

1043-117

12/1/2009

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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
Amerse 2
EPA Registration No. 1043-117
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	Registration	OPP Identifier Number
	Environmental Protection Agency Washington, DC 20460	Amendment <input checked="" type="checkbox"/> Other	

Application for Pesticide - Section I

1. Company/Product Number 1043-117	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification
4. Company/Product (Name) Amerse 2	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		<input checked="" type="checkbox"/> Metal	
*Certification must be submitted	If “Yes” Unit Packaging wgt. container	No. per	If “Yes” Package wgt	No. per container	<input checked="" type="checkbox"/> Plastic
					<input checked="" type="checkbox"/> Glass
					<input checked="" type="checkbox"/> Paper
					<input checked="" type="checkbox"/> Other (Specify) <u>foil pouch</u>
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label Container		4. Size(s) Retail Container 1 fl. oz, 1 pt., 1 qt., and 1 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 checked="" 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 Amerse 2 (EPA Reg. No. 1043-117)
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

AMERSE® 2
Interim Instrument Decontamination Solution

NOTIFICATION
Date Reviewed: 11/10/09
Reviewed By: R. Whitaker

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%
Total	100.00%

NOTIFICATION
Date Reviewed:
Reviewed By:

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.
HOTLINE 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.	

See side panel for additional precautionary statements.

NET CONTENTS:
STERIS Corporation
7501 Page Avenue
St. Louis, MO 63133 U.S.A.

EPA REG. NO. 1043-117

EPA Est. No. 1043-MO-2

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PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive; causes eye and skin damage. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Wear goggles or face shield (safety glasses), protective clothing and chemical resistant rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse.

(For 5 gal. size and larger 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 product represents a germicidal detergent system that is both research-developed and state of the art technology. It is effective in hard water and in the presence of serum. It has been formulated as a concentrate to clean, disinfect and deodorize simultaneously. Use this product for easy cleaning and disinfecting of all washable hard, non-porous environmental surfaces such as floors, walls, woodwork, bathroom fixtures, equipment and furniture. It may be used for cleaning and disinfecting chrome, stainless steel, other metal surfaces, porcelain, glass, tile, washable painted or varnished surfaces, as well as resilient vinyl, asphalt, linoleum, terrazzo or other combination type floors. This product is not for use in the neonatal (newborn) units in hospitals, specifically isolates and other infant contact surfaces. This germicidal detergent is intended for use in institutions such as hospitals and nursing homes, industrial plants, schools, medical and dental offices, pharmaceutical plants, veterinary clinics and other indoor areas where disinfection, cleaning and deodorizing are a necessity.

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.

GERMICIDAL: Passes A.O.A.C. Germicidal Use-Dilution Method (*S. aureus*, *S. 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 pass the A.O.A.C. Use-Dilution Test in 400 ppm A.O.A.C. hard water at a dilution of 1:128 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
Staphylococcus aureus, (MRSA),
Multiply (Methicillin)-Resistant
Clinical Isolate
Proteus mirabilis, Clinical Isolate

Proteus vulgaris, ATCC 13315
Pseudomonas aeruginosa, ATCC 27853
Pseudomonas cepacia, ATCC 25416
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 epidermidis, ATCC 12228
Streptococcus faecalis, ATCC 19433
Streptococcus pyogenes, ATCC 19615

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Amerse 2 is effective in 3 minutes at 20°C against *Pseudomonas aeruginosa* ATCC 13388, according to the A.O.A.C. Use Dilution Test when diluted with 400 ppm hard water to make a 1:64 (2 ounces per gallon) solution, in the presence of 5% added organic soil (serum).

FUNGICIDAL: Passes A.O.A.C. Fungicidal Test (*Trichophyton mentagrophytes*) 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.

TUBERCULOCIDAL: Passes A.O.A.C. Tuberculocidal Test (*Mycobacterium 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 Proposed Method) [Influenza A₂ (Japan), Herpes Simplex Type 2, Vaccinia Virus, and Adenovirus Type 2, Avian Infectious Bronchitis, Avian Laryngotracheitis, Avian Newcastle Disease, and Porcine 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) in 10 minutes at 20°C. When tested by an EPA-approved Dilution Method, the HIV-1(AIDS) virus, with added 10% organic soil (serum), was completely inactivated by a 1:128 (1 ounce per 1 gallon) solution in 400 ppm A.O.A.C. hard water in 60 seconds at 20-25°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 and leaving a pleasant fragrance.

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. Allow treated surfaces to soak for 10 minutes. Then 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. This is a complete product. Do not add other chemicals. If frozen, thaw and re-mix. Use only as directed.

CLEANING AND DISINFECTING WASHABLE, HARD, NON-PORUS SURFACES: To make a one gallon (1:128) solution, loosen cap from dispensing chamber. Gently squeeze bottle to fill measuring chamber to the 1 fluid ounce line (30 cc.). Remove cap from the dispensing chamber. Pour measured product (concentrate) from the chamber into one gallon premeasured cold water. Apply solution with a cloth, sponge, mop, brush or from spray bottle using normal cleaning methods. Treated surfaces should remain wet for 10 minutes. Then 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. This is a complete product. Do not add other chemicals. If frozen, thaw and remix. Use only as directed.

SOLUTION TABLE FOR CONCENTRATE

Water	1 Gallon	5 Gallons
Concentrate	1 fl. oz.	5 fl. oz.

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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 becomes dirty for decontaminating pre-cleaned items.

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.

(For foil packets)

Container Disposal: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

(For containers ≤ 5 gallons)

Container Disposal: 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.

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