

1043-115

6-26-2002

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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 1043-115
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 Comments

1. Delete the following statement:

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

2. Delete the statement "other combination type floors" The type of floors must specified.

CONCURRENCES

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

- 3. 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 reuse.

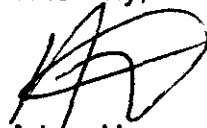
- 4. The ingredient statement must be revised to include the sum of the percentages of the active and inert ingredient to read:

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: 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.

ENVIRONMENTAL HAZARD STATEMENT: (For 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:

Add 1 fl. oz. (30 cc) 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. Thoroughly wet all surfaces all surfaces to be cleaned. Treated surfaces should remain wet for 10 minutes. 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. A properly prepared solution of Vespene Iise 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. Use only as directed.

SOLUTION TABLE FOR CONCENTRATE

| | | | |
|-------------|-----------|-------------|-----------|
| Water | 1 gallon | **2 gallons | 5 gallons |
| Concentrate | 1 fl. oz. | **2 fl. oz. | 5 fl. oz. |

(** For 2 oz. Foil Packet)

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care 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 1 (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 or 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 (1 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.

For Interim Instrument Decontamination prior to Terminal Cleaning and Sterilization of Surgical Instruments and Apparatus: The removal of heavy soils and the cleaning of all surfaces prior to application of this product is required. All instruments and devices must be thoroughly cleaned to remove excess organic debris, rinsed and then rough dried before immersion. Clean and rinse the lumens of hollow instruments before filling with solution. After cleaning, immerse articles and wet all surfaces thoroughly in a 1:128 solution for 10 minutes. Rinse and dry.

Not recommended for prolonged storage of instruments. Avoid splashing and cover, where possible, when transporting soiled instruments. Prepare a new solution daily or when solution turns cloudy or dirty for decontaminating pre-cleaned items.

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. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

PROCESS VESPHENE® IIst

STERILE

ONE-STEP IN THE PRESENCE OF SERUM GERMICIDAL DETERGENT

EPA REG. NO. 1043-115 EPA Est. No. 1043-MO-2

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

Germicide Fungicide Virucide* Tuberculocide
Deodorizer Cleaner Detergent

Active Ingredients

| | |
|-------------------------------|---------------|
| o-phenylphenol..... | 9.09% |
| p-tertiary amyphenol..... | 7.66% |
| Inert Ingredients..... | 83.25% |

**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 or doctor, or going for treatment. | |
| NOTE TO PHYSICIAN | |
| Probable mucosal damage may contraindicate the use of gastric lavage. | |

STERILE UNLESS PACKAGING IS COMPROMISED

NET CONTENTS: JUN 26 2002

STERIS Corporation Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1043-115

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food, or feed by prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL: This germicide, if solutions or residues disposed of in a toilet or service sink served by a sanitary sewerage system, is not to be considered a pesticide.

CONTAINER DISPOSAL: Triple rinse and deposit in a well-labeled container approved for pesticide containers.

GENERAL: Consult local, state or federal disposal authorities for disposal methods such as limited open burning.

This product represents a germicidal detergent system and state of the art technology. It is effective in hard water. It is formulated as a concentrate to be used simultaneously. Use this product for easy cleaning of hard, non-porous environmental surfaces such as floor, fixtures, equipment and furniture. It may be used for chrome, stainless steel, other metal surfaces, porcelain, varnished surfaces, as well as resilient vinyl, asphalt, combination type floors.

This germicidal detergent is intended for use on washable environmental surfaces such as floors, walls, counter-tops, in clean rooms, pharmaceutical plants and in other areas where measures are necessary.

GERMICIDAL: Passes A.O.A.C. Germicidal Use-Choleraesuis, Ps. aeruginosa) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

BROAD SPECTRUM DATA: In addition, the following organisms were tested in 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, 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
- Multiply (Methicillin)-Resistant Staphylococcus aureus, (MRSA), Clinical Isolate
- Proteus mirabilis, Clinical Isolate
- Proteus vulgaris
- Pseudomonas
- Salmonella
- Salmonella
- Serratia marcescens
- Shigella flexneri
- Shigella sonnei
- Staphylococcus aureus
- Staphylococcus aureus
- Streptococcus
- Streptococcus

FUNGICIDAL: Passes A.O.A.C. Fungicidal Test (with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

TUBERCULOCIDAL: Passes A.O.A.C. Tuberculocidal (tuberculosis, var. bovis) when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

***VIRUCIDAL:** Passes Virucidal Assay (EPA Prop (Japan), Herpes Simplex Type 2, Vaccinia Virus, and Infectious Bronchitis, Avian Laryngotracheitis, Avian Pseudorabies), when diluted with 400 ppm A.O.A.C. hard water to make a 1:128 (1 ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20°C.

When tested by an EPA-approved Dilution Method, added 10% organic soil (serum), was completely inactivated in 400 ppm A.O.A.C. hard water in 1 minute contact time has been shown to be sufficient for other organisms. U.S. EPA Disinfection against all of the organisms claimed.

ODOR CONTROL: It eliminates many odors by chemically neutralizing their odors.