

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98.



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

243633

Application for Pesticide - Section I

1. Company/Product Number 11725-8	2. EPA Product Manager Ruth Douglas	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) TEK-PHENE Cleaner, Disinfectant-Deoderant	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Bio-Tek Industries, Inc. 1380 West Marietta Street, NW Atlanta, GA 30318 <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.: <u>TEK-PHENE Cleaner, Disinfectant, Deoder.</u> Product Name <u>11725-8</u>	

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 checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

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

Notification of minor changes in label language as per PR Notice 95-2. Notification is consistent with PR 95-2 (See attached statement).

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	If "Yes" Unit Packaging wgt. No. per container		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		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 <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

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 & Pazianos 1338 G St., SE Washington DC 20003	Title Agent for Bio-Tek	Telephone No. (Include Area Code) 202-546-8427
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 (Stamped)
2. Signature 	3. Title Agent for Bio-Tek Industries, Inc.	
4. Typed Name Wendy A. McCombie	5. Date 1-5-96	

Strikethrough = deleted language  
Underline/Bold = added language  
(FRONT PANEL)

**TEK-PHENE**  
CLEANER \* DISINFECTANT \* DEODORANT  
STAPHYLOCIDAL \* PSEUDOMONOACIDAL \* SALMONELLACIDAL  
TUBERCULOCIDAL \* VIRUCIDAL\*  
FUNGICIDAL \* CONDUCTIVE \* BIODEGRADABLE\*\*

ACTIVE INGREDIENTS:

- 1. para-tertiary-Amylphenol 10.0%
- 2. ortho-Benzyl-para-chlorophenol 6.5%
- 3. ortho-Phenylphenol 6.0%

INERT INGREDIENTS:

Total 77.5%  
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 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 be needed.

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 56A.

Manufactured by:



BIO-TEK INDUSTRIES, INC.  
1275 Ellsworth Industrial Dr., NW;  
Atlanta, GA 30318, USA  
Telephone (404) 351-7048 Telex: 671-2844  
FAX: 4043529091

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 in use dilutions and excellent solubility.

++After this products use as a disinfectant, it will biodegrade in sewage systems and/or the environment.

The TEK-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 1/2 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 ideally suited for disinfecting and cleaning all environmental surfaces 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.

TEK-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 1/2 oz. per gallon of water (1:256). 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 TEK-PHENE at 1/2 oz. per gallon (1:256) and rinsed with potable water prior to reuse.

Toxicity tests required by the U.S. Environmental Protection Agency for TEK-PHENE CLEANER-DISINFECTANT-DEODORANT have been 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 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<sub>B</sub> strain of HIV-1 (AIDS virus)
- Vaccinia Virus ATCC # VR-325
- Human adenovirus ATCC # VR-5

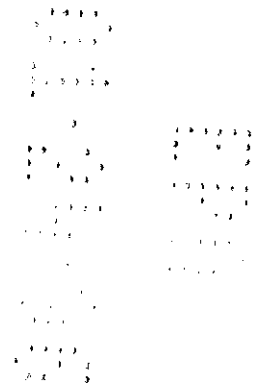
TEK-PHENE has also been tested according to A.O.A.C. use dilution test methods and proven effective as a disinfectant against the following organisms at 500 ppm water hardness as calcium carbonate and 5% horse serum (as organic soil):

- 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. All dilutions were tested at 1:256.

+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



### 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 pre-clean 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 **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 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:

TEK-PHENE is effective against all organisms listed at 500 ppm water hardness and 5% organic soil. NOTE: TEK-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.

6/7

(RIGHT PANEL (CONTINUED))

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).

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.

