

1043-91

12-01-2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DEC 1 2009

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

Subject: Notification in Accordance with PR Notice 98-10
LpH Master
EPA Registration No. 1043-91
Application Date: November 5, 2009
Receipt Date: November 9, 2009

Dear Mr. Sarli:

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

Proposed Notification

Notification of additional influenza A virus per PR Notice 95-2

General Comments

Based on a review of the material submitted, the following comments apply:

The notification is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6427 or email address at: Carlisle.shaRon@epa.gov or Renae Whitaker by telephone at (703) 308-7003 or email at whitaker.renae@epa.gov during the hours of 8:00 am to 3:30 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

ShaRon Carlisle
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

EPA United States Environment: otection 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 ShaRon Carlisle	3. Proposed Classification
4. Company/Product (Name) LpH Master Product	PM # 34	<input checked="" type="checkbox"/> None Restricted
5. Name and Address of Applicant (include Zip Code) STERIS Corp. P.O. Box 147 St. Louis, MO 63166-0647 Check if this is a new address	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

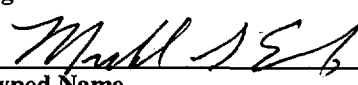
Amendment – Explain below. Resubmission in response to Agency letter dated	Final printed labels in response to Agency letter dated “Me Too” Applicaton
<input checked="" type="checkbox"/> Notification – Explain below.	Other – Explain below.

Explanation: Notification of label change per PR Notice 2007-4 and Notification of Additional Influenza A virus per PR Notice 95-2.
 This notification is consistent with the guidance in PR Notice 2007-4, PR Notice 95-2 and the requirements of EPA's regulations at 40 CFR §§ 152.46, 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for 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 the amended label is not consistent with the requirements of 40 CFR §§ 152.46, 156.10, 156.140, 156.144, 156.146, and 156.156, 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 Metal <input checked="" type="checkbox"/> Plastic Glass Paper Other (Specify) <u>foil pouch</u>
Child-Resistant Packaging Yes* <input checked="" type="checkbox"/> No	Unit Packaging Yes <input checked="" type="checkbox"/> No If “Yes” Unit Packaging wgt. container	No. per No. per	
*Certification must be submitted		If “Yes” Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1/8 fl. oz., 1 fl. oz, 1 qt., 1 gal., 5 gal. And 55 gal.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product	<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	Other	

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 Lead Regulatory Specialist	Telephone No. (Include Area Code) 314-290-4704
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 Lead Regulatory Specialist	
4. Typed Name Michael G. Sarli	5. Date 11/05/09	

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✓
STERIS®



November 5, 2009

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Regulatory Management Branch 1
Antimicrobials Division (7510C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
Attn: ShaRon Carlisle, PM #34

Re: Notification for LpH Master Product (EPA Reg. No. 1043-91)
Revision of Container Disposal Language in Compliance with PR Notice 2007-4
Addition of H1N1 Influenza Virus in Compliance with PR Notice 95-2

Dear Ms. Carlisle:

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

- Application for Pesticide (EPA Form 8570-1)
- Labeling (1 copy) - Changes described with comments
- Labeling (1 copy) - "Clean" copy

The Container Disposal statement has been revised in compliance with PR Notice 9007-4. The language related to the H1N1 Influenza A virus is drawn verbatim from the "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)" EPA publication.

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

Sincerely,

Michael G. Sarli
Lead Regulatory Specialist
STERIS Corporation

Enclosures

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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%
Total100.0%

NOTIFICATION
Date Reviewed: 12/16/09
Reviewed By: *[Signature]*

KEEP OUT OF REACH OF CHILDREN
DANGER

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.	

STERILE UNLESS PACKAGING IS COMPROMISED

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

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. 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.

- | | |
|---|--|
| Acinetobacter calcoaceticus, ATCC 19606 | Pseudomonas aeruginosa, ATCC 27853 |
| Aeromonas Aeromonas hydrophila, ATCC 7965 | Salmonella enteritidis, ATCC 13076 |
| Bordetella avium, ATCC 35086 | Salmonella sp. serovar pullorum, ATCC 19945 |
| Campylobacter jejuni, ATCC 29428 | Salmonella typhi, ATCC 6539 |
| Candida albicans, Clinical Isolate | Salmonella typhimurium, ATCC 14028 |
| Candida parapsilosis, Clinical Isolate | Serratia marcescens, ATCC 8100 |
| Citrobacter freundii, ATCC 8090 | Shigella flexneri, ATCC 12022 |
| Enterobacter aerogenes, ATCC 13048 | Shigella sonnei, ATCC 25931 |
| Enterobacter cloacae, ATCC 23355 | Staphylococcus aureus, ATCC 25923 |
| Escherichia coli, ATCC 25922 | Staphylococcus aureus, (MRSA),
Multiply (Methicillin)-Resistant
Clinical Isolate |
| Klebsiella pneumoniae, ATCC 13883 | Staphylococcus epidermidis, ATCC 12228 |
| Listeria monocytogenes, ATCC 15313 | Streptococcus faecalis, ATCC 19433 |
| Mycoplasma gallisepticum, ATCC 19610 | Streptococcus pyogenes, ATCC 10615 |
| Pasteurella multocida, ATCC 29977 | Streptococcus suis, ATCC 43765 |
| Proteus mirabilis, Clinical Isolate | |
| Proteus vulgaris, ATCC 13315 | |

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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], 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. 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 . . . 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:

(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 contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete

revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

GENERAL: Consult Federal, State, or Local disposal authorities for approved alternative procedures such as limited open burning.