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Mr. William E. Brown, Ph.D.
 BioSentry, Inc.
 1481 Rock Mountain Blvd.
 Stone Mountain, GA 30083

SUBJECT: BIO-PHENE LIQUID DISINFECTANT
 EPA Registration No. 65020-7
 Amendment of May 14, 1993

This is is response to your request to amend your labeling to add additional bacterial, fungicidal and virucidal claims with accompanying efficacy data. The following comments apply.

The submitted microbiological data developed by the Official Methods of Analysis of the AOAC, 14th edition may be relied upon to support the product effectiveness at a test dilution of 1:256 in the presence of 400 ppm of hard water and 5% horse serum when used on specified, hard, nonporous, inanimate surfaces which are thoroughly wetted and allowed to remain for at least 10 minutes with a single application.

See the enclosed study review for complete listing of acceptable microorganisms.

The label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable subject to the comments listed below. Submit five copies of the finished label before you release the product for shipment bearing the amended labeling.

A. On the center panel, delete the term "excellent" wherever it appears and replace it with the word "effective".

B. Under the use directions for general farm disinfectant, revise the wordings "...Treated surfaces must remain moist for at least 10 minutes for proper germicidal action..." to read "...Treated surfaces must remain saturated for at least 10 minutes for proper germicidal action...".

The highlighted microorganisms indicated on the right panel are acceptable as listed.

CONCURRENCES							
SYMBOL	7505C						
SURNAME	Frank						
DATE	10-20						

2014

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If you have any further questions, please contact Ms. Barbara Pringle at 703-305-6484.

Sincerely,



Ruth G. Douglas
Product Manager 32
Antimicrobial Program Branch
Registration Division (7505C)

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BioSentry®

BIO-PHENE™ LIQUID DISINFECTANT

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.

Disinfectant-Cleaner

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%

DILUTION: 1 to 256 (one-half ounce per gallon)

**KEEP OUT OF REACH OF CHILDREN
DANGER**

(See back panel for additional precautionary statements.)



**BioSentry®
Agricultural
Sanitation
Systems**

BioSentry®, Inc., Stone Mountain, GA 30083 USA

NET CONTENTS: _____ Gallons

AC with EPA
EPA
OCT
Under the Fungicide, was amended registered
65
BIOPHENE 5
7 42887 50

BEST AVA

Handwritten mark: "Fogger"

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

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

*To clean and disinfect hard surfaces, use 1/2 ounce of BioPhene per gallon of water. 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 1 1/2 ounces per gallon of water.

* 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 1/2 ounce per gallon. Allow to dry without wiping. Reapply as new growth appears.

For Health-Care Facilities: At 1/2 ounce per gallon of water, BioPhene Liquid Disinfectant is an excellent cleaner and germicide in operating rooms, emergency rooms, patient rooms, laboratories, clinics, veterinary facilities and animal care premises.

For Schools, Motels, Institutional and Industrial Uses: At 1/2 ounce per gallon of water, BioPhene 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.

GENERAL FARM DISINFECTANT USES: (1/2 OUNCE PER GALLON) (a) Remove all livestock and feeds from premises, trucks, coops or crates to be treated. (b) Remove all litter, bedding and manure from floors, walls and surfaces of facilities traversed or occupied by animals. (c) Empty all feeding devices and watering appliances. (d) Clean all surfaces with water or water and a compatible detergent. (e) Saturate all surfaces with this product diluted at 1/2 ounce per gallon using a brush, cloth, mop or mechanical spraying device. Small items (forks, shovels, scrapers) may be immersed. Treated surfaces must remain moist for at least 10 minutes for proper germicidal action. (f) Ventilate buildings, trucks, coops and other closed spaces. Do not house livestock or use equipment until treatment has thoroughly dried. (g) Thoroughly scrub treated feeding and watering equipment with detergent and rinse with potable water before reuse.

VEAL, CALVING, HOG, CATTLE AND HORSE OPERATIONS. Between depopulations of facilities, cleaning and disinfection of pens, hutches, 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 of BioPhene 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 in farm boot baths. Change solution daily and anytime it becomes visibly soiled. Use a nylon brush to clean soils from boots.

SANITIZING POULTRY HOUSES AND LIVESTOCK BUILDINGS USING BIOPHENE 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 BioPhene 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 of BioPhene for each 6000-8000 square feet of floor space. If the area is more than 25 feet high, use 2 gallons 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: This fog generated by the BioSentry Fogger is very irritating to eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone within twenty-four hours of the actual fogging. If the building must be entered, then, the individuals entering the building must wear a self-contained respirator approved by NIOSH/MSHA, goggles and long shirt sleeves and pants. If feeders and waterers 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 BioPhene to five (5) parts

water. (1/2 gallon BioPhene 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 BioPhene to 122 ounces water. Fog 3-8 ounces of this into setters and hatches immediately after transfer. Repeat daily in setters and every 12 hours in hatches. 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 hatches with a 1/2 ounce per gallon solution of BioPhene 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.

POULTRY HATCHERIES: BioPhene Liquid Disinfectant is excellent for cleaning and disinfecting hatches, setters, buggies, trays, racks, equipment, utensils and other environmental surfaces in avian hatcheries. After initial cleaning and disinfecting with BioPhene diluted 1/2 ounce per gallon, 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 of BioPhene and apply by immersion, foaming, low pressure spraying, flushing or wet misting. Water temperatures from 95° F to 110° F are recommended. Use on hatching eggs only. Do not apply on eggs that are to be consumed.

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

<i>Pseudomonas aeruginosa</i>	<i>Staphylococcus aureus</i>	<i>Salmonella choleraesuis</i>
<i>Salmonella enteritidis</i>	<i>Enterobacter aerogenes</i>	<i>Streptococcus pyogenes</i>
<i>Pasteurella multocida</i>	<i>Candida albicans</i>	<i>Shigella dysenteriae</i>
<i>Brevibacter ammoniagenes</i>	<i>Klebsiella pneumoniae</i>	<i>Trichophyton mentagrophytes</i>
<i>Enterococcus faecium</i>	<i>Escherichia coli</i>	<i>Alcaligenes faecalis</i>
(<i>Streptococcus faecalis</i>)	<i>Salmonella schottmuelleri</i>	<i>Brucella abortus</i>

Aspergillus fumigatus

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

<i>Pseudorabies</i>	Parainfluenza	Transmissible gastroenteritis
Infectious bronchitis	Canine parvovirus	Avian laryngotracheitis
<i>Mycoplasma iners</i>	<i>Mycoplasma gallisepticum</i>	Newcastle's disease
Infectious bursal disease (Gumboro)		

STORAGE & DISPOSAL

Store only in tightly closed, original container in a secure area inaccessible to children. Do not contaminate water, food, or feed by storage and disposal. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture, or rinseate 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.

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

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER
KEEP OUT OF REACH OF CHILDREN**

Corrosive: Causes eye damage and skin irritation. May produce severe burns. Harmful or fatal if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Avoid contamination of food. Wash thoroughly after handling.

Statement of Practical Treatment: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse. If swallowed, drink large quantities of water. Avoid alcohol. Call a physician immediately.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

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