

11725-9

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 17, 2003

Ms. Wendy A. McCombie,
Agent for Bio-Tek Industries, Inc.
122 C Street NW, Suite 740
Washington, DC 20001

Subject: ***Opti-Phene CleanerDisinfectant Deodorant***
EPA Registration No. 11725-9
Application Dated July 24, 2003

Dear Ms. McCombie:

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

Label Comments

1. Delete the word "Biodegradable" from the label (see EPA letter dated 2/4/03).

General Comment

A stamped copy is enclosed for your records.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or Lisa McKelvin at (703) 308-7496.

Sincerely,

A handwritten signature in cursive script that reads "Lisa McKelvin".

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

Enclosure

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. [Do not discharge effluent containing this product into lakes, ponds, streams, 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.]

DIRECTIONS FOR USE

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

General Precautions and 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. Following application as a low pressure or high pressure spray, do not enter or allow others to enter the treated area until sprays have dried. Thoroughly ventilate entire closed area after fogging applications. 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 the fog has been completely dissipated, all persons must wear the PPE, including a full-face respirator, required in the Precautionary Statement Section of this labeling for applicators and other handlers.

General Information:

OPTI-PHENE is a synthetic detergent with wide spectrum kill of gram positive and gram negative microorganisms, provides good cleaning and disinfecting in one operation, non-flammable and non-volatile use dilutions and excellent stability.

The OPTI-PHENE detergent system has been especially formulated to provide cleaning, wetting and penetration of soils and organic matter and easy rinsing of surfaces. Good foam is obtained at 1 oz. per gallon of water (1:128) to provide prolonged contact time.

OPTI-PHENE at 1 ounce per gallon of water (1:128) provides residual control of odor-causing bacteria in the presence of moisture.

OPTI-PHENE is recommended for use when used as directed on ceramic and glazed tile surfaces, stainless steel, aluminum, chrome, galvanized metal, glass, and other non-porous surfaces such as treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), polystyrene, vinyl, fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

OPTI-PHENE at 1 oz. per gallon of water (1:128) is suited for disinfecting and cleaning all environmental surfaces in Hospitals, Medical Research Centers, Health Care Facilities, Schools, Animal Care Facilities and Research Centers, Laboratories, Veterinary Facilities, Zoos, Kennels and Swine Operations. In Poultry and Turkey barns, Breeder and Laying Operations, Poultry House Grow-out Operations, Hatcheries - in hatchers and setters, humidifying systems and ceiling fans, live haul equipment, chick buses, transfer trucks, trays, coop washing, polyethylene chick boxes, foot pans and feed bins.

Toxicity tests required by the U.S. Environmental Protection Agency for OPTI-PHENE are done, in conformity with the FDA and EPA Good Laboratory Practice Regulations.

Proven effective as a disinfectant by the following tests: A.O.A.C. (use dilution test method) in conformance with the 14th Edition 1984. The following organisms tested at 1,000 ppm water hardness as calcium carbonate and 10% blood serum as organic soil:

Mycobacterium bovis (BCG) ATCC #35743 A.O.A.C. Tuberculous Test
Staphylococcus aureus, Methicillin resistant (MRSA) ATCC #25923
Salmonella paratyphi B ATCC #9281
Staphylococcus aureus ATCC #6538
Salmonella schottmulleri ATCC #8759
Enterobacter aerogenes ATCC #13048
Streptococcus pyogenes ATCC #19815
Salmonella typhimurium ATCC #13311
Shigella sonnei ATCC #25931
Klebsiella pneumoniae ATCC #4352

• The following Viruses tested in accordance with U.S. Environmental Protection Agency Pesticide Assessment Guidelines on inanimate environmental surfaces. Tested at 1,000 ppm water hardness as calcium carbonate and 10% blood serum as organic soil:

Vaccinia Virus ATCC # VR-325 Human adenovirus ATCC # VR-5
Human Immunodeficiency Virus, HTLV-IIIb strain of HIV-1 (AIDS virus)

OPTI-PHENE has also been tested according to A.O.A.C. use dilution test methods and proven effective as a disinfectant against the following organisms at 500 ppm water hardness as calcium carbonate and 5% blood serum as organic soil. All tests done in accordance with the 14th Edition, 1984.

Trichophyton mentagrophytes ATCC #9533 A.O.A.C. Fungicidal Test
Escherichia coli ATCC #11228 Salmonella choleraesuis ATCC #10708
Pseudomonas aeruginosa ATCC #15442

• The following Viruses tested in accordance with U.S. Environmental Protection Agency Pesticide Assessment Guidelines on inanimate environmental surfaces. Tested at 500 ppm water hardness as calcium carbonate and 5% blood serum as organic soil:

Herpes simplex Type 1 Human Influenza A/Hong Kong Virus

General Use Directions:

OPTI-PHENE is effective against all organisms tested at 500 ppm water hardness and 5% blood serum. NOTE: OPTI-PHENE is also effective against a number of organisms (identified in the left panel) under more stringent conditions of 1,000 ppm water hardness and 10% blood serum.

1. To clean, disinfect and deodorize walls, floors, tiles, restroom fixtures, drinking fountains, sinks, stoves, garbage cans, refrigerators, janitor closets, other hard, non-porous environmental surfaces. Remove gross filth and heavy soil with preliminary cleaning step prior to application of OPTI-PHENE. Apply solution of 1 oz. of OPTI-PHENE per gallon of water (1:128) with a sponge, mop, mechanical spray device or foaming apparatus, making sure that all surfaces are wetted thoroughly. Allow surface to remain wet for 10 minutes.

2. To clean and disinfect such articles as combs, brushes, hats, scissors, and rubber goods: Wipe articles clean and soak for 10 minutes in a solution containing 1/2 oz. of OPTI-PHENE per gallon of water (1:128).

3. To disinfect fabrics such as sheets, linens, aprons and uniforms: First rinse to remove gross filth or heavy soil, then soak for 10 minutes in a solution containing 1 oz. of OPTI-PHENE per gallon of water (1:128).

OPTI-PHENE

CLEANER • DISINFECTANT • DEODORIZER
STAPHYLOCIDAL • PSEUDOMONACIDAL • SALMONELLACIDAL •
TUBERCULOCIDAL • VIRUCIDAL • FUNGICIDAL • CONDUCTIVE • BIODEGRADABLE

ACTIVE INGREDIENTS:

para-tertiary-Amylphenol 5.25%
ortho-Benzyl-para-chlorophenol 3.00%
ortho-Phenylphenol 3.00%

INERT INGREDIENTS: 88.75%
TOTAL: 100.0%

EPA REG. NO. 11725-9

EPA EST. NO. 11725-GA-1

KEEP OUT OF REACH OF CHILDREN DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. Harmful if swallowed, absorbed through skin or inhaled. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and handlers must wear:

- Long-sleeved shirt and long pants,
- socks plus shoes
- goggles or face shield
- chemical-resistant gloves (such as barrier laminate, nitrile rubber, neoprene rubber and viton)

In addition, applicators and handlers exposed to fog during fogging applications, and until fog has dissipated and the enclosed area has been thoroughly ventilated, must wear a full face dust/mist filtering respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister for pesticides (MSHA/NIOSH approved respirator with an organic-vapor cartridge or canister with any N, P, R or H prefilter)

Follow manufacturers' instructions for cleaning/maintaining PPE. If no such instructions exist 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.
 - Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
 - Remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible wash thoroughly and change into clean clothing.

FIRST AID

IF ON SKIN OR ON 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 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 INHALED:	• Remove person from the exposure area. If breathing is difficult, give artificial respiration. • Call a poison control center or doctor for treatment advice.
IF SWALLOWED:	• Call 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.
In case of emergency call toll free: 1-855-216-4174. 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 hypoxia may be needed.

PHYSICAL AND CHEMICAL HAZARDS with COMMENT

Do not apply this product in or on electrical equipment due to the possibility of shock hazard.

CONDUCTIVE

OPTI-PHENE has been tested by Hood Patterson-Dewar, Electrical Testing Engineers, for its effect on conductive flooring. The method used conforms to the specifications known as NFPA Standard No. 56A, published by the National Fire Protection Association, Second Edition, 1987. OPTI-PHENE meets the requirement of NFPA Standard No. 56A.

Manufactured by: BIO-TEK INDUSTRIES, Inc.
1380 West Marietta Street, N.W.
Atlanta, GA 30348
Telephone 404-799-2550
FAX: 404-799-2058

Net Contents _____

4. To clean gross filth or heavy soil on environmental surfaces prior to disinfection, use 1 oz. of OPTI-PHENE per gallon of water (1:128).

Directions For Fogging (Wet Misting) Operations:

OPTI-PHENE is recommended for fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures.

1. The recommended dilution is 1 oz. per gallon of water (1:128).
2. All food and packaging items must be removed or carefully protected.
3. Set the automatic timer on the Bio-Tek Fogger to fog for 8 minutes for 1,000 cu. ft. and leave the room.
4. Allow at least 2 hours before entering the area that has been fogged.
5. Treated food contact surfaces must be thoroughly scrubbed with OPTI-PHENE at 1 oz. per gallon (1:128) and rinsed with potable water prior to reuse.

Hospital Use Directions:

1. To clean, disinfect, and deodorize floors, walls, and other non-porous environmental surfaces: Use 1 oz. of OPTI-PHENE per gallon of water (1:128). Apply with cloth, sponge, mop, mechanical spray device, making sure all surfaces are wetted thoroughly. Allow surface to remain wet for 10 minutes. For heavily soiled areas a preliminary cleaning is required. Remove gross soil and proceed per General Use Directions.
2. When completed rinse with clear water.
3. OPTI-PHENE is an effective tuberculocide against Mycobacterium bovis in 10 minutes at 20°C when used on hard, non-porous inanimate environmental surfaces. Follow above directions, including removal of gross filth or heavy soil prior to application of OPTI-PHENE.

KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) associated with AIDS.

Special Instructions For Cleaning And Decontamination Against HIV Of Surfaces/ Objects Soiled With Blood/Body Fluids:

Personal Protection: When handling items soiled with blood or body fluids, use protective equipment such as disposable rubber gloves, gowns, masks or eye coverings. **Cleaning Procedures:** Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** To kill HIV-1 (AIDS virus) a contact time of 10 minutes at room temperature must be allowed. **Disposal Of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

This product is not to be used on as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

Directions: For Use In Farm Premises:

1. Do not use in milking stalls, milking parlors, or milk houses (for phenolics, cresylic acid, and pine oils).
2. Remove all animals and feed from premises, vehicles, and enclosures.
3. 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.
4. Remove all troughs, racks, and other feeding and watering appliances.
5. Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.
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7. Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.
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10. Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Directions For Use In Poultry Premises:

1. Remove all poultry and remove litter, manure, bedding, coops, and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
3. Remove all troughs, racks, and other feeding and watering appliances.
4. Thoroughly scrub all surfaces with soap or detergent and rinse with water.
5. Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.
6. Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.
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STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.
Pesticide Storage: Store only in original container away from heat or open flame. Keep container closed when not in use. Storage must be secured sufficiently to make product inaccessible to children or persons unfamiliar with its proper use.
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. Do not reuse empty container.

OP-07-00-2003

OCT 17 2003
Under the Federal Insecticide,
Fungicide and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 11725-9

Footnote 1: As per EPA PR Notice 95-1, the effluent discharge language appears only on containers with a net content greater than or equal to 5 gallons