

65020-7

1/20/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 20, 2004

Alan Sumner
Technical Director
BioSentry
1481 Rock Mountain Blvd.
Stone Mountain, GA 30083-9986

Subject: BioPhene™ Liquid Disinfectant
EPA Registration No. 65020-7
Application Date: December 4, 2003
EPA Received Date: December 5, 2003

Dear Mr. Sumner:

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:

Proposed Amendment

- Revised labeling in response to Agency letter dated September 11, 2003

Conditions

1. On Page 3, delete the statement "...and other similar hard surfaces..." Use sites must be specific and this statement is too broad.
2. On Page 3, revise the statement "...hard, non-porous surfaces such as restrooms..." to read "...hard, non-porous surfaces: restrooms..."

CONCURRENCES

| | | | | | | | |
|---------|---------|--|--|--|--|--|--|
| SYMBOL | 7510c | | | | | | |
| SURNAME | John | | | | | | |
| DATE | 1-20-04 | | | | | | |

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three(3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling. Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,



Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)

BioSentry[®] BioPhene[™] Liquid Disinfectant

DISINFECTANT-CLEANER

Proven Effective as a One-Step Cleaner-Disinfectant in the Presence of 5% Organic Serum for Poultry, Swine, Animal Care Facilities, Livestock and Veterinary Uses.
DILUTION: 1 to 256 (one-half ounce per gallon)

ACTIVE INGREDIENTS:

| | |
|-------------------------------|----------------|
| o-Phenylphenol..... | 7.92% |
| o-Benzyl-p-chlorophenol..... | 9.97% |
| p-tert-Amylphenol..... | 1.95% |
| INERT INGREDIENTS..... | 80.16% |
| TOTAL INGREDIENTS..... | 100.00% |

EPA REG NO 65020-7

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 INDUSTRIAL AND COMMERCIAL USE ONLY

MANUFACTURED BY:

BioSentry, Stone Mountain, Georgia, 30083 USA

For general information, call 1-800-788-4246, Monday through Friday, 9 a.m. to 4 p.m. EST.

NET CONTENTS: (as indicated on container)

ACCEPTED
with COMMENTS

EPA Letter Dated:
JAN 20 2004

(Faint regulatory text)
65020-7

BACTERIA & FUNGI: Using AOAC Use dilution test, Bio-Phene is an effective disinfectant in 400 ppm hard water and 5% serum against the following bacteria and fungi.

- Alcaligenes faecalis
- Aspergillus fumigatus
- Brevibacter ammoniagenes
- Brucella abortus
- Candida albicans
- Enterobacter aerogenes
- Enterococcus faecium (Streptococcus faecalis)
- Escherichia coli
- Klebsiella pneumoniae
- Mycoplasma gallisepticum
- Mycoplasma iners
- Pasteurella multocida
- Pseudomonas aeruginosa
- Salmonella choleraesuis
- Salmonella enteritidis
- Salmonella schottmuelleri
- Shigella dysenteriae
- Staphylococcus aureus
- Streptococcus pyogenes
- Trichophyton mentagrophytes

VIRUSES: Using accepted virus propagation and hard surface test methods, Bio-Phene is effective at 1:256 in 400 ppm hard water and 5% serum against the following:

- Avian influenza
- Avian laryngotracheitis
- Canine parvovirus
- Infectious bronchitis
- Infectious bursal disease (Gumboro)
- Newcastle's disease
- Parainfluenza
- Porcine parvovirus
- Pseudorabies
- Swine PRRS virus
- Transmissible gastroenteritis
- Vesicular stomatitis virus

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Bio-Phene Liquid Disinfectant is a one-step germicide, fungicide, soapless cleaner and deodorant, effective in the presence of organic soil.

- To clean and disinfect hard non-porous surfaces, use ½ ounce of Bio-Phene per gallon of water (4 ml/ liter). Apply liquid with a mop, sponge, cloth or bowl mop to thoroughly wet surfaces. Prepare fresh solutions daily or when solution becomes visibly dirty.
- To clean badly soiled areas use 1½ ounce per gallon of water (12 ml/ liter).
- To disinfect, allow treated surfaces to stand for at least 10 minutes before wiping.
- To control mold and mildew growth on previously cleaned, hard, non-porous surfaces, use ½ ounce per gallon. Allow to dry without wiping. Reapply as new growth appears.

GENERAL FARM DISINFECTANT USES:

(1/2 ounce per gallon) (4 ml/ liter).

- (a) Remove all animals, poultry and feed from premises, trucks and enclosures.
- (b) Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities occupied or traversed by animals or poultry.
- (c) Empty all troughs, racks, and other feeding and watering appliances.
- (d) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- (e) Saturate all surfaces with the recommended solution for a period of 10 minutes.
- (f) Immerse all halters, ropes and other types of equipment used in handling and restraining animals or poultry, as well as the cleaned forks, shovels, and scrapers used for removing litter and manure, in the recommended use solutions.
- (g) Ventilate buildings, vehicles, trailers and other closed spaces. Do not house livestock or poultry or employ equipment until treatment has been absorbed, set or dried.
- (h) Thoroughly scrub treated feeding and watering equipment with detergent and rinse with potable water before reuse.

POULTRY HATCHERIES: Bio-Phene Liquid Disinfectant is effective for cleaning and disinfecting hatching, setters, buggies, trays, racks, equipment, utensils and other environmental surfaces in avian hatcheries. After initial cleaning and disinfecting with Bio-Phene diluted 1/2 ounce per gallon (4 ml/ liter), rinse and reapply a fresh disinfecting solution. Do not rinse again. One step cleaning and disinfecting is not recommended in hatcheries.

SANITIZING HATCHING EGGS: Use 1/2 ounce per gallon (4 ml/ liter) of Bio-Phene and apply by immersion, foaming, low pressure spraying, flushing or wet misting. Water temperatures from 75° F to 110°F (24°C to 44°C) are recommended. Use on hatching eggs only. Do not apply on eggs that are to be consumed.

FOR FOG APPLICATIONS: Thoroughly ventilate entire enclosed area following application. This fog generated by the BioSentry Fogger is very irritating to eyes, skin and mucous membranes. Do not enter, allow other persons to enter, house livestock, or use equipment in the treated area until ventilation is complete and any liquid has been absorbed, set, or dried. For entry into fogged areas before ventilation is complete and fog has completely dissipated, all persons must wear the personal protective equipment, including a full-face respirator, required for applicators and other handlers.

SANITIZING POULTRY HOUSES AND LIVESTOCK BUILDINGS USING BIO-PHENE THROUGH THE BIOSENTRY® FOGGER 185: After the house has been depopulated and cleaned as in (a) (b) (c) and (d) under "General Farm Disinfectant Uses", double check to be sure that all people, poultry, livestock and pets have vacated the building. Close all windows, doors, louvers, curtains, etc.,

making the house as closed and tight as possible. Mix 1 part Bio-Phene with two parts water in the reservoir of the BioSentry Fogger. With the setting on maximum output, fog the treatment into the room or building to be sanitized. (Use a total of 1 gallon (3.79 liters) of Bio-Phene for each 6000-8000 square feet of floor space. If the area is more than 25 feet high, use 2 gallons (7.6 liters) per 6000-8000 square feet of floor space. In multi-story buildings, the application must be repeated for each floor that is to be sanitized). The Fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the Fogger may be inserted through a suitable opening in the door or building. The opening should be just large enough to accommodate the nozzle. After fogging, the building should be kept closed for twenty-four hours. After twenty-four hours, the fog should have settled and the house can now be opened and aired. The house should be opened for a minimum of twenty-four to forty-eight hours before it is repopulated with poultry or livestock.

NOTE: If feeders and waters were not removed from the premises during the treatment, or were not adequately covered to prevent contact with treatment, they should be washed with detergent and water before use for poultry or livestock.

SANITIZING HATCHERY ROOMS USING BIOSENTRY FOGGER 185: Close room off so fog is confined to room to be treated. Mix one (1) part Bio-Phene to five (5) parts water (1.8 liters to 9.0 liters of water) (1/2 gallon Bio-Phene to 2.5 gallons water). Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute for each 4,000 cubic feet of space in the room. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-2 hours in this environment.

INCUBATOR AND HATCHER FOGGING: Prepare a stock solution of 6 ounces Bio-Phene to 122 ounces water (1.8 liters to 3.6 liter). Fog 3-8 ounces (88-236 ml) of this into setters and hatching immediately after transfer. Repeat daily in setters and every 12 hours in hatcheries.

NOTE: *Discontinue hatcher treatments at least 24 hours prior to pulling the hatch.* Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). It is also satisfactory to fog setters and hatcheries with a 1/2 ounce per gallon (4 ml/ liter) solution of Bio-Phene on an hourly or every other hour basis. If this is done, fog for 30-90 seconds once per hour or once every two hours. Fogging is to be used as an adjunct to acceptable manual cleaning and disinfecting of room and machine surfaces.

VEAL, CALVING, HOG, CATTLE AND HORSE OPERATIONS: Between depopulations of facilities, cleaning and disinfection of pens, hatches, aisles, ventilation equipment, utensils and other environmental surfaces may be required. Flush soils from these areas and clean and disinfect with 1/2 ounce per gallon (4 ml/ liter) of Bio-Phene

Liquid Disinfectant. Take care to avoid spray and other contact with animals, feed or feed equipment or in water or watering devices. If spray is used on or contacts feeders or waterers, scrub them and rinse well with potable water before they are reused.

FARM BOOT BATH: Use 1 ounce per gallon (8 ml/ liter) in farm boot baths. Change solution daily and anytime it becomes visibly soiled. Use a nylon brush to clean soils from boots.

FOR HEALTH-CARE FACILITIES: At ½ ounce per gallon of water (4 ml/ liter), Bio-Phene Liquid Disinfectant is an effective cleaner and germicide for floors, walls, bedframes, bathroom fixtures, bathtubs, toilets, sinks, countertops and other similar hard surfaces in operating rooms, emergency rooms, patient rooms, laboratories, clinics and veterinary facilities.

FOR SCHOOLS, MOTELS, INSTITUTIONAL AND INDUSTRIAL USES: At ½ ounce per gallon of water (4 ml/ liter), Bio-Phene Liquid Disinfectant is an effective cleaner and disinfectant in areas that contain hard, non-porous surfaces such as restrooms, shower and bath areas, exercise facilities and garbage storage areas.

FOR SPRAY APPLICATIONS: Following application as a low pressure or high-pressure spray, do not enter or allow others to enter treated area until sprays have dried.

APPLICATION RESTRICTIONS: Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Harmful if swallowed, or absorbed through skin or inhaled. Do not get in eyes, on skin or clothing. Avoid contact with skin. Avoid breathing spray mist. Wear long-sleeved shirt and long pants, socks and shoes, goggles or face and chemical resistant gloves. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

Personal Protective Equipment (PPE):

Applicators and other handlers must wear

- Long-sleeved shirt and pants
- Socks plus shoes
- Goggles or face shield
- Chemical-resistant apron
- Chemical-resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, PVC, or viton, 14 mils).

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USER SAFETY REQUIREMENTS:

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS:

Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users should remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

PHYSICAL AND CHEMICAL HAZARDS:

Combustible. Do not use or store near heat or open flame.

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. Remove and wash contaminated clothing before reuse.

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.

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 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 (leak, fire and medical exposure only) on this product, call Infotrac at 1-800-535-5053 (US & Canada) or 1-352-323-3500 (all other areas).

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.

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(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 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.