

Environmental Assessment

1. *Date:* 8/27/04

2. *Name of Applicant/Petitioner:*

Bio-Cide International, Inc.

3. *Address:*

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

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4. Description of the proposed action.

Existing regulations permit the usage of the food additive, acidified sodium chlorite solutions, as an antimicrobial agent in the processing of red meat, red meat parts, and organs, and on processed, formed, and comminuted meats applied directly to the meat or meat products. Applied as a dip or spray the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a solution of pH 2.5 to 2.9.

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 on red meat, red meat parts, and organs, and on processed, formed, and comminuted meats. The proposed additive is produced by mixing an aqueous solution of sodium chlorite with any generally regarded as safe (GRAS) acid to achieve a pH in the range of 2.2 to 3.0 and then further diluting this solution with a pH elevating agent such that the resultant sodium chlorite concentration is between 300 and 1,200 ppm, and the pH of the solution is between 5.0 and 7.5. The solution, thus produced, is applied as an antimicrobial agent in the processing of red meat, red meat parts, and organs and on processed, comminuted, and formed meat products in the form of a dip or spray.

The proposed action is needed to avoid problems inherent in the current, permitted use of acidified sodium chlorite on meat, specifically, pickling of the meat and corrosion of processing equipment, resulting from the low pH of the permitted 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 maintained in the proposed FCS usage.

The locations where the Food Contact Substance is intended for use are meat processing facilities such as abattoirs, and sites where further processing of meat products is performed, such as packaging, or ready to eat meat product operations. The Food Contact Substance is neither intended for use in, nor will be marketed to, other meat processing sites such as restaurants, retail establishments, delis, or in the home. Food additive petitions FAP 9A4692, FAP 7A4532, and FAP 0A4724 are cited by reference and provide detailed descriptions of locations where the FCS is intended for use.

The sodium chlorite precursor products intended for use under the proposed action will be manufactured at the Bio-Cide International Inc. production facility which is located at 2650 Venture Drive 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, or activator, are manufactured in large volumes with many diverse applications. The projected volumes of GRAS acid usage as the activator is only a fractional percentage of the other applications, thus, the production sites of these acids is not considered relevant to this environmental assessment. The pH elevating agents such as sodium carbonate, and sodium bicarbonate

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are also GRAS compounds with numerous food additive applications. As with the GRAS acids the projected volumes of pH elevating compounds is a fractional percentage used in other applications and, thus, the production sites for these compounds is not considered relevant to this environmental assessment.

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

IDENTITY OF SODIUM CHLORITE:

Common Name: Sodium Chlorite

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

Empirical Formula: NaClO₂

Molecular Weight: 90.45

METHOD OF PRODUCTION:

The methods for production of the sodium chlorite precursors are considered to be confidential business information. A description of the manufacturing process is enclosed as a **CONFIDENTIAL** attachment. Copies of product labels and material safety data sheets for the FCS sodium chlorite precursor products are attached at Item 15 (A) and (B).

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) CAS No. 5949-29-1 (monohydrate) Conforms with 21 CFR 182.1033 Multiple Purpose GRAS
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Phosphoric Acid	CAS Reg. No. 7664-38-2 Conforms with 21 CFR 182 Multiple Purpose GRAS
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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	CAS Reg. No. 497-19-8 Conforms with 21 CFR 184.1742 GRAS
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Sodium Bicarbonate	CAS Reg. No. 111-58-8 Conforms with 21 CFR 184.1736 GRAS
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The proposed usage of the Food Contact Substance is described as follows. The sodium chlorite precursor products are diluted with water to an intermediate solution with a sodium chlorite concentration in the range of about 0.5% to 3.5%. The pH of this intermediate 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 solution is then diluted to the final use concentration of between 300 and 1,200 ppm. The dilution is performed by mixing the 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 carbonate solutions, bicarbonate solutions or, most preferably, unacidified sodium chlorite solutions. The solutions prepared by this proposed method are then applied to red meat, meat products, or ready to eat meat products by means of dipping or spraying. The desired antimicrobial effect on the treated meat products is achieved without the deleterious pickling of the meat seen with acidified sodium chlorite solutions.

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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.

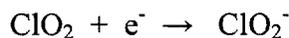
B. Emission substances from the use of the Food Contact Substance.

The FCS solutions which are the subject of this environmental assessment will be produced on site immediately before application in the meat processing facilities such as abattoirs, meat packaging facilities, and ready to eat meat operations. The potential for introduction into the environment for chemical species of concern such as chlorine dioxide, chlorite, and chlorate and acids are expected to be essentially identical to that associated with current permitted usages of acidified sodium chlorate. 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.

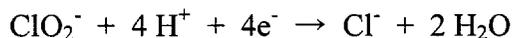
It is anticipated that the high organic loads of the receiving wastewater streams for either on-site or POTW water treatment facilities would result in very rapid reduction of chlorine dioxide, chlorite, and chlorate to innocuous levels of the chloride ion. A more detailed description of the fate of introduced substances is described in Item 7.

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



The chlorite ion is also an effective oxidizing agent and will be consumed through oxidation-reduction reactions with oxidizable material. These occur as follows:



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 typically would be expected to occur prior to release into the environment. It will also contain illustrations of the reactions involved in the fate of which would occur through an accidental release into the environment.

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7. Fate of emitted substances in the environment

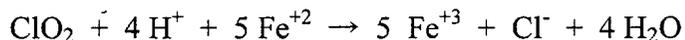
Sodium chlorite, sodium chlorate, and chlorine dioxide released into the environment will likely undergo reduction in contact with organic matter, inorganic chemical reactions. Ultimately the oxy chlorine species will be reduced to the chloride ion.

(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 ClO₂ 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 meat 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 ClO₂ and biodegradation of ClO₂ and chlorite would be expected. The large volumes of water used in meat processing would also dilute the quantities of ClO₂ and chlorite to extremely low levels, even if the above reactions did not occur. Various reactions of ClO₂ and chlorite which are documented in the scientific literature are presented below

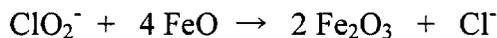
(i) Reactions of ClO₂ and ClO₂⁻ with inorganic compounds:

(a) Reactions with ferrous iron and manganese: In aqueous solutions with pH below neutrality ClO₂ reacts with Fe⁺² and Mn⁺² with the oxidation of the divalent cation and reduction of ClO₂ 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. The acids, phenolic in nature, are oxidized. Stoichiometrically, the reaction of ClO₂ with ferrous iron is: (3)

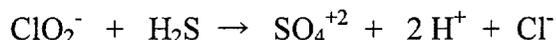
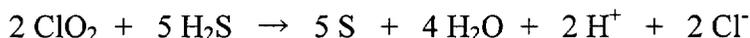


Under alkaline conditions, where the chlorite ion might predominate, salts of ferrous iron and manganese are oxidized quantitatively by sodium chlorite. (4)

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(b) Reactions with sulfides: The formation and control of sulfides are common problem in wastewater treatment. Sulfides will 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:



The efficacy of such reactions in H_2S 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 (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 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 Cl_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. (8)

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 ClO_2 , but at rates considerably lower than for ClO_2 . (9)

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. (10)

Chlorine dioxide has been shown to react with and eliminate various pesticides, including products highly toxic to fish such as rotenone. (11) Chlorine dioxide has been shown to be the oxidant of choice for the removal of phenylamide pesticides from water. (12) Other pesticides which can be eliminated by reaction with ClO_2 are methoxychlor (DMDT) and aldrin. (13) Herbicides such as paraquat and diquat are oxidized by chlorine dioxide. (14)

The photolytic decomposition of chlorine dioxide also occurs in aqueous systems. The principle decomposition products are expected to be chlorate and chloride. (15)

Finally, enzymatic mechanisms for the bio-degradation of chlorite and chlorine dioxide have been shown to exist in eukaryotic systems. (16) 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)
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1 mole chlorite	0.4 mole chloride, 0.6 mole chlorate, and 0.13 mole oxygen (O_2)
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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.

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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 EPA 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 included in Item 15.

(A) Air.

As previously stated, only trace amounts, at most, of ClO_2 would be released in to the air by the proposed usage. It is doubtful that any toxic concentration could be achieved under normal use. The OSHA TLV is 0.1 ppm as established by the American Congress of Government Industrial Hygienists.

Masschelein cites several studies on the effects of exposure in air of ClO_2 to laboratory test animals. These include: "The exposure of rats to 1.0 ppm O_2 for 5 hours/day, 5 days/week for two months, does not effect weight gain, leucocyte or erythrocyte counts or hepatic and pulmonary parenchyma. Rats and rabbits were exposed for 30 days to 2.5, 5.0 or 10.0 ppm ClO_2 , respectively for 4 to 7 hours/day, 2 hours/day and 2 hours/day. Localized bronchopneumonia with elevated leucocyte counts was observed after exposures to 10 and 5 ppm, while only slight reversible pulmonary lesions were found after the 2.5 ppm, exposure. Another study reports that two-to-four 15 minute exposures to 5.0 ppm ClO_2 per day for one month did not alter the blood composition or lung histology of rats." (19)

We believe 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:

With the increased interest in the use of ClO_2 as a disinfectant for drinking water, much work has been done to determine the potential health effects of ClO_2 , ClO_2^- and ClO_3^- on human populations. Since the FCS may contains all of these oxychlorine species, toxicity studies from the literature are applicable in showing the very low potential toxicity of the FCS at recommended usage concentrations and expected residual levels.

The principal health concern for chlorine dioxide, chlorate and chlorite centers on the fact that very large doses of these oxidants can produce methemoglobinemia in test animals. Methemoglobinemia is an abnormal condition of the oxygen binding protein hemoglobin found in the erythrocytes. Hemoglobin consists of four polypeptide chains linked to a non-peptide prosthetic group called heme. Heme is an iron porphyrin complex and is the

binding site for oxygen molecules. The iron atom in the heme can exist in either the ferrous (+2) or the ferric (+3) oxidation state. These corresponding forms are called ferrohemoglobin and ferrihemoglobin, respectively. Only ferrohemoglobin, the +2 oxidation state, can bind oxygen. Therefore, persons with methemoglobinemia have a reduced capacity for blood transport of oxygen.

Certain human subpopulations may represent groups at higher risk to erythrocyte oxidant stress. The largest two groups are person with lowered G6PD activity and neonates. Glucose-6-phosphate dehydrogenase (G6PD) deficient cells have a reduced ability to produce NADPH via the pentose phosphate pathway and, consequently, produce less glutathione (GSH). Since glutathione is the primary mechanism of red blood cells defense against oxidant stress, persons with deficient G6PD levels have a reduced capacity for protection against oxidants. Neonates have a variety of deficiencies and differences in their blood cells that enhance their susceptibility to oxidant stress and methemoglobinemia.

A large body of literature exists concerning toxicological studies on chlorine dioxide, chlorite and chlorate. Numerous researchers have performed a wide variety of testing, including acute toxicity, chronic toxicity, rising dose toxicity and epidemiological studies. A consistent pattern is observed that any toxic effects and alterations in hematological parameters are dose related and that significant changes occur only at chronically administered higher dosages (100 mg/l to 1,000 ml/l) in test animals or humans. The following literature citations are aimed at general evaluation of ClO_2 , ClO_2^- and ClO_3^- toxicity and evaluations of increased risk potential to these populations with high oxidant stress susceptibility.

Calabrese, et al., did a literature survey on the health effects of chlorine dioxide, "The Health Effects of Chlorine Dioxide as a Disinfectant in Potable Water: A Literature Survey". They concluded that concentrations of chlorine dioxide at 10 mg/l is not considered a toxic agent in a variety of animals. At higher concentrations and chronic administration (≥ 100 mg/l), some animal models exhibited altered hematological parameters, usually at very high concentrations and apparently dose related. (18)

Lubbers, et al., conducted an extensive controlled clinical evaluation on the effects of ClO_2 , ClO_2^- and ClO_3^- in non-human, "Controlled Clinical Evaluations of Chlorine Dioxide, Chlorite and Chlorate in Man". This double blind study was conducted in three phases: (1) Rising dose tolerance acute toxicity study; (2) Chronic studies at 5 mg/l and (3) Administration at 5.0 mg/l to persons with G6PD deficiencies, ergo, sensitive to oxidant stress. They concluded that no observable undesirable sequellae were noted by participating subjects or by the observing medical team. Any treatment associated trends were judged to be of no physiological consequence. (17)

Bercz, et al., examined the subchronic toxicity of ClO_2 , ClO_2^- and ClO_3^- in non-human primates, "Subchronic Toxicity of Chlorine Dioxide and Related Compounds in Drinking Water in the Nonhuman Primate". Concentrations rose from 0 to 400 mg/l over the test period. The only significant toxic effect was elicited by ClO_2 , which inhibited thyroid

metabolism at 100 mg/l. This effect was unexplained and, indeed, was considered paradoxical, since ClO_2 is rapidly reduced by oral and gastric secretions, they presume, to Cl^- . They concluded that it is unlikely that absorption of a simple chlorine oxide species caused the thyroid effect. (20)

Moore and Calabrese examined the effects of ClO_2 , ClO_2^- and NO_2^- on mice with G6PD deficiencies. Their study hypothesis was that ClO_2 and ClO_2^- would exhibit significant toxic effects on an animal population with erythrocytes susceptible to oxidant stress, "Effect of Chlorine Dioxide, Chlorite and Nitrate on Mice with Low and High Levels of Glucose-6-Phosphate Dehydrogenase (G6PD) in Their Erythrocytes". They found no significant effects on sensitive mice at concentrations of 10 ppm. Again, any physiological effects were dose related and were deemed significant only at 100 ppm ClO_2^- . No adverse additive or synergistic effects were observed between ClO_2^- and NO_2^- when administered concurrently. (21)

A rising dose tolerance study was performed by Lubbers, et al., as reported in "Effects of the Acute Rising Dose Administration of Chlorine Dioxide, Chlorate and Chlorite to Healthy Adult Male Volunteers". The study was undertaken to assess the relative safety and tolerance of the acute administration of ClO_2 and its by-products, ClO_2^- and ClO_3^- to healthy male volunteers. Evaluation of an extensive battery of tests and vital signs showed no adverse physiological effects. (22)

Lubbers, et al., also examined the effects of chronic administration of ClO_2 and its by-products on a healthy adult population in, "The Effects of Chronic Administration of Chlorine Dioxide, Chlorite and Chlorate to Normal Healthy Adult Male Volunteers". A daily dose (500 ml, 5.0 ppm) was administered to the volunteers for a twelve week period. An analysis of the qualitative and quantitative parameters of an extensive body of tests showed no clinically important physiological effects. (23)

Lubbers, et al., also examined the effects of chronic administration of chlorite to a susceptible population as reported in, "The Effects of Chronic Administration of Chlorite to Glucose-6-Phosphate Dehydrogenase Deficient Healthy Adult Male Volunteers". The test subjects were administered daily doses (500 ml, 5.0 ppm ClO_2^-) for twelve weeks. An evaluation of an extensive battery of tests designed to measure the bio-chemical and physiological response to chlorite ingestion detected no significant changes. (24)

In, "Evaluation of Chemicals Used for Drinking Water Disinfection for Production of Chromosomal Damage and Sperm-head Abnormalities in Mice", Meier, et al., determined that chlorine as hypochlorite and hypochlorous acid at 4.0 to 8.0 mg/kg dosages induced significant increases in the level of sperm-head abnormalities. Other disinfectants, including chlorine dioxide, sodium chlorite and sodium chlorate gave no evidence of any such effects. (25)

Suh, et al., conducted a study to determine the effect of ClO_2 and its metabolites on the formation of chloroform in rats. Male rats were administered 0, 10, 100 mg/l ClO_2 or 1, 10 mg/ ClO_2^- or ClO_3^- daily for one year in drinking water. Blood chloroform levels were

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significantly decreased in the ClO_2 group at 2, 10 and 12 month treatment. Chlorite and chlorate groups showed similar decreases in blood chloroform concentration after one year. Chlorine dioxide at 5 mg/l inhibited the formation of chloroform by HOCl (5, 10, 20 mg/l) and sodium citrate at 1.0 mM. (26)

Michael, et al., conducted an epidemiological study on the effects of ClO_2 in drinking water on the population of a rural town. The study compared a population of 178 persons exposed for three months to water with a chlorite concentration of about 5.0 ppm to an unexposed population of 118 people. Data analysis failed to find any exposure related effects. This was reported in "Chlorine Dioxide Water Disinfection: A Prospective Epidemiology Study". (27)

Harrington; et al., conducted a developmental toxicity study to determine the teratogenic effects of sodium chlorite on rabbits. The study concluded no maternal or fetal effects at 200 ppm NaClO_2 . (28)

Another review article concerning the application of ClO_2 to water treatment concluded that available studies suggested no adverse health risks for both chlorine dioxide and chlorite at concentrations used in drinking water treatment. (29)

A review of the literature provides no evidence of significant human health risks for ClO_2 , ClO_2^- and ClO_3^- at concentrations below 10 ppm. As previously stated, the amounts of the FCS which would be released into the environment would be well below 10 ppm. Commercial products chemically identical to the FCS have E.P.A registrations for use in stored potable water treatment at 5.0 ppm and is considered safe for human consumption at this concentration.

The International Research Agency for Research on Cancer (IARC) has assigned a Class 3 rating to sodium chlorite - "Not Classified As To Its Carcinogenicity To Humans". This is published in Vol. 52 of the IARC series. (30)

There was little information found in the literature concerning the potential effects of ClO_2 , ClO_2^- and ClO_3^- on non-mammalian species. However, data was found concerning the toxicity of oxychlorine species to representatives of the Classes Osteichthyes, Aves and Insecta; these are reported below.

The acute toxicity of sodium chlorite to bluegill and rainbow trout was reported in, "Acute Toxicity of Sodium Chlorite to Bluegill (*Leponis machrchirus*) and Rainbow Trout (*Salmo gairdneri*)". The TL50 for bluegill was determined to be 208 mg/l and to be 50.6 mg/l for rainbow trout. (31)

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. (32)

Calandra reported the LD50 of sodium chlorite in mallard ducks to be 1000 mg/kg in,

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"Acute Oral Toxicity Study with Sodium Chlorite in Mallard Ducks". (33)

The toxic effects of a stabilized chlorine dioxide solution on honey bees was 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 ClO₂ dying within a week. (34)

The following listed studies related to terrestrial and aquatic eco-toxicity are co-owned by Bio-Cide International, Inc. Terms of the ownership agreement permit submission to regulatory agencies only as confidential information. Therefore, copies of these studies are enclosed as **CONFIDENTIAL** attachments.

- (1) Effect of Sodium Chlorite on Seed Germination/Seedling Emergence
- (2) Effect of Sodium Chlorite on Vegetative Vigor in Plants
- (3) Acute Flow-through Toxicity of Sodium Chlorite to the Mysid, *Mysidopsis bahia*
- (4) Acute Flow-through Mollusc Shell Deposition Test with Sodium Chlorite
- (5) Static Acute Toxicity of Sodium Chlorite to the Freshwater Alga, *Selenastrum capricornutum*
- (6) Acute Flow-through Toxicity of Sodium Chlorite to the Sheepshead Minnow, *Cyprinodon variegatus*

The Pesticide Information Profile on sodium chlorate available from the Extension Toxicology Network indicates a relatively low mammalian toxicity for sodium chlorite. The possible 48 hour LC50 for sodium chlorite 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. A copy of the profile is attached at Item 15. No additional information on the eco-toxicity of sodium chlorate was found in searches of EPA sources such as IRIS documents or pesticide chemical fact sheets.

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

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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.

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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 essential no 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. A copy of "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 enclosed at Item 15 and lists endangered and threatened species in Oklahoma. 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 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.

(E.) 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. Included in Item 15 are the relevant portions of the National Register of Historic Places, for Cleveland County, Oklahoma, published by the Oklahoma Historic Preservation Office. This document contains a county by county listing of all sites in 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.

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10. Mitigation Measures

Mitigation measures for the proposed action need not be considered because no potentially adverse effects have been identified.

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11. Alternatives to the Proposed Action

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

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12. Preparer

This Environmental Assessment was prepared by James P. Ringo, M.S., of 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 Pollutions Control.

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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: August 27, 2004

Signature:

A rectangular red box redacting the signature of James P. Ringo.

Name: James P. Ringo
Title: Director

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14. References

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15. Appendices

- (a) Label - Keeper®
- (b) Label - Keeper® Professional
- (c) Material Safety Data Sheet - Keeper®
- (d) Material Safety Data Sheet - Keeper® Professional
- (e) EPA letter dated 21 April 1992
- (f) Oklahoma Endangered and Threatened Species and Species of Special Concern
- (g) National Register of Historic Places
- (h) Extension Toxicology Network – Pesticide Information Profile for Sodium Chlorate

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