

1043-91

6-26-2002

1/3

JUN 26 2002

Mr. Michael G. Sarli
Regulatory Specialist
Steris Corp.
P.O. Box 147
St. Louis, MO 63166-0647

Subject: Revised Labeling
LpH Master Product
EPA Registration Number 1043-91
Application Dated May 9, 2002

Dear Mr. Sarli:

The following amendment, submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable comments:

Proposed Amendment

- revised the First Aid PR Notice 2001-1
- amend use directions for a 14 day holding period for the end use dilution.

General Comment

1. Delete the following statement:

"..and other areas where antibacterial control measures are necessary. "This statement is too broad.

2. Revise the precautionary statement to read:

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 was clothing before

| | | | | | | | |
|---------|-------|--|--|--|--|--|--|
| SYMBOL | reuse | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

- 3. The ingredient statement must be revised to include the sum of the percentages of the active and inert ingredient to read:

Total.....100%

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any question or comments concerning this letter, please contact me at (703) 308-6422 or Drusilla Copeland at (703) 308-6224.

Sincerely,



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

Enclosure

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS: Concentrate 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.

(5 gal. or greater package only) **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.

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 and gently mix until solution is uniform. **NOTE:** Always add this product (concentrate) to pre-measured water. Apply solution with a cloth, sponge, coarse spray, mop or brush 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. Before cleaning begins, always sweep or dust mop area to be cleaned thoroughly, removing any gross filth. A properly prepared solution of Vesphene flac 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. This is a complete product. Do not add other chemicals. If frozen, thaw and re-mix before use. Use only as directed.

ANIMAL HUSBANDRY, ANIMAL RESEARCH, POULTRY, POULTRY HOUSE FACILITY CLEANING AND DISINFECTION: Do not use in milking stalls, milking parlors or milk houses. Remove or cover all food, feedstuffs, packaging materials and livestock. Remove all litter, manure and other debris from floors and walls; scrape if necessary. Empty all troughs, racks, feed and water appliances. Saturate all surfaces with a 1:256 solution (one half ounce per gallon prepared as directed above). Scrub to loosen adhering soils. Allow to soak for 10 minutes, then pick up excess with a wrung-out applicator. Flush feeders and waterers with potable water after disinfecting. Drain all surfaces, ventilate buildings and allow to air dry before use or rehousing animals.

FOGGING AS AN ADJUNCT TO REGULAR CLEANING AND DISINFECTING: This product may be used in fogging (wet misting) as an adjunct either preceding or following regular cleaning and disinfecting procedures in research and manufacturing facilities, in poultry operations, hatcheries, swine operations, animal care facilities, animal research facilities, livestock operations, veterinary facilities, zoos and kennels. Use a 1:256 dilution (one-half ounce per gallon of water). Remove all animals and feed from areas to be fogged. Remove all litter and manure from surfaces or areas traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces. Fog the desired area at 32 to 64 ounces of use dilution per 1000 cubic feet using equipment with an automatic timer. Do not remain in treated areas; allow at least two hours after fogging is complete before reentering fogged area. Before fogging remove or cover any food or packaging material with waterproof coverings. Treated surfaces must be thoroughly scrubbed with LpH Master Product at a 1:256 dilution and rinsed with potable water before reuse. Do not rehouse livestock or employ equipment until treatment has dried.

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 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). 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 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®

Master Product

STERILE

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)

EPA REG. NO. 1043-91 EPA Est. No. 1043-MO-1

FOR AGRICULTURAL, INDUSTRIAL AND INSTITUTIONAL USE ONLY

Active Ingredients:

o-phenylphenol.....7.7%

p-tertiary amyphenol.....7.6%

Inert Ingredients:.....84.7%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

| FIRST AID | |
|--|--|
| 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. |
| If on skin or clothing | •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 | •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 | •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, doctor, or going for treatment. | |
| NOTE TO PHYSICIAN | |
| Probable mucosal damage may contraindicate the use of gastric lavage. | |

**ACCEPTED with COMMENTS
EPA Letter Dated:**

This state of the art, non-alkaline, phenolic purpose product specifically developed to concentrated system for use on hard, non-aseptic rooms and boods; air locks; gowning piping systems. The use-solution is designed simple one step process. In addition the hard water scale which can harbor bacteria porous environmental surfaces such as floor equipment in food processing preparation husbandry, poultry and feed processing facilities, pharmaceuticals, biotechnology, and other areas where anti-bac-

GERMICIDAL: The 1:256 (one half ounce Germicidal Use-Dilution Test (S. aureus, S. with 400 ppm A.O.A.C. hard water, in the minutes at 20°C.

BROAD SPECTRUM DATA: The follo Dilution Test in 400 ppm A.O.A.C. hard w 5% organic soil (serum), 10 minutes at 20°

- Acinetobacter calcoaceticus, ATCC 19606
- hydrophila, ATCC 7965
- Bordetella avium, ATCC 35086
- Campylobacter jejuni, ATCC 29428
- 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
- Listeria monocytogenes, ATCC 15313
- Mycoplasma gallisepticum, ATCC 19610
- Pasteurella multocida, ATCC 29977
- Proteus mirabilis, Clinical Isolate
- Proteus vulgaris, ATCC 13315

FUNGICIDAL: The 1:256 (one half ounce Fungicidal Test (T. mentagrophytes) when in the presence of 5% organic soil (serum).

TUBERCULOCIDAL: The 1:256 (one h A.O.A.C. Tuberculocidal Test (Mycobacter diluted with 400 ppm A.O.A.C. hard water 10 minutes at 20°C.

***VIRUCIDAL:** A 1:256 (one half ounce p Assay (EPA Proposed Method) against the diluted with 400 ppm A.O.A.C. hard water in 10 minutes at 20±25°C. Influenza A₂ [J Virus, Adenovirus Type 2, Avian Reovirus, Canine Distemper, Pseudorabies, Infectious Laryngotracheitis, Transmissible Gastroent A 1:64 (2 fl. oz. per gallon) solution passes Method) against Canine Parvovirus and Inanimate surfaces when diluted with 400 5% organic soil (serum) 10 minutes at 20° †When tested by an EPA-approved Dilutio added 5% organic soil (serum), was complete (10 min) solution in 400 ppm A.O.A.C. E efficacy at 1 minute contact time has been not be sufficient for other orga disinfection against all of the organisms cla

ODOR CONTROL: It eliminates many o simultaneously chemically neutralizing the

STERILE UNLESS PACKAGING IS COMPROMISED JUN 26 2002

Net Contents:

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

**Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1043-91**