

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

October 7, 2002

Steven D. Goodspeed
Bio-Cide International, Inc.
2845 Broce Drive
Norman, OK 73072

Subject: Pro-Oxine
EPA Registration No. 9804-9
Amendment Dated: April 4, 2002
EPA Receipt Date: April 17, 2002

Dear Mr. Goodspeed:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is accepted with the conditions listed below.

- for use as a lube additive to control bacteria slime and odor on moving conveyors and chains in food processing facilities
- to lower concentration as "Terminal Sanitizing Rinse for Stainless Steel and Other Hard Nonporous Food Contact Surfaces"

Condition

You must revise for preparation of the sanitizing solution from 2/3 fl. oz. to 1.6 fl. oz. on page 2 of the label. (See attached review for explanation.)

General Comments

The request to add label claims of Pro-Oxine as a sanitizing rinse on hard, non-porous, inanimate food-contact surfaces when used a concentration of 50 ppm with a contact time of 1 minute are approved.

The label claim stating that this product may be used as a "lube additive" to control bacterial slime and odor on moving conveyors and chains in food processing facilities is supported by the sanitization study included in this submission.

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

CONCURRENCES

SYMBOL	17							
SURNAME	Ni							
DATE								

Should you have any questions or comments concerning this letter, please contact Wanda Mitchell at (703) 308-6345.

Sincerely,



*Robert S. Brennis
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)*

PRO-OXINE®

SANITIZER

Active Pro-Oxine®

ACCEPTED
with COMMENTS
EPA Letter Dated:

OCT - 7 2002

DISINFECTANT
FUNGICIDAL-BACTERICIDAL

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. *9804-9*

FOOD PROCESSING PLANTS
BOTTLING PLANTS - INDUSTRIAL USE

Active Ingredient: Chlorine Dioxide.....	5%
Inert Ingredients.....	95%
TOTAL.....	100%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

SEE SIDE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS

STORE IN COOL DARK PLACE - KEEP FROM FREEZING
E.P.A. Reg. No. 9804-9 E.P.A. Reg. No. 9804-OK-1

BIO-CIDE International, Inc.
Norman, Oklahoma 73070

Net Contents: 5 Gal. Γ 30 Gal. Γ 55 Gal. Γ

PROPER ACTIVATION OF PRO-OXINE®

The active biocidal component of the Pro-Oxine® system is free chlorine dioxide. Unactivated Pro-Oxine® in the neutral to mildly alkaline pH range is bacteriostatic. For higher level microbial control, such as disinfection and sanitation, activation of Pro-Oxine® is required to generate free chlorine dioxide. The use of citric acid as an activator is specified in most Pro-Oxine® label applications. Alternatives to citric acid for activation include organic acids, such as acetic acid, and inorganic acids such as phosphoric, hydrochloric, and sulfuric acids. Activation equivalent to that of citric acid may be achieved by adjusting the Pro-Oxine® solution to pH 2-3 with an alternative acid. The activated Pro-Oxine® is then diluted to the required use concentration in accordance with label instructions. For food processing applications only food grade activator acids may be used. Bio-Cide International, Inc. or your Pro-Oxine® distributor can guide you in proper activation techniques.

IN FOOD PROCESSING PLANTS SUCH AS POULTRY, FISH & MEAT AND IN RESTAURANTS, DAIRIES, BOTTLING PLANTS AND BREWERIES:

AS A TERMINAL SANITIZING RINSE FOR STAINLESS STEEL AND OTHER HARD NONPOROUS FOOD CONTACT SURFACES SUCH AS TANKS, TRANSFER LINES AND OTHER FOOD PROCESSING EQUIPMENT.

DIRECTIONS FOR USE:

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

- 1) All gross food particles and soil should be removed prior to sanitizing by use of a pre-flush, pre-scrape or pre-soak treatment.
- 2) Clean tank, line or surface thoroughly using a suitable detergent and rinse with clean potable water before sanitizing.
- 3) Preparation of sanitizing solution: Place ^{1.6} 2/3 fl. oz. of Pro-Oxine® concentrate into a clean plastic pail or container and add 5 grams (1 Teaspoon) of Bio-Cide Activator Crystals or food grade citric acid of no less than 99% purity. Prepare in a well ventilated area. Avoid breathing any fumes which may be produced while crystals are dissolving. Allow five (5) minutes reaction time for crystals to dissolve completely. To this solution, add five (5) gallons of clean, potable water. This will yield a working solution containing 50 ppm available chlorine dioxide.
- 3) To apply: Fill, flush, immerse or spray tank, line, equipment or food contact surface with active solution making sure surface area is thoroughly wet for at least one (1) minute. After sanitizing, drain tank, line or equipment and allow to air dry. Fresh sanitizing solution should be made up daily or more often if solution becomes diluted or soiled.

2) Pro-Oxine should be added to the water dilution step of the lube system just prior to its injection into the distribution system. Addition of Pro-Oxine into the lube/water mixture should be at the rate of 0.26 fl. Oz. to 0.52 fl. Oz. per 10 gallons of diluted lube. This will result in a final Pro-Oxine concentration of between 10 and 20 ppm in the lube solution.

3) For best results use with natural (fatty acid, soap based) lubricant products. For advice on lube compatibility contact your BCI distributor.

TO DISINFECT WALLS, CEILINGS, AND FLOORS.

DIRECTIONS FOR USE:

- 1) Before disinfection, all gross filth must be removed from areas to be disinfected and thoroughly cleaned with a suitable detergent followed by a clean, potable water rinse.
- 2) Preparation of active disinfecting solution (500 ppm ClO₂): Place 1 1/3 fl. oz. of Pro-Oxine concentrate per gallon of working solution into a clean, plastic pail and add ten (10) grams of Bio-Cide Activator Crystals or food grade citric acid of no less than 99% purity. Prepare in a well ventilated area, avoid breathing any fumes which may be produced while crystals are dissolving. Allow five (5) minutes reaction time for crystals to dissolve completely. To this solution, add one (1) gallon of clean, potable water. This will yield a working solution containing 500 ppm of available chlorine dioxide.
- 3) To apply: Spray disinfectant solution onto surface to be disinfected using a suitable spraying device and making sure that the area is thoroughly wet for at least ten (10) minutes. Active solutions may be irritating when breathed; therefore, always use an applicable NIOSH/MSHA approved respirator appropriate for chlorine dioxide when spraying these solutions. After application, allow to air dry. Treat as required. Always apply freshly made solutions. Never reuse activated solutions.

FOR USE AS A LUBE ADDITIVE TO CONTROL BACTERIAL SLIME AND ODOR ON MOVING CONVEYORS AND CHAINS IN FOOD PROCESSING FACILITIES.

Directions for Use:

- 1) Prior to beginning application of Pro-Oxine to the diluted lube mixture, all conveyors, lube lines, spray nozzle heads, conveyor surfaces, and other associated structures should be thoroughly cleaned and sanitized.

TO CONTROL THE BUILD-UP OF ODOR AND SLIME FORMING BACTERIA IN ICE MAKING PLANTS AND MACHINERY.

DIRECTIONS FOR USE:

1) Ice making machinery should be disassembled and thoroughly cleaned using a suitable detergent followed by a potable water rinse.

2) Preparation and application of solution: The Pro-Oxine[®] solution should be applied to the incoming water line of the ice machine via a chemical feed pump or injector system and proportioned at the rate of 6 fl. oz. per 100 gallons of potable water (20 ppm available ClO₂)

TO CONTROL ODOR AND SLIME FORMING BACTERIA IN COOLING AND WARMING WATERS, SUCH AS CANNING RETORT AND PASTEURIZER COOLING WATERS, USED TO DECREASE OR INCREASE PACKAGED PRODUCT TEMPERATURE BY IMMERSION IN OR BY SPRAYING WITH THE TREATED PROCESS WATERS.

DIRECTIONS FOR USE:

1) All tanks, tunnels, conveyor chains, heat exchangers, heat exchange towers, lines, spray bars and nozzles should be thoroughly cleaned, when possible, and completely rinsed using clean, potable water prior to treatment.

2) Preparation of solution: Water systems including the cooling or warming tanks or spray systems, towers, lines and all water containing parts of the system may be batch loaded at start up with 12.8 fl. oz. Pro-Oxine[®] per one thousand (1000) gallons of potable water (5.0 ppm available ClO₂). To maintain the 5.0 ppm available ClO₂ in the water system a timed or electronically controlled chemical feed pump or injector system can be used for additions to the system or for treating the make-up water. Make up new Pro-Oxine[®] solutions daily. Optional activated solution: If heavy use of cooling or warming water, or introduction of additional bacteria loads is expected or if slime buildup is heavy, an additional activation step may be used in preparation of solution.

3) Preparation of activated solution: Prepare in a well ventilated area, avoid breathing any fumes which may be produced while crystals are dissolving. For each one thousand (1000) gallons of system water to be treated, measure out 12.8 fl. oz. of Pro-Oxine[®] and pour into a clean plastic container, pail or drum. To this Pro-Oxine[®] amount, add Bio-Cide Activator Crystals or food grade citric acid of no less than 99% purity, at the rate of 3.3 ounce (95 grams) crystals per 12.8 fl. oz. of Pro-Oxine[®]. Allow five (5) minutes reaction time for crystals to dissolve.

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Cooling or warming water systems may be batch loaded at start up using 12.8 fl. oz. of the prepared solution per one thousand (1000) gallons of potable water (5.0 ppm available ClO₂). Batch or timed additions of the prepared solution can be made or an electronically controlled chemical feed pump or injector system can be used for additions of the prepared solution to the process water to maintain 5.0 ppm available ClO₂. Make up new Pro-Oxine[®] solutions daily.

TO CONTROL ODOR AND SLIME FORMING BACTERIA BUILD-UP IN COMMERCIAL WATER FILTRATION SYSTEMS, SAND BEDS, GRAVEL BEDS AND CHARCOAL FILTERS WITH ACCESSIBLE SERVICE HATCHES.

DIRECTIONS FOR USE:

1) Drain all existing water from sand and carbon filters and rinse once with clean, potable water. Fill sand filter with potable water and adjust pH of water to 6.0 using citric acid or equivalent pH adjuster.

2) To prepare solution: Measure out eight (8) fl. oz. of Pro-Oxine[®] concentrate for each ten (10) gallons of filter system volume (300 PPM available ClO₂) and add to the sand filter through access hatch. Fill system with clean, potable water and circulate system 30 minutes. Allow system to soak two (2) to three (3) hours. After treatment, drain system and rinse with clean, potable water until residue is no longer detectable using the Bio-Cide test kit and when pH is normal.

TO CONTROL THE BUILD-UP OF ODOR AND SLIME FORMING BACTERIA IN STAINLESS STEEL TRANSFER LINES AND ON-LINE EQUIPMENT SUCH AS HYDRO-COOLERS, PASTEURIZERS AND THE LIKE OVERNIGHT AND OVER WEEKENDS.

DIRECTIONS FOR USE:

1) Clean equipment or line thoroughly using a suitable detergent followed by a clean, potable water rinse before treatment.

2) Preparation and application of solution: For each ten (10) gallons of volume in lines and/or equipment, add 1/2 oz. of Pro-Oxine[®] (20 PPM available ClO₂) to potable make up water. Mix and fill lines and equipment overnight. Drain and allow to air dry just prior to next run start-up.

FOR USE AS A SLIMICIDE IN PULP AND PAPER WHITEWATER SYSTEMS.

DIRECTIONS FOR USE:

- 1) For initial start-up or for severe slime contamination Pro-Oxine® should be prepared by the addition of one pound of citric acid activator per 50 gallons of Pro-Oxine or by addition of other suitable acid to adjust the Pro-Oxine® solution to approximately pH 7.0.
- 2) The activated Pro-Oxine® solution should then be proportioned into the whitewater system by means of a suitable metering pump at a continuous rate to produce an in-stream concentration of 1.25 - 5.0 ppm. This concentration is obtained by proportioning the Pro-Oxine® into the system at a rate of 3.2 -12.8 fluid ounces per 1,000 gallons of process water. The system should be monitored by use of a BIO-CIDE International, Inc. Test Kit, or other suitable means and feed rate adjustments made accordingly. After slime control is established the Pro-Oxine® feed rates may be lowered to maintain the desired level of slime control.

FOR ENCLOSED AND RECIRCULATING COOLING WATER SYSTEMS.

DIRECTIONS FOR USE:

- 1) Severely fouled systems should be cleaned prior to treatment.
- 2) For initial start-up or heavy microbial contamination Pro-Oxine® should be added to the cooling water system at a rate of one gallon of Pro-Oxine® per 10,000 gallons of system water. This is equivalent to 5.0 ppm as available chlorine dioxide. Dosage should be repeated daily until microbial control is achieved.
- 3) When microbial contamination is under control the concentration and frequency of treatment may be reduced to levels adequate to maintain the desired level of microbial control.

FOR MICROBIAL CONTROL IN SWEETWATER COOLING SYSTEMS.

- 1) Pro-Oxine® may be batch loaded or metered into sweetwater cooling systems at the rate of 13

fluid ounces per 1,000 gallons of sweetwater to produce an in stream concentration of 5.0 ppm
2) Pro-Oxine® concentrations should be monitored using a Bio-Cide test kit to maintain a 5.0 ppm concentration.

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STORAGE AND DISPOSAL

Storage: Store in a cool dark area in original container. Avoid storage in direct sunlight. In case of spill, flood with water before discarding to drain. Do not contaminate water, food or feed by storage or disposal.

Container Disposal: Triple rinse. Then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill; or by incineration; or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals: Harmful if swallowed. Harmful if inhaled. Avoid breathing vapor or spray mist. Remove contaminated clothing and wash clothing before reuse. Causes moderate eye irritation. Avoid contact with eyes and clothing. Wash thoroughly with soap and water after handling.

ENVIRONMENTAL HAZARDS

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 Pollutant 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 plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

NOTE: Chemical feed pumps and injectors must be chlorine resistant for best operation. Available ClO₂ levels should be confirmed using a Bio-Cide Test Kit, available from your local Pro-Oxine® distributor.

FIRST AID Class IV	
If inhaled	<ul style="list-style-type: none">- Move person to fresh air.- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.- Call a poison control center or doctor for further treatment advice.
If on skin or clothing	<ul style="list-style-type: none">- Take off contaminated clothing.- Rinse skin immediately with plenty of water for 15-20 minutes.- Call a poison control center or doctor for treatment advice.
If eyes	<ul style="list-style-type: none">- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lens, if present, after the first 5 minutes, then continue rinsing eye.- Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none">- Call a poison control center or doctor immediately for treatment advice.- Have a person sip a glass of water if able to swallow.- Do not induce vomiting unless told to do so by a poison control center or doctor.- Do not give anything by mouth to an unconscious person.