

OCT 10 1992

Walter G. Legge Company, Inc.
444 Central Avenue
P. O. Box 591
Pookskill, NY 10566

Attention: Jeffery S. Bauer

Gentlemen:

Subject: Elimstaph No. 2
EPA Registration Number 2212-2
Your Submission Dated July 13, 1992
EPA Received Date August 17, 1992

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, to add the claim for effectiveness against HIV-1, is acceptable.

The submitted data supports the effectiveness of the product as a virucide against HIV-1 when tested in the presence of organic soil and 400 ppm of hard water and used diluted (1 ounce per gallon; 1:128) for a contact time of 10 minutes at room temperature on hard, non-porous, inanimate surfaces.

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

- A. The phrase "Keep Out Of Reach Of Children" should be placed above the signal word "Warning".
- B. Revise the "Inert Ingredients" statement to read as follows: "Inert Ingredients %".
- C. On the left side panel, revise the subheading "Directions" to read "Directions for Use".
- D. Revise your disposal statement to read:

STORAGE AND DISPOSAL

PROHIBITIONS

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

(For metal container)

Triple rinse (or Equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities.

(For plastic containers)

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by State and local authorities, by burning. If burned, stay out of smoke.

The "Storage and Disposal" statement must be the same type size as the child hazard warning statement.

E. Place the appropriate precautionary statements to read as follows:

Precautionary Statements

Hazards to Humans and Domestic Animals

Warning: Keep out of Reach of Children.
Causes eye of skin irritation. Do not get in eyes on skin or on clothing. Harmful if swallowed.
Avoid contamination of food.

Note To Physician

In case of contact, immediately flush eyes of skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician.

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

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

If you have any questions concerning this letter, please contact Karen M. Leavy at (703)-305-6966.

Sincerely yours,

John H. Lee
Product Manager-31
Antimicrobial Program Branch
Registration Division (H7505-C)

DIRECTIONS:

ELIMSTAPH NO. 2 is intended for Institutional and Industrial use. To clean, disinfect and deodorize walls, floors and other hard surfaces, use one (1) ounce ELIMSTAPH NO. 2 per gallon of water. Apply ELIMSTAPH NO 2 using a mop, cloth or sponge so as to thoroughly wet all surfaces. Allow treated surfaces to remain wet for 10 minutes and air dry. Gross filth and heavy soil deposits must be removed prior to cleaning. Change work solution daily or as it becomes visibly dirty. Please see technical brochure for additional information.

***VIRUCIDAL PERFORMANCE**

At 1 oz. per gallon use-level, ELIMSTAPH NO. 2 was evaluated in the presence of 5% serum and 400 ppm hard water for a contact time of 10 minutes at room temperature (20-25°C) against the HIV-1 (AIDS VIRUS) found on inanimate, hard, non-porous environmental surfaces.

*Kills HIV 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

Contact Time: Leave surface wet for 10 minutes with 1 oz. per gallon use dilution.

Cleaning Procedure: Blood and other body fluids containing HIV must be thoroughly

**ELIMSTAPH NO. 2
ONE STEP ANTIMICIDAL
CLEANER**

**CLEANS * DISINFECTS * SANITIZES
DEODORIZES**

ACTIVE INGREDIENTS:

n-alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride 5.00%
tetrasodium ethylene diamine tetraacetate..... .76%

INERT INGREDIENTS:

Water and octylphenoxypolyethoxyethanol... 94.22%
NON-FLAMMABLE * NON-VOLATILE * ODORLESS

Do Not Mix with soap or other detergents.
For additional information see technical brochure.

WARNING:

KEEP OUT OF REACH OF CHILDREN

Avoid contamination of food. Causes eye irritation. Avoid contact with skin -- May cause skin irritation. In case of contact, flush with water. If irritation persists, get medical attention.

FIRST AID:

In case of contact with eyes flush out immediately with plenty of water and get medical attention. If taken internally, drink milk, egg whites, or gelatin solution or, if these are not available, drink large quantities of water. Avoid alcohol. **TRIPLE RINSE EMPTY CONTAINER THOROUGHLY WITH WATER AND DISCARD.**

**FOR SALE FOR USE AND STORAGE BY
MAINTENANCE PERSONNEL ONLY.**

EPA Registration No. 2212-2
EPA Establishment Registration No. 2212-NY-1

cleaned from surface application of ELIMSTAPH NO. 2
Personal Protection: Cleaners should be done wearing protective masks, and eye protection
Disposal of Infectious Materials: Cleaning materials should be autoclaved and disposed of in accordance with local regulations for infectious waste.



Walter G. LE SUE
Environmental Maintenance
444 Central Avenue
Peekskill, NY 10868
800-345-3443
FAX 800-345-3444

OCT 19 1992

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