

3862-104

11-18-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

NOV 18 2009

**FILE COPY**

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

Subject: Notification Application per PR Notice 95-2  
**Hospital Surface Disinfectant Room Deodorizer**  
EPA Registration Number: 3862-104  
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,

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

<b>1. Company/Product Number</b> 3862-104	<b>2. EPA Product Manager</b> ShaRon Carlisle	<b>3. Proposed Classification</b> <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
<b>4. Company/Product (Name)</b> Hospital Surface Disinfectant Room Deodorizer	<b>PM#</b> 34	
<b>5. Name and Address of Applicant (Include ZIP Code)</b> ABC Compounding Co., Inc. PO Box 16247 Atlanta, GA 30321 <input type="checkbox"/> Check if this is a new address	<b>6. Expedited Review.</b> 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

**1. Material This Product Will Be Packaged In:**

<b>Child-Resistant Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Unit Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt.    No. per container	<b>Water Soluble Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt    No. per container	<b>2. Type of Container</b> <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
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*\* Certification must be submitted*

<b>3. Location of Net Contents Information</b> <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	<b>4. Size(s) Retail Container</b> 8-20 oz aerosol can	<b>5. Location of Label Directions</b> <input checked="" type="checkbox"/> On label
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**6. Manner in Which Label is Affixed to Product**  
 Lithograph     Other \_\_\_\_\_  
 Paper glued      
 Stenciled

### Section - IV

**1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)**

<b>Name</b> Kim Inman	<b>Title</b> Regulatory Chemist	<b>Telephone No. (Include Area Code)</b> 770-968-9222
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<p style="text-align: center;"><b>Certification</b></p> 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.	<p style="text-align: center;"><b>6. Date Application Received (Stamped)</b></p> _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____
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<b>2. Signature</b> 	<b>3. Title</b> Regulatory Chemist
<b>4. Typed Name</b> Kim Inman	<b>5. Date</b> 10-29-09



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**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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**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.

~~Kills Pandemic 2009 H1N1 Influenza A virus (formerly called Swine Flu)~~

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%

NOTIFICATION 11/18/09  
Date Reviewed: \_\_\_\_\_  
Reviewed By: Y. GARME

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

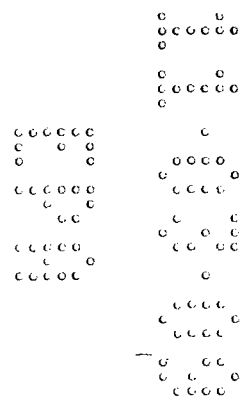
NET WT.: VOLUME:

MANUFACTURED BY:

ABC COMPOUNDING CO., INC.

P.O. BOX 16247

ATLANTA, GA 30321



**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 exhibits disinfectant efficacy in 10 minutes 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)]; Herpes Simplex Type II (ATCC VR-734) and Influenza A2/Hong Kong (ATCC VR-544). **BACTERICIDAL** – Pseudomonas aeruginosa (ATCC 15442), Staphylococcus aureus (ATCC 6538), Methicillin resistant Staphylococcus aureus (MRSA, ATCC 33592), and Salmonella enterica (ATCC 10708). **FUNGICIDAL** – Athlete’s Foot Fungus (Trichophyton mentagrophytes [ATCC 9533], a cause of ringworm).

Disinfects and controls mold and mildew on hard, nonporous surfaces such as metal surfaces, stainless steel surfaces, porcelain, ceramic tile, plastic surfaces, 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**

**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.

**\*KILLS HIV-1 ON PRE-CLEANED 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-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.**

**PERSONAL PROTECTION:** When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, and eye coverings. **CLEANING PROCEDURES:**



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:** Allow surface to remain wet for 10 minutes.

*(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*, ATCC 6275) 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.

<b>FIRST AID:</b>	
<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 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 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 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 INFLAMABILE**



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.

