

2212-16

01/05/2010
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

JAN 5 2010

Ms. Elizabeth A. Bauer,
Walter G. Legge Co., Inc.,
444 Central Ave,
Peekskill, N.Y. 10566

Subject: Elimstaph No.2
EPA Registration No. 2212-16
Application Date: 10/06/09
Receipt Date: 10/07/09

Dear Ms. Bauer,

The following amendment submitted in connection with registration under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable as proposed below:

Proposed Amendment

- "Disposal of Infectious Material" statement under the HIV directions

General Comments

A stamped copy of the accepted label 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 Velma Noble PM Team 31 at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,

Velma Noble,
Product Manager, Team 31
Regulatory Management Branch
Antimicrobials Division (7510P)

Enclosure

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

PROOF OK'D

By: _____

Cust: _____

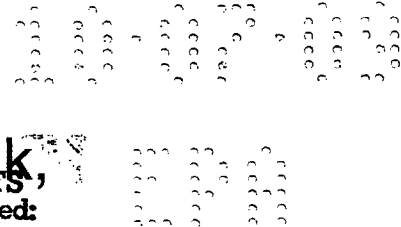
Date: _____

PLEASE SIGN AND RETURN

Walter Legge Co.
 4³/₄" x 10¹/₂" R.C.R. Labels
 Revised Copy—
 Prints: PMS 334 Green, 23rd Pink,
 Reflex Blue & Black

ACCEPTED
 WITH COMMENTS
 in EPA Letter Dated:
JAN - 5 2010

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



**PRECAUTIONARY STATEMENTS
 HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (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 to 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 System (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.

(Containers less than 1 gallon)

STORAGE AND DISPOSAL

Do not store on side. Avoid creasing or impacting of sidewalls. 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: 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

E.P.A. Registration No. 2212-16
 E.P.A. Establishment Registration No. 2212-NY-1

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. ELIMSTAPH NO. 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 |
| Staphylococcus aureus Methicillin-Resistant (MRSA) ATCC #33591 | Serratia marcescens |
| Salmonella enterica | |
| *HIV-1 (AIDS Virus) | |
| *Influenza Virus (A-Z/Hong Kong/68) | *Vaccinia (Pox Virus) |
| *Herpes Simplex Type 1 | |



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 444 Central Avenue • Peekskill, NY 10566
 800-345-3443 or 914-737-5040
 FAX 800-332-2636
 email: info@leggesystems.com www.leggesystems.com

Please call, FAX or write us with your questions or comments.

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.

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 swab exposed surfaces and under rim. Allow to stand for 10 minutes, then flush.

***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 must be autoclaved and disposed of according to local regulations for infectious waste disposal.

At 1 oz. per gallon use level ELIMSTAPH NO. 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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