

2212-17

6/22/2005

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 22, 2005

Jeff Bauer
Walter G. Legge Company, Inc.
444 Central Avenue
Peekskill, NY 10566

Subject: LEGPHENE 2
EPA Registration Number 2212-17
Application Date: March 22, 2005
EPA Received Date: March 28, 2005

Dear Mr. Bauer:

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

Proposed Amendment

- Revised labeling

Other Comments

Please note that there is a typographical error on page three of the product label. Revise the Decontamination directions by changing "... (20E - 23E C/68E - 72E F)..." to read "... (20° - 23° C/68° - 72° F)..."

General Comments

A stamped copy of the accepted labeling is enclosed. Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)

CONCURRENCES

SYMBOL	7510C						
SURNAME	Heyward						
DATE	6/22/05						

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CENTER PANEL

LEGPHENE 2[®]
BROAD SPECTRUM
GERMICIDAL CLEANER
CONCENTRATE
1 oz./gallon

Detergent, Disinfectant, Deodorant,
Germicidal, Fungicidal, *Virucidal, Tuberculocidal

ACTIVE INGREDIENTS:

Ortho-benzyl-para-chlorophenol	... 3.80%
Para-tertiary amylphenol	... 3.74%
Ortho-phenylphenol	... 2.35%
INERT INGREDIENTS:	... <u>90.11%</u>
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER PELIGRO

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

E.P.A. Registration No. 2212-17
E.P.A. Establishment Registration No. 2212-NY-1

Formulated for hospital use, LEGPHENE 2 contains three distinctive active phenols, carefully formulated with selected surfactants, wetting, chelating and solubilizing agents, in effect, providing the industry with a reliable and versatile germicidal concentrate.

For use in Hospitals, Nursing Homes, Public Areas, Institutions, Hotels, and Industrial areas. LEGPHENE 2 is recommended for operating room use.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Hard non-porous surfaces: To clean, disinfect and deodorize walls, floors, furniture, shower/bathing areas, lavatories and other hard non-porous inanimate surfaces add (1) ounce LEGPHENE 2 per gallon of water. Apply solution using a mop, cloth or coarse spray device so as to wet all surfaces thoroughly. Remove gross filth and heavy soil and preclean prior to disinfecting. Allow treated surfaces to remain wet for 10 minutes and air dry. Prepare a fresh solution daily or more often if the solution becomes diluted or soiled. Do not reuse solution. LEGPHENE 2 has been tested under the AOAC Tuberculocidal activity test method, effective in 10 minutes at 20 C.

Walter G. LEGGE Company, Inc.
444 Central Ave
Peekskill NY 10566

914-737-5040 or 800-345-3443
FAX 914-737-2636 or 800-332-2636

email: info@leggesystems.com www.leggesystems.com
Please call or write with questions and suggestions.

ACCEPTED
with COMMENTS
EPA Letter Dated:

JUN 22 2005

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 2212-17

3 8 4

LEFT PANEL

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

DANGER: Corrosive. May cause irreversible eye damage or skin burns. Harmful if swallowed, absorbed through the skin, or inhaled. Do not get in eyes, on skin, or on clothing. Avoid breathing spray mist. Wear coverall over long-sleeved shirt and long pants, socks and chemical resistant gloves (such as Barrier laminate, or Butyl/nitrile/Neoprene rubber, PVC, Viton with ≥ 14 mils). Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash 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.

HOTLINE NUMBER

In case of emergency call toll-free 1-800-336-6997. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

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

For Containers 1 gallon and less: Do not store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

For Containers Over 1 gallon: Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE

Do not store on side. Avoid creasing or impacting of side walls.

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.

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.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washable, use detergent and hot water. Keep and wash PPE separately from other laundry.

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

General Precautions and Restrictions

Following application as a low-pressure or high-pressure spray, do not enter or allow others to enter the treated area until sprays have dried. For all spray applications: Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during applications. For pour, pump, mop, and wipe applications: Do not apply this product in a way that will contact other persons. Only protected handlers may be in the area during application.

PHYSICAL OR CHEMICAL HAZARD

Combustible: Do not use or store near heat or open flame.

Right Panel

***VIRUCIDAL PERFORMANCE**

At 1 oz. per gallon use level, LEGPHENE 2 was evaluated in the presence of 5% serum and 400 ppm hard water for a contact time of 10 minutes at room temperature (20-23 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 Type1 (HIV-1) (associated with AIDS).

FOR USE IN ULTRASONIC CLEANING MACHINE. LEGPHENE 2 Germicidal Hospital Grade Ultrasonic Cleaner Concentrate is designed to be used in an Ultrasonic Cleaning System as a cleaner or decontaminant prior to terminal sterilization or high level disinfection of non-porous items such as instruments or appliances.

DILUTION: To supply the proper dose of solution, remove cap from unit dose chamber and squeeze bottle to fill reservoir. Use at a dilution level of ½ ounce of LEGPHENE 2 Germicidal Cleaner per half gallon of water or 1 ounce per gallon of water (1:128). Pour concentrate into tray, pan or ultrasonic tank and add water to recommended level.

PRE-SOAK: Place contaminated instruments in a holding tray or auxiliary pan filled with properly diluted LEGPHENE 2. Transfer to an L&R Ultrasonic Cleaning System also filled with LEGPHENE 2 when ready for cleaning cycle. Dispose of solution daily.

DECONTAMINATION: Place contaminated instruments and/or appliances after they have been thoroughly cleaned (preferably in an L&R Ultrasonic Cleaning System) into properly mixed LEGPHENE 2. Make sure to properly rinse and dry instruments prior to placing in tray or pan. Completely immerse for 10 minutes at room temperature (20E-23E C/68E-72E F) for proper decontamination. Instruments and appliances must be removed and thoroughly rinsed prior to terminal sterilization or high level disinfection. Change solution daily or sooner if required.

ULTRASONIC CLEANING EQUIPMENT: Add LEGPHENE 2 Ultrasonic Cleaner Concentrate and water, at the proper dilution ratio, as stated above (1:128) to your ultrasonic machine. Fill the basket with pre-cleaned instruments, place cover on machine and run a cycle of 10 minutes. DO NOT use the heater on the machine, as this will cause vaporization of the germicide. After completing the cycle, turn off machine and lift the basket, allowing drainage and then rinse in running water. The solution should be replaced daily, more often if heavy contamination occurs. **DO NOT MIX WITH ANY OTHER MATERIALS.**

NOTE: This product is not to be used as a terminal sterilant / 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.

"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 cleaned from surfaces and objects before application of LEGPHENE 2.

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

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.

GERMICIDAL ACTIVITY:

LEGPHENE 2 is effective against a wide range of organisms as demonstrated by the AOAC test method, modified in 400 ppm hard water (as CaCO₃). Representative organisms include: HIV-1, Staphylococcus Aureus, Pseudomonas Aeruginosa, and Salmonella Choleraesius. Additional testing was performed using the standard AOAC test method without the addition of hard water. Representative organisms include: Serattia Marcescens, Herpes Simplex 2, (TB) Mycobacterium Bovis BCG, and Trichophyton mentagrophytes.