

65020-4

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 4 2003

Mr. Alan Summer
BioSentry, Inc.
1481 Rock Mountain Boulevard
Stone Mountain, GA 30083

Subject: Guardall Iodine Disinfectant
EPA Registration Number 65020-4
Application Date: June 12, 2003
Receipt Date: June 26, 2003

Dear Mr. Summer:

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

- To update the "first aid" statement in accordance with PR Notice 2001-1

Conditions

- You must provide a Hotline Telephone Number under the First Aid Statement as per PR Notice 2001-1.
- The correct name for this product is "Guardall Iodine Disinfectant" and not "BioSentry® Iodine Disinfectant". If you wish to change the name of your product, you must submit to the Agency an amendment requesting a product name change.

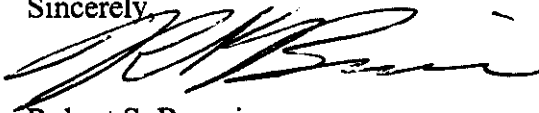
General Comments

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							
SURNAME							
DATE							

Should you have any questions or comments concerning this letter, please contact Delores Williams at (703) 308-6372.

Sincerely,



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

BioSentry® Iodine Disinfectant

HOSPITAL STRENGTH FOR ONE-STEP CLEANING AND DISINFECTION

Food Plants - Livestock Buildings - Hospitals - Veterinary Clinics

- No rinse food plant sanitizer
- Poultry drinking water sanitizer

BACTERICIDE, VIRUCIDE*

*Kills Herpes Simples Type II when used as directed for disinfection

ACTIVE INGREDIENTS:

alpha-(p-nonylphenyl)-omega-hydroxypoly
(oxyethylene)-iodine complex 18.05%
(Providing 1.75% titratable iodine)

INERT INGREDIENTS: 81.95%

TOTAL INGREDIENTS: 100.00%

EPA REG NO 65020-4

EPA EST NO 65020-GA-1

KEEP OUT OF REACH OF CHILDREN DANGER

See (left) (side) (right) (back) panel for Precautionary Statements and First Aid

FOR MEDICAL, INDUSTRIAL, COMMERCIAL AND AGRICULTURAL USE ONLY

MANUFACTURED BY:

BioSentry, Stone Mountain, Georgia, 30087

NET CONTENTS: (as indicated on container) 2003

ACCEPTED
with COMMENTS
EPA Letter Dated:
SEP 4 2003
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 65020-4

DIRECTIONS

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

APPLICATION INFORMATION

For use on hard, non-porous, inanimate surfaces (glass, stainless steel, galvanized metal, porcelain, linoleum, tile, enameled and finished wood surfaces). Use on walls, floors, appliances, furnishings, utensils and equipment.

Prepare fresh solutions daily. Do not reuse solutions. Discard solutions that are visibly soiled. Apply use solutions by flooding, immersion, swabbing, mopping or brushing to thoroughly wet all surfaces.

FOR DISINFECTION

In hospitals, nursing homes, food plants, commercial freezers, restrooms, restaurants, and veterinary clinics, farm premises and poultry houses: Use 1 oz. of Iodine Disinfectant in 2 gallons of water (4 ml/ liter) for one-step cleaning and disinfecting of light and moderately soiled surfaces. Heavily soiled surfaces should be cleaned and rinsed before disinfecting. For effective action, surfaces must remain wet for at least 10 minutes.

Food contact surfaces and all surfaces in edible food processing areas of Federally inspected meat and poultry plants must be rinsed with potable water before reuse when using Iodine Disinfectant at this concentration. Always carefully protect or remove food and packaging materials from the area before disinfecting.

For farms and poultry use: Remove all animals, poultry and feed from premises. Remove all litter and manure from surfaces occupied or traversed by livestock. Empty all troughs, racks, and other feeding and watering equipment. Then clean and disinfect as above. Ventilate buildings, coops and other closed spaces. Do not house animals or poultry until treatment has been absorbed, set or dried.

Disinfecting toilet bowls and urinals: Remove gross soils from surfaces with bowl brush. Add 1 oz. of Iodine Disinfectant to the bowl water. Use brush or swab to thoroughly clean bowl surfaces, especially under the rim. Flush commode or urinal several times and rinse bowl brush well.

Sanitizing of non-food contact surfaces: Such as walls, floors, desk and counter tops, telephone receivers, door knobs, chairs, toilet seats, bathroom sinks, tubs and shower stalls, in offices, hotels, industrial and commercial buildings, and non-critical areas of hospitals and nursing homes: clean and sanitize in one operation by spraying or wiping a solution of 1 oz. of Iodine Disinfectant in 5 gallons of water onto the surface to be sanitized. Allow solution contact for 5 minutes before wiping clean or rinsing. If surfaces are heavily soiled, preclean before sanitizing.

Sanitization of poultry drinking water: Add 1 ounce of Iodine Disinfectant to every 10 gallons of drinking water (8 ml/ 10 liters). Regular use in the drinking water also helps control slime and mineral deposits in waterers.

Sanitization of meat & food processing equipment and utensils: Remove gross soils by flushing, scraping or mopping. Preclean surfaces with 1 oz. of Iodine Disinfectant per gallon of water (8 ml/ liter) or with another suitable cleaner. Rinse well. Sanitize with 1 oz. of Iodine Disinfectant in 5 gallons of water (8 ml/ 5 liters) (25 ppm titratable iodine). Sanitizing solution

should contact surfaces for 1-2 minutes. Drain well and air dry. Rinsing is not required.

Hand Sanitization in Meat and Poultry Processing Plants: For sanitizing hands of food handlers, rinse hands with water and immerse hands in a 1 oz. per 5 gallons of water (8 ml/ 5 liters) sanitizing solution (25 ppm titratable iodine) for 30 to 60 seconds.

Shoe Bath Sanitization: To help prevent tracking disease organisms into poultry houses, farrowing houses and hog barns, place a shoe bath with 3 ounces of Iodine Disinfectant per gallon of water (24 ml/ liter) inside the doorway. Scrape off shoes outside doorway and stand in shoe bath for 30 seconds prior to entering.

For Cleaning Sows: Before placing sow in farrowing pens or crates, scrub down flanks and udder with lukewarm solution of 1 ounce of Iodine Disinfectant per gallon of water (8 ml/ liter). Use a soft-bristled brush. Let sow drain dry and do not rinse until just before farrowing.

In Retort Cooling Water For Canning Operations: Depending on the need, use 1 oz. of Iodine Disinfectant in each 5-10 gallons (0.8-1.6 ml/ liter) of retort cooling water to control odor or slime. Add at the start of operations and as needed thereafter to maintain a titratable iodine reading of 12-25 ppm in the cooling water.

Deodorant: Iodine Disinfectant destroys many odors as it sanitizes and disinfects. For general deodorant applications (garbage pails, refuse containers, etc.) swab on a solution of 1 ounce of Disinfectant per gallon of water (8 ml/ liter).

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER. Corrosive. Harmful or fatal if swallowed. Causes eye damage and skin irritation. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and rubber gloves when handling. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse. Avoid contamination of food.

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.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes.

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

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Epa draft label update 061203

vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

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.

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

(Note to reviewer: If the container size is one gallon or less, the following storage and disposal statements will be used.)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

(Note to reviewer: If container is greater than one gallon, the following environmental hazards and storage and disposal statements will be used.)

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.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE:

Do not store on side. Avoid creasing or impacting of side walls.

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 DISPOSAL

Triple rinse (or equivalent). Then offer for recycling or reconditioning or, if allowed by state and local authorities by burning. If burned, stay out of smoke.

ACCEPTED
with COMMENTS
EPA Letter 88-011
EPA Reg. No. 65020-4
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 65020-4