

UNIT STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

MAY 21 2009

Michael Rekhelman  
ABC Compounding  
P.O. Box 16247  
Atlanta, Georgia 30321-00247

Subject: **Hospital Surface Disinfectant Room Deodorizer**  
EPA Registration No. 3862-104  
Application Date: December 12, 2008  
Receipt Date: December 29, 2008

Dear Mr. Rekhelman:

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

**Proposed Amendment:**

Additional claims to the label

**Acceptable Data**

**Efficacy**

Data Requirement	Means of Support	Status
<i>Staphylococcus aureus-MRSA</i>	Submitted study, MRID 476345-01	Acceptable, contact time 10 minutes, 5% soil

Please see the attached DER for additional details regarding the review of the submitted data.

**Conditions:**

Revise the label as follows:

1. Reorder the First Aid Statement to reflect the most toxic to least toxic route of exposure as stated in PR Notice 2001-1:

IF IN EYES  
 IF INHALED  
 IF ON SKIN OR CLOTHING  
 IF SWALLOWED

2. Revise the label to include the composition of surfaces such as chrome, glass and stainless steel on page 2 where "Disinfects and controls mold and mildew on hard, ... areas"

SYMBOL	SURNAME	DATE
	3. Change " <i>Salmonella choleraesuis</i> " to " <i>Salmonella enterica</i> " on current and future labels.	
	4. The ATCC designation numbers are required in one of the following locations:	

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On the data matrix  
 On the master label (as optional text) with the listing of the organisms claimed; or  
 As the final page of the master label (as optional text)

5. Change "Aids Virus" to "AIDS Virus" at the bottom of page 2
6. Change the 2 minute HIV contact time (on page 2) to 10 minutes. You have not provided efficacy data to support a 2 minute contact time. You may provide efficacy data support the 2 minute contact time claim at your next label amendment. The following language must precede the special instructions for use of a virucidal agent claiming efficacy against HIV: **\*KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care setting 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 ADIS).

**"SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS**

**Personal Protection:** Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks and eye coverings. (Alternate statement:

**Cleaning Procedure:** Blood and other body fluids (containing HIV-1) must be thoroughly cleaned from surfaces and objects before application of this product.

**Disposal of Infectious Materials:** Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

**Contact Time:** Leave surface wet for 10 minutes with this product. This 2 minute contact time will not control other common type of viruses and bacteria listed on this label."

7. Delete the directions for use of this product as a "Total Release Air Deodorizer." on page 3. Delete beginning with the statements: "(Note: if packaged in aerosol container with a total release valve..." through "...for Disinfecting Hard Surfaces... and point can to area to be sprayed." Also delete the Physical and Chemical Hazards Statements for total release foggers on page 4. These label statements must be deleted due to the following concerns:
  - A.) The formula of a total release fogger differs from that of an aerosol spray. Your current formulation can not support the current aerosol disinfectant as well as a total release fogger.
  - B.) Additional precautionary and physical chemical hazards language is required for total release foggers as per PR Notice 98-6. When changes to the formulation require changes to this type of precautionary language, a separate registration for that formulation is required.
  - C.) Your directions for total release foggers indicate that this use also disinfects hard surfaces. You have not provided efficacy data to support this claim.
8. Delete the Physical Chemical Hazards language for non aerosol containers on page four. Your product is registered as an aerosol spray. You may not include language on your label for any other formulation.

**CONCURRENCES**

<b>SYMBOL</b>	9. Delete the phrase: "(other than total release foggers)" from the physical chemical hazards for the aerosol containers.						
<b>SURNAME</b>							
<b>DATE</b>	10. The use of this product as an automatic aerosol for deodorizing air is inconsistent with the use of						

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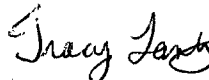
this product as a disinfectant on hard nonporous surfaces. It is misleading for this label to indicate that air is deodorized as the user may incorrectly assume that additional efficacy may be achieved. Please note that at reregistration this use may not be allowed for this product.

**General Comments**

Please refer to the attached efficacy review dated January 30, 2009 for guidance regarding MRID #476345-01AOAC Germicidal Spray Method: Staphylococcus aureus-MRSA (ATCC 33592)..

Should you have any questions concerning this letter, you may contact me by telephone at (703) 308-6415 or by e-mail at [lantz.tracy@epa.gov](mailto:lantz.tracy@epa.gov) or Stacey Grigsby by telephone at (703) 305-6440 or by email at [grigsby.stacey@epamail.epa.gov](mailto:grigsby.stacey@epamail.epa.gov) during the hours of 8:00 am to 4:00 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,



Tracy Lantz  
(Acting) Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Enclosure: Stamped Label  
DER D360630

**CONCURRENCES**

SYMBOL								
SURNAME								
DATE								

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**Hospital Surface  
Disinfectant  
ROOM DEODORIZER**

SAVES MOP FROM ODOR AND DECAY

KILLS HIV-1 (AIDS VIRUS) AND HERPES SIMPLEX TYPE II VIRUSES ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS.

A BROAD-SPECTRUM ANTIMICROBIAL AGENT FOR ENVIRONMENTAL SURFACES.

ELIMINATES ODORS BY ATTACKING THEM AT THEIR SOURCE.

DISINFECTANT - \*VIRUCIDE - FUNGICIDE (against pathogenic fungi) - MILDEWSTAT (on hard, non-porous, inanimate surfaces) - TUBERCULOCIDAL  
DESINFECTANTE

SI USTED NO ENTIENDE LA ETIQUETA, BUSQUE A ALGUIEN PARA QUE SE LA EXPLIQUE A USTED EN DETALLE.

(IF YOU DO NOT UNDERSTAND THIS LABEL, FIND SOMEONE TO EXPLAIN IT TO YOU IN DETAIL)

**ACTIVE INGREDIENTS:**

Orthophenylphenol:.....0.08%

Paratertiary amylphenol:.....0.02%

**INERT INGREDIENTS:**.....99.90%

TOTAL:..... 100.00%

KEEP OUT OF REACH OF CHILDREN

**CAUTION**

CONTENTS UNDER PRESSURE

SEE ADDITIONAL PRECAUTIONARY STATEMENTS ON SIDE PANEL

EPA REG. NO. 3862-104 EPA EST. NO. 9143-TX-1

NET WT.: VOLUME:

MANUFACTURED BY:

ABC COMPOUNDING CO., INC.

P.O. BOX 16247

ATLANTA, GA 30321

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

MAY 21 2009

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

3862-104

**TUBERCULOCIDAL ACTIVITY:** This product exhibits disinfectant efficacy against Mycobacterium tuberculosis var. bovis in 10 minutes at 20° C when used as directed on previously cleaned, hard, nonporous, inanimate surfaces.

This product is effective against the following organisms when used as directed on hard, non-porous, inanimate surfaces in the presence of 5% blood serum:

**\*VIRUCIDAL** - Human Immunodeficiency Virus Type I [HIV-1: A retro virus that causes "AIDS" (Acquired Immune Deficiency Syndrome)] when the treated surface is allowed to remain wet for 2 minutes; Herpes Simplex Type II and Influenza A2/Hong Kong when the treated surface is allowed to remain wet for 10 minutes. **BACTERICIDAL** - Pseudomonas aeruginosa, Staphylococcus aureus, Methicillin resistant Staphylococcus aureus (MRSA), and Salmonella choleraesuis when the treated surface is allowed to remain wet for 10 minutes. **FUNGICIDAL** - Athlete's Foot Fungus (Trichophyton mentagrophytes, a cause of ringworm) when the treated surface is allowed to remain wet for 10 minutes.

Disinfects and controls mold and mildew on hard, nonporous surfaces such as bathroom fixtures, empty garbage cans and diaper pails, furniture in sick rooms and nurseries, fishing equipment and sports equipment such as skate shoes and bowling shoes. Spray in the shower stalls, shoes, and walking areas.

**USED IN: HOSPITALS AND OTHER MEDICAL, INDUSTRIAL, INSTITUTIONAL, COMMERCIAL AND RESIDENTIAL FACILITIES.**

*(NOTE: if packaged in aerosol containers with a metered valve, use the following additional statement:)*

Stops unwanted odors and deodorizes the air in bathrooms, kitchens and any other areas where a malodor exists. The metered valve delivers precise spray volumes in an ultra fine mist to effectively freshen rooms up to 6,000 cubic feet. A fine spray pattern keeps areas smelling fresh longer.

**DIRECTIONS FOR USE:** It is a violation of federal law to use this product in a manner inconsistent with its labeling.

This product is not for use on critical or semi-critical medical device surfaces.

**STORAGE AND DISPOSAL**

*(for non-aerosol containers)*

**GENERAL:** Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container. **PESTICIDE STORAGE:** Keep in a cool, dry, locked area inaccessible to children and away from flames, sparks, sunlight, or other sources of heat or ignition.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

*(for aerosol containers)*

**GENERAL:** Do not contaminate other materials, including water, food or feed during transport, use, storage, or disposal. If damaged or leaking, soak up and wrap waste, then dispose of as below. **Storage:** Keep in a cool, dry, locked area inaccessible to children and away from flames, sparks, sunlight, or other sources of heat or ignition. Containers heated above 130°F (54°C) may burst. **Disposal:** Refasten protective cap on container and discard in trash or offer for recycling, if available. Do not incinerate or puncture.

**GENERAL: HOLD CONTAINER UPRIGHT. SHAKE OCCASIONALLY DURING USE.**

**SPECIAL INSTRUCTIONS for cleaning and decontaminating against HIV-1 (Aids Virus) on surfaces/objects soiled with blood/body fluids:** wear disposable gloves, gowns, masks, and eye

coverings when handling items soiled with blood/body fluids. Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. Blood and other body fluids, and cleaning materials removed from surface/objects should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

*(Note: if packaged in aerosol containers with a total release valve, use the following additional statements:)*

**FOR USE AS A TOTAL RELEASE AIR DEODORIZER: DO NOT** use more than one fogger per room. **DO NOT** use in small, enclosed spaces such as closets, cabinets or under counters or tables. Do not use in a room 5 ft. X 5 ft. or smaller; instead, allow fog to enter from other rooms. Turn off **ALL** ignition sources such as pilot lights (shut off gas valves), other open flames or running electrical appliances that cycle off and on (i.e., refrigerators, thermostats, etc.). Call your gas utility or management company if you need assistance with your pilot lights. Cover exposed food, dishes and food handling equipment. Open cabinets and doors to area to be treated. Shut off fans and air conditioners. Close doors and windows. Point valve opening away from face and eyes when releasing. Use one unit for each 6,000 cubic feet of unobstructed area. Use additional units for remote rooms or where free flow of mist is not assured. Do not remain in the area during treatment and ventilate thoroughly before re-entry. Do not use this unit in a cabinet or under a counter or table. Do not use this unit in an area less than 100 cubic feet. Do not use more than one unit per average size room. **TO OPERATE VALVE:** Place several layers of newspaper or pad on stand or table in the center of the room. To lock fogger valve in open position for automatic discharge, press valve button all the way down hooking in catch. Then place fogger on the stand or table. Leave building at once and keep building closed for two hours before airing out. Open all doors and windows and allow to air for 30 minutes.

**ONE UNIT TREATS UP TO 6,000 CUBIC FEET**

**FOR DISINFECTING HARD SURFACES** as directed below, lightly depress valve (do not press valve button all the way down, do not lock) and point can to area to be sprayed.

**FOR TUBERCULOCIDAL USE:** Remove heavy soil and thoroughly clean surfaces prior to application of this product. Spray from 6-8" until thoroughly wet. Allow surface to remain undisturbed for at least 10 minutes at 20° C before wiping.

**FOR DISINFECTING and deodorizing:** remove heavy soil and spray from 6-8" until thoroughly wet. Allow surface to remain undisturbed for at least 10 minutes before wiping.

**TO CONTROL MOLD AND MILDEW (Aspergillus niger)** and the odors they cause on pre-cleaned, hard, non-porous inanimate surfaces, spray from 6-8" until thoroughly wet. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

*(note: if packaged in aerosol containers with a metered valve, use the following additional statements:)*

**FOR USE IS AN AUTOMATIC AEROSOL DISPENSER UNIT FOR DEODORIZING AIR:** Remove protective cap and install in an Automatic Aerosol Dispenser unit. Dispenser should be mounted 7 ft. from the floor and at least 8 ft. away from exposed foods. Position so that the concentrated spray will not hit people, animals, foods, drinks, feeds, food processing surfaces, or solvent-sensitive surfaces (such as polished or varnished materials). Use only in a well ventilated area. Avoid inhaling spray mist or vapor.

This can contains 3900 controlled sprays for use in closed areas that will last for approximately 30 days when used on a 24 hour basis or 60 days if used 12 hours per day when set to dispense every 15 minutes.

**FOR DEODORIZING MOPS:** Shake well before using. Rinse wet mops thoroughly with clean water and wring out prior to treatment. Shake dust and debris from dust mops prior to application. Hold can upright 6 to 8 inches

from mop and spray until yarn surfaces are wet. Turn mop over and also inside out to allow spray to contact all yarn surfaces. Hang mop in well ventilated area. Allow dust mops to dry before use (at least ten minutes)

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
CAUTION**

Causes temporary eye irritation; do not spray on or toward eyes or face. Avoid breathing spray mist or vapors. Do not contaminate food or feed, nor surfaces that they may contact.

FIRST AID:	
<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>
<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 15-20 minutes.</li> <li>• Call a poison control center or doctor for further 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 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>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

**PHYSICAL AND CHEMICAL HAZARDS**

*For non-aerosol containers*

Flammable. Keep away from heat and open flames. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

*For aerosol containers (other than total release foggers):*

Flammable. Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

*For total release foggers:*

**HIGHLY FLAMMABLE INGREDIENT  
INGREDIENTE ALTAMENTE INFLAMABLE**



Contents under pressure. Keep away from heat, sparks and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. This product contains a highly flammable ingredient. It may cause a fire or explosion if not used properly. Follow the "Directions for Use" on this label very carefully.

(note: if container size is 5 gallons or greater, the following environmental hazards statements must be used)

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, 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.