

2212-16

11/10/2005

Page 183

NOV 10 2005

Ms. Elizabeth Bauer
Walter G. Legg Company, Inc.
444 Central Ave.
Peekskill, NY 10566

Subject: Elimstaph 3
EPA Registration No. 2212-16
Amendment Date: August 18, 2005
EPA Receipt Date: August 24, 2005

Dear Ms. Bauer,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the conditions listed below.

- Cancellation of EPA Registration No. 2212-2
- Transfer all data supporting 2212-2 to EPA Reg. No. 2212-16
- New Primary Brand Name

Conditions

Revise the label as follows:

1. The "Storage and Disposal" section must be reorganized to reflect the following:

(Containers less than 1 gallon)
STORAGE and DISPOSAL

Do not store on the side. Avoid creasing or impacting the walls. Do not mix with soap or other detergents. Do not reuse empty container. Discard in trash or recycle if available.

(Containers greater than 1 gallon)
STORAGE and DISPOSAL

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

STORAGE: statements proposed on label are accurate.

PESTICIDE DISPOSAL: statements proposed on label are accurate.

CONTAINER DISPOSAL: statements proposed on label are accurate.

2. Since this product may be used in lavatories for disinfection, you must either state for use on the "Exterior surfaces of a toilet" or add the following directions:

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2 8 3

Toilet Bowls Disinfection: Remove heavy soil prior to disinfection. Empty toilet bowl and apply 1 oz per gallon of water. Using a cloth, mop, brush, or sponge, swab exposed surfaces and under the rim. Allow to stand for 10 minutes, then flush.

General Comments

The proposed primary brand name, Elimistaph No. 2, is acceptable for this product.

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

Should you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. May cause irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eye wear (goggles, face shield or safety glasses), protective clothing and rubber gloves. Harmful if swallowed and/or if absorbed through the skin. Wash thoroughly with soap and water after handling. Remove contaminated clothing before reuse.

FIRST AID

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling poison control center or doctor or going for treatment.
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes then continue rinsing eye.
IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth for an unconscious person.
IF INHALED: 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.
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination Systems (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

Do not contaminate food, feed or water by storage and disposal. For containers one gallon or less: Do not store on side. Avoid creasing or impacting of side walls. Do not mix with soap or other detergents. Do not reuse empty container. Discard in trash or recycle. For containers greater than one gallon: Do not contaminate food, feed or water by storage and disposal.
STORAGE: Do not store on side. Avoid creasing or impacting side walls. Do not mix with soap or other detergents.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray or mixture of 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.

CONTAINER DISPOSAL

Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration or if allowed by state and local authorities by burning. If burned, stay out of smoke.

ELIMSTAPH NO. 2

ONE STEP GERMICIDAL CLEANER AND STATIC ELIMINATOR

CLEANS * DISINFECTS * DEODORIZES
for Hospitals, Homes, Institutional and Industrial Use

ACTIVE INGREDIENTS:

n-alkyl (50% C14, 40% C12, 10% C16) dimethyl benzyl ammonium chloride 5.00%
INERT INGREDIENTS: 95.00%

NON-FLAMMABLE * NON-VOLATILE * ODORLESS

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

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO
SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No. 2212-16

EPA Establishment Registration No. 2212-NY-1



Walter G. LEGGE Co., Inc.

444 Central Ave, Peekskill, NY 10566

800-345-3443 FAX 800-332-2636

email: info@leggesystems.com www.leggesystems.com

Please call or write with questions and suggestions.

DIRECTIONS FOR USE:

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

ELIMSTAPH # 2 is a hospital use disinfectant at 1:128 dilution (1 oz per gallon). Bactericidal according to the current AOAC Use-Dilution Test Method and Virucidal* according to the virucidal qualification modified in the presence of 400 ppm hard water plus 5% organic serum against:

- | | |
|-------------------------------------|-----------------------|
| Pseudomonas aeruginosa | Staphylococcus aureus |
| Salmonella choleraesuis | Serratia marcescens |
| *HIV-1 (AIDS Virus) | |
| *Influenza Virus (A-Z/Hong Kong/68) | |
| *Herpes Simplex Type 1 | *Vaccinia (Pox Virus) |

ACCEPTED with COMMENTS

NOV 10 2005

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 2212-16

ELIMSTAPH NO. 2 is intended for use in Hospitals, nursing homes, doctor's offices, schools, locker rooms, lavatories, barber shops, office spaces and clubs.

Cleaning/Deodorization: To clean and deodorize hard, non porous surfaces prepare a use solution of 1 oz of product per gallon of water. Using a mop, sponge, or cloth, wet surfaces and allow to air dry.

General Disinfection: Pre-cleaning is required for heavily soiled areas. To disinfect hard non-porous surfaces such as walls, floors, Mix 1 oz to 1 gallon of water, apply use solution with sponge, cloth or mop as to thoroughly wet surfaces. Let stand for 10 minutes and allow to air dry. Change use solution daily or as it becomes visibly dirty/soiled.

Barber (Salon) Instruments and Tools Disinfection: Pre-cleaning is required for heavily soiled instruments and tools. To disinfect hard, non porous instruments and tools mix 1 oz. to 1 gallon of water. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the solution becomes visibly diluted, cloudy, or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean, non contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

Disinfection of Personal Safety Equipment: To disinfect personal safety equipment such as hard hats, face shields, goggles, spectacles, protective headgear, hearing protectors, gas masks, and self-contained breathing apparatus (SCBA), Mix 1 oz to 1 gallon of water, apply use solution by immersion or with sponge or cloth as to thoroughly wet surfaces. Let stand for 10 minutes then thoroughly rinse equipment with clean water. Allow to air dry before reuse. Change use solution daily or as it becomes visibly dirty/soiled. Use product in conjunction with the use instructions provided with the safety equipment to avoid damage.

***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 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"

Personal Protection: Clean-up should always be done wearing protective latex gloves, gowns, masks and eye protection.

Cleaning Procedure: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of ELIMSTAPH NO.2.

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

Disposal of Infectious Material: Blood, body fluids, cleaning materials, and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

At 1 oz per gallon use level ELIMSTAPH # 2 eliminates static electricity on surfaces not affected by water. Lightly spray the area where you want to control static electricity and let air dry.

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