

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICID
AND TOXIC SUBSTANCE

OCT 22 2009

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

Subject: **Hospital Surface Disinfectant Room Deodorizer**
EPA Registration No. 3862-104
Application Date: August 17, 2009
Receipt Date: August 24 13, 2009

Dear Mr. Rekhelman:

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

Proposed Amendment:

- Withdraw Alternate Confidential Statement of Formula (CSF) #1, dated 1/18/09
- Amend Label to remove non-aerosol use directions

Other Comment(s):

Future labeling amendments may be accomplished by submitting a copy of the electronic label. Refer to the following website for guidance on electronic submissions, including label: <http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm>.

If you have any questions concerning electronic label submissions, please refer to the above website for a list of contact personnel for more information.

Enclosed is a copy of the stamped labeling.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2/8

General Comment:

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6427 or by e-mail at carlisle.sharon@epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at grigsby.stacey@epa.gov during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



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

Enclosure: EPA stamped accepted labeling

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

**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

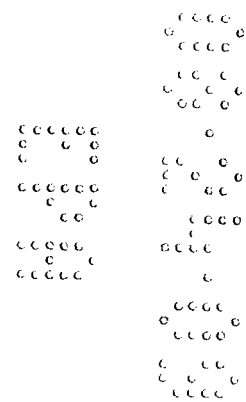
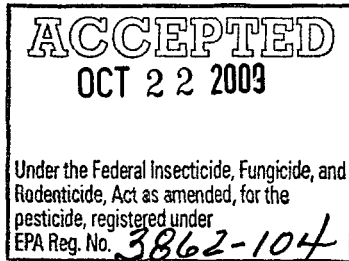
SEE ADDITIONAL PRECAUTIONARY STATEMENTS ON SIDE PANEL

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



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:**

ACCEPTED
OCT 22 2003
Under the Federal Insecticide, Fungicide, and Rodenticide, Act as amended, for the pesticide, registered under EPA Reg. No. 3812-1014

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.

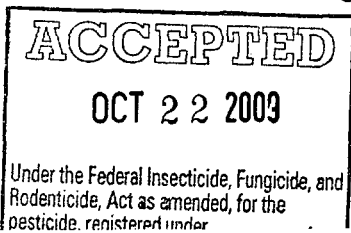
FOR TUBERCULOCIDAL USE: Remove heavy soil and thoroughly clean surfaces prior to application of this product. Spray from 6-8" until thoroughly wet. Allow surface to remain undisturbed for at least 10 minutes at 20° C before wiping.

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.

FIRST AID:	
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 further treatment advice.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for further treatment advice.
If on skin or 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 further treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor for further 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.
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 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.

ACCEPTED
OCT 22 2009
 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. **3862-104**

