

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 21 1995

ABC Compounding Co., Inc.
P.O. BOX 16247
Atlanta, GA 30321

Attention: Michael Rekhelman
Technical Director

Subject: Lem-O-Dis 27-42
EPA Registration No. 3862-49
MOU Compliance Amendment dated March 21, 1995

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, will be acceptable provided that you make the labeling changes listed below before you release the product for shipment bearing the amended label.

1. Change Trichophyton interdigitale to read Trichophyton mentagrophytes.
2. Specify whether the product is effective against Herpes simplex Type 1 or Type 2.

A stamped copy is enclosed for your records. Submit five (5) copies of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely,



Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

LEMON ODOR DISINFECTANT is a cleaner and disinfectant designed for institutional use, such as hospitals, nursing homes, and schools where housekeeping will be of prime importance in controlling the hazard of cross-contamination from environmental surfaces.

LEMON ODOR DISINFECTANT can provide the assurance you need in this area, when used as directed. For use on floors, walls, sink tops, garbage pails, telephones, rest rooms, bed pans and operating rooms. Effective against Staphylococcus aureus, Salmonella choleraesuis and Pseudomonas aeruginosa. Also effective against pathogenic fungi, Trichophyton interdigitale.

This product is not to be used as a terminal sterilant or 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.

DISINFECTION

Use at 2 ounces per gallon. This product will be effective against Pseudomonas aeruginosa PRD-10 at this level. This has been substantiated by the AOAC Use Dilution Confirmation Test. At this level, the product is fungicidal against pathogenic fungi.

For best results, use LEMON ODOR DISINFECTANT with a cloth or mop and apply to walls, floors and other hard surfaces.

For heavily soiled areas, a preliminary cleaning is required. Thoroughly wet all surfaces. Treated surfaces must remain wet for 15 minutes. Fresh solution should be prepared daily or when the use solution becomes visibly dirty.

This product when used on environmental, inanimate, hard surfaces at 2 ounces per gallon of water, is effective against Influenza A2, Herpes Simplex, Adenovirus type 2, and Vaccinia viruses.

EPA EST. NO. 3862-GA-1
EPA REG. NO. 3862-49

FOR INDUSTRIAL USE ONLY
No warranty, express or implied
merchantability, fitness or otherwise is made

Lem-O-Dis 27-42

**CLEANER • DISINFECTANT
DEODORIZER • FUNGICIDE**

LEMON ODOR DISINFECTANT

Designed for Hospital and Institutional Use

ACTIVE INGREDIENTS:
n-alkyl (60% C14, 30% C16, 5% C12, 5% C18)
dimethyl benzyl ammonium chlorides 2.25%
n-alkyl (68% C12, 32% C14) dimethyl
ethylbenzyl ammonium chlorides 2.25%
INERT INGREDIENTS 95.50%
TOTAL 100.00%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See right side panel for additional precautionary statements

Manufactured By:
ABC Compounding Co., Inc.
P.O. Box 16247
Atlanta, GA 30321

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 21 1995

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

3862-49

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES SOILED WITH BLOOD/BODY FLUIDS in other settings in which there is an expected contact with blood or body fluids, and in which the fluids can be associated with the potential for HIV-1 (HIV-1) (associated with AIDS).
SPECIAL INSTRUCTIONS FOR CLEANING SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:
When handling items soiled with blood or body fluids, wear gloves, masks, or eye coverings.
CLEANING PROCEDURES: Blood and body fluids should be removed from surfaces and objects before application of this product.
CONTACT TIME: Allow surface to remain wet for 15 minutes.
DISPOSAL OF INFECTIOUS MATERIALS: Dispose of according to local regulations and disposed of according to local regulations.

PRECAUTIONS
Hazards to Humans and Domestic Animals

Keep Out of Reach of Children. Corrosive to eyes, on skin or on clothing. Wear goggles. Harmful if swallowed. Avoid contamination of food.

NOTE:
Probable mucosal damage may contraindicate use in patients with respiratory depression.

STATEMENT OF FIRST AID:
In case of contact, immediately flush eyes with water for 15 minutes. For eyes, call a physician. Remove and discard contaminated clothing. If swallowed, drink milk, egg whites, gelatin or other bland food. Call a physician.

ENVIRONMENTAL PRECAUTIONS:
Do not discharge effluent containing this product into surface waters or other waters unless in accordance with the National Pollution Discharge Elimination System (NPDES) permit and the local sewerage treatment authority prior to discharge. Do not discharge effluent into surface waters unless previously notifying the local sewerage treatment authority or Regional Office of the EPA.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Store in a dry place no lower than 50°F. PESTICIDE DISPOSAL: Pesticide wastes are acutely toxic. Do not dispose of by use according to label instructions. Contact your local health, environmental control agency, or the Hazardous Waste Office for guidance.

CONTAINER DISPOSAL: Triple rinse for 30 seconds. Do not reuse. Puncture and dispose of in a sanitary manner. Do not burn. Do not incinerate. Do not use for disposal. Do not use for disposal.

NET CONTENTS:
1 GALLON
FOR INDUSTRIAL USE ONLY

BEST COPY AVAILABLE