

1043-91

7/19/2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

July 19, 2004

Michael G. Sarli
Senior Regulatory Specialist
Steris Corporation
P.O. Box 147
St. Louis, MO 63166-0147

Subject: LpH Master Product
EPA Registration No. 1043-91
Application Date: April 30, 2004
EPA Received Date: May 3, 2004

Dear Mr. Sarli:

The following amendment, submitted under connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

Proposed Amendment

- Revised labeling

Conditions

Revise the label as follows:

1. Revise the Precautionary Statements by including the signal word "DANGER" to be placed directly proceeding the statement beginning "Corrosive. Causes irreversible..."

CONCURRENCES

SYMBOL	TSOC						
SURNAME	[Signature]						
DATE	7-19-04						

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General Comments

A stamped copy of the labeling accepted with conditions 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 questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,



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

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS: Corrosive Causes irreversible eye damage Causes skin burns Harmful if swallowed Do not get in eyes, on skin or on clothing Wear protective eyewear, protective clothing and gloves Wash hands thoroughly with soap and water after handling Remove contaminated clothing and wash clothing before reuse
(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-POROUS 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 15e 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 reuse 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 Material 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 wastewater 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: 64101
o-phenylphenol..... 7.7%
p-tertiary amylphenol..... 7.6%
Inert Ingredients:..... 84.7%
Total..... 100.0%

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.	

This state of the art, non-alkaline, phenolic germicidal detergent is a sterile, multi-purpose product specifically developed to be both hard water and serum effective in a concentrated system for use on hard, non-porous critical environment surfaces found in aseptic rooms and hoods; air locks; gowning; barrier isolation; process equipment and piping systems The use-solution is designed to clean, disinfect and deodorize in a simple one step process In addition the non-alkaline formula removes soap scum and hard water scale which can harbor bacteria Use this product on washable hard non-porous environmental surfaces such as floors, walls, counters, tools, carts, and other equipment in food processing preparation and service facilities, in animal and avian husbandry, poultry and feed processing facilities, veterinary clinics, animal research facilities, pharmaceuticals, biotechnology, medical device and FDA regulated facilities.

GERMICIDAL: The 1:256 (one half ounce per gallon) solution passes the A.O.A.C. Germicidal Use-Dilution Test (*S. aureus*, *S. choleraesuis*, *Ps. aeruginosa*) when diluted with 400 ppm A.O.A.C. hard water, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

BROAD SPECTRUM DATA: The following organisms also 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>Pseudomonas aeruginosa</i> , ATCC 27853 |
| <i>Aeromonas hydrophila</i> , ATCC 7965 | <i>Salmonella enteritidis</i> , ATCC 13076 |
| <i>Bordetella avium</i> , ATCC 35086 | <i>Salmonella sp. serovar pullorum</i> , ATCC 19945 |
| <i>Campylobacter jejuni</i> , ATCC 29428 | <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>Listeria monocytogenes</i> , ATCC 15313 | <i>Streptococcus faecalis</i> , ATCC 19433 |
| <i>Mycoplasma gallisepticum</i> , ATCC 19610 | <i>Streptococcus pyogenes</i> , ATCC 19615 |
| <i>Pasteurella multocida</i> , ATCC 29977 | <i>Streptococcus suis</i> , ATCC 43765 |
| <i>Proteus mirabilis</i> , Clinical Isolate | |
| <i>Proteus vulgaris</i> , ATCC 13315 | |

FUNGICIDAL: The 1:256 (one half ounce per gallon) solution passes the A.O.A.C. Fungicidal Test (*T. Mentagrophytes*) when diluted with 400 ppm A.O.A.C. hard water, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

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

***VIRUCIDAL:** A 1:256 (one half ounce per gallon) solution passes the Virucidal Assay (EPA Proposed Method) against the following on hard inanimate surfaces when diluted with 400 ppm A.O.A.C. hard water, in the presence of 5% organic soil (serum), 10 minutes at 20°-25°C: Influenza A; [Japan], Herpes Simplex Type 2, Vaccinia Virus, Adenovirus Type 2, Avian Reovirus, Avian Influenza Virus, Newcastle Disease, Canine Distemper, Pseudorabies, Infectious Bronchitis, Porcine Rotavirus, Infectious Laryngotracheitis, Transmissible Gastroenteritis, Marek's Disease.

A 1:64 (2 fl. oz. per gallon) solution passes the Virucidal Assay (EPA Proposed Method) against Canine Parvovirus and Infectious Bursal Disease Virus on hard inanimate surfaces when diluted with 400 ppm A.O.A.C. hard water, in the presence of 5% organic soil (serum) 10 minutes at 20° - 25°C.

†When tested by an EPA-approved Dilution Method, the HIV-1(AIDS) virus, with added 5% organic soil (serum), was completely inactivated by a 1:256 (one half ounce per 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.

EPA Letter Dated:

JUL 19 2004

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended by the FIFRA Act of 1990

Registration No. 1043-91

STERILE UNLESS PACKAGING IS COMPROMISED
Net Contents:

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

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