

1043-26

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
1-Stroke Environ®
EPA Registration No. 1043-26
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,

A handwritten signature in cursive script that reads "ShaRon Carlisle".

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

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 1043-26	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification
4. Company/Product (Name) 1 Stroke Environ	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	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 _____ <input checked="" type="checkbox"/> Notification - Explain below.	Final printed labels in response to Agency letter dated "Me Too" Applicaton Other - Explain below.
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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 No <input checked="" type="checkbox"/>	Water Soluble Packaging Yes No <input checked="" type="checkbox"/>	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt
*Certification must be submitted	No. per container	No. per container	Metal Plastic <input checked="" type="checkbox"/> Glass Paper Other (Specify)		
3. Location of Net Contents Information		4. Size(s) Retail Container		5. Location of Label Directions	
Label <input checked="" type="checkbox"/> Container		1 gallon and 55 gallon		On Label <input checked="" type="checkbox"/> On Labeling accompanying product <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product			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	5. Date		
Michael G. Sarli	11/05/09		

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1-STROKE ENVIRON®

Germicidal Detergent

EPA REG. NO. 1043-26

EPA Est. No. 1043-MO-002

EPA Est. No. 6658-MO-001 x

Germicide Fungicide Virucide* Deodorant

ACTIVE INGREDIENTS:

o-phenylphenol	10.0%
o-benzyl-p-chlorophenol	8.5%
p-tertiary-amylphenol	2.0%
INERT INGREDIENTS	79.5%
Total	100.0%

NOTIFICATION
 Date Reviewed: 6/21/09
 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.

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.

For Industrial and Institutional Use Only
NET CONTENTS:

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

U.S. PATENT NO. 3,538,217

Product Made in U.S.A.

DRAFT 11/05/09

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS**

DANGER: Read carefully the following statement which applies to the contents of this container: Corrosive to tissues. Causes eye and skin damage. Harmful or fatal if swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles and rubber gloves when handling. Avoid contamination of food.

ENVIRONMENTAL HAZARD STATEMENT: (For use on containers 5 gallons and larger) This pesticide is toxic to fish. 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.

1-Stroke Environ is a detergent based germicide developed especially for use on surfaces in the agricultural and food industries, and by the veterinary profession. It is intended for use on precleaned hard non-porous surfaces including floors, walls, counters, equipment in food processing areas, feed racks, troughs, and automatic feeders. It may be used in food processing, preparation and service facilities, in animal and avian husbandry, poultry and feed processing facilities, veterinary clinics, and animal research facilities.

When used as directed, this product is effective against pathogenic bacteria such as *S. aureus*, *S. choleraesuis*, and fungi (*T. mentagrophytes*) when tested at 1:256 by official A.O.A.C. methods in either hard (400 ppm) or soft water; and *viruses (Influenza A₂, Herpes Simplex type 2, Adenovirus, Vaccinia, Newcastle disease, Infectious Laryngotracheitis, Infectious Bronchitis, Marek's Agent (JM-V), Hog Cholera) on inanimate environmental surfaces in 10 minutes at 20°C. In addition, 1-Stroke Environ is effective against Avian Reovirus ATCC VR-2040, when tested at 1:256 by official A.O.A.C. methods in hard (400 ppm) water, in the presence of 5% added organic soil (serum).

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.

When tested according to A.O.A.C. Use-Dilution Testing, 1-Stroke Environ was shown to be effective against the following when diluted 1:256 (one-half ounce per gallon) in 400 ppm A.O.A.C. hard water and 5% organic soil (serum) in 10 minutes at 20°C:

- Aeromonas hydrophilia, ATCC 7965
- Bordatella avium, ATCC 35086
- Corynebacterium sepeidonicum, ATCC 9850
- Salmonella enteritidis, ATCC 13076
- Salmonella sp. serovar pullorum, ATCC 19945

- Mycoplasma gallisepticum, ATCC 19610
- Pasteurella multocida, ATCC 29977
- Pseudomonas aeruginosa, ATCC 13388
- Klebsiella pneumoniae, ATCC 23357

1-Stroke Environ was shown to be effective against *Escherichia coli* ATCC 11229, *Streptococcus suis* ATCC 43765, *Listeria monocytogenes* ATCC 15313 and *Campylobacter jejuni* ATCC 29428 when tested at a 1:256 dilution by official A.O.A.C. methods in hard (400 ppm) water on inanimate environmental surfaces in 10 minutes at 20°C. 1-Stroke Environ has been proven effective against the following viruses*; pseudorabies virus, porcine rotavirus and transmissible gastroenteritis virus by the EPA proposed virucidal assay method when diluted 1:256 with 400 ppm hard water in 10 minutes at 20°C on inanimate environmental surfaces.

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GERMICIDAL QUALIFICATION (A.O.A.C. Use Dilution Confirmation), 10 minutes at 20°C, when diluted 1:256 in (400 ppm CaCO₃) A.O.A.C. hard water.
Fungicidal Test (A.O.A.C. T. mentagrophytes), 10 minutes at 20°C when diluted 1:256 in (400 ppm CaCO₃) A.O.A.C. hard water.

GERMICIDAL, AND FUNGICIDAL BY OFFICIAL A.O.A.C. QUALIFICATION IN SOFT OR HARD WATER (A.O.A.C. 400 ppm as CaCO₃) IN TEN MINUTES AT 20°C.

This product is recommended for use on washable hard nonporous surfaces such as counters, equipment, resilient tile flooring, terrazzo and painted or varnished surfaces.

1-Stroke Environ 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.

For use on all washable precleaned, hard environmental nonporous surfaces, use a 1:256 (one-half fluid ounce/gallon of water) solution. For accurate solution preparation, use 1-Stroke Dispenser (one stroke delivers one-half fluid ounce of product). This is a complete product. Do not add other chemicals. Use only as directed.

CLEANING AND DISINFECTING ANIMAL AND POULTRY FACILITIES - Do not use in milking stalls, milking parlors, or milk houses. Cover or remove all food, feedstuffs, packaging material, and animals. Remove all dirt, litter and debris from surfaces to be disinfected. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply use solution with a sponge, mop or coarse spray to thoroughly wet all surfaces. Allow the surface to remain wet for 10 minutes and remove excess solution with a wrung-out applicator. Discard solutions when they become soiled and replace with a fresh solution of this product. Wash all feeders and waterers with a detergent and rinse with potable water before reuse. Ventilate buildings, coops, and other closed spaces. Allow disinfected areas to dry before rehousing livestock. Always remove gross filth and heavy soil before application of the solutions of this product.

CLEANING AND DISINFECTING FOOD CONTACT SURFACES, TOOLS AND EQUIPMENT - Cover or remove all food and packaging material. Thoroughly clean surfaces to be disinfected before application of the solutions of this product. Apply use solution to the surface being disinfected with a sponge, mop or cloth and allow to remain wet for 10 minutes. Discard soiled solutions and replace with fresh use solutions. Rinse all surfaces with a potable water rinse after disinfection, and allow to air dry before reuse.

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 Poultry operations, Hatcheries, Swine operations, Animal Care facilities, Animal Research facilities, Livestock operations and Veterinary facilities, Zoos, and Kennels. Use a 1:256 dilution (one-half ounce per gallon of water). Fog the desired area at 32 to 64 ounces of use dilution per 1,000 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 carefully protect all food and packaging materials with waterproof coverings. Treated food contact surfaces must be thoroughly scrubbed with 1-Stroke Environ at a 1:256 dilution and rinsed with potable water before reuse.

MUSHROOM FARM USE - A normal use-solution (one-half ounce per gallon of water) may be used between crops to clean and sanitize non-food contact surfaces. Use on tanks, air conditioners, air ducts, fans, and breezeways, compost wharf, concreted surfaces, inside and outside walls of mushroom house, lofts, floors, spawning machines, tampers, casing rings, storage sheds and track alleys before spawning. Thoroughly clean all surfaces with soap or detergent and rinse with water. Then apply use-solution with cloth, sponge, mop or coarse spray to thoroughly wet all surfaces; allow to remain wet for 10 minutes. Apply ONLY to surfaces that do not come in contact with the crop. Do not apply to the crop, compost or casings.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Do not store on side. Avoid creasing or impacting of side walls.

If frozen, thaw and remix before use.

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

(For containers ≤ 5 gallons)

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 containers > 5 gallons)

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.

