

11725-8

10/16/2001

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OCT 16 2001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Stuart Heller, President
Bio-Tek Industries, Inc.
P.O. Box 93746
1380 West Marietta Street NW
Atlanta, GA 30318

Subject: Revised Label
Tek-Phene
EPA Registration No. 11725-8
Your Letter Dated October 2, 2001

Dear Mr. Heller:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following comments.

GENERAL COMMENTS

1. The subheading "Statement of Practical Treatment" must be changed to "First Aid." and the text revised as follows:

FIRST AID	
IF ON SKIN OR 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. - Call a poison control center or doctor for treatment advice.
IF SWALLOWED	<ul style="list-style-type: none"> - 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 by a Poison Control Center or doctor. - Do not give anything by mouth to an unconscious person
HOT LINE NUMBER	
1.	"In case of emergency call toll free (registrant fill in the number)."
2.	"Have the product container or label with you when calling a poison control center or doctor or going for treatment."
NOTE TO PHYSICIAN	
<p>"Probable mucosal damage may contraindicate the use of gastric lavage." Measures against circulatory shock, respiratory depression, or convulsion may be needed. NOTICE: California has determined that a chemical contained in this product causes cancer based on tests performed on laboratory animals.</p>	

2. The Storage and Disposal statement must be revised as follows:

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”

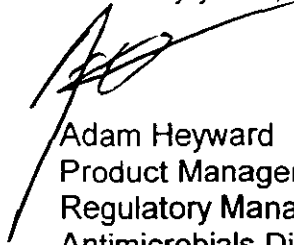
CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer....If burned, stay out of smoke.

Submit three (3) copies of your final printed labeling before you release the product for shipment bearing the revised labeling.

A stamped copy is enclosed for your records.

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

Sincerely yours,



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

Enclosure

DIRECTIONS FOR USE

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

Do not apply this product in a way that will contact workers and other persons, either directly or through drift. Only protected handlers may be in the area during application. Following application as a low or high pressure spray, do not enter or allow others to enter the treated areas 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 areas 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 Statements section of this labeling for applicators and other handlers.

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

Proven effective as a disinfectant by the following tests: AOAC (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 AOAC Tuberculocidal Test	
Staphylococcus aureus, Methicillin resistant (MRSA) ATCC#25923	
Salmonella paratyphi B ATCC#9281	Staphylococcus aureus ATCC#6538
Salmonella schottmuelleri ATCC#8759	Enterobacter aerogenes ATCC#13048
Streptococcus pyogenes ATCC#19615	Salmonella typhimurium ATCC#13311
Shigella sonnei ATCC#25931	Kebsiella 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-111B strain of HIV-1 (AIDS virus)

TEK-PHENE has also been tested according to AOAC 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 14th Edition, 1984. All dilutions at 1:256.

Trichophyton mentagrophytes ATCC#5533, AOAC 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

NET CONTENTS: 1 U.S. Gallon

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 16 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 11725-8

DESCRIPTION

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 oz. 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.

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, 2nd Edition, 1987. TEK-PHENE meets the requirements of NFPA Standard No. 56A.

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.

Manufactured by:



BIO-TEK INDUSTRIES, INC.
1380 West Marietta St NW
Atlanta, GA 30318
Ph. 404-799-2050
Fax 404-799-2056
www.bio-tekusa.com

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

ANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield, protective clothing, and chemical resistant rubber gloves when handling. Harmful if swallowed. 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 sleeve shirt and long pants, socks plus shoes, chemical resistant gloves. In addition, for applicators and other 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 respirator with a canister or cartridge approved for pesticides (MSHA/NIOSH approval number TC-14G).

STATEMENT OF PRACTICAL TREATMENT

IF ON SKIN: Wash with plenty of soap and water. Get Medical attention. **IF IN EYES:** Hold eyelids open and flush with a steady stream of water for 15 minutes. Get Medical attention. **IF SWALLOWED:** Call a physician immediately. Drink promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, large quantities of water. Never induce vomiting or give anything by mouth to an unconscious person. Avoid alcohol.

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

NOTICE: California has determined that a chemical contained in this product causes cancer based on tests performed on laboratory animals

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Apply with surfaces
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