



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 25, 2006

Michael G. Sarli
Lead Regulatory Specialist
STERIS Corporation
P.O. box 147
St. Louis, MO 63166-0147

Subject: Notification Application Per PR Notice 98-10
1 Stroke Environ
EPA Registration No. 1043-26
Application Date: March 24, 2006
Receipt Date: April 6, 2006

Dear Mr. Sarli:

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

Proposed Notification:

- Minor label revisions
 - Deleted reference to cross- contamination
 - Inserted Storage and Disposal verbiage
 - Added "For Industrial and Institutional Use Only"

General Comment:

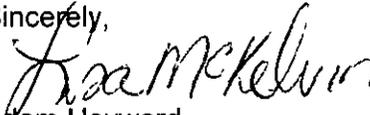
Based on a review of the material submitted, the following comment apply:

A copy of the notification is accepted and has been inserted in your file for future reference.

Note that your cover letter stated " Final Labeling (3 copies)", however, your application indicates this action to be processed under PR Notice 98-10. Therefore, the application was processed as a notification. If you desire a stamped copy of the labeling, the application must be re-submitted as an amendment.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or Lisa McKelvin at (703) 308-7496.

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)





March 24, 2006

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
Attn: Adam Heyward, PM #34
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Re: Notification of Minor Label Revision for 1 Stroke Environ, EPA Reg. No. 1043-26 and Submission of Final Printed Labels in Response to EPA Letter dated August 28, 2003

Dear Mr. Heyward:

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

- Application for Pesticide (EPA Form 8570-1)
- Final Labeling (3 copies).

The labeling has been modified by deleting reference to cross-contamination, inserting Storage and Disposal verbiage and adding the phrase "For Industrial and Institutional Use Only".

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

STERIS Corporation • P.O. Box 147 • St. Louis, MO 63166-0147 • USA • 314-290-4600

4. Typed Name	5. Date	
Michael G. Sarli	3/24/06	

EPA United States Environmental Protection Agency Washington, DC 20460	Registration Amendment X Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 1043-26	2. EPA Product Manager Adam Heyward	3. Proposed Classification
4. Company/Product (Name) I Stroke Environ	PM # 34	X None 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

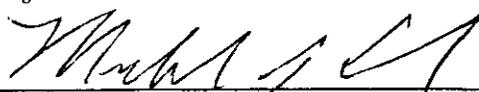
Explanation: "Notification of minor label revision per PR Notice 98-10."

"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 and false statement to EPA. I further understand that if this statement 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:			
Child-Resistant Packaging Yes* X No	Unit Packaging Yes No X If "Yes" Unit Packaging wgt.	Water Soluble Packaging Yes No X If "Yes" Package wgt	No. per container No. per container
*Certification must be submitted		2. Type of Container Metal Plastic X Glass Paper Other (Specify)	
3. Location of Net Contents Information Label X Container	4. Size(s) Retail Container 1 gallon and 55 gallon	5. Location of Label Directions On Label X On Labeling accompanying product X	
6. Manner in Which Label is Affixed to Product Lithograph X Paper glued X 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 Regulatory Specialist	Telephone No. (Include Area Code) 314-535-2198
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 3/24/06	

STERIS®



1-Stroke Environ®

The Technology of Clean®

Germicidal Detergent

Recorder Number: 5397-08
 Net Contents: 3.78 Liters (1 Gal.)

Germicide • Fungicide • Virucide* • Deodorant
 U.S. Patent No. 3,538,217

ACTIVE INGREDIENTS:

o-phenylphenol	10.0%
o-benzyl-p-chlorophenol	8.5%
p-tertiary-amyphenol	2.0%
INERT INGREDIENTS	79.5%
TOTAL	100.00%

EPA REG. NO. 1043-26 EPA Est. No. 1043-MO-002 ☐
 6658-MO-001 ☒

**KEEP OUT OF REACH OF CHILDREN
 DANGER**

FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY
 See side panel for additional precautionary statements.

STERIS Corporation
 7501 Page Avenue
 St. Louis, MO 63133 ■ USA
 800-JIT-4-USE (800-548-4873)
 www.steris.com



FIRST AID	
If inhaled	• 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	• 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	• 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	• 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.	

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 pre-cleaned 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 A₁, Herpes Simplex type 2, Adenovirus, Vaccinia, Newcastle disease, Infectious Laryngotracheitis, Infectious Bronchitis, Marek's Agent (J-M-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).

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 fluid ounce/gallon) in 400 ppm A.O.A.C. hard water and 5% organic soil (serum) in 10 minutes at 20°C:

- | | |
|--|---|
| <i>Aeromonas hydrophilia</i> , ATCC 7965 | <i>Pseudomonas aeruginosa</i> , ATCC 13388 |
| <i>Klebsiella pneumoniae</i> , ATCC 23357 | <i>Corynebacterium sepeidonicum</i> , ATCC 9850 |
| <i>Bordetella avium</i> , ATCC 35086 | <i>Pasteurella multocida</i> , ATCC 29977 |
| <i>Salmonella enteritidis</i> , ATCC 13076 | <i>Salmonella sp. serovar pullorum</i> , ATCC 19945 |
| <i>Mycoplasma gallisepticum</i> , ATCC 19610 | |

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.

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 non-porous surfaces such as counters, equipment, resilient tile flooring, terrazzo, and painted or varnished surfaces.
DEODORIZER: 1-Stroke Environ eliminates many odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors.

**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.

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 pre-cleaned, hard environmental non-porous surfaces, use a 1:256 (one-half fluid ounce/gallon of water) solution. For accurate solution preparation, use the 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 used in and disinfect Care fac Zoos, a desired an auto is comp food an must be potable

Methro be used condit and out casing surfaces sponge. 10 mini apply to

Do not Pesticid frozen.

Pesticid should approve

Contain contain

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