

2212-17

04/07/2000

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U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (H7505C)  
431 "M" St., S.W.  
Washington, D.C. 20460

EPA Reg. Number:  
2212-17

Date of Issuance:  
APR 7 2000

NOTICE OF PESTICIDE:  
 Registration  
 Reregistration

Term of Issuance:  
Conditional

Name of Pesticide Product:  
Legphene 2

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Walter G. Legge Co, Inc.  
444 Central Ave.  
Peekskill, NY 10566  
ATTN. Larry LePore

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

- a. Revise the EPA Registration Number to read, "EPA Reg. No. 2212-17".
- b. In the "Active and Inert Ingredients" add both ingredients and TOTAL 100.0% on front panel.

Signature of Approving Official:

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

Date:

APR 7 2000

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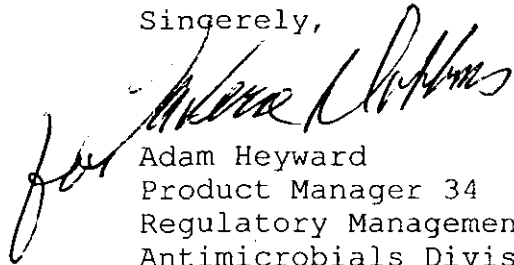
- c. Warranty Statements of disclaimer must be added to the proposed product labeling regarding your company's liability on back panel.
- d. Registrant Name and Address must be listed on hang tag bottom back panel.
- e. Submit a revised Confidential Statement of Formula and in block 13b, 14a and 14b enter the correct nominal concentrations which would agree with the label claim for the subject product. Enclosed for your information is a copy of the corrected CSF nominal concentrations dated February 24, 2000, in which you must filled-out correctly and submit to this Agency for the record.
- f. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label and CSF dated February 24, 2000 are enclosed for your records.

If you have any questions concerning this letter, please contact LaVerne Dobbins at (703) 308-6378.

Sincerely,



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

Enclosure

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HANG TAG FRONT:

**LEGPHENE 2**

Germicidal Hospital Grade Ultrasonic Cleaner Concentrate  
1oz/gallon

One step: 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	90.11%

Contents: 16 fl. oz. (473 ml) makes 16 gallons

**KEEP OUT OF THE REACH OF CHILDREN**  
**DANGER:**

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

**DIRECTIONS FOR USE:** For use in Ultrasonic Cleaning Machines. **LEGPHENE 20** 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 1/2 ounce of **LEGPHENE 20** 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 20** Germicidal. Transfer to a L&R Ultrasonic Cleaning System also filled with **LEGPHENE 20** Germicidal 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 20** Germicidal. Make sure to properly rinse and dry instruments prior to placing in tray or pan. Completely immerse for 10 minutes at room temperature (20°-23° C/68°-72° 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** Germicidal Hospital Grade 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.

ACCEPTED  
WITH COMMENTS  
DATE: 4/7/2000

APR '7 2000  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide  
registered under EPA Reg. No.

2212-17

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**HANG TAG BACK:**

"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 Germicidal. Personal Protection: Clean up should always be done wearing protective latex gloves, gowns, masks, and eye protection. 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 Germicidal is effective against the following organisms as demonstrated by the AOAC test method, modified in 400 ppm hard water (as CaCO<sub>3</sub>): Mycobacterium Bovis (TB), HIV-1, Staphylococcus aureus, Salmonella choleraesuis and Pseudomonas aeruginosa. Additional testing was performed using the standard AOAC test method. Representative organisms include: Seratia marcescens, Influenza A2 (Hong Kong), Herpes simplex, Vaccinia (pox virus), Trichophyton interdigitale, and Escherichia coli.

ACCEPTED  
with COMMENTS  
Letter Dated:  
APR 7 2000.

for the Federal Insecticide,  
Fungicide, and Rodenticide Act or  
intended for the pesticide  
registered under EPA Reg. No.

**PRECAUTIONARY STATEMENT  
HAZARD TO HUMAN AND DOMESTIC ANIMALS**

**DANGER:**

**CORROSIVE.** Causes eye damage 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 with eyes, flush out immediately with plenty of water and get medical attention. If contact with skin occurs, flush off with water. If swallowed, promptly drink a large quantity of water. Avoid alcohol. Call a physician.

LEGPHENE 2 Germicidal contains three distinctive active phenols, carefully formulated with selected surfactants, wetting, chelating and solubilizing agents, in effect, providing a reliable germicidal disinfectant concentrate.

**STORAGE AND DISPOSAL:** Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

**PESTICIDE DISPOSAL:** Pesticide spray mixture or rinse water that cannot be used according to label instructions must be disposed of according to federal or approved state procedures under subtitle C of the Resource, Conservation and Recovery Act.

**CONTAINER DISPOSAL:** Triple rinse (or equal) then offer for recycling or reconditioning or dispose of in a sanitary landfill or by incineration if allowed by state and local authorities.

**GENERAL DISPOSAL:** Consult Federal, State or Local Disposal authorities for approved alternate procedures.

CAS NUMBER	CHEMICAL NAME	CAS NUMBER	CHEMICAL NAME
7732-18-5	Water	119345-4-9	Dowfax 2A1 Solution
67-63-0	Isopropanol	64-02-8	Tetrasodium EDTA Tetrahydrate
120-32-1	o-benzyl-p-chlorophenol	7757-83-7	Sodium sulfite
80-46-6	para-tertiary-amylphenol	1310-58-3	Potassium hydroxide
90-43-7	o-phenylphenol	Mixture	Perfume

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

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Bottle LABEL FRONT:

LEGPHENE 2

Germicidal Hospital Grade Ultrasonic Cleaner Concentrate

One Step: Detergent, Disinfectant, Deodorant,

Active Ingredients:

Ortho-benzyl-para-chlorophenol	3.80%
Para-tertiary-amylphenol	3.74%
Ortho-phenylphenol	<u>2.35%</u>
Inert Ingredients	90.11%

**DANGER: KEEP OUT OF REACH OF CHILDREN**

Refer to back label and hang tag for additional information.

Manufactured by:

Walter G. Legge Company, Inc.

444 Central Ave

Peekskill NY 10566

914-737-5040 Fax 914-737-2636

E.P.A. Registration No. 2212-RT

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

Contents 16 fl. oz.

(473 ml)

Product Code UD036

1 ounce concentrate makes 1 gallon solution.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

APR 7 2000

for use Federal Insecticide  
and acaricide labels  
intended for the pesticide  
registered under EPA Reg. No.

2212-17

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Bottle LABEL BACK

**PRECAUTIONARY STATEMENT  
HAZARD TO HUMAN AND DOMESTIC ANIMALS**

**DANGER:**

**CORROSIVE.** Causes eye damage 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.

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **FOR USE IN ULTRASONIC CLEANING MACHINE.** LEGPHENE 20 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.

See hang tag for additional precautions and First Aid.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
APR 7 2000

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended for the pesticides,  
registered under EPA Reg. No.

2212-17