



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 2, 2015

Mr. James P. Ringo
Vice President of Regulatory Affairs
Bio-Cide International, Inc.
Post Office Box 722170
Norman, OK 73069

Subject: PRIA Label Amendment – Addition of Product Efficacy Claims Against the
Porcine Epidemic Diarrhea (PED) Virus
Product Name: **ProOxine®**
EPA Registration Number: **9804-9**
Application Date: October 3, 2014
Decision Number: 496080

Dear Mr. Ringo:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Page 2 of 2
EPA Reg. No. 9804-9
Decision No. 496080

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Benjamin Chambliss by phone at 703-308-8174, or via email at Chambliss.Benjamin@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Wanda J. Fuller, for". The signature is written in a cursive style.

Demson Fuller, Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: EPA-stamped Product Label

IN ANIMAL REARING AND CONFINEMENT FACILITIES

TO DISINFECT COMMERCIAL ANIMAL CONFINEMENT FACILITIES SUCH AS POULTRY HOUSES, SWINE PENS, CALF BARN AND KENNELS

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

- 1) Remove all animals and feed from premises, vehicles, enclosures, coops and crates
- 2) Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.
- 3) Empty all troughs, racks and other feeding and watering applications.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Preparation of active disinfecting solution: (500 ppm ClO₂) Place 1 1/3 fl. oz. of ProOxine® concentrate per gallon of working solution into a clean, plastic pail and add ten (10) grams (2 teaspoons) 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.
- 6) To apply: Using a commercial sprayer, saturate all surfaces with the activated ProOxine® solution for a period of ten (10) minutes. Active solution may be irritating when breathed, therefore, always use an applicable NIOSH/MSHA approved respirator appropriate for chlorine dioxide when spraying these solutions. Immerse all ladders, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. After treatment, ventilate buildings, coops or other enclosed spaces and allow to air dry. Repopulate only when solution has dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before use.

TO DISINFECT POULTRY HOUSES

Special Instructions for Inactivating Avian Influenza A

Kills Avian Influenza A on pre-cleaned environmental surfaces

- 1) Remove all poultry and feed from premises, vehicles, enclosures, coops and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities and fixtures occupied or traversed by poultry.
- 3) Empty all troughs, racks and other feeding and watering applications
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Preparation of active disinfecting solution: (500 ppm ClO₂) Place 1 1/3 fl. oz. of ProOxine® concentrate per gallon of working solution into a clean, plastic pail and add ten (10) grams (2 teaspoons) 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.
- 6) To apply: Using a commercial sprayer, saturate all surfaces with the activated ProOxine® solution for a period of 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. Immerse all equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and droppings. After treatment, ventilate buildings, coops or other enclosed spaces and allow to air dry. Repopulate only when solution has dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before use.

TO CONTROL THE BUILD-UP OF ODOR AND SLIME FORMING BACTERIA IN ANIMAL CONFINEMENT AREAS

- 1) Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, cases and other facilities and fixtures occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with clean water.
- 2) Preparation of solution: Place 2.6 fl. oz. ProOxine® concentrate per gallon of working solution (1000 ppm available ClO₂) into a clean, plastic pail. Dilute concentrate with one (1) gallon clean, potable water.
- 3) To apply: Using a commercial sprayer or fogger, saturate all surfaces with the ProOxine® solution.

TO DISINFECT WATER SUPPLY FOR POULTRY, SWINE, CATTLE AND OTHER LIVESTOCK

- i) Use Bio-Cide International, Inc. automated activation equipment to generate an aqueous chlorine dioxide solution. Alternatively, ProOxine® may be manually activated to generate an aqueous chlorine dioxide solution. The activated ProOxine® solution can be either batch loaded or metered into the poultry and drinking water supply at a point in the system which insures uniform mixing and distribution of up to 5 ppm chlorine dioxide.
- ii) **Automated Activation Method:** Bio-Cide International, Inc. automated activation equipment may be used to generate an aqueous chlorine dioxide solution for metering into the water supply to treat 3 to 5 ppm activated ProOxine® concentration.
- iii) **Manual Activation Method:** Activated ProOxine® concentrate may be prepared by manual mixing and subsequent dilution for treatment of the water supply at 3 to 5 ppm according to the activation and dilution charts.

For example, to manually prepare activated ProOxine® to treat 1,000 gallons of water at 3 ppm activated ProOxine®:

- 1) Preparation of active solution: Place 8 fl. oz. of ProOxine® concentrate into a plastic container and add 60 grams of citric acid. Prepare in a well ventilated area. Avoid breathing and fumes while crystals are dissolving. Gently stir until citric acid crystals are completely dissolved. Allow five minutes reaction time.
- 2) The activated concentrate may then be added to 1,000 gallons of water. Allow ten minutes before delivery to livestock water lines.

ProOxine® SANITIZER DISINFECTANT Bacteriostat/Deodorizer

FUNGICIDAL - BACTERICIDAL - VIRUCIDAL

ANIMAL REARING AND CONFINEMENT FACILITIES

ProOxine® has demonstrated efficacy against the following animal viruses:

Avian Influenza A Virus

Porcine Epidemic Diarrhea Virus

Porcine Reproductive & Respiratory Disease Syndrome Virus

Pseudorabies Virus

Newcastle Disease Virus

Canine Parvovirus

Low Corrosion - Guaranteed Shelf Life - Non-Flammable

Active Ingredient:	
Chlorine Dioxide.....	5.0%
Other Ingredients.....	95.0%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

CAUTION

STORE IN A DARK PLACE

KEEP FROM FREEZING

E.P.A. REG # 9804-9

E.P.A. Est. No. 9804-OK-1



For Organic Use

Net Contents: 5 gallons

TO SANITIZE CLEAN SHELL EGGS INTENDED FOR FOOD OR FOOD PRODUCTS

- 1) Preparation of sanitizing solution: Prepare an activated working solution containing 100-200 ppm available chlorine dioxide.
- 2) Spray eggs thoroughly with activated solution making sure surface area is thoroughly wet for at least one (1) minute and allow to drain. Solution must be equal to or warmer than the eggs, but not to exceed 130° F.
- 3) Eggs that have been sanitized with this chlorine dioxide compound may be broken in the manufactory dry before casing or breaking. Never reuse activated solutions.

TO CONTROL THE BUILDUP OF SLIME AND ODOR CAUSING BACTERIA IN FEED WATERS

- 1) Feed water should be treated at the rate of 0.4 fl. oz. of ProOxine® per 30 gallons of water (5ppm available ClO₂) and may be injected or batch loaded.
- 2) Feed water storage tanks should be sufficiently sealed to prevent outside contamination and direct sunlight.

STORAGE AND DISPOSAL

Product 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: Do not reuse or refill this container. Offer for recycling if available. Offer for reconditioning if appropriate. Triple rinse container, or equivalent, promptly after emptying. **Triple rinse as follows:** Empty the remaining contents into application equipment or a mix tank and drain for ten seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this process two more times.

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: CAUTION: Causes moderate eye irritation. Harmful if swallowed. Harmful if inhaled. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or going to the restroom. Remove contaminated clothing and wash before reuse. Handlers applying chlorine dioxide in an occupational setting must wear gloves.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and 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 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

FIRST AID

If in eyes	- Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes then continue rinsing eye. - Call a poison control center or doctor for treatment advice.
If swallowed	- Call a poison control center or doctor immediately for treatment advice. - Have 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.
If inhaled	- 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 treatment advice.
If on skin or clothing	- 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.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For 24 hour emergency information on this product call NPHC at 800-858-7378

For 24 hour transportation emergency information on this product call Chemtrec at 1-800-424-9300 (U.S., Canada, Puerto Rico, Virgin Islands) or 703-527-3887 (All Other Areas)

Seller expressly warrants that the product conforms to its chemical description. To the extent consistent with applicable law, seller makes no other warranties, either express or implied, including, but not limited to, the warranties of merchantability or fitness for a particular purpose or use, that extend beyond the statements made on this label.