

11725-8

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

AUG 21 2002

Ms. Wendy A. McCombie
Lewis & Harrison Consultants
Agent for Bio-Tek Industries Inc.
122 C Street, N.W., Suite 740
Washington, DC 20001

Subject: Revised label in response to EPA's letter
Tek-Phone Cleaner Disinfectant Deodorant
EPA Registration No. 11725-8
Your Application Dated July 29, 2002

Dear Ms. McCombie:

The following amendments, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are acceptable with comment.

Proposed Amendments:

- Revisions made per EPA letters March 5, June 27, 2002 and October 16, 2001
- Addition of Tanning beds to use sites

Label Comments

Per Pesticide Registration (PR) Notice 83-3 you must add "Pesticide Storage" instructions to the label. See information below:

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions considering, when applicable, the following factors:

Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

CONCURRENCES

SYMBOL	SURNAME	DATE					
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

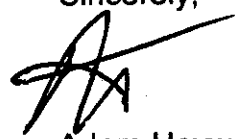
- Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage temperature, potential for breakage of glass, crushing or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
- Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
- Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
- General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
- General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

General Comment:

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed label before you release the product for shipment bearing the amended label.

If you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,



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

Enclosure

CONCURRENCES

SYMBOL							
SURNAME							

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:

TEK-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 solubility.

*After this product's use as a disinfectant, it will biodegrade in sewage systems and/or the environment.

The TEK-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 1/2 oz. per gallon of water (1:256) to provide prolonged contact time.

TEK-PHENE at 1/2 ounce per gallon of water (1:256) provides residual control of odor-causing bacteria in the presence of moisture.

TEK-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.

TEK-PHENE at 1/2 oz. per gallon of water (1:256) is suited for disinfecting and cleaning all environmental surfaces in Hospitals, Medical Research Centers, Health Care Facilities, Schools, Research Centers and Laboratories.

Toxicity tests required by the U.S. Environmental Protection Agency for TEK-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. All dilutions at 1:256. The following organisms tested at 1,000 ppm water hardness as calcium carbonate and 10% blood serum as organic soil:

- Vancomycin resistant enterococcus faecalis (VRE) ATCC #51299
- Mycobacterium bovis (BCG) ATCC #35743 A.O.A.C. Tuberculoicidal Test
- Staphylococcus aureus, Methicillin resistant (MRSA) ATCC #25923
- Salmonella paratyphi B ATCC #9281 Staphylococcus aureus ATCC #6538
- Salmonella schotmulleri ATCC # 8759 Enterobacter aerogenes ATCC #13048
- Streptococcus pyogenes ATCC #19615 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)

TEK-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. All dilutions at 1:256.

- 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

Manufactured by: BIO-TEK INDUSTRIES, Inc.
1380 West Marietta Street, N.W.
Atlanta, GA 30338
Telephone 404-799-2050
FAX: 404-799-2058
www.bio-tekusa.com

Net Contents _____

TEK-PHENE

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

ACTIVE INGREDIENTS:	
para-tertiary-Amylphenol	10.0%
ortho-Benzyl-para-chlorophenol	6.5%
ortho-Phenylphenol	6.0%
INERT INGREDIENTS:	77.5%
TOTAL:	100.0%

EPA REG. NO. 11725-8

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:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • 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 SWALLOWED:	<ul style="list-style-type: none"> • 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: 1-888-216-4174. 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 contra-indicate the use of gastric lavage. Measures against respiratory depression and convulsion may be needed.

NOTICE: This product contains a chemical known to cause cancer.

PHYSICAL AND CHEMICAL HAZARDS

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

CONDUCTIVE

TEK-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. TEK-PHENE meets the requirements of NFPA Standard No. 56A.

Hospital Use Directions:

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

Footnote 1: As per EPA PR Notice 98-10 the effluent discharge language appears only on containers with a net content greater than or equal to 5 gallons

1. To clean, disinfect, and deodorize floors, walls, and other non-porous environmental surfaces: Use 1/2 oz. of TEK-PHENE per gallon of water (1:256). 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. TEK-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 TEK-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 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 stentant/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.

General Use Directions:

TEK-PHENE is effective against all organisms listed at 500 ppm water hardness and 5% blood serum. NOTE: TEK-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, tables, restroom fixtures, drinking fountains, sinks, stoves, garbage cans, refrigerators, lanning beds and other hard, non-porous environmental surfaces: Remove gross filth and heavy soil with a preliminary cleaning step prior to application of TEK-PHENE. Apply solution of 1/2 oz. of TEK-PHENE per gallon of water (1:256) 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, and rubber goods: Wipe articles clean and soak for 10 minutes in a solution containing 1/2 oz. of TEK-PHENE per gallon of water (1:256).
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 1/2 oz. of TEK-PHENE per gallon of water (1:256).
4. To clean gross filth or heavy soil on environmental surfaces prior to disinfection, use 1/2 oz. of TEK-PHENE per gallon of water (1:256).

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 1/2 oz. of TEK-PHENE per gallon of water (1:256), 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 TEK-PHENE at 1/2 oz. per gallon of water (1:256). 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 TEK-PHENE at 1/2 oz. per gallon of water (1:256). 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

Do not contaminate water, food, or feed by storage or disposal. **Pesticide Storage:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **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.

ACCEPTED
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