



UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 10, 2006

Michael G. Sarli
STERIS Corporation
P.O. Box 147
St. Louis, MO 63166-0147

Subject: **Staphene Disinfectant Spray and Deodorizer**
EPA Registration No. 1043-19
Application Dated: March 24, 2006
Receipt Date: March 30, 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 Revision: adding "Note to Physician"

General Comment:

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

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

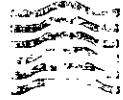
Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Stacey Grigsby at (703) 305-6440.

Sincerely,

Stacey Grigsby

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

STERIS® 74



March 24, 2006

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
Attn: Marshall Swindell, PM #33
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

Re: Notification of Minor Label Revision for Staphene Disinfectant Spray and
Deodorizer, EPA Reg. No. 1043-19

Dear Mr. Swindell:

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 adding "Note to Physician" in the first aid section.

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

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing before reuse. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

PHYSICAL AND CHEMICAL HAZARDS

Contents under pressure. Do not puncture. Do not use or store near heat or open flame. Exposure to temperature above 130°F may cause bursting. Never throw container into incinerator.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Following application as a spray, do not enter or allow others to enter the treated area until sprays have dried. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application.

General and Tuberculosis Disinfection, Elimination of Fungi and Viruses*: Spray hard, non-porous environmental surfaces from any angle, even upside down, from a distance of 6-8 inches for 2-3 seconds or until surface is thoroughly wet. Allow surfaces to remain wet for 10 minutes or allow to air dry without wiping or rinsing. Gross filth or heavy soils must be removed before disinfection.

***KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in healthcare 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 surface/object 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. 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 Material Disposal: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

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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.

To Deodorize and Refreshen the Air: Direct spray upward toward the center of the room for 3-5 seconds.

Staphene Disinfectant Spray and Deodorizer is an aerosol-dispensed, spot disinfectant, and deodorant for schools; medical, dental and business offices; homes; sick rooms; nursing homes and general hospital use.

- Bedside and office furniture
- Telephones
- Sinks
- Waste cans and laundry hampers
- Trash carts

Germicidal: Passes A.O.A.C. Germicidal Spray Products Test (Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa) in the presence of 5% blood serum, 10 minutes at 20°C.

Tuberculocidal: Passes A.O.A.C. Germicidal Spray Products Test (Mycobacterium tuberculosis var. bovis) in the presence of 5% blood serum, 10 minutes at room temperature (25°C / 77°F) on hard inanimate surfaces. Gross filth or heavy soils must be removed before disinfection.

Fungicidal: Passes A.O.A.C. Germicidal Spray Products Test (Trichophyton mentagrophytes) in the presence of 5% blood serum, 10 minutes at 20°C.

***Virucidal:** Passes virucidal assay (EPA Proposed Method) [Influenza A, Herpes simplex Type 2, Rhinovirus Type 1A] in the presence of 5% blood serum, 10 minutes at 20°C on hard inanimate surfaces.

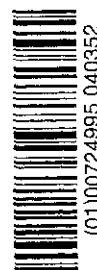
When tested by an EPA-approved Dilution Method, the HIV-1 (AIDS) virus, with added 10% organic soil (serum), was completely inactivated in 60 seconds at 20-25°C. Although efficacy at 1-minute contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for disinfection against all of the organisms claimed.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Do not use or store near heat or open flame. Open dumping is prohibited. Do not reuse empty container. Wrap container and put in trash.

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

Product Made in U.S.A.



STERIS®



Staphene®

Disinfectant Spray & Deodorizer

Reorder Number: **6389-Y3** Net Weight: **453g (16 oz.)**

**Germicidal • Tuberculocidal • Air Deodorizer
Fungicidal • Virucidal***

ACTIVE INGREDIENTS:

o-benzyl-p-chlorophenol.....	0.077%
p-tertiary amylphenol.....	0.074%
o-phenylphenol.....	0.041%
N-alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethylbenzyl ammonium chlorides.....	0.042%
N-alkyl (50% C ₁₂ , 30% C ₁₄ , 17% C ₁₆ , 3% C ₁₈) dimethyl ethylbenzyl ammonium chlorides.....	0.042%
ethanol.....	53.096%
INERT INGREDIENTS.....	46.628%
TOTAL.....	100.000%

EPA Reg. No. 1043-19 EPA Est. No 33915-MI-001☒

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

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, and 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.	

See right side panel for additional precautionary statements.

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