



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 5, 2012

Gary E. Gaumer
Preserve International
P.O. Box 17003
Reno, NV 89511

Subject: IODIS
EPA Registration Number: 66171-10
Letter Date: February 1, 2012
EPA Receipt Date: February 6, 2012

Dear Mr. Gaumer:

The label amendment, submitted in connection with registration under section of the federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is accepted with conditions.

Proposed Amendment

- Label Amendment: ATP Failure-Removal of *Pseudomonas aeruginosa* and *Staphylococcus aureus* and Hospital/Broad Spectrum Disinfection Claim

Conditions

Revise the label as follows:

- 1.) Revise the first claim under the heading to read, "**Limited** Disinfectant-Cleaner-Sanitizer-Deodorizer," since the product is efficacious against gram-negative bacteria only when used as a disinfectant.
- 2.) Revise the claim under the "Disinfection" directions to read "IODIS is a proven "one-step cleaner-*limited* disinfectant-sanitizer-deodorizer ..."
- 3.) Delete the virucidal claim against Avian Influenza (H3N2) since the product is no longer a broad spectrum disinfectant.
- 4.) Revise 3rd and 6th statements under the "Precautionary Statements" to read "Causes *irreversible* eye damage ..." and "Wash thoroughly with soap and water after handling *and before eating, drinking, chewing gum, smoking tobacco, or using the toilet.*"

CONCURRENCES

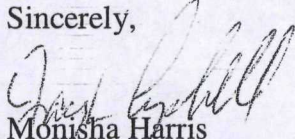
SYMBOL							
SURNAME							
DATE							

General Comments

A stamped copy of the label is enclosed for your record. Submit a final printed label before selling or distributing the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Adam Heyward via email at heyward.adam@epa.gov or by telephone at (703) 347-0274 during the hours of 6:00 am to 2:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Monisha Harris
 Product Manager (32)
 Regulatory Management Branch II
 Antimicrobials Division (7510P)

Enclosure: Stamped Label

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. For disinfection remove gross filth or heavy soil. Apply IODIS with a cloth, mop or mechanical coarse spray device. When applied with a mechanical coarse spray device, surface must be sprayed until thoroughly wetted. Treated surfaces must remain wet for 10 minutes. Fresh solution must be prepared daily or more often if the solution becomes diluted or soiled.

IODIS is a proven "one-step" cleaner-disinfectant-sanitizer-deodorizer in the presence of moderate amounts of organic soil and 400ppm hard water.

Disinfection - Veterinary Clinics, Fish Hatcheries, Industry, Schools, Farm Premises, Poultry Houses, Food Processing Plants, and Kitchens and Lunchrooms:

Remove gross filth or heavy soil. Apply 1/2 oz. per gallon IODIS to walls, floors and other hard (inanimate) non-porous surfaces such as tables, chairs, countertops, glazed tile, glazed porcelain and bed frames. Allow surfaces to remain wet for at least 10 minutes. For heavily soiled areas, a preliminary cleaning is required.

For farms and poultry use, prior to disinfection, all poultry, other animals and their feeds must be removed from the premises. This includes emptying all troughs, racks and other feeding and water appliances. Remove all litter and droppings from floors, walls and other surfaces occupied or traversed by poultry or other animals.

After 10 minutes disinfection, ventilate buildings, coop and other closed spaces. Do not house poultry, or other animals or employ equipment until treatment has been absorbed, set or dried.

TO CLEAN AND DISINFECT TOILET BOWLS AND URINALS:

Flush toilet. Add directly to the toilet bowl, 1 ounce iodis per gallon water present. Brush to cover all bowl surfaces including under the rim. Allow disinfectant to remain for at least 10 minutes. Flush toilet. Rinse metal parts with water after disinfecting to prevent corrosion.

SANITIZING MEAT AND FOOD PROCESSING EQUIPMENT AND UTENSILS:

Remove heavy soils by flushing, scraping, or mopping. Wash with 1 oz. per gallon of IODIS (or other good cleaner). Rinse with clean water and sanitize surfaces with 1 oz. IODIS per 5 gallons of water. (25ppm titratable iodine). Surface must remain in contact with solution for 1-2 minutes. Drain well and air dry. No potable water rinse is required.

SANITIZING FOOD GRADE EGG SHELLS:

To sanitize clean shell eggs intended for food or food products, spray with a solution of 1 ounce of product in 5 gallons of water (providing 25 ppm active). The solution must be equal to or warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs that have been freshly washed may be sanitized with this compound only if the eggs are rinsed prior to application of the compound. A subsequent potable water rinse is not required. Eggs must be reasonably dry before casing or breaking. The solution must not be reused for sanitizing eggs.

SANITIZING POULTRY AND LIVESTOCK DRINKING WATER:

Add 1 ounce of IODIS per 10 gallons of drinking water.

SHOE BATH SANITIZER:

To prevent cross contamination of organisms into animal areas, scrape shoes and place in a 3 oz. per gallon solution of IODIS for 30 seconds prior to entering area.

DEODORIZING:

IODIS destroys many odors as it sanitizes and disinfects. For general deodorant applications (garbage pails, refuse containers, etc.), swab surface to be treated with a solution containing 1/2 ounce iodis per gallon of water. Allow treated surfaces to drain and air dry.

SANITIZING MILKING EQUIPMENT UTENSILS AND BULK TANKS:

Before and after each milking, flush milking equipment, utensils, and bulk tanks with a solution of 1 ounce iodis per 5 gallons of water (providing 25ppm titratable iodine). Allow a 1-2 minute contact time. Drain thoroughly and air dry before use.

REMOVAL OF MILKSTONE AND HARD WATER DEPOSITS:

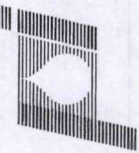
Yellow color may appear on equipment after the first use of IODIS. This may indicate the presence of milkstone or hard water deposits. Remove these by applying a solution containing equal parts of IODIS and lukewarm water. Wait 2-3 minutes, brush and then rinse with potable water. Daily use of IODIS will help prevent the formation of milkstone and hard water deposits.

ACCEPTED
with COMMENTS
EPA Letter Dated:

APR -5 2012

Salmonella enterica A.T.C.C. 10708
Aspergillus fumigatus A.T.C.C. 36607
Escherichia Coli F18

Manufactured Under the Federal Insecticide, Fungicide and Rodenticide Act as



PRESERVE
INTERNATIONAL
EPA Reg. No. 66171-10

Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com

IODIS

Disinfectant-Cleaner-Sanitizer-Deodorizer
With Organic Soil and 400 ppm
Hard Water Tolerance for Industrial,
Schools, Kitchens and Lunch Rooms, Restrooms,
Food Processing Plants, and Dairy

Active Ingredient

Iodine* 1.75%

Inert Ingredients 98.25%

*from Nonylphenoxypoly (ethyleneoxy) ethanol-iodine complex

KEEP OUT OF REACH OF CHILDREN

DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

FIRST AID

IF IN EYES: Hold eye 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 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.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further 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 the poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

SANITIZING GLASSES, DISHWARE, POTS, PANS, AND UTENSILS IN FOOD SERVICE OPERATIONS:

1: Pre-rinse or pre-scrape equipment and utensils. If needed, pre-soak to remove gross food particles and soil.

2: Wash equipment and utensils in lukewarm water that contains adequate amount of a good detergent or cleaner. Keep this water clean by changing it frequently.

3: Rinse equipment and utensils free of wash water prior to sanitization.

4: Sanitize equipment and utensils by immersing them in a solution of 1 ounce iodis per 5 gallons of water (providing 25ppm titratable iodine). Allow 1-2 minutes contact time (or longer if required by local sanitation codes). Fresh solution should be prepared if the solution becomes diluted or soiled. Use an approved iodine test kit to check for proper concentrations.

5: After required contact time of 1-2 minutes or more, allow equipment and utensils to drain and then air dry. Do not rinse before use.

SANITIZING PREVIOUSLY CLEANED FOOD CONTACT SURFACES:

Sanitize previously cleaned and rinsed hard, non-porous surfaces such as glass, metal, plastic and porcelain with a solution of 1 ounce iodis per 5 gallons water. Immerse equipment with sanitizing solution and allow 1-2 minutes of contact time. Drain solution from equipment; do not rinse. Iodis used at 1 ounce per 5 gallons of water provides 25ppm titratable iodine and does not require a final rinse with potable water in accordance with Federal Food Additive regulation 178.1010.

EPA Reg. No. 66171-10
EPA Est. No. 66171-TN-001, 66171-CA-001

NET CONTENTS:

NFPA HAZARD CLASSIFICATION		HEALTH FIRE REACTIVITY SPECIFIC	
Health	Fire	Reactivity	Specific
2	0	0	Acid

Batch No.:

FOR SANITIZING DAIRY EQUIPMENT AND UTENSILS:

1: Wash the equipment to be sanitized using a Preserve International manual cleaner. Be sure to follow label directions. Rinse and allow to drain.

2: Prepare a solution by mixing 1 ounce of Iodis sanitizer for each 5 gallons of water, or add 1/2 ounce of sanitizer per 10 quarts of water. This will provide 25ppm titratable iodine.

3: Immerse equipment: milking claws, liners, teat cups, into solution making sure that all surfaces are in contact with the solution. A contact time of 1-2 minutes is required.

4: For equipment that can't be immersed (bulk coolers, receiver groups, etc.) coarse spray a 25ppm iodine solution onto all pre-cleaned surfaces for a sparkling, spot free shine.

5: Allow solution to air dry.

6: Prepare a fresh solution if sanitizing solution fades noticeably or becomes diluted or soiled.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS & DOMESTIC ANIMALS

DANGER CORROSIVE. Causes eye damage and skin irritation. Harmful if swallowed. Do not get in eyes, on skin or on clothes. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling. Avoid contamination of food and foodstuffs. Avoid breathing spray mist. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and aquatic organisms. 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.

PHYSICAL AND CHEMICAL HAZARDS: Do not use, pour, spill or store near heat or open flame.

STORAGE AND DISPOSAL Do not contaminate water, food, or feed by storage and disposal

Storage: Store only in tightly closed, original container in a secure area inaccessible to children. Do not contaminate water, food, or feed by storage or disposal.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the hazardous waste representative at the nearest EPA Regional Office for guidance.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. (For 5 gallons or less) 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 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. 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 procedure two more times.

General: Consult Federal, State or local disposal authorities for approved alternative procedures.

DOT SHIPPING NAME
Corrosive Liquid, n.o.s.
(Contains Phosphoric Acid), 8,
UN1760, PG III