

3862-178

11/18/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

NOV 18 2009

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Kim Inman  
Regulatory Chemist  
ABC Compounding Co., Inc.  
6970 Jonesboro Road  
Morrow, GA 30260

**FILE COPY**

Subject: Notification Application per PR Notice 95-2  
**Tek-Phene**  
EPA Registration Number: 3862-178  
Application Date: October 29, 2009  
Receipt Date: November 3, 2009

Dear Ms. Inman:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 95-2.

**Proposed Notification:**

Addition of Influenza A virus (H1N1) label claim

**General Comment:**

Based on a review of the material submitted, the following comment applies:

The notification is acceptable.

Should you have any questions concerning this letter, please contact Heather Garvie at (703) 308-0034 or by email address at [garvie.heather@epa.gov](mailto:garvie.heather@epa.gov).

Sincerely,

A handwritten signature in cursive script that reads "ShaRon Carlisle".

ShaRon Carlisle  
(Acting) Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

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

1. Company/Product Number 3862-178	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Tek-Phene	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) ABC Compounding Co., Inc. PO Box 16247 Atlanta, GA 30321 <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 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 addition of the following text: "Kills Pandemic 2009 H1N1 Influenza A virus (formerly called Swine Flu)." per PR Notice 95-2."

"This notification is consistent with the provisions of PR Notice 95-2 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 18U.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 95-2 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."

**Section - III**

<b>1. Material This Product Will Be Packaged In:</b>				<b>2. Type of Container</b>	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
<b>3. Location of Net Contents Information</b>		<b>4. Size(s) Retail Container</b>		<b>5. Location of Label Directions</b>	
<input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		55,35,20,5,1 gallon & quart		<input checked="" type="checkbox"/> On label	
<b>6. Manner in Which Label is Affixed to Product</b>			<input type="checkbox"/> Other _____		
<input checked="" type="checkbox"/> Lithograph			<input checked="" type="checkbox"/> Paper, glued		
<input checked="" type="checkbox"/> Stenciled					

**Section - IV**

<b>1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</b>			
Name Kim Inman	Title Regulatory Chemist	Telephone No. (Include Area Code) 770-968-9222	
<b>Certification</b>			<b>6. Date Application Received (Stamped)</b>
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.			Received _____ (Stamped)
2. Signature 	3. Title Regulatory Chemist		
4. Typed Name Kim Inman	5. Date 10-29-09		



**ATLANTA, GEORGIA**  
 P.O. Box 16247  
 Atlanta, GA 30321 0247  
 Phone: 770.968.9222  
 Toll Free: 800.795.9222  
 Fax: 770.968.7281

**DALLAS, TEXAS**  
 Phone: 972.988.9200  
 Fax: 972.641.8170

ShaRon Carlisle, Product Manager 34  
 Regulatory Management Branch II  
 Office of Pesticide Programs  
 U.S. Environmental Protection Agency  
 Ariel Rios Building  
 1200 Pennsylvania Ave., NW  
 Washington, D.C. 20460

November 2, 2009

Ms. Carlisle,

Enclosed are 8570-1 forms for PR Notice 95-2 for 3862-104, 3862-177 and ~~3862-178~~. Please send your decision via e-mail to [kim.inman@abccompounding.com](mailto:kim.inman@abccompounding.com).

Thank you,

Kim Inman  
 Regulatory Chemist  
 ABC Compounding Co., Inc.  
 PO Box 16247  
 Atlanta, GA 30321  
 phone 678-833-2107  
 fax 770-960-1059  
[kim.inman@abccompounding.com](mailto:kim.inman@abccompounding.com)

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NOTIFICATION 11/18/09  
Date Reviewed:                       
Reviewed By:                     

# 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%

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.** Cause irreversible eye damage and skin burns. Do not get in eyes or on clothing. 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"> <li>Hold eye open and rinse slowly and gently with water for 15-20 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>
If on skin or clothing	<ul style="list-style-type: none"> <li>Take off contaminated clothing.</li> <li>Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or doctor for further treatment advice.</li> </ul>
If swallowed	<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>
If inhaled	<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>

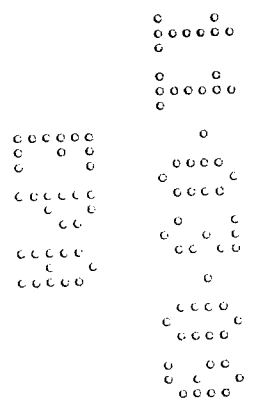
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.  
**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

### 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 it's 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.



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 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 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, viton, ethylene propylene, nitrile, acrylic and polyurethane.

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

**General Information:**

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. Tuberculooidal Test
- Staphylococcus aureus, Methicillin resistant (MRSA) ATCC #25923
- Salmonella paratyphi B ATCC #9281
- Salmonella choleraesuis ATCC #8759
- Streptococcus pyogenes ATCC #19615
- Shigella sonnei ATCC #25931
- Staphylococcus aureus ATCC #6538
- Enterobacter aerogenes ATCC #13048
- Salmonella typhimurium ATCC #13311
- 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-IIIB 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 AHong Kong Virus

This product is for use in fogging (wet misting) operations as an adjunct sanitizer of room surfaces either preceding or following regular cleaning and disinfecting procedures. For use in poultry houses, farm premises, hatcheries, food processing plants and basements of buildings. Use at a dilution of 1/2 oz. per gallon (1:256). Close room off so fog is confined to room to be treated. Leave the room when fogging. Before fogging in food processing areas, all food and food packaging items must be removed or carefully protected. To thoroughly clean and disinfect room surfaces, before or after fogging, scrub with this product at 1/2 oz. per gallon (1:256). Food contact surfaces must be rinsed with potable water prior to reuse.

Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus. Vacate the area of all personnel during fogging and for a minimum of 2 hours after fogging.

Note: The fog generated is irritating to the eyes, skin and mucous membranes. Under no circumstances will a room be entered by anyone within two hours of the actual fogging and a minimum of 4 hours air exchanges (ACH) per hour in the facility.

**Net Contents:**

**Batch No.:**

670141SA.0910

**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**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. 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, 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 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 and scissors: 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 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).

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

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 recommended 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.

**PERSONAL PROTECTIVE EQUIPMENT (PPE)**

Applicators and handlers must wear:

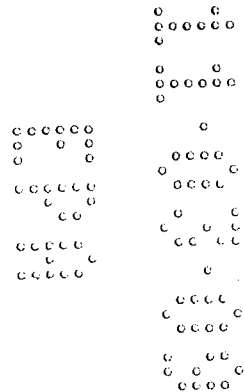
Long-sleeved shirt and long pants, socks plus shoes, goggles or face shield, chemical-resistant gloves (such as barrier laminate, nitrile rubber, neoprene rubber and viton).

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 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.



Directions for use (continued):

Hospital Use Directions:

1. To clean, disinfect, and deodorize floors, walls, and other non-porous environmental surfaces: Use 1/2 oz. of this product 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 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.

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.

**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 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 - (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 for 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 for 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.

### 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.

Manufactured by:

ABC Compounding Co., Inc.  
 P.O. Box 16247 • Atlanta, GA 30321-0247  
 Toll Free 800-795-9222

