

1043-91

05/09/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

MAY - 9 2011

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: LpH Master Product
EPA Registration No.: 1043-91
Notification Date: 04/25/2011
EPA Receipt Date: 04/26/2011

Dear Mr. Michael Sarli,

This acknowledges the receipt of your notification, submitted under the provision of PR Notice 98-10 and FIFRA section 3(c)9.

Proposed Notification

- Revision of Storage & Disposal statements
- Alternate source of active ingredient (Alternate Formulation #2)

General Comments

Based on a review of the submitted materials, your notification for the revised Storage & Disposal statements and the alternate source of the active ingredient is acceptable and has been made a part of the records on file.

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. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Jacqueline Campbell-McFarlane
Jacqueline Campbell-McFarlane
Product Manager (34)

Regulatory Management Branch II
Antimicrobials Division (7510P)

SYMBOL							
SURNAME							
DATE							

EPA United States Environmental Protection Agency Washington, DC 20460	Registration Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 1043-91	2. EPA Product Manager Jacqueline Campbell-McFarlane	3. Proposed Classification
4. Company/Product (Name) LpH Master Product	PM # 34	<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (include Zip Code) STERIS Corporation P.O. Box 147 St. Louis, MO 63166-0147 Check if this is a new address <input type="checkbox"/>		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

Amendment - Explain Below <input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	Final printed labels in response to Agency letter dated "Me Too" Application Other - Explain below.
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Explanation: Notification of label with minor additions/revisions and revised CSFs with minor revisions as per PR Notice 98-10.

"This notification is consistent with the provisions of PR Notice 98-10 and EPA Regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

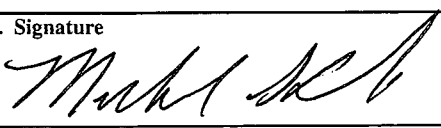
Section - III

1. Material This Product will be Packaged In:				2. Type of Container	
Child-Resistant Packaging Yes* <input checked="" type="checkbox"/> No	Unit Packaging Yes No <input checked="" type="checkbox"/>	Water Soluble Packaging Yes No <input checked="" type="checkbox"/>	If "Yes" Unit Packaging wgt.	No. per container	Metal Plastic <input checked="" type="checkbox"/> Glass Paper Other (Specify) <u> X foil pouch</u>
3. Location of Net Contents Information		4. Size(s) Retail Container		5. Location of Label Directions	
Label <input checked="" type="checkbox"/> Container		1/2 fl. oz., 1 fl. oz., 1 gal., 5 gal. and 55 gal.		On Label <input checked="" type="checkbox"/> On Labeling accompanying product <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product					
Lithograph Paper glued <input checked="" type="checkbox"/> Stenciled					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Michael G. Sarli	Title Manager Regulatory Affairs	Telephone No. (Include Area Code) 314-290-4704
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Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Manager Regulatory Affairs	
4. Typed Name Michael G. Sarli	5. Date 04/25/11	

STERIS®



April 25, 2011

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Regulatory Management Branch II
Antimicrobials Division (7510C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attn: Jacqueline Campbell-McFarlane, PM Team 34

Re: Notification for LpH Master Product (EPA Reg. No. 1043-91) — Minor Label Revisions and Minor Revision to CSFs

Dear Ms. McFarlane:

Enclosed in support of the subject action, please find the following:

- Application for Pesticide (EPA Form 8570-1)
- Labeling – (1 copy)
- Confidential Statement of Formula (Form 8570-4) – Basic
- Confidential Statement of Formula (Form 8570-4) – Alternate #1

We incorporated the revisions to labeling that were identified in your correspondence of 3/30/11 as conditions of approval of our amendment submitted 12/28/10 and have made minor changes to the Storage and Disposal section of the label. The Pesticide Storage and Pesticide Disposal statements have been revised with the identical verbiage that the Agency instructed STERIS to use for the product LpHse (EPA Reg. No. 1043-92).

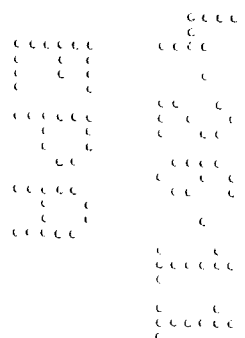
The basic formulation has been revised to identify LANXESS Preventol PTAP (EPA Reg. No. 39967-82) as the source of the active ingredient p-tertiary-amylphenol. LANXESS purchased the technical active ingredient registration from Clariant that was originally cited as the source of p-tertiary-amylphenol.

Alternate Formula #2 cites Dow as an alternate source of o-phenylphenol which holds a different purity than the LANXESS source of o-phenylphenol.

If you have any questions, I can be reached at 314-290-4704 or at mike_sarli@steris.com or Mike Ebers at 314-290-4701 or at mike_ebers@steris.com.

Sincerely,

Michael G. Sarli
Regulatory Affairs
STERIS Corporation



Enclosures

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS: DANGER: 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.

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. enterica*, *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.

- Acinetobacter calcoaceticus, ATCC 19606
- Aeromonas 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

- Pseudomonas aeruginosa, ATCC 27853
- Salmonella enteritidis, ATCC 13076
- Salmonella sp. serovar pullorum, ATCC 19945
- 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
- Streptococcus suis, ATCC 43765

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), in 10 minutes at 20°-25°C. Influenza A₂ [Japan] virus, Herpes Simplex Type 2 virus, Vaccinia virus, Adenovirus Type 2 virus, Avian Reovirus, Avian Influenza virus, Newcastle Disease virus, Canine Distemper virus, Pseudorabies virus, Infectious Bronchitis virus, Porcine Rotavirus, Infectious Laryngotracheitis virus, Transmissible Gastroenteritis virus, Marek's Disease virus.

A 1:64 (2 fl. oz. per gallon) solution passes the Virucidal Assay 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 a 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.

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.

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 this product 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: Before fogging remove or cover any food or packaging material with waterproof coverings. This product may be used in fogging (wet misting) as an adjunct 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. 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 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). 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

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

