

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 30 2002

Wendy A. McCombie
Agent for Bio-Tek Industries Inc.
Lewis & Harrison
122 C Street NW Ste 740
Washington DC 20001

Subject: Notification Per PR Notice 98 -10
Tek-Phene Cleaner Disinfectant Deodorant
EPA Registration No. 11725-8
Application Dated: July 11 2002

Dear Ms. Wendy A. McCombie

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3 (c) 9.

Proposed Notification

- Addition of Terminal Sterilant Statement Required for Disinfectant Products Used in Hospitals

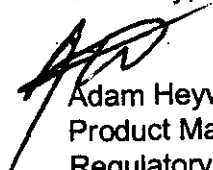
General Comments

Based on a review of the material submitted, the following comments apply:

This application for notification is acceptable. A copy has been inserted in the file for future reference.

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

Sincerely,



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

CONCURRENCES

SYMBOL	7510(c)							
SURNAME	A. Petas							
DATE	7/29/02							

 EPA	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other <i>NOTIFICATION</i>	OPP Identifier Number 265394
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Application for Pesticide - Section I

1. Company/Product Number 11725-8	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) TEK-PHENE CLEANER DISINFECTANT DEODORANT	PM# Team 34	
5. Name and Address of Applicant (Include ZIP Code) BIO-TEK INDUSTRIES INC. 1380 West Marietta Street, NW Atlanta, GA 30318 <i>NOTE: PLEASE SEND ALL CORRESPONDENCE TO</i> <i>"CONTACT POINT" LISTED BELOW</i> <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for Notification Under PR Notice 94-4:

Terminal Sterilant Statement Required For Disinfectant Products Used In Hospitals

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.


Signature: _____

Date: 07-11-2002

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph – or- <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued – or- <input type="checkbox"/> Stenciled – or-					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Wendy A. McCombie, Lewis & Harrison 122 C Street, NW Ste. 740 – Washington DC 20001	Title Agent for Bio-Tek Industries, Inc.	Telephone No. (Include Area Code) 202-393-3903 ext. 13
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received <div style="text-align: center; border: 1px solid black; padding: 5px;"> (Stamped) </div>
2. Signature 	3. Title Agent for Bio-Tek Industries, Inc.	
4. Typed Name Wendy A. McCombie, Lewis & Harrison	5. Date July 11, 2002	

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 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.

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. Tuberculocidal Test
- Staphylococcus aureus, Methicillin resistant (MRSA) ATCC #25923
- Staphylococcus aureus ATCC #6538
- Salmonella paratyphi B ATCC #9281
- Salmonella typhimurium ATCC # 13311
- Salmonella scholmeulleri 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 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
- Salmonella choleraesuis ATCC #10708
- Pseudomonas aeruginosa ATCC #15442
- Escherichia coli ATCC #11228

*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

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 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.

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 requirement of NFPA Standard No. 56A.

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.

Manufactured by:

BIO-TEK INDUSTRIES, Inc.
1380 West Marietta Street, N.W.
Atlanta, GA 30318
Telephone 404-799-2050
FAX: 404-799-2058
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
DANGER**

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 other 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 approved for pesticides (MSHA/NIOSH approval number prefix TC-14G)

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: 1-800-843-7667. 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 convulsion may be needed.
NOTICE: California has determined that a chemical contained in this product causes cancer based on tests performed on laboratory animals.	

HOSPITAL USE DIRECTIONS:

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 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.

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, 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 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).

Net Contents

NOTIFICATION
Date Reviewed: 7-16-02
Reviewed By: [Signature]