

3862-104

9-2-2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

September 2, 2003

Michael rekhelman  
VP Technical Services  
ABC Compounding Co., Inc.  
P.O. Box 16247  
Atlanta, GA 30321

Subject: **Hospital Surface Disinfectant Room Deodorizer**  
EPA Registration No. 3862-104  
Application Dated June 3, 2003

Dear Mr. Rekhelman:

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

**Proposed Amendments**

- alternate formulas #1 and #2 (see CSFs dated 6/03/03)
- Revised Labeling

**Labeling Comments:**

1. The ingredient statement must include Total.....100%.
2. For containers greater than 1 gallon, the Storage and Disposal statement format must read as follows:

**Storage and Disposal**

Do not contaminate water, food or feed by storage or disposal

**Pesticide Storage:** Keep in a cool, dry, locked area...ignition.

**Pesticide Disposal:** Wastes resulting...facility.

**Container Disposal:** Triple rinse...discard in trash.

Refer to PR Notice 83-3 for appropriate language.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

General Comments

Copies of the alternate Confidential Statement of Formulas (CSFs) (formulas 1 and 2) have been inserted in your file for future reference.

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

*Renae J. Whitaker*  
Adam Heyward  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Enclosure

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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ACCEPTED  
with COMMENTS  
EPA Letter Dated:

# Hospital Surface Disinfectant

SEP 2 2003

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

## 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.  
BACTERICIDAL PSEUDOMONICIDAL  
STAPHYLOCIDAL TUBERCULOCIDAL  
FUNGICIDAL VIRUCIDAL\*  
A BROAD-SPECTRUM ANTIMICROBIAL AGENT FOR  
ENVIRONMENTAL SURFACES.  
CONTROLS MOLD/MILDEW  
ELIMINATES ODORS BY ATTACKING THEM AT THEIR SOURCE.

### 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%

EPA REG. NO. 3862-104  
SDA - TEX- 822  
EPA EST. NO. 9143-TX-1

KEEP OUT OF REACH OF CHILDREN

### CAUTION

CONTENTS UNDER PRESSURE.

See additional precautionary statements on side panel.

Net Wt.:

MANUFACTURED BY:  
ABC COMPOUNDING CO., INC.  
P.O. BOX 16247  
ATLANTA, GA 30321

**CLAIMS AND USES:** "VIRUCIDAL" - Inactivates these agents: Human Immunodeficiency Virus Type I [HIV-1: A retro virus that causes "AIDS" (Acquired Immune Deficiency Syndrome)]; Herpes Simplex Type II; Influenza A2/Hong Kong on hard, non-porous, inanimate surfaces. Kills most dangerous Staphylococcus aureus; Herpes simplex virus, Type II, and Mycobacterium tuberculosis, var bovis on

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environmental surfaces. 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. Aids in the control of athletes foot fungi (*Trichophyton mentagrophytes*) on environmental surfaces. Controls *Staphylococcus aureus* and *Salmonella choleraesuis*. Spray in the shower stalls, shoes, and walking areas.

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

[REDACTED]

**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 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

**STORAGE AND DISPOSAL**

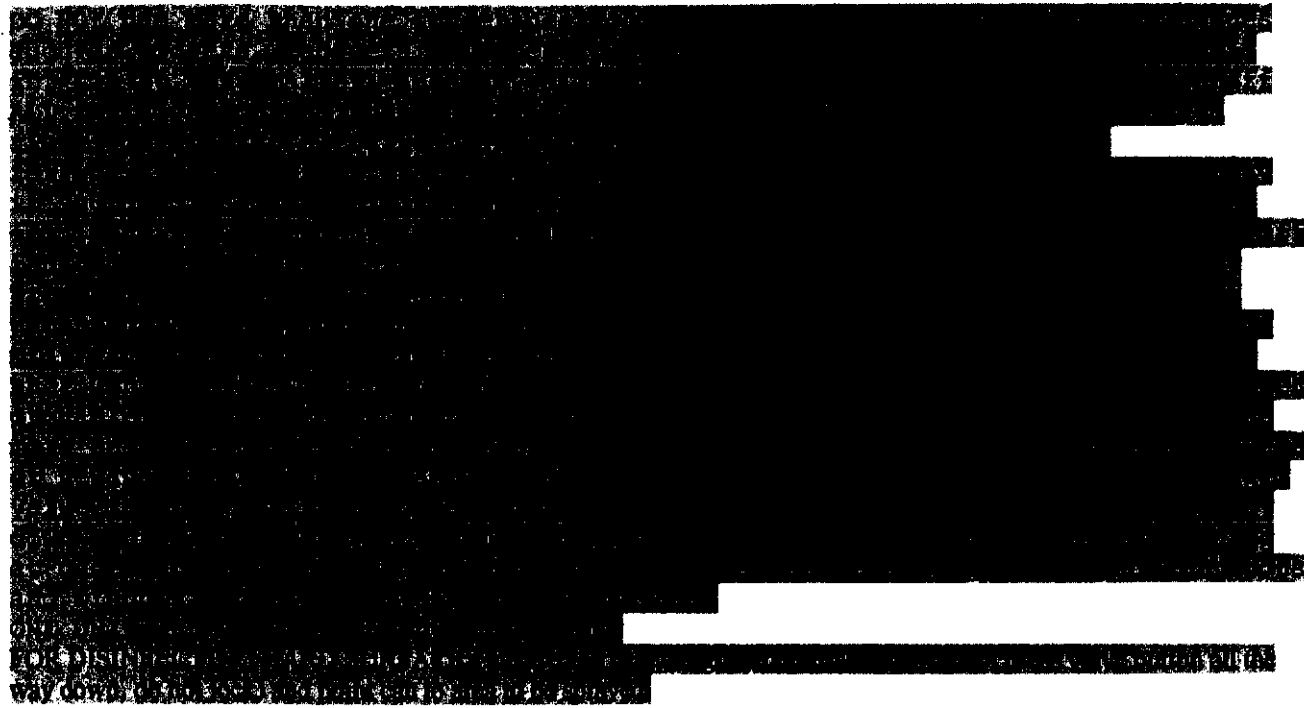
[REDACTED]

**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, securely wrap in several layers of newspaper, and discard in trash. Do not incinerate or puncture.

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

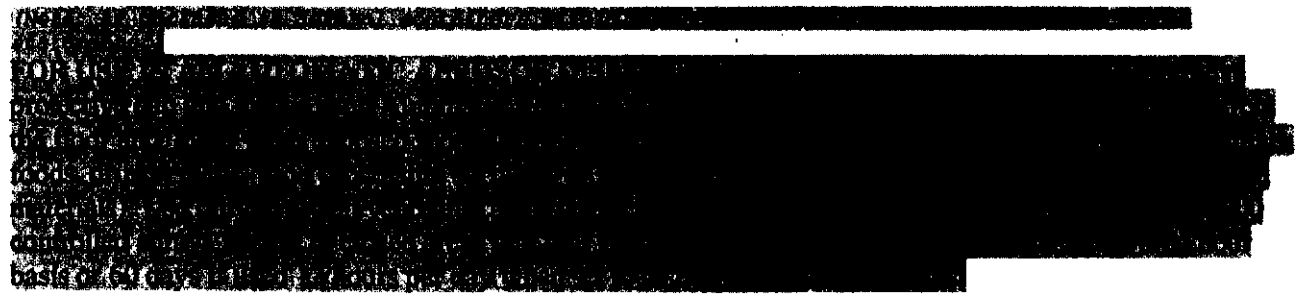
**SPECIAL INSTRUCTIONS for cleaning and decontaminating against HIV-1 (Aids Virus) on surfaces/objects soiled with blood/body fluids:** wear disposable gloves, gowns, masks, or eye coverings when handling items soiled with blood/body fluids. Blood and other body fluids must be thoroughly cleaned from 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:**



**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, mildew control, and deodorizing of clean surfaces:** spray from 6-8" until thoroughly wet. For disinfection, allow surface to remain undisturbed for at least 10 minutes before wiping. Repeat treatment weekly to maintain effective control of mildew.



**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.

