



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 6, 2008

Michael G. Sarli
Steris Corporation
7501 Page Avenue
P.O. Box 147
St. Louis, MO 63166-0147

Subject: Minor Label Amendment
Product Name: LpH® se
EPA Reg. Number: 1043-92
Application Date: 22-July-2008
Receipt Date: 24-July, 2008

Dear Mr. Sarli:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable. A stamped copy of the label is enclosed for your record.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6422 or by e-mail at heyward.adam@epamail.epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at grigsby.stacey@epamail.epa.gov during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "A. Heyward".

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

Enclosure: Stamped label

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. 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 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.

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 dust mop area to be cleaned thoroughly, removing any gross filth. This is a complete product. Do not add 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.

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 or 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

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.

LpH[®] se

ONE-STEP

GERMICIDAL DETERGENT

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)

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

Active Ingredients:

o-phenylphenol.....7.7%

p-tertiary amyphenol.....7.6%

Inert Ingredients:.....84.7%

Total:100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for additional precautionary statements

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.	

ACCEPTED
AUG - 6 2008
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under 17612-92

NET CONTENTS:

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

EPA Est. No. 1043-MO-2

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 glazed 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* (A 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.

<i>Acinetobacter calcoaceticus</i> , ATCC 19606	<i>Salmonella typhi</i> , ATCC 6539
<i>Candida albicans</i> , Clinical Isolate	<i>Salmonella typhimurium</i> , ATCC 14028
<i>Candida parapsilosis</i> , Clinical Isolate	<i>Serratia marcescens</i> , ATCC 8100
<i>Citrobacter freundii</i> , ATCC 8090	<i>Shigella flexneri</i> , ATCC 12022
<i>Enterobacter aerogenes</i> , ATCC 13048	<i>Shigella sonnei</i> , ATCC 25931
<i>Enterobacter cloacae</i> , ATCC 23355	<i>Staphylococcus aureus</i> , ATCC 25923
<i>Escherichia coli</i> , ATCC 25922	<i>Staphylococcus aureus</i> , (MRSA), Multiply (Methicillin)-Resistant Clinical Isolate
<i>Klebsiella pneumoniae</i> , ATCC 13883	<i>Staphylococcus epidermidis</i> , ATCC 12228
<i>Proteus mirabilis</i> , Clinical Isolate	<i>Streptococcus faecalis</i> , ATCC 19433
<i>Proteus vulgaris</i> , ATCC 13315	<i>Streptococcus pyogenes</i> , ATCC 19615
<i>Pseudomonas aeruginosa</i> , ATCC 27853	

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 A₂ (Japan) (Clinical Isolate), Herpes simplex Type 2 (ATCC VR 734), Vaccinia (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 by an EPA-approved Dilution Method, 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.

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-PORUS SURFACES" directions.