

1043-119

05-26-2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



Office of Pesticide Programs

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

MAY 26 2010

Attention: Michael G. Sarli, Manager
Regulatory Specialist

Subject: SPOR-KLENZ RTU
EPA Registration No. 1043-119
Notification Dated May 4, 2010

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)(9).

Proposed Notification

- Revision of Container Disposal Language per PR Notice 2007-4

General Comments:

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

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
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 1043-119	2. EPA Product Manager Marshall Swindell	3. Proposed Classification
4. Company/Product (Name) SPOR-KLENZ® RTU	PM # 33	<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	

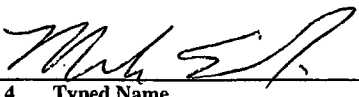
Section - II

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.
<p>Explanation: Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, 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</p>	

Section - III

1. Material This Product will be Packaged In:					
Child-Resistant Packaging Yes* <input checked="" type="checkbox"/> No	Unit Packaging Yes No <input checked="" type="checkbox"/> If "Yes" Unit Packaging wgt.	No. per container	Water Soluble Packaging Yes No <input checked="" type="checkbox"/> If "Yes" Package wgt	No. per container	2. Type of 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 quart, 50 gallon		On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product					
Lithograph Paper glued <input checked="" type="checkbox"/> Stenciled			Other		

Section - IV

I. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Michael G. Sarli	Title Manager, Regulatory Affairs	Telephone No. (Include Area Code) 314-290-4704			
<p align="center">Certification</p> 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.					Date Application Received (Stamped)
2. Signature 	3. Title Manager, Regulatory Affairs				
4. Typed Name Michael G. Sarli	5. Date 5/4/10				

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STERIS®



May 4, 2010

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: Marshall Swindell, PM #33

Re: Notification for SPOR-KLENZ® RTU (EPA Reg. No. 1043-119)
Revision of Container Disposal Language in Compliance with PR Notice 9007-4

Dear Mr. Swindell:

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

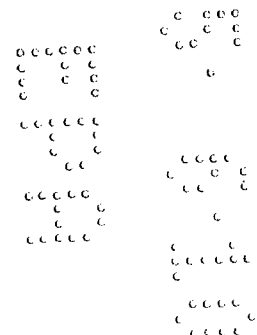
A Container Disposal statement for a > 5 gallon package has been added in compliance with PR Notice 9007-4.

If you have any questions I can be reached at 314-290-4704 or at mike_sarli@steris.com.

Sincerely,

Michael G. Sarli
Regulatory Affairs
STERIS Corporation

Enclosures



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SPOR-KLENZ® RTU
COLD STERILANT

For Use in Pharmaceutical, Medical Device, Biotech and Cosmetic Manufacturing Facilities

Sterilant/Sporicidal, Bactericidal, Tuberculocidal, Fungicidal, *Virucidal,
Non-food Contact Sanitizer

Active Ingredients:

Hydrogen Peroxide 1.00%
Peroxyacetic Acid 0.08%

Inert Ingredients:

98.92%
Total 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

See side panel for precautionary statements

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 ON 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.
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	
For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night (800) 424-9300, (703) 527-3887.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact Chemtrec at 1-800-424-9300 for emergency medical treatment information.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

NET CONTENTS:

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

EPA Reg. No. 1043-119 EPA Est. No. 52252-MN-01

Exp. Date: Lot No.:



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PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals.

DANGER – PELIGRO

Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin. Do not get in eyes, on skin, or on clothing. Avoid contact with skin. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash hands before reuse. Caution should be used when applying indoors because pets may be at risk.

Personal Protective Equipment (PPE)

Handlers must wear: Goggles or face shield, and protective rubber gloves.

Environmental Hazards

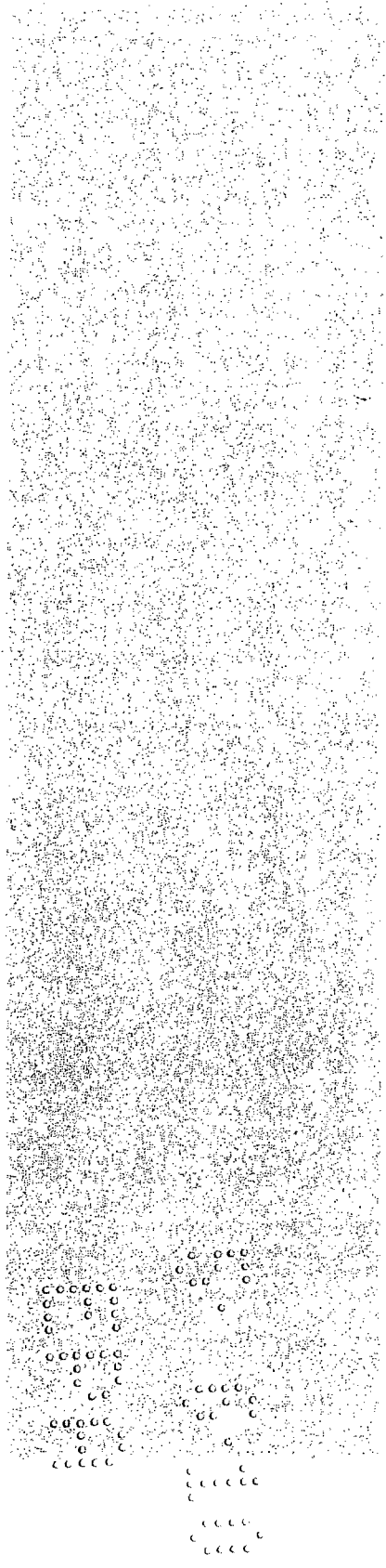
This pesticide is toxic to birds, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage plant authority. For guidance, contact your State Water Board or Regional Office of the U.S. Environmental Protection Agency.

Physical and Chemical Hazards

This product contains an oxidizing agent.

PRODUCT CLAIMS	
Sterilant/Sporicidal [B. subtilis (ATCC 19659), C. sporogenes (ATCC 3584)] Bactericidal Fungicidal Virucidal	undiluted 5 1/2 hours 20°C
Sporicidal – Non-porous Surfaces [B. subtilis (ATCC 19659), C. sporogenes (ATCC 3584)]	undiluted 30 minutes 20°C
Broad Spectrum Disinfectant [Staphylococcus aureus (ATCC 6538), Salmonella enterica (ATCC 10708), Pseudomonas Aeruginosa (ATCC 15442)] Tuberculocidal (Mycobacterium bovis BCG) (Clinical Isolate) Mycoplasma gallisepticum (ATCC 15302) *HIV-1** (Clinical Isolate) *Minute virus of mice (Clinical Isolate) *Murine parainfluenza virus type 1 (Sendai) (ATCC VR-907) *Mouse hepatitis virus (Clinical Isolate) *Murine norovirus (Clinical Isolate)	undiluted 10 minutes 20°C
Mouse parvovirus (Clinical Isolate)	Undiluted 25 minutes at 20°C
Aspergillus niger (ATCC 16404)	undiluted 5 minutes 20°C
Germicidal Spray Disinfectant [S. aureus (ATCC 6538), S. enterica (ATCC 10708)]	undiluted 30 seconds 20°C
Non-food Contact Surface Sanitizer [S. aureus (ATCC 6538), K. pneumoniae (ATCC 4352)]	diluted 50X (1 part to 49 part water) for 5 minutes 21°C

**KILLS HIV- 1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODILY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling 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 HIV-1 (Human Immunodeficiency Virus Type 1 - associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks and eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before the application of the sterilant.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

CONTACT TIME: Leave surfaces completely immersed with undiluted SPOR-KLENZ Ready to Use for a minimum of 10 minutes.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in shipping carton. Do not expose to direct sunlight. Maintain temperature below 75° F (24° C). Avoid contact with combustible materials. Store in original closed container. For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night (800) 424-9300, (703) 527-3887.

Pesticide Disposal

Wastes resulting from the use of this product may be disposed of on-site in a sanitary sewer or at an approved waste disposal facility. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for Guidance.

Container Disposal

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

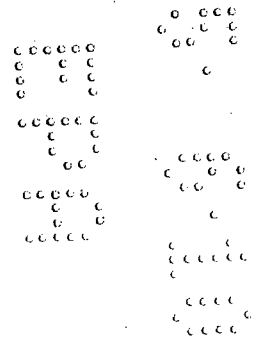
(For ≤ 5 gal.): Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application 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 > 5 gal.): 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.

Comment [ms1]: Standard container disposal language added for 50 gallon package size.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.



Do not use after Expiration Date. Do not allow SPOR-KLENZ Ready to Use to mix with alkaline substances such as bleach (Sodium Hypochlorite) or other oxidizing agents. Use purified water (e.g. deionized) for making dilutions, cleaning and rinsing. Some materials may be incompatible with SPOR-KLENZ Ready to Use. Test material prior to use. Spor-Klenz Ready to Use has been shown to be compatible with Polyvinyl chloride, polypropylene, polyurethane, aceto-copolymers, polycarbonate, polysulfone, polystyrene, stainless steel. Reuse of diluted SPOR-KLENZ Ready to Use is not recommended.

DIRECTIONS FOR STERILIZATION

SPOR-KLENZ Ready to Use is not to be used as a terminal sterilant on any critical/semi-critical medical device. Remove any obvious debris or organic material from the surface to be sterilized. This can often be accomplished by rinsing with water or by detergent cleaning followed by a water rinse. Immerse the item to be sterilized in a sufficient volume of undiluted SPOR-KLENZ Ready to Use to cover the item and fill all passages requiring sterilization. Hold in the sterilizing solution for a minimum of 5½ hours at 20°C temperature (68°F). Remove items after 5½ hours and rinse with sterile water until rinse water shows levels of 10 ppm or The solution may be used and reused for up to 14 days in a manual system with 5½ hours immersion.

DIRECTIONS FOR USE AS A SPORICIDE: Use only on hard, non-porous surfaces.

Remove any obvious debris or organic material from the surface to be sterilized. This can often be accomplished by rinsing with water or by detergent cleaning followed by a water rinse. Immerse hard, non-porous surfaces in a sufficient volume of undiluted Spor-Klenz Ready to Use. Treated surfaces must remain completely immersed for 30 minutes. Wipe dry or allow to air dry.

DIRECTIONS FOR BROAD SPECTRUM DISINFECTION/TUBERCULOCIDE/VIRUCIDE*

[HIV-1, Mouse hepatitis virus Murine parainfluenza virus type 1 (Sendai), Mouse parvovirus and Murine novovirus]/ Mycoplasma gallisepticum/ Aspergillus niger: Use only on hard, non-porous surfaces. This product is not to be used as a terminal high level disinfectant on any critical/semi-critical medical device. Remove any obvious debris or organic material from the surface to be disinfected. This can often be accomplished by rinsing with purified water (e.g. deionized), mechanical action, or by detergent cleaning followed by a water rinse. Apply product to hard, non-porous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge, sprayer, or by immersion. Treated surfaces must remain wet for 10 minutes (For Aspergillus niger, contact time is 5 minutes) (For mouse parvovirus, keep surfaces completely immersed for 25 minutes). Wipe dry with a cloth, sponge or mop or allow to air dry. For sprayer applications, use a coarse spray device. Spray 6 – 8 inches from the surface, rub with a brush, sponge or cloth. Do not breathe spray.



FOGGING AS AN ADJUNCT TO REGULAR CLEANING AND DISINFECTING: This product may be used in fogging as an adjunct either preceeding or following regular cleaning and disinfecting procedures for hard room surfaces. Prior to fogging, remove or carefully protect all food products and packaging materials. Ensure room is properly ventilated. Vacate all personnel from the room during fogging and for a minimum of 2 hours after fogging or until the hydrogen peroxide air concentration is below 0.5 ppm. Fog areas using one quart (946 ml) per 1,000 cu. Ft. (28.3 m³) of room volume with undiluted SPOR-KLENZ Ready to Use solution. Allow surfaces to dry thoroughly before operations are resumed. Note: In all applications, always prepare a new solution daily to ensure effectiveness. Do not reuse solutions. Dispose of any unused solution.

DIRECTIONS FOR USE AS A GERMICIDAL DISINFECTANT SPRAY: Use only on hard, non-porous surfaces. Spray SPOR-KLENZ Ready to Use undiluted onto cleaned surfaces using a plastic spray bottle. Allow to remain on surface for 30 seconds. Let air dry or rinse with purified water, drain off excess water if possible and allow to dry.

DIRECTIONS FOR USE AS A CLEANER/SANITIZER (Non-food contact surfaces): Using water or mechanical action, remove heavy soil or gross filth from hard surfaces such as formica, stainless steel or vinyl surfaces. Apply by cloth, mop or sponge so as to wet all surfaces thoroughly, a freshly made 50X dilution (1 part product to 49 part water) of SPOR-KLENZ READY TO USE, made using purified water, to the pre-cleaned surface or immerse pre-cleaned items to be sanitized in the solution. Allow 5 minutes of contact time. Let air dry or rinse with purified water, drain excess if possible and allow to dry. May not be reused as a cleaner/sanitizer.

USES

Primarily intended for sterilization, or disinfection of:

- Stainless Steel
- Plastic Items and surfaces
- Hard Surfaces e.g. counter tops
- Floors
- Walls
- Bathroom Fixtures
- Glass
- Formica
- Vinyl

