in poultry processing water for use in accordance with current industry practices as a component of spray, dip, or chill water solutions to treat intact carcasses, carcass parts, poultry meat, organs, and related trim.

(3) Limitations and Specifications. For use as a spray or dip solution the additive is produced by mixing an aqueous solution of sodium chlorite with any generally recognized as safe (GRAS) acid to achieve a pH in the range of 2.2 to 3.0, then further diluting this solution with a pH elevating agent such that the resultant sodium chlorite concentration does not exceed 1,200 mg/kg, and the chlorine dioxide concentration does not exceed 30 mg/kg. The pH of the use solution is between 5.0 and 7.5.

For use in a prechiller or chiller solution the additive is produced by mixing an aqueous solution of sodium chlorite with any generally recognized as safe (GRAS) acid to achieve a pH in the range of 2.2 to 3.0, then further diluting this solution with a pH elevating agent such that the resultant sodium chlorite concentration does not exceed 150 mg/kg and the chlorine dioxide concentration does not exceed 4 mg/kg. The pH of the use solution is between 5.0 and 7.5.

The proposed action is needed to avoid problems inherent in the existing permitted use of acidified sodium chlorite on poultry, specifically, discoloration of the poultry and corrosion of processing equipment, resulting from the low pH of the acidified sodium chlorite solutions. The proposed action will result in no increased risks to the user, consumer, or the environment greater than the existing permitted usages of acidified sodium chlorite. Effective microbial control is achieved with the proposed FCS usage.

The locations where the Food Contact Substance (FCS) is intended for use are poultry processing facilities and sites where further processing of poultry products is performed, such as packaging, or ready to eat product operations. Poultry processing facilities and sites where further processing of poultry products is performed are found in all regions of the country. The FCS is not intended for use at other sites where processing of poultry may occur such as restaurants, retail establishments, delicatessens, or in the home.

The sodium chlorite precursor products intended for use as the sodium chlorite solutions under the proposed action will be produced at the Bio-Cide International Inc. production facility which is located in Norman, Oklahoma. Sodium chlorite is currently permitted for use in a number of food additive applications, typically as acidified sodium chlorite. Generally regarded as safe (GRAS) acids, such as citric acid, phosphoric acid, lactic acid and hydrochloric acid, used as the acidifier, are manufactured in large volumes with many, diverse commercial applications. The projected volume of GRAS acid usage as the activator is only a tiny fraction of the other applications, thus, the production sites of these acids are not considered relevant to this environmental assessment. The pH elevating agents such as sodium carbonate and sodium bicarbonate are also GRAS compounds with numerous food additive applications. As with the GRAS acids the projected volumes of pH elevating compounds are only a very small percentage used in other applications, thus, the production sites for these compounds is not considered relevant to this environmental assessment.

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 with an upper limit of sodium chlorite at 1,200 mg/kg and an upper limit of chlorine dioxide at 30 mg/kg in the intended usages The pH of the use solution is in the range of 5 0 to 7.5

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

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 which may be used as acidifiers of the sodium chlorite solutions include

Citric acid $HOC(CH_2CO_2)_2CO_2H$	CAS No 77-92-9 (anhydrous) CAS No 5949-29-1 (monohydrate) Conforms to 21 CFR 184 1033 Citric acid.
Phosphoric acid H_3PO_4	CAS Reg No. 7664-38-2 Conforms to 21 CFR 182 1073 Phosphoric acid

Identity of pH Elevators.

Examples of GRAS compounds that may be used to raise the pH of the intermediate acidified sodium chlorite solutions include.

Sodium carbonate Na_2CO_3	CAS Reg No. 497-19-8 Conforms to 21 CFR 184.1742. Sodium carbonate
Sodium bicarbonate $NaHCO_3$	CAS Reg. No. 144-58-8 Conforms to 21 CFR 184 1736. Sodium bicarbonate.

The proposed usage of the Food Contact Substance is described as follows.

The pH of a sodium chlorite precursor solution is lowered by the use of a GRAS acid, such as citric acid or phosphoric acid, to a value between 2.2 and 3.0 and the intermediate solution is then diluted to the final use concentration of up to 1,200 ppm sodium chlorite and up to 30 ppm chlorine dioxide. The dilution is performed by mixing the desired intermediate acidified solution with a second solution of suitable alkalinity to achieve a final use solution pH between 5.0 and 7 5. Dilution solutions may be comprised of GRAS compounds such as sodium carbonate solutions, sodium bicarbonate solutions or, most preferably, unacidified sodium chlorite solutions. The solutions prepared by this proposed method are then applied to poultry as a dip, spray, or in chillers or prechillers.

6. Introduction of substances into the environment:

A Manufacturing process. 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 FCS use solutions which are the subject of this environmental assessment will be produced on site immediately prior to application in the poultry processing 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 current permitted usages of acidified sodium chlorite The potential for air and water releases 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.

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 (Accessed June 25, 2006)

The EA for FAP 9A4692 is available at:
http://www.fda.gov/OHRMS/DOCKETS/98fr/992907e2.pdf and the FONSI at
http://www.fda.gov/OHRMS/DOCKETS/98fr/992907fn.pdf (Accessed June 25, 2007)

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 (Accessed June 25, 2007)

The following excerpt is from the supplement to the Environmental Assessment (EA) that FDA prepared for FCN 450:

"Under Format Item 6.b ("Emission substances from the use of the Food Contact Substance") of the EA, the notifier incorporated by reference the EAs for three petitions (FAP 7A4532, FAP 9A4962, and FPA 04724) to discuss the potential for air and water releases and their effects on on-site wastewater treatment plants and on publicly owned treatment works (POTWs). In these EAs, the levels of dissolved chlorine dioxide that are typically generated with the acidified sodium chlorite solution (the food additive) will not exceed 1 to 2 mg/liter, *i.e.*, 1 to 2 ppm Based on the 2 ppm generated within the acidified sodium chlorite solution, the EA for FAP 0A4724 estimated the concentration of the chlorine dioxide to be 0.02 ppm in the plant effluent or 2 6 ppb in an average POTW influent.

These estimated environmental introduction concentrations of chlorine dioxide are not applicable to the subject FCN, because the concentration of chlorine dioxide in the FCS can reach up to 30 ppm, which is 15 times higher that what was described in the three referenced EAs It is reasonable to expect the concentration of chlorine dioxide in the plant effluent or in an average POTW influent as a result of the proposed action to be 15 times higher than what was estimated in the EA for FAP 0A4724; *i e.*, 0.3 ppm (0 02 x 15 = 0.3 ppm) in the plant effluent for the subject FCN.

However, since chlorine dioxide is highly reactive, we expect that it will react with the organic matter and microorganisms on the meat surfaces and will be reduced to chlorite, chloride, and chlorate. Furthermore, because oxychlorine species (chlorite, chlorate and chlorine dioxide) readily react with organic matter and microorganisms in water and soil (sediments) and will undergo ultimate degradation into chloride ion, we anticipate that the expected environmental concentrations for these oxychlorine species will be very small and, thus, will be of no environmental concern "

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 The generalized reaction for the reduction of chlorite can be expressed as the following.

$$ClO_2^- + 4\,H^+ + 4e^- \rightarrow Cl^- + 2\,H_2O$$

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

The following, Item 7, contains illustrative reactions of oxychlorine species with oxidizable materials which would be expected to occur prior to release into the environment. It also contains illustrative reactions involved in the fate of oxychlorine species which would occur through an accidental release into the environment.

*7. **Fate of emitted substances in the environment:***

A review of the environmental fate of chlorine dioxide, chlorite, and related oxychloro species is presented in "*Toxicological Profile for Chlorine Dioxide and Chlorite*", Agency for Toxic Substances and Disease Registry, U.S Department of Health and Human Services Sep. 2004 This document is readily accessible on the web at http://www.atsdr.cdc.gov/toxprofiles/tp160.pdf (Accessed June 25, 2007).

Generally, chlorine dioxide, chlorite, and chlorate will react with and be reduced by inorganic and organic compounds in aquatic and terrestrial environments. The ultimate reduction product of these species is the chloride ion, Cl^-. On page 91, of the ATSDR document is presented Table 6-2, entitled "Chlorine Speciation in Aqueous Solutions" Many of these species, such as chlorous acid, hypochlorite ion, and chlorine, are unlikely to be produced in the chemical system of the proposed Food Contact Substance due to pH considerations and other factors Chlorine, hypochlorous acid, and hypochlorite are generally associated with chlorine dioxide produced from the oxidation of chlorite by chlorine or acidified hypochlorite, methods of generating chlorine dioxide frequently used for drinking water treatment Quantities of chlorine or hypochlorite in excess of stoichiometric are often required to drive the reactions to complete conversion to chlorine dioxide and the unreacted species then become part of the treated water. Additionally, chlorine byproducts are often present in chlorine dioxide produced by the reduction of chlorates, methods which are generally associated with chlorine dioxide generation used in pulp and paper bleaching applications. We have identified no reaction mechanisms by which perchlorate would be produced from the proposed Food Contact Substance if released into the environment. In summary, chlorite, chlorine dioxide, and chlorate are the primary oxychloro species of concern for substances which might be emitted to the environment. Other listed oxychlorine species are unlikely to be present in the proposed FCS or to be produced if the proposed FCS is emitted into the environment

On pages 92 – 93 of the "*Toxicological Profile for Chlorine Dioxide and Chlorite*" there is a review of the formation of chlorinated organics by reaction with chlorine dioxide, chlorite, and associated species Although it is well known that chlorine dioxide can react with organic compounds to form chlorinated organics, it is concluded that the types and quantities of chlorinated organics formed is significantly less than that of chlorine in similar applications

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

B. Freshwater, marine and estuarine ecosystems: Chlorine dioxide and chlorite are the primary substances of environmental concern which might be released into aquatic environments. If used in accordance with the instructions for the proposed usage the

possibility of the release of toxic substances into aquatic environments in harmful quantities is remote Discharges from a poultry processing 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 chlorine dioxide and biodegradation of chlorine dioxide and chlorite would be expected The large volumes of water used in meat processing would also dilute the quantities of chlorine dioxide and chlorite to very low levels, even if the above reactions did not occur Various reactions of chlorine dioxide and chlorite which are documented in the scientific literature are presented below.

(1) Reactions of chlorine dioxide and chlorite with inorganic compounds

(a) Reactions with ferrous iron and manganese In aqueous solutions with pH at or below neutrality chlorine dioxide reacts with Iron(II) and Manganese (II) with the oxidation of the divalent cation and corresponding reduction of chlorine dioxide to chloride These reactions occur when iron and manganese are present in a reduced state or are coupled with organic compounds such as humic and fulvic acids These acids, phenolic in nature, are oxidized Stoichiometrically, the reaction of chlorine dioxide with ferrous iron (Iron II) 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 chlorine dioxide and chlorite. The exact reactions which would occur are dependent upon pH and other factors The expected reactions are as follows

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

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

The efficacy of such reactions in hydrogen sulfide control is illustrated by the fact that Bio-Cide International, Inc is the owner of a patent for the use of aqueous chlorine dioxide based solutions for the control of hydrogen sulfide in drilling fluids (U.S. Patent No 4,473,115).

(c) Reactions with ammonia and amines: In wastewater containing ammonia and primary amines, no residual oxidants corresponding to chloramines are formed since

chlorine dioxide 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 chlorine dioxide instead of chlorine The reactions of organic compounds in red meat, with chlorine dioxide from acidification of sodium chlorite are expected to be the same as those which occur from the chlorine dioxide 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 chlorine dioxide 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 chlorine dioxide and chlorite with phenols and phenolic acid derivatives (7)

The U.S. EPA has reviewed a large body of literature concerning the reaction products of chlorine dioxide and chlorite 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 chlorine dioxide is used as the disinfectant rather than chlorine 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 chlorine dioxide 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 proposed 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 program for pesticide products regulated under the Federal Insecticide, Fungicide and Rodenticide Act, the U S. Environmental Protection Agency has determined that the potential health and environmental effects for chlorine dioxide and chlorite are essentially identical By letter of 21 April 1992, EPA notified Bio-Cide International, Inc that data for sodium chlorite and chlorine dioxide would be mutually acceptable for ecological effects, environmental fate, toxicology, and residue considerations A copy of this letter is attached at Item 15.

The human health risks associated with chlorine dioxide, chlorites, and chlorates have been thoroughly reviewed in following documents which are readily available on the web.

> Registration 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/oppsrrd1/reregistration/REDs/chlorine_dioxide_red.pdf (Accessed June 25, 2007).
>
> Reregistration Eligibility Decision (RED) for Inorganic Chlorates· EPA 738-R-06-014. U.S Environmental Protection Agency. Washington. D.C. Jul. 2006 http·//www.epa.gov/pesticides/reregistration/REDs/inorganic_chlorates_red.pdf (Accessed June 25, 2007).
>
> Toxicological Profile for Chlorine Dioxide and Chlorite: Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services. Sep 2004. http·//www.atsdr.cdc.gov/toxprofiles/tp160.pdf (Accessed June 25, 2007)

Exposure of humans through disposal of the FCS, except to chloride, is not expected because the solution will be disposed of in the waste water which is in contact with the offal stream The offal and wastewater contain high levels of organic materials that would react with the by-products of the antimicrobial solution to form chloride (16) As no human exposure, other than possibly to chloride, is expected to occur from the proposed uses, we have not summarized human health toxicity endpoints in this EA. Exposure of humans through the ingestion of poultry treated with the FCS is reviewed independently in other parts of the FCN and need not be duplicated in this EA

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 chlorine dioxide into the air and due to the expected photochemical decomposition of chlorine dioxide in air

B Aquatic and Terrestrial Ecosystem

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 (Accessed June 25. 2007)
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> Reregistration Eligibility Decision (RED) for Inorganic Chlorates. EPA 738-R-06-014, U S Environmental Agency. Washington, D C., July. 2006. http://www.epa.gov/oppsrrd1/REDs/inorganicchlorates_red.pdf (Accessed June 25, 2007).
>
> ECOTOX Database, http://cfpub.epa.gov/ecotox/quick_query.htm (Accessed June 25, 2007).

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. (17)

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" (18)

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. (19)

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, searchable database on the chemical toxicity for aquatic and terrestrial life in the ECOTOX Database The ECOTOX Database is accessible on the web at http·//cfpub.epa.gov/ecotox/quick_query.htm (Accessed June 25, 2007). 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 available data strongly suggest 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 no anticipated increase in 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 the proposed Food Contact Substance The document entitled "Oklahoma's Endangered and Threatened Species and Species of Special Concern", published by the Natural Resources Section of the Oklahoma Department of Wildlife Conservation, is available on the web at http://www.wildlifedepartment.com/endanger2.htm (Accessed June 25, 2007) Of the species listed, only 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 of acidified sodium chlorite and 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.

C Historical Sites·

There are no anticipated effects on any sites listed or eligible for listing in the National Register of Historic Places, from either the production or use of the FCS precursors. Available on the web at http://www.nationalregisterofhistoricplaces.com/ok/Cleveland/state.html (Accessed June 25, 2007), is a listing of all sites in Cleveland County, Oklahoma 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.

10. Mitigation Measures:

The United States Environmental Protection Agency (EPA) recently published the "Reregistration Eligibility Decision (RED) for Chlorine Dioxide and Sodium Chlorite (CASE 4023)" (16) The RED gives a comprehensive review of the use of chlorine dioxide and sodium chlorite as an antimicrobial and this review is applicable to the proposed use in this food-contact notification (FCN) and also helps to support a FONSI The EPA risk assessment listed uses applicable to this FCN on Page 75 (16) Sodium chlorite is listed for use in poultry chiller water at 50 to 150 ppm and 500 to 1200 ppm for carcass spray. (16) The risk assessment was done for the "once-through cooling tower use of chlorine dioxide/sodium chlorite. ..because out of all the uses of these chemicals. it is the one expected to have the most potential for environmental exposure "(20) Excerpts from the risk assessment summarize acute and chronic risk findings below.

> "Acute risk is anticipated for aquatic organisms from the use of chlorine dioxide/sodium chlorite in once-through cooling towers At the highest doses on current labels (25 ppm). there is risk to the freshwater and marine/estuarine fish and invertebrates and aquatic plants, and at the lowest dose there is risk only to freshwater invertebrates To mitigate this risk, the maximum application rate for this use pattern must be reduced from 25 ppm to 5 ppm for intermittent applications "(16)

> "Chronic risk to aquatic organisms cannot be assessed at this time due to the lack of chronic toxicity endpoints for fish and aquatic invertebrates. When the required aquatic chronic toxicity testing described below is submitted, chronic risks to these organisms will be assessed. All other exposure and risk estimates are below the Agency's level of concern."(16)

As stated by EPA, "The generic data base supporting the reregistration of chlorine dioxide and sodium chlorite has been reviewed and determined to be substantially complete" (16) The EPA determined that , "chlorine dioxide and sodium chlorite are eligible for reregistration provided that (i) additional data that the Agency intends to require confirm this decision, and (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to reflect these measures" (16) The risk mitigation measures and label amendments are listed and clearly identified in the RED and include requiring the following statement on the label in the ecological effects language.

> "This product is toxic to fish, aquatic invertebrates, oysters, and shrimp Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge Do not discharge effluent containing this product to sewer systems without previously notifying the

local sewage treatment plan authority. For guidance contact your State Water Board or Regional Office of the EPA." (16)

The risk mitigation measures and label requirements identified in the RED will also be required for use of chlorine dioxide and sodium chlorite as an antimicrobial in food processing facilities and will help to mitigate any adverse environmental impact from the proposed uses

The product labels for antimicrobial pesticide products manufactured by Bio-Cide International, Inc. and registered with the U.S. EPA in accordance with the Federal, Insecticide, Fungicide, and Rodenticide Act contain the ecological effects language shown above. The same language will be incorporated into product labels for the proposed Food Contact Substance.

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 microbiology, chemistry, and environmental sciences with professional experience in microbiology, oxychlorine chemistry, environmental regulatory affairs, and has served as an Environmental Planner for the Oklahoma Department of Pollution 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: June 25, 2007

Signature:

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

14. References:

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15. Appendix:

1 EPA letter dated 21 April 1992

16. Confidential Attachments:

1 Method of Production – [redacted]