



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 08, 2015

Kim Inman
Regulatory Chemist
ABC Compounding Company, Inc.
P.O. Box 16247
Atlanta, GA 30321

- Subject: Label Notification per PRN 98-10 –Updating the First Aid Section, Plus updating the mixing directions on the Master label per the PR Notice 98-10.
Product Name: Tek-Phene
EPA Registration Number: 3862-178
Application Date: April 30, 2015
Decision Number: 506616

Dear Ms. Inman:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

If you have any questions, you may contact Lorena Rivas at 703-305-5027 or via email at rivas.lorena@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jacqueline Hardy".

for

Jacqueline Hardy, Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

TEK-PHENE

- CLEANER • DISINFECTANT • DEODORIZER • BACTERICIDAL • STAPHYLOCIDAL
 • PSEUDOMONACIDAL • SALMONELLACIDAL • TUBERCULOCIDAL
 • VIRUCIDAL† • FUNGICIDAL • CONDUCTIVE**
- KILLS PANDEMIC 2009 H1N1 INFLUENZA A VIRUS (formerly called Swine Flu)**

ACTIVE INGREDIENTS:

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

INERT INGREDIENTS:.....77.5%

TOTAL:.....100.0%

NOTIFICATION

3862-178

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

07/08/2015

**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, skin or on clothing. Wear protective eye wear, protective clothing, and rubber gloves. Harmful if swallowed. Avoid breathing (dust, vapor or spray mist). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID:	
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 further treatment advice.
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 further treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor for further 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.
If Inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
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.	

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:

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 other handlers exposed to vapors, mist, or unexpected splash back must wait until mist has dissipated and the enclosed area has been thoroughly ventilated, or if needed, 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 INSTRUCTIONS

Users must: 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.

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.

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 0.54 ($\frac{1}{2} + \frac{1}{25}$) ounce per gallon of water (1:237) to provide prolonged contact time.

This product at 0.54 ($\frac{1}{2} + \frac{1}{25}$) ounce per gallon of water (1:237) provides excellent odor reduction properties.

This product is for use when used as directed on glazed ceramic and glazed tile surfaces, stainless steel, aluminum, chrome, galvanized metal, glass, and other non-porous surfaces such as finished wood, polyethylene, polypropylene, PVC (polyvinyl chloride), polystyrene, vinyl, viton, ethylene propylene, nitrile, acrylic and polyurethane.

This product at 0.54 ($\frac{1}{2} + \frac{1}{25}$) ounce per gallon of water (1:237) is for disinfecting and cleaning surfaces in Homes, Hospitals, Medical Research Centers, Health Care Facilities, Schools, Research Centers, Laboratories, and other institutions.

General Information:

BACTERICIDAL ACTIVITY: At 0.54 ($\frac{1}{2} + \frac{1}{25}$) ounce per gallon of water, this product demonstrates effective disinfectant activity against the organisms:

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, Salmonella paratyphi B ATCC #9281, Staphylococcus aureus ATCC #6538, Salmonella schotmeulieri ATCC #8759, Enterobacter aerogenes ATCC #13048, Streptococcus pyogenes ATCC #19615, Salmonella typhimurium ATCC #13311, Shigella sonnei ATCC #25931, Klebsiella pneumoniae ATCC #4352, Escherichia coli ATCC #11228, Salmonella enterica ATCC #10708, Pseudomonas aeruginosa ATCC #15442

+VIRUCIDAL ACTIVITY: This product when used on environmental, inanimate, hard, non-porous surfaces at 0.54 ($\frac{1}{2} + \frac{1}{25}$) ounce per gallon of water exhibits effective virucidal activity against:

Vaccinia Virus ATCC #VR-325, Human adenovirus ATCC #VR-5, Human Immunodeficiency Virus, HTLV-III B Strain of HIV-1 (AIDS virus), Herpes simplex Type 1, Human Influenza A/Hong Kong Virus

FUNGICIDAL ACTIVITY: At the 0.54 ($\frac{1}{2} + \frac{1}{25}$) ounce per gallon dilution, this product is also fungicidal against the pathogenic fungi, Trichophyton mentagrophytes ATCC #9533

EFFICACY TESTS HAVE DEMONSTRATED THAT THIS PRODUCT IS AN EFFECTIVE BACTERICIDE, FUNGICIDE, AND VIRUCIDE AGAINST THE LISTED ORGANISMS IN WATER UP TO 400 PPM HARDNESS (as CaCO₃) IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM).

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product may be applied only by the methods specified on the labeling.

Use Directions:

1. *To clean, disinfect and deodorize walls, floors, tables, restroom fixtures, exterior surfaces of drinking fountains, sinks, stoves, garbage cans, exterior surfaces of 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 0.54 ($\frac{1}{2} + \frac{1}{25}$) ounce of this product per gallon of water (1:237) with a sponge, mop or mechanical spray device, making sure that all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes.
2. *To clean and disinfect barber/beauty salon instruments and tools.* Clean and disinfect such articles as combs, brushes, razors and scissors. Wipe articles clean and soak for 10 minutes in a solution containing 0.54 ($\frac{1}{2} + \frac{1}{25}$) ounce of this product per gallon of water (1:237).
3. *To clean gross filth or heavy soil on environmental surfaces prior to disinfection,* use 0.54 ($\frac{1}{2} + \frac{1}{25}$) ounce of this product per gallon of water (1:237).

DIRECTIONS FOR DISINFECTION IN POULTRY HOUSES AND FARM PREMISES

1. Do not use in milking stalls, milking parlors, or milk houses.
2. Remove all animals and feed from premises, vehicles, and enclosures.
3. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
4. Empty all troughs, racks, and other feeding and watering appliances.
5. Thoroughly clean all surfaces with soap or detergent and rinse with water.
6. Saturate all surfaces with the disinfecting solution for a period of 10 minutes.
7. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
8. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
9. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Hospital Disinfection Directions:

1. To clean, disinfect, and deodorize floors, walls, and other non-porous environmental surfaces: Use 0.54 ($\frac{1}{2} + \frac{1}{25}$) ounce of this product per gallon of water (1:237). 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 as above.
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.

Disinfection of Hard Non-Porous Surfaces in Whirlpool Foot Spas, Air-Jet Basins, "Pipe-less" Foot Spas, and other Circulating Spas: After using the whirlpool unit or foot spa, drain and preclean 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. Preclean and rinse screen and inlet. Refill the unit with fresh water to just cover the intake valve. Add 0.54 ($\frac{1}{2} + \frac{1}{25}$) ounce of this product per gallon of water (1:237). Turn jets on for the 10 minute contact time. Drain and rinse all surfaces with fresh water.

Disinfection of Tanning Beds: Preclean and rinse to remove heavy soil from surface. Apply a solution of 0.54 ($\frac{1}{2} + \frac{1}{25}$) ounce of this product per gallon of water (1:237) 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.

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, disposable rubber gloves, gowns, masks and 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.

STORAGE AND DISPOSAL

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

Commercial Use:

PESTICIDE 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 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 HANDLING - (For containers greater than 5 gallons):** Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke.

(For containers equal to or less than 5 gallons): Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke.

Household / Residential Use:

CONTAINER HANDLING - Nonrefillable container. Do not reuse or refill this container. Securely wrap original container in several layers of newspaper and discard in trash or offer for recycling if available.

ENVIRONMENTAL HAZARDS

(For containers 5 gallons or greater): 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.

EPA Reg. No. 3862-178 EPA Est. No. 3862-GA-1

Manufactured by:
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