

1043-92

12/08/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DEC 8 2009

December 8, 2009

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

Subject: **LpHse**
EPA Registration No. 1043-92
Application Date: November 5, 2009
Receipt Date: November 9, 2009

Dear Mr. Sarli:

This acknowledges receipt of the notification identified above submitted under the provision section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10.

Proposed Amendment:

- Add Influenza A H1N1 Claim

General Comment:

Based on a review of the material submitted, the following comment applies:

A copy of this accepted notification has been inserted in your file for future reference.

Should you have any questions concerning this letter, you may contact Stacey Grigsby by telephone at (703) 305-6440 or by email at grigsby.stacey@epamail.epa.gov during the hours of 8:00 am to 4:00 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 (7510F)

SYMBOL							
SURNAME							
DATE							

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

Application for Pesticide - Section I

1. Company/Product Number 1043-92	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification
4. Company/Product (Name) LpHse	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 Additional Influenza A virus claim per PR Notice 95-2
This notification is consistent with the provisions of PR Notice 95-2 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 18U.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 95-2 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 <input checked="" type="checkbox"/> No	Water Soluble Packaging Yes <input checked="" type="checkbox"/> No	*Certification must be submitted.	If "Yes" No. per Unit Packaging wgt. container	If "Yes" No. per Package wgt container	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper Other (Specify) <u>foil pouch</u>
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label 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 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) C C C C C C C
2. Signature 		3. Title Lead Regulatory Specialist C C C C C C C			C C C C C C C
4. Typed Name Michael G. Sarli		5. Date 11/05/09 C C C C C C C			C C C C C C C

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 LpHse (EPA Reg. No. 1043-92)
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

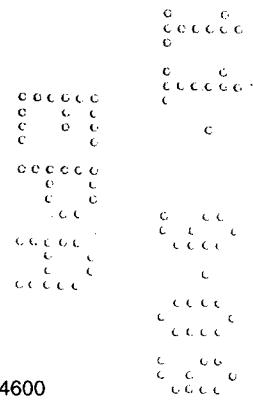
The language related to the H1N1 Influenza A virus is drawn verbatim from the "Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)" EPA publication.

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



LpH[®] se
ONE-STEP GERMICIDAL DETERGENT
(or SERUM EFFECTIVE 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)

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

- Active Ingredients:**
- o-phenylphenol.....7.7%
 - p-tertiary amyphenol.....7.6%
- Inert Ingredients:**.....84.7%
- Total:**100.0%

NOTIFICATION
 Date Reviewed: 12/12/09
 Reviewed By: *S. Grayby*

KEEP OUT OF REACH OF CHILDREN
DANGER

See side panel for additional precautionary statements

FIRST AID	
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 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 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 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.	

NET CONTENTS:

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

EPA REG. NO. 1043-92

EPA Est. No. 1043-MO-2

**PRECAUTIONARY STATEMENTS
Hazard to Humans and Domestic Animals:**

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 wash clothing before reuse.
ENVIRONMENTAL HAZARD STATEMENT: (For use on 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.

This non-alkaline phenolic germicidal detergent is a state-of-the-art, concentrated scientifically developed product effective in hard or soft water even in the presence of organic soil (5% blood serum). The use-solution of this product when diluted one-half ounce per gallon of water is specially formulated to clean, disinfect and deodorize in a simple one-step process. With its non-alkaline base, it will remove soap scum and hard water salts which can harbor bacteria. Use this product on washable, hard, non-porous environmental surfaces: floors, walls, counters in food processing preparation and service facilities, veterinary clinics, animal research facilities, healthcare facilities, hospitals, medical and dental offices.

This product is not for use in the neonatal (newborn) units in hospitals specifically isolettes and other infant contact surfaces.

Use for one-step cleaning, disinfecting and deodorizing of stainless or galvanized steel and chrome, glazed porcelain, plastics, glass, glazed tile, washable painted or varnished surfaces, as well as resilient vinyl, linoleum, rubber, glazed terrazzo and glazed concrete floors.

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 blood stream 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.

GERMICIDAL-When tested against *S. aureus* (ATCC 6538), *S. enterica* (ATCC 10708), *P. Aeruginosa* (ATCC 15442), it passes the A.O.A.C. Germicidal Use-Dilution Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one half ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

BROAD SPECTRUM DATA: The following additional organisms 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 | 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 |
| Proteus mirabilis, Clinical Isolate | Streptococcus faecalis, ATCC 19433 |
| Proteus vulgaris, ATCC 13315 | Streptococcus pyogenes, ATCC 19615 |
| Pseudomonas aeruginosa, ATCC 27853 | |

FUNGICIDAL: When tested against *T. mentagrophytes* (ATCC 9533), it passes the A.O.A.C. Fungicidal Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

TUBERCULOCIDAL: When tested against *Mycobacterium tuberculosis* var. *bovis*, BCG (ATCC 35743), it passes the A.O.A.C. Tuberculocidal Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

***VIRUCIDAL:** When tested against Influenza A₂ (Japan) (Clinical Isolate), Herpes simplex Type 2 (ATCC VR 734), Vaccinia (Clinical Isolate) and, Adenovirus Type 2 (ATCC VR 846), it passes the Virucidal Assay (EPA Proposed Method) when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20°C.

When tested against Duck Hepatitis B virus (DHBV) as a surrogate for Human Hepatitis B virus (HBV) it passes Virucidal Efficacy Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 24°C.

When tested by an EPA-approved Dilution Method, the HIV-1(AIDS) virus (Clinical Isolate), with added 5% organic soil

(serum), was completely inactivated by a 1:256 (one-half ounce per 1 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. 6/7

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 and leaving a pleasant fragrance. Follow "**CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES**" directions.

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 [or one 1/8 fl. Oz (3.70ml) packet per quart (0.946) 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, mop, brush or by coarse spray 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. A properly prepared solution of LpHse 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. Before cleaning begins, always sweep or dust mop area to be cleaned thoroughly, removing any gross filth. This is a complete product. Do not add other chemicals. If frozen, thaw and re-mix before use. Use only as directed.

Directions for use with Twin-Neck Dispensing Bottle: To make one gallon (1:256) solution, loosen cap from dispensing chamber. Gently squeeze bottle to fill measuring chamber to the 1/2 fluid ounce line. Remove cap from dispensing chamber. Pour measured product (concentrate) from the chamber into one gallon (128 ounces) of pre-measured cold water and mix well. Apply as directed above.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) and HBV 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) [or one 1/8 fl. Oz (3.70ml) packet per quart (0.946) of water]. 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 HBV and 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 1/4 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.

