

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG - 6 2002

Lawrence M. LePore  
Vice President of Sales  
Walter G. Legge Co., Inc.  
444 Central Avenue  
Peekskill, NY 10566

Subject: Notification per PR Notice 98-10  
Legphene 2  
EPA Registration No 2212-17  
Application Dated: July 10, 2002  
EPA Received Date: July 12, 2002

Dear Mr. LePore:

This letter acknowledges receipt of your notification, submitted in connection with registration under FIFRA 3(c)9 and PR Notice 98-10.

**Proposed Notification**

- Addition of the statement "...without the addition of hard water." following the statement "Additional testing was performed using the standard AOAC test method."
- Delete the following organisms: Influenza, Vaccina and Escherichia from the label
- Move the TB statement to after the statement "without the addition of hard water"

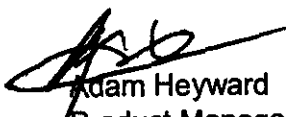
**General Comments**

Based on a review of submitted materials, the following comment applies:

The application for notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions regarding 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	7510.C							
SURNAME	Heyward							
DATE	8-5-02							



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 2212 -17	2. EPA Product Manager Adam Hayward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Walter G. Legge Co., Inc. Legphene 2	PM#	
5. Name and Address of Applicant (Include ZIP Code) Walter G. Legge Co., Inc. 444 Central Ave Peekskill NY 10566 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)  
minor label change as described in attached letter and on enclosed label.

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 4oz sample, quart, 1, 2.5, 5, 55 gallon		5. Location of Label Directions <input type="checkbox"/> affixed to container	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled			<input type="checkbox"/> Other _____		

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name	Title	Telephone No. (Include Area Code) 914-737-5040
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamp)    
2. Signature	3. Title	
4. Typed Name Jeff Bauer	5. Date 05/15/02	

HANG TAG BACK:

**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 Typel (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 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>): Representative organisms include: HIV-1, Staphylococcus aureus, Pseudomonas aeruginosa and salmonella Choleraesuis. Additional testing was performed using the standard AOAC test method without the addition of hard water.. Representative organisms include: Seratia marcescens, Herpes simplex 2, Mycobacterium Bovis (TB), and Trichophyton.

**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 store on side. Avoid creasing or impacting of side walls. Do not reuse empty container. Discard in trash or recycle.

**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 s 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.

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-amyphenol	1310-58-3	Potassium hydroxide
90-43-7	o-phenylphenol	Mixture	Perfume

E.P.A. Registration No. 2212-17

**NOTIFICATION**  
Data Reviewed: A Peters  
Reviewed By: 7.15.02

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-amyphenol	3.74%
Ortho-phenylphenol	2.35%
Inert Ingredients	<u>90.11%</u>
Total	100.00%

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 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 ¼ 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® Germicidal. Transfer to a L&R Ultrasonic Cleaning System also filled with LEGPHENE 2® 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 2® 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.

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Bottle LABEL FRONT:

### LEGPHENE 2

Germicidal Hospital Grade Ultrasonic Cleaner Concentrate

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	<u>90.11%</u>
Total	100.00%

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

Refer to back label and hang tag for additional information.

E.P.A. Registration No. 2212-17-72869

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

Contents 16 fl. oz.

(473 ml)

Product Code UD036

1 ounce concentrate makes 1 gallon solution.

Manufactured by:

Walter G. LEGGE Company, Inc.

444 Central Ave

Peekskill NY 10566

6 7 6

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.**