

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 28 1995

Bio-Tek Industries, Inc.
1380 West Marietta Street, NW
Atlanta, GA 30318

Attention: Wendy A. McCombie
Agent

Subject: Opti-Phene Cleaner-Disinfectant-Deodorant
EPA Registration No. 11725-9
MOU Compliance Amendment dated February 28, 1995

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, will be acceptable provided that you make the labeling change list below before you release the product for shipment bearing amended label.

1. On the front panel, revise the EPA Reg. No. to read 11725-9.

A stamped copy of your labeling is enclosed for your records. Submit five (5) copies of the final printed label prior to release of the product for shipment.

If you have any question concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely,



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

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

2 7 8
[FRONTPANEL]

OPTI-PHENE

CLEANER * DISINFECTANT * DEODORANT
STAPHYLOCIDAL * PSEUDOMONACIDAL * SALMONELLACIDAL
TUBERCULOCIDAL * VIRUCIDAL *
FUNGICIDAL *

ACTIVE INGREDIENTS:

1. para-tertiary-Amylphenol	5.25%
2. ortho-Benzyl-para-chlorophenol	3.00%
3. ortho-Phenylphenol	3.00%

INERT INGREDIENTS:	88.75%
Total	100.0%

EPA REG. NO. 11725-

EPA EST. NO. 11725-GA-1

ACCEPTED
with COMMENTS
in EPA Letter Dated:

KEEP OUT OF REACH OF CHILDREN

JUN 28 1995

DANGER

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

PRECAUTIONARY STATEMENTS:

11725-9

Hazards to Humans and Domestic Animals

Danger. Corrosive. Causes eye and skin damage or skin irritation. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed.

STATEMENT OF PRACTICAL TREATMENT

FIRST AID: In case of contact, immediately flush eyes or skin with plenty of water. For eyes, call a physician. Remove and wash contaminated clothing before reuse. If swallowed, drink promptly large quantities of water. Avoid alcohol and call a physician.

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

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 56A.

Manufactured by:

LOGO

BIO-TEK INDUSTRIES, INC.
1380 West Marietta Street, N.W.
Atlanta, GA 30318, USA
Telephone (404) 799-2050 Telex: 671-2844
FAX: 404-799-2055 FAX: 404-799-2058

DESCRIPTION

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 in use dilutions and excellent solubility.

The OPTI-PHENE foaming 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.

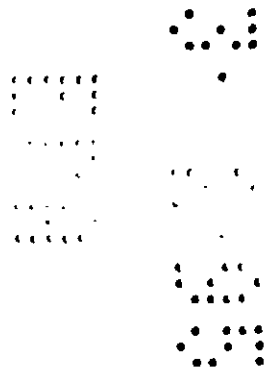
OPTI-PHENE at 1 oz. per gallon of water (1:128) is ideally suited for disinfecting and cleaning in all areas of Hospitals, Medical Research Centers, Health Care Facilities, Schools, Animal Care Facilities and Research Centers, Laboratories, Veterinary Facilities, Zoos, Kennels and Swine Operations. In 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 busses, transfer trucks, trays, coop washing, polyethylene chick boxes, foot pans and feed bins.

OPTI-PHENE is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. The recommended dilution is 1 oz. per gallon of water (1:128). Set the automatic timer on the BIO-TEK Fogger, fog for 6 minutes for 1,000 cu. ft. - leave the room. Allow at least 2 hours before entering area that has been fogged. All food and food packaging items must be removed or carefully protected. 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.

Toxicity tests required by the U.S. Environmental Protection Agency for OPTI-PHENE CLEANER-DISINFECTANT-DEODORANT have been done, in conformity with EPA Good Laboratory Practice regulations.

Proven effective as a disinfectant by the A.O.A.C. (use dilution test method) in conformance with the 14th Edition 1984. OPTI-PHENE is effective against the following organisms tested at 1000 ppm water hardness as calcium carbonate and 10% horse serum (as organic soil):

- Mycobacterium bovis (BCG) ATCC #35743
A.O.A.C. Tuberculocidal Test
- Staphylococcus aureus, Methicillin resistant ATCC #25923
- Staphylococcus aureus ATCC #6538
- Salmonella paratyphi B ATCC #9281
- Salmonella typhimurium ATCC # 13311



Salmonella schotmeulleri ATCC # 8759
Klebsiella Pneumoniae ATCC #4352
Streptococcus pyogenes ATCC #19615
Shigella sonnei ATCC # 25931
Enterobacter aerogenes ATCC #13048

+ The following Viruses tested in accordance with U.S. Environmental Protection Agency Pesticide Assessment Guidelines on inanimate environmental surfaces. Tested at 1000 ppm water hardness as calcium carbonate and 10% horse serum (as organic soil):

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

OPTI-PHENE is effective as a disinfectant against the following organisms at 500 ppm water hardness as calcium carbonate and 5% horse serum (as organic soil):

Trichophyton mentagrophytes ATCC #9533
A.O.A.C. Fungicidal Test
Salmonella choleraesius ATCC #10708
Pseudomonas aeruginosa ATCC #15442
Escherichia coli ATCC #11229

All tests were in conformance with the 14th Edition, 1984.

+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% serum (as organic soil):

Herpes simplex Type 1
Human Influenza A/Hong Kong Virus

[RIGHTPANEL]

DIRECTIONS FOR USE

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

This product is not to be used 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

HOSPITAL USE DIRECTIONS:

1. To clean, disinfect, and deodorize walls and other non-porous 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 surfaces. Follow above directions, including removal of gross filth or heavy soil prior to application of OPTI-PHENE.
4. 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 PROCEDURE: 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.

GENERAL USE DIRECTIONS:

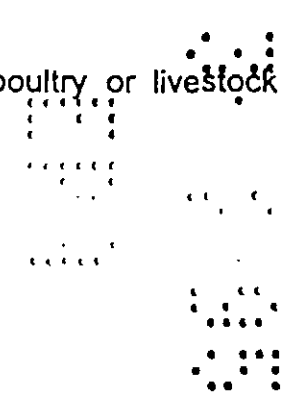
OPTI-PHENE is effective against all organisms listed at 500 ppm water hardness and 5% organic soil. NOTE: OPTI-PHENE is also effective against a number of organisms (identified in the left label panel) under the more stringent conditions of 1000 ppm water hardness and 10% organic soil.

1. To clean, disinfect and deodorize walls, floors, tables, drinking fountains, sinks, refrigerators, stoves, restroom fixtures, and garbage cans: Remove gross filth and heavy soil with a 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, razors, scissors, instruments and rubber goods: Wipe articles clean and soak for 10 minutes in a solution containing 1 oz. 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).
4. To clean gross filth or heavy soil on surfaces prior to disinfection, use 1 oz. of OPTI-PHENE per gallon of water (1:128).

DIRECTIONS FOR USE IN POULTRY HOUSE AND FARM PREMISE:

Do not use in milking stalls, milking parlors, or milk houses.

1. Remove all poultry, animals, and feed from the premises.
2. Remove all trucks, coops, crates, water troughs and feed racks.
3. Remove all gross soil, litter, manure, droppings from animals and poultry from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals and poultry.
4. Thoroughly clean and saturate all surfaces with a solution of 1 oz. of OPTI-PHENE per gallon of water (1:128), using conventional spraying methods.
5. Allow to remain in contact for at least ten minutes.
6. Immerse halters, ropes and other types of equipment used in handling and restraining animals, forks, shovels, scrapers used for removing litter and manure, in a solution of OPTI-PHENE at 1 oz. per gallon of water (1:128). Allow to remain in contact for 10 minutes.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers, and mangers with a solution of OPTI-PHENE at 1 oz. per gallon of water (1:128). Rinse with potable water before reuse.
8. Ventilate buildings, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.

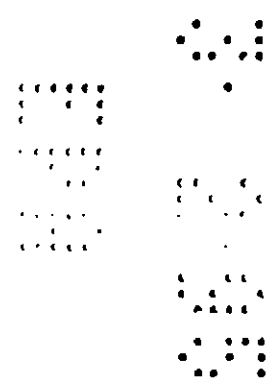


STORAGE AND DISPOSAL

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

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.

Net Contents _____ U.S. Gallons



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