

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 29 1994

ABC Compounding Company, Inc.
P.O. Box 16247
Atlanta, GA 30321-0247

Attn: Michael Rekhelman
Technical Director

Subject: Hi-Foam Germicidal Spray and Wipe Cleaner
EPA Registration No. 3862-97
Letter Dated June 25, 1993

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to upgrade the product use areas from general to hospital usage, and to add HIV claims, is acceptable, provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

a. The product name "Hi-Foam Germicidal Spray and Wipe Cleaner" is not acceptable. To insure an effectiveness of 10 minutes for precleaned, hard nonporous surfaces, revise "Hi-Foam Germicidal Spray and Wipe Cleaner" to read "Hi-Foam Germicidal Spray Wipe and Cleaner. The name "Germicidal Spray and Wipe cleaner" infers an instant product activity.

b. On the right panel, under the use directions, revise "For use in hospital, homes, schools, hotels, motels, and similar environments to read "For use on hard, nonporous inanimate environmental surfaces in hospitals, homes, schools, hotels, and motels."

c. Under the directions for disinfection, revise "For disinfecting, remove gross food particles and heavy soil deposits..." to read "For disinfecting, remove gross filth and heavy deposits...". Delete gross food particles. Refer to item 3 of DIS/TSS-15 enclosure.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

d. If the product intent is to use the product as a virucide as proposed under the directions for use, the recommended usage as a virucide should be indicated on the front panel. The word "Virucidal" should be listed on the front panel as "Virucidal*".

e. Under the directions for use, revise "...Virucidal against *HIV-1 (AIDS virus) to read "...Virucidal* against HIV-1 (AIDS virus) on hard, inanimate, surfaces.

2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 305-6982.

Sincerely,



Marshall Swindell
Acting Product Manager 31
Antimicrobial Program Branch
Registration Division 7505C

Enclosure

BEST AVAILABLE COPY

Hi-Foam

GERMICIDAL SPRAY AND WIPE CLEANER

ACTIVE INGREDIENTS:
 n-Alkyl (50% C14, 10% C16, 40% C12)
 Dimethyl Benzyl Ammonium Chloride 0.15%
 INERT INGREDIENTS 99.85%
 TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN WARNING

Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 130°F may cause bursting. Never throw container into fire or incinerator. See side panel for additional precautionary statements.

STORAGE AND DISPOSAL
 DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.
 STORAGE — Store in a dry place no lower in temperature than 50 deg F. or higher than 120 deg. F.
 CONTAINER DISPOSAL — Replace cap and discard containers in trash. Do not incinerate or puncture.
 PESTICIDE DISPOSAL — Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

DIRECTIONS FOR USE
 It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
 USE: For use in hospitals, homes, schools, hotels, motels, and similar environments.
 Kills Salmonella choleraesuis, Pseudomonas aeruginosa, and Staphylococcus aureus. Virucidal against HIV-1 (AIDS virus).
 CLEANS: Formica, wood, plastic, metal table tops, bath tubs, walls, woodwork, shower stall, porcelain, vinyl, leather, stainless steel.
 DIRECTIONS: Shake well before each use. Remove protective overcap. For disinfecting, remove gross food particles and heavy soils deposits. Pre-clean all surfaces prior to disinfecting.
 Hold container six to eight inches from surface to be treated. Spray area for 2-3 seconds. Allow foam to penetrate and remain wet for 10 minutes. No scrubbing is necessary. Wipe off with a clean cloth, mop or sponge. The product will not leave grit or soap scum.
 *Kills HIV-1 (AIDS virus) on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare settings or other settings where 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 (AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.
 Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures. Cleaning Procedures: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant. Contact Time: Effective against HIV-1 (AIDS virus) on hard non-porous surfaces in the presence of a moderate amount of organic soil (5% blood serum) (providing 1500 ppm of active quaternary) for a contact time of 5 minutes at room temperature (20-25°C). Use a ten (10) minute contact time for disinfection against all other bacteria claimed (listed above). Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**
 WARNING
 Keep Out of Reach of Children. Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed. Avoid contamination of food.
STATEMENT OF PRACTICAL TREATMENT
 In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash all contaminated clothing before reuse. If swallowed, drink egg whites, or gelatin solution or if these are not available, drink large quantities of water. Call a physician immediately.
 NOTE TO PHYSICIAN
 Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and dehydration may be needed.

NET WT. 19 OZ. (539GM)
 E.P.A. REG. NO. 3862-97
 E.P.A. EST. NO. 9143-TX-1

Manufactured By:
 ABC COMPOUNDING COMPANY, INC.
 ATLANTA, GA

ACCEPTED
 with COMMENTS
 by EPA Letter Dated:

MAR 29 1994

Under the Federal Insecticide,
 Fungicide, and Rodenticide Act,
 as amended, for the pesticide
 registered under EPA Reg. No.
 3862-97