

1043-118

8-13-2002

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460-0001

EPA Reg. Number:

1043-118

Date of Issuance:

August 13, 2002

NOTICE OF PESTICIDE:

Registration
 Reregistration

(Under FIFRA, as amended)

Terms of Issuance:

Conditional

Name of Pesticide Product:

LpH®

Name and Address of Registrant (include ZIP Code):

STERIS CORPORATION
P.O. Box 147
St. Louis, MO 63166-0147

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 section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA section 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 Registration Number 1043-118"

Signature of Approving Official:


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

Date: August 13, 2002

- b. Since this product was not tested in the presence of an organic soil load, all claims for simultaneous cleaning and disinfection must be removed from the label.
- c. Additional directions for precleaning surfaces prior to application of the product must be added to the label.
- d. Since this product is not intended for use in hospitals as a precleaner or decontaminant, the following statement must be deleted from the label:

“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.”

- e. Revise the precautionary statement to read as follows:

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

Corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed, absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shields (safety glasses). Wear protective clothing (long-sleeve shirt and long pants, socks plus shoes and chemical resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

- f. The ingredient statement must total 100%, i.e., Total . . . 100.00%.

g. The storage and disposal text must be revised to read as follows:

STORAGE AND DISPOSAL

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

"PESTICIDE STORAGE: (As per PR Notice 83-3, you must include appropriate storage instructions)

"PESTICIDE DISPOSAL. : Wastes resulting from the use of this product maybe disposed of on site or at an approved waste disposal facility.

"CONTAINER DISPOSAL: Triple rinse and deposit in a waste container for incineration or in a landfill approved for pesticide containers.

GENERAL: Consult Federal, State, or Local disposal authorities for approved alternate procedures such as limited open burning.

Refer to PR Notice 83-3 for appropriate instructions as per container sizes.

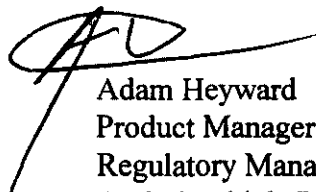
3. The basic Confidential Statement of Formula dated November 11, 2002 is acceptable. Within one year form the date of this notice, you must submit a corrosion characteristics study using Good Laboratory Practices in support of the subject product.
4. It is also understood that a one-year storage stability study is being conducted on the proposed product.

Submit three (3) copies of the revised final printed label bearing the revisions prior to releasing this product for sale.

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

A stamped copy of the label is enclosed for your records.

Sincerely,



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

Enclosure:

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed.

(For 5 gal. or larger containers) ENVIRONMENTAL HAZARD STATEMENT: 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.

DESCRIPTION: LpH is a low pH, research-developed, concentrated, hard water effective, broad spectrum germicidal detergent for simultaneous cleaning, disinfection, and deodorization. With its detergents and 880 ppm acid-phenolic germicide, LpH solution simultaneously cleans, disinfects and deodorizes all washable hard surfaces such as bathroom fixtures, walls, woodwork, equipment, furniture, chrome, stainless steel, porcelain, glass, tile, washable painted or varnished surfaces, terrazzo, resilient vinyl, asphalt, linoleum, and rubber floors.

USE AREA: LpH is intended for use in commercial facilities, industrial plants, veterinary hospitals and agricultural facilities.

GERMICIDAL: Passes A.O.A.C. Germicidal Use-Dilution Method (*S. aureus*, *S. choleraesuis*) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in 10 minutes at 20°C.

DIRECTIONS FOR USE

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

CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES: Add 1 fl. oz. (30 ml) to each measured gallon of water used. Always add this product to pre-measured water. Thoroughly mix solution until uniform. Apply solution with a cloth, sponge, mop or brush using normal cleaning methods. Allow treated surfaces to soak for 10 minutes. Then remove excess solution with a wrung-out applicator. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution daily or when it becomes dirty and replace with a fresh solution. This is a complete product. Do not add other chemicals. If frozen, thaw and re-mix. Use only as directed.

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.

STORAGE AND DISPOSAL

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

PESTICIDE DISPOSAL: This germicide, its solutions or rinsings from empty containers, should be disposed of in a toilet or service sink served by a sanitary sewer, or in a landfill approved for pesticides.

CONTAINER DISPOSAL: Triple rinse and deposit in a waste container for incineration or in a landfill approved for pesticide containers.

GENERAL: Consult Federal, State, or Local disposal authorities for approved alternative procedures such as limited open burning.

(Logo) STERIS Corporation
7501 Page Ave.
St. Louis, MO 63133 U.S.A.

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

AUG 13 2002

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

1043-118

LpH[®]
GERMICIDAL DETERGENT

EPA REG. NO. 1043-XXX

EPA Est. No. 1043-MO-2

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

Active Ingredients:

Ortho-benzyl-para-chlorophenol 6.4%
Para-tertiary-amylphenol 3.0%
Ortho-phenylphenol 0.5%

Inert Ingredients 90.1%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See side panel for additional precautionary statements.

NET CONTENTS:

FIRST AID	
If inhaled	<ul style="list-style-type: none"> • 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.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. • Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call 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 the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER	
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.	

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