

3862-179

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAY 7 2014

Michael Rekhelman
ABC Compounding Co., Inc.
P.O. Box 16247
Atlanta, GA 30321

Subject: OPTI-PHENE
EPA Registration No.: 3862-179
Application Date: May 01, 2014
Receipt Date: May 01, 2014

Dear Mr. Rekhelman:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3(c)7a, as amended, is acceptable.

Proposed Amendment:

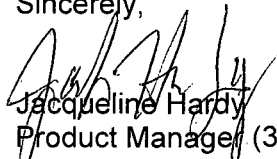
- Updating Re-submission amendment dated 11-15-2013, to reflect the deficiencies with the CSF. Revised the basic and alternate formulations Confidential Statements of Formula (CSFs) dated 11/15/13 to substitute one of the inerts.
- Revise the label to comply with EPA letter dated 4/01/2013 deleting all fogging/mister directions

General Comment:

The basic formulation and alternate formulation dated 11/15/13 are acceptable. The accepted basic and alternate CSFs have been inserted in your file for future reference. Plus; updated the label to delete all fogging/mister directions. A stamped accepted label is enclosed for your records. This labeling supersedes all previous labeling. The next printing of this product must use this labeling unless subsequent changes have been approved. You must submit one copy of the final printed label before selling or distributing the product bearing the revised labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling, or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulation at 40 CFR 152.3.

If you have further questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at hardy.jacqueline@epa.gov or Lorena Rivas by telephone at (703) 305-5027 or by email at rivas.lorena@epa.gov . When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing

Sincerely,



Jacqueline Hardy
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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:	100.00%

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	
IF ON SKIN OR ON 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 treatment advice.
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 treatment advice.
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for 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.

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.

NOTE TO PHYSICIAN: 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

ACCEPTED
05/07/2014

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under
EPA Reg. No. 3862-179
EPA Reg. No. 3862-479
EPA EST. NO. 3802-GA-1

Net Contents:	Batch No.:
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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.

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.

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 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 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 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. Proven effective as a disinfectant against the following:

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 choleraesuis ATCC #10708, Pseudomonas aeruginosa ATCC #15442, Vaccinia Virus ATCC #VR-325, Human adenovirus ATCC #VR-5, Human Immunodeficiency Virus, HTLV-IIIB Strain of HIV-1 (AIDS virus), Herpes simplex Type 1, Human Influenza A/Hong Kong Virus, Trichophyton mentagrophytes ATCC #9533 A.O.A.C. Fungicidal Test.

General Use Directions:

This product is effective against all organisms listed at 400 ppm water hardness and 5% 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 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 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 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.

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 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 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.

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.

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).

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.