

3862-179



02/10/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

FEB 10 2009

Kim Inman  
Regulatory Chemist  
ABC Compounding Co., Inc.  
PO Box 16247  
Atlanta, GA 30321

Subject: Opti-Phone Cleaner Disinfectant Deodorizer  
EPA Registration No. 3862-179  
Application Date: January 15, 2009  
Receipt Date: January 15, 2009

Dear Ms. Inman:

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

**Proposed Notification**

- Revision of Storage and Disposal statement per PR Notice 2007-4

**General Comments**

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

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-8583 or email address at: [Mitchell.Emily@epa.gov](mailto:Mitchell.Emily@epa.gov) during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in cursive script that reads "Emily Mitchell".

Emily Mitchell  
(Acting) Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)



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	United States <b>Environmental Protection Agency</b> Washington, DC 20460	<input type="checkbox"/> Registration	OPP Identifier Number
		<input type="checkbox"/> Amendment	
		<input checked="" type="checkbox"/> Other	

**Application for Pesticide - Section I**

1. Company/Product Number 3862-179	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Opti-Phone Cleaner Disinfectant Deodorizer	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 label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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**

1. Material This Product Will Be Packaged In:				2. Type of Container	
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
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt No. per container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55,35,20,5,1 gallon & quart		5. Location of Label Directions <input checked="" type="checkbox"/> On label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" 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 Kim Inman	Title Regulatory Chemist	Telephone No. (Include Area Code) 770-968-9222
<b>Certification</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.		<b>6. Date Application Received (Stamped)</b>
2. Signature 	3. Title Regulatory Chemist	
4. Typed Name Kim Inman	5. Date 1-15-09	

# OPTI-PHENE

CLEANER • DISINFECTANT • DEODORIZER

STAPHYLOCIDAL • PSEUDOMONACIDAL

SALMONELLACIDAL • TUBERCULOCIDAL • VIRUCIDAL+

FUNGICIDAL • CONDUCTIVE

**ACTIVE INGREDIENTS:**

para-tertiary-Amylphenol.....5.25%

ortho-Benzyl-para-chlorophenol.....3.00%

ortho-Phenylphenol.....3.00%

**INERT INGREDIENTS:**.....88.75%

**TOTAL:**.....100.0%

**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.

FIRST AID	
<b>IF ON SKIN OR ON CLOTHING:</b>	<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 treatment advice.</li></ul>
<b>IF IN EYES:</b>	<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 treatment advice.</li></ul>
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"><li>• Call a poison control center or doctor immediately for 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>
In case of emergency call toll free: 1-888-216-4174. 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 contra-indicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.	

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**

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

EPA Reg. No. 3862-179  
EPA Est. No. 3862-GA-1

#### DIRECTIONS FOR USE

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

##### 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.

##### General Information:

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 oz. per gallon of water (1:128) to provide prolonged contact time.

This product at 1 ounce per gallon of water (1:128) 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, vilon, ethylene propylene, nitrile, acrylic and polyurethane.

This product at 1 oz. per gallon of water (1:128) is suited for disinfecting and cleaning all environmental surfaces in Hospitals, Medical Research Centers, Health Care Facilities, Schools, Research Centers and Laboratories, Veterinary Facilities, Zoos, Kennels, and Swine Operations. In Poultry and Turkey barns, Breeder and Laying Operations, Poultry House Grow-out Operations, Hatcheries - In hatcheries 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.

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. The following organisms tested at 1,000 ppm water hardness as calcium carbonate and 10% blood serum as organic soil:

*Mycobacterium bovis* (BCG) ATCC #35743 A.O.A.C. Tuberculoicidal Test  
*Staphylococcus aureus*, Methicillin resistant (MRSA) ATCC #25923, *Salmonella paratyphi B* ATCC #9281, *Staphylococcus aureus* ATCC #6538, *Salmonella schotmeuieri* ATCC #8759, *Enterobacter aerogenes* ATCC #13048, *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-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.

*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

##### 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 oz. of this product per gallon of water (1:128) 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 oz. of this product per gallon of water (1:128). 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 oz. of this product per gallon of water (1:128). 4. To clean gross filth or heavy soil on environmental surfaces prior to disinfection, use 1 oz. of this product per gallon of water (1:128).

##### Hospital Use Directions:

1. To clean, disinfect, and deodorize floors, walls, and other non-porous environmental surfaces: Use 1 oz. of this product per gallon of water (1:128). Apply with cloth, sponge, mop, mechanical spray device, making sure all surfaces are wetted thoroughly. Allow surfaces 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 On 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.

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.

##### Directions For Use In Farm Premises:

1. Do not use in milking stalls, milking parlors, or milk houses (for phenolics, cresylic acid, and pine oils). 2. Remove all animals and feed from premises, vehicles, and enclosures. 3. Remove all litter and manure from floors, walls and surface of hams, 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 a solution of OPTI-PHENE at 1 oz. per gallon of water (1:128) 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 in a solution of OPTI-PHENE at 1 oz. per gallon of water (1:128). 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.

##### Directions For Use In Poultry Houses:

1. Remove all poultry and feeds from premises, trucks, coops, and crates. 2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. 3. Empty all troughs, racks, and other feeding and watering appliances. 4. Thoroughly clean all surfaces with soap or detergent and rinse with water. 5. Saturate surfaces with a solution of OPTI-PHENE at 1 oz. per gallon of water (1:128) for a period of 10 minutes. 6. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried. 7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

Net Contents:

Batch No.:

**Directions For Fogging (Wet Misting) Operations:**

OPTI-PHENE is recommending for fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures

1. The recommended dilution is 1 oz. per gallon of water (1:128). 2. All food and packaging items must be removed or carefully protected. 3. Set the automatic timer on the Bio-Tek Fogger to fog for 6 minutes for 1,000 cu. ft. and leave the room. 4. Allow at least 2 hours before entering the area that has been fogged. 5. Treated food contact surfaces must be thoroughly scrubbed with OPTI-PHENE at 1 oz. per gallon (1:128) and rinsed with potable water prior to reuse

**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 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.

**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.

**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.

**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.