

3862-178

01/31/2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

January 31, 2007

Michael Rekhelman  
VP Technical Services  
**ABC Compounding Co., Inc.**  
P.O. Box 16247  
Atlanta, GA 30321

Subject: **Tek-Phene**  
EPA Registration No. 3862-178  
Application Dated: January 5, 2007  
Receipt Date: January 9, 2007

Dear Mr. Rekhelman:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comment:

**Proposed Amendment**

- Revised labeling

**General Comments**

1. The use directions for Whirlpool and foot spa are partially consistent with Agency guidance, as outlined on <http://www.epa.gov/pesticides/factsheets/pedicure.htm>. Revise the instruction to read as follows: "To disinfect **whirlpool foot spas, air-jet basins, "pipe-less" foot spas, and other circulating spas** by turning the unit on to **circulate** the disinfectant for the entire contact time", not the one minute circulation, as interpreted from the proposed label.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

**Other Comments**

A stamped copy of the accepted labeling is enclosed.

Should you have any questions or comments concerning this letter, please contact me by telephone at (703) 308-6422 or email address at: [heyward.adam@epa.gov](mailto:heyward.adam@epa.gov), or Renae Whitaker by telephone at (703) 308-7003 or email address at: [whitaker.renae@epa.gov](mailto:whitaker.renae@epa.gov).

Sincerely,

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

Enclosure: (EPA stamped approved label)

**CONCURRENCES**

<b>SYMBOL</b>								
<b>SURNAME</b>								
<b>DATE</b>								

# TEK-PHENE

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

<b>ACTIVE INGREDIENTS:</b>	
para-tertiary-Amylphenol.....	10.0%
ortho-Benzyl-para-chlorophenol.....	6.5%
ortho-Phenylphenol.....	6.0%
<b>INERT INGREDIENTS:</b> .....	<b>77.5%</b>
<b>TOTAL:</b> .....	<b>100.0%</b>

EPA Reg. No. 3862-178

EPA Est. No. 3862-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.

<b>First Aid:</b>	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-30 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-30 minutes.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor for further treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
<b>NOTE TO PHYSICIAN-</b> Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.	

**PHYSICAL AND CHEMICAL HAZARDS**

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

**CONDUCTIVE**

This product 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. This product meets the requirement of NFPA Standard No. 56A.

**Net Contents:**

**ACCEPTED**  
**with COMMENTS**  
**EPA Letter Dated:**

**JAN 31 2007**

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

**3862-178**

This product 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. This 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.

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

This product 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.

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

**General Information:**

Toxicity tests required by the U.S. Environmental Protection Agency for this product is done in conformity with the FDA and EPA Good Laboratory Practice Regulations.

Proven effective as a disinfectant by the following test: A.O.A.C. (use dilution test method) in conformance with the 14<sup>th</sup> 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 #8281
- Enterobacter aerogenes ATCC #13048
- Salmonella schotmoulieri ATCC #8759
- Salmonella typhimurium ATCC #13311
- 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-III B Strain of HIV-1 (AIDS virus)

This product 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 14<sup>th</sup> 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

**DIRECTIONS FOR USE**

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

**General Use Directions:**

This product is effective against all organisms listed at 500 ppm water hardness and 5% blood serum. NOTE: This product 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, tanning beds and other hard, non-porous environmental surfaces: Remove gross filth and heavy soil with a preliminary cleaning step prior to application of this product. Apply solution of 1/2 oz. of this product 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 surfaces 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 this product 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 this product 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 this product per gallon of water (1:256).

**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.

**DIRECTIONS FOR USE IN POULTRY HOUSE AND FARM PREMISE**

- Do not use in milking stalls, milking parlors or milk houses.
- 1. Remove all poultry, livestock 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 livestock 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 disinfectant to remain in contact for at least ten minutes.
- 6. Immerse halters, ropes and other types of equipment used in handling and restraining livestock, forks, shovels, scrapers used for removing litter and manure in a solution of 1/2 oz. TEK-PHENE 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.

**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.

**Directions for use (continued):**

**Hospital Use Directions:**

1. To clean, disinfect, and deodorize floors, walls, and other non-porous environmental surfaces: Use ½ oz. of this product per gallon of water (1.25%). 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. This product 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 this product.

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 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.

**Disinfection of Hard Non-Porous Surfaces in Whirlpool Units:** After using the whirlpool unit or footspa, drain and pre-clean the interior surfaces to remove heavy soil, making sure to clean under rim and in crevices. Remove screen and all debris trapped behind the screen. Pre-clean and rinse screen and inlet. Refill the unit with fresh water to just cover the intake valve. Add ½ ounces of this product to each gallon of fresh water added. Turn jets on for 1 minute, then turn off and let soak for 9 minutes. Drain and rinse all surfaces with fresh water.

**Disinfection of Tanning Beds:** Pre-clean and rinse to remove heavy soil from surface. Apply a solution of ½ ounces of this product per gallon of water with a cloth, sponge, or mechanical spray device, making sure all surfaces are wetted thoroughly. Treated surfaces must remain wet for 10 minutes. Rinse with fresh water.

**STORAGE AND DISPOSAL**

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

**Pesticides Storage:** Store only in original container away from heat or open flame. Keep container closed when not in use. Storage must be secured sufficiently to make product inaccessible to children or persons unfamiliar with its proper use. **Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinse 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. Do not reuse empty container.

**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.

Manufactured By:

**ABC Compounding Co., Inc.**  
**Atlanta, GA 30321-0247**  
**Toll Free 800-795-9222**