

1043-92

4/5/2011

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

APR - 5 2011

Mr. Michael G. Sarli
Manager, Regulatory Affairs
STERIS Corporation
P.O. Box 147
St. Louis, MO 63166-0147

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: LpH®se
EPA Registration No.: 1043-92
Application Date: 01/10/2011
Receipt Date: 01/12/2011

Dear Mr. Michael G. Sarli:

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions.

Proposed Amendment

- Addition of EPA Est. No. 211-KS-001

Conditions

- 1) On page three, in the Personal Protection under Special Instructions for Cleaning and Decontamination against HIV-1, delete "or" and state "and."
- 2) Revise the third statement under "Container Disposal" for all sizes to read "Offer for recycling if available or dispose in sanitary landfill or by other procedures approved by state and local authorities."

General Comments

A stamped label with conditions is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov.

Sincerely,

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

Enclosure: Stamped label

2015

LpH[®] se
ONE-STEP GERMICIDAL DETERGENT
(or SERUM EFFECTIVE ONE-STEP GERMICIDAL DETERGENT)

Reorder Number:
6466-08
6466-01

Net Contents:
3.78 Liters (1 Gal.)
208.18 Liters (55 Gal.)
1/8 fl. oz.
1 fl. oz.

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

ACCEPTED
with COMMENTS
EPA Letter Dated:

Active Ingredients:
o-phenylphenol.....7.7%
p-tertiary amyphenol.....7.6%
Inert Ingredients:.....84.7%
Total:100.0%

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

KEEP OUT OF REACH OF CHILDREN
DANGER

1043-92

See side panel for additional precautionary statements

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.	

STERIS Corporation
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St. Louis, Mo 63133 U.S.A.
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EPA Reg. No. 1043-92 EPA Est. No. 1043-MO-2
EPA Est. No. 211-KS-001



Product Made in U.S.A.

DRAFT 3/3/11
1 of 4

This non-alkaline phenolic germicidal detergent is a state-of-the-art, concentrated scientifically developed product 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-half 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, counters in food processing preparation and service facilities, veterinary clinics, animal research facilities, healthcare facilities, hospitals, medical and dental offices.

This product is not for use in the neonatal (newborn) units in hospitals specifically isolettes and other infant contact surfaces.

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), *S. enterica* (ATCC 10708), *P. Aeruginosa* (ATCC 15442), 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 1:256 (one half ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

BROAD SPECTRUM DATA: The following additional organisms pass the A.O.A.C. Use-Dilution Test in 400 ppm A.O.A.C. hard water at a dilution of 1:256 in the presence of 5% organic soil (serum), 10 minutes at 20°C.

- Acinetobacter calcoaceticus, ATCC 19606
- Candida albicans, Clinical Isolate
- Candida parapsilosis, Clinical Isolate
- Citrobacter freundii, ATCC 8090
- Enterobacter aerogenes, ATCC 13048
- Enterobacter cloacae, ATCC 23355
- Escherichia coli, ATCC 25922
- Klebsiella pneumoniae, ATCC 13883
- Proteus mirabilis, Clinical Isolate
- Proteus vulgaris, ATCC 13315
- Pseudomonas aeruginosa, ATCC 27853

- Salmonella typhi, ATCC 6539
- Salmonella typhimurium, ATCC 14028
- Serratia marcescens, ATCC 8100
- Shigella flexneri, ATCC 12022
- Shigella sonnei, ATCC 25931
- Staphylococcus aureus, ATCC 25923
- Staphylococcus aureus, (MRSA), Multiply (Methicillin)-Resistant Clinical Isolate
- Staphylococcus epidermidis, ATCC 12228
- Streptococcus faecalis, ATCC 19433
- Streptococcus pyogenes, ATCC 19615

FUNGICIDAL: When tested against *T. mentagrophytes* (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 1:256 (one-half ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

TUBERCULOCIDAL: When tested against *Mycobacterium tuberculosis* var. *bovis*, BCG (ATCC 35743), it passes the A.O.A.C. Tuberculocidal Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

***VIRUCIDAL:** When tested against Influenza Virus A₂ (Japan) (Clinical Isolate), Herpes simplex Virus Type 2 (ATCC VR 734), Vaccinia Virus (Clinical Isolate) and, Adenovirus Type 2 (ATCC VR 846), it passes the Virucidal Assay (EPA Proposed Method) when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20°C.

When tested against Duck Hepatitis B virus (DHBV) as a surrogate for Human Hepatitis B virus (HBV) it passes Virucidal Efficacy Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 24°C.

When tested, the HIV-1(AIDS) virus (Clinical Isolate), with added 5% organic soil (serum), was completely inactivated by a 1:256 (one-half ounce per 1 gallon) solution in 400 ppm A.O.A.C. hard water in 60 seconds at 20°C. Although efficacy at 1 minute contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for disinfection against all of the organisms claimed.

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.

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS:**

DANGER: Corrosive. Causes irreversible eye damage. Do not get in eyes, or on clothing. Wear protective eyewear. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash 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.

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-PORUS SURFACES: To make solution, add one-half fl. oz (15 cc) to each pre-measured gallon of water [or one 1/8 fl. Oz (3.70ml) packet per quart (0.946) 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. As solution becomes dirty, discard and replace with a fresh one. A properly prepared solution of LpHse intended for use as a hard surface disinfectant has a shelf life of 14 days (use life) when stored in a closed container such as a spray bottle. Before cleaning begins, always sweep or dustmop 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.

Directions for use with Twin-Neck Dispensing Bottle: To make one gallon (1:256) solution, loosen cap from dispensing chamber. Gently squeeze bottle to fill measuring chamber to the 1/2 fluid ounce line. Remove cap from dispensing chamber. Pour measured product (concentrate) from the chamber into one gallon (128 ounces) of pre-measured cold water and mix well. Apply as directed above.

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 and HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in healthcare 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 Type HIV-1 (associated with AIDS) or Hepatitis B Virus (HBV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) and HBV 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 1:256 use-solution (one-half ounce per 1 gallon) [or one 1/8 fl. Oz (3.70ml) packet per quart (0.946) of water]. Prepare and apply solution as directed in paragraph above.

Contact Time: While the HIV-1 virus is inactivated in 1 minute, use a 10-minute contact time for disinfection of HBV and all organisms on this label.

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

CLEANING AND DISINFECTING FOOD PREPARATION, PROCESSING FACILITIES AND EQUIPMENT: Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the use-solution (one-half ounce per gallon prepared as directed above): Scrub to loosen all soils. Allow to soak for 10 minutes; then pick up excess solution with a wrung-out applicator. Thoroughly rinse all wetted and cleaned food contact surfaces with potable water.

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.

(For ≤5 gal:) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. 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. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ 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.