



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

1043-127

Date of Issuance:

7/10/17

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

LpH III se Phenolic Disinfectant

Name and Address of Registrant (include ZIP Code):

Steris Corp
7501 Page Avenue
St. Louis, MO 63133

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials 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 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). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Jacqueline Hardy, Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date:

7/10/17

2. You are required to comply with the data requirements described in the DCI or EDSP Order identified below:
 - a. o-phenylphenol: GDCI-64103-1427
 - b. 2-benzyl-4-chlorophenol: GDCI-62201-1354

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 1043-127.”
4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the basic CSF dated 9/19/2016.

If you have any questions, please contact Lorena Rivas by phone at (703) 308-8075, or via email at rivas.lorena@epa.gov.

Sincerely,

A handwritten signature in red ink that reads "Jacqueline Hardy". The signature is written in a cursive style and is enclosed within a faint, light-colored rectangular border.

Jacqueline Hardy, Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Stamped approved label

LpH[®] III se Phenolic Disinfectant

Reorder Number: XXX

Net Contents: XXX

Germicide • Fungicide • Virucide* • Tuberculocide • Deodorizer • Cleaner • Detergent

[When diluted with soft or hard water (400 ppm CaCO₃) even in the presence of organic soil (5% serum)]

INTENDED FOR INDUSTRIAL AND INSTITUTIONAL USE

Active Ingredients:

o-phenylphenol.....6.00%

o-benzyl-p-chlorophenol.....13.00%

Inert Ingredients:81.00%

Total:100.00%

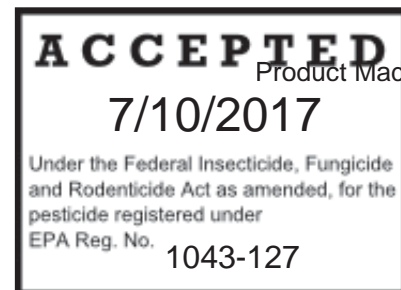
EPA Reg. No. 1043-XXX [EPA Est. No. 211-KS-001] [EPA Est. No. 1043-MO-2] [EPA Est. No. 11563-MI-1]

**KEEP OUT OF REACH OF CHILDREN
DANGER**

FIRST AID	
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 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 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 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.	

See [side panel] [back panel] [insert] for additional precautionary statements [and][or][directions for use].

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



[Brackets denote optional text.]

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS:

DANGER: Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes, on skin or on clothing. Avoid vapor or spray mist. Wear goggles, face shield or safety glasses. Wear waterproof gloves, long-sleeved shirt, long pants and shoes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARD STATEMENT: *(For use on containers 5 gallons and larger)* Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters 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.

This non-alkaline phenolic germicidal detergent is effective in hard or soft water even in the presence of organic soil (5% blood serum). The use-solution of this product when diluted one ounce per gallon of water is specially formulated to clean, disinfect and deodorize in a simple one-step process. With its non-alkaline base, it will remove soap scum and hard water salts which can harbor bacteria. Use this product on washable, hard, non-porous environmental surfaces: floors, walls, and counters in veterinary clinics, animal research facilities, healthcare facilities, hospitals, medical and dental offices.

Use for one-step cleaning, disinfecting and deodorizing of stainless or galvanized steel and chrome, glazed porcelain, plastics, glass, glazed tile, washable painted or varnished surfaces, as well as resilient vinyl, linoleum, rubber, glazed terrazzo and sealed concrete floors.

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 blood stream 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.

GERMICIDAL: When tested against *S. aureus* (ATCC 6538), *P. aeruginosa* (ATCC 15442), *T. interdigitales* (ATCC 9533), and Influenza A2 Virus (H2N2), A/2/Japan/305/57 it passes the A.O.A.C. Germicidal Use-Dilution Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (one ounce per one gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

BACTERICIDAL: When tested against *A. baumannii* (ATCC 19606), *E. coli* (ATCC 25922), *E. cloacae* (ATCC 13047), *M. luteus* (ATCC 7468) and *S. marcescens* (ATCC 14756), it passes the A.O.A.C. Germicidal Use-Dilution Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (one ounce per one gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

FUNGICIDAL: When tested against *T. interdigitales* (ATCC 9533), it passes the A.O.A.C. Fungicidal Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (one ounce per one gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

TUBERCULOCIDAL: When tested against *Mycobacterium tuberculosis* var. bovis, BCG, it passes the A.O.A.C. Tuberculocidal Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (one ounce per one gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

* **VIRUCIDAL:** When tested against Influenza A2 Virus (H2N2), A/2/Japan/305/57, Adenovirus Type 2, Virus (ATCC VR 846) and Avian Influenza Virus (H9N2) it passes the Virucidal Assay (EPA Proposed Method) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (one ounce per one gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20°C.

When tested, the HIV-1(AIDS) virus (Clinical Isolate), with added 5% organic soil (serum), was completely inactivated by a 1:128 (one ounce per one gallon) solution in 400 ppm A.O.A.C. hard water in 10 minutes at 20°C.

[This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus. or
Kills Pandemic 2009 H1N1 influenza A virus formerly called swine flu.]

ODOR CONTROL: It eliminates many odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors and leaving a pleasant fragrance. Follow “**CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES**” directions.

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: To make solution, add one fluid ounce (30 cc) to each pre-measured one gallon of water [or one packet per quart (0.946 L) of water] and gently mix until solution is uniform. **NOTE:** Always add this product (concentrate) to pre-measured water. Apply solution with a cloth, sponge, mop, brush or by coarse spray using normal cleaning methods. Allow treated surfaces to soak for 10 minutes, then remove excess solution with a wrung-out applicator. Prepare a fresh dilution at least daily or as solution becomes dirty, discard and replace with a fresh one. Before cleaning begins, always sweep or dust mop area to be cleaned thoroughly, removing any gross filth. This is a complete product. Do not add or dilute with other chemicals. If frozen, thaw and re-mix before use. Use only as directed.

Veterinary Clinics and Animal Research Facilities: Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter, droppings, and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with the disinfecting solution for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, coops, cars, boats, and other closed spaces. Do not house livestock or empty equipment until treatment has been absorbed, set, or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in 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 HIV-1 (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks and eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of a 1:128 use-solution (one ounce per one gallon) [or one ¼ fluid ounce (7.40 ml) packet per quart (0.946 liter) of water]. Prepare and apply solution as directed in paragraph above.

Contact Time: The HIV-1 virus is inactivated in 10 minutes.

Infectious Materials Disposal: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Do not store near heat or open flame. If frozen, thaw and remix before use.

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:

(For Packet:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or dispose in sanitary landfill or by other procedures approved by state and local authorities.

(For ≤5 gal:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or dispose in sanitary landfill or by other procedures approved by state and local authorities. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(For > 5 gal:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available or dispose in sanitary landfill or by other procedures approved by state and local authorities. Clean container promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

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

[Sterile unless packaging is compromised.]