



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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

JUN 25 2008

Attention: Michael G. Sarli
Regulatory Manager

Subject: Spor-Klenz RTU
EPA Reg. No. 1043-119
Amendment Application Date: January 29, 2008
EPA Received Date: February 5, 2008

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided the following label revisions are incorporated:

1. Submit and/or cite all data or material required for registration/reregistration of your product under FIFRA sec. 3(e)(5) or FIFRA sec. 4 when the agency required all registrants of similar products or submit such data.
2. Make the following changes on the proposed labeling.
 - On page 3, under **Contact Time**, change "Leave surfaces wet with undiluted Spor-Klenz Ready to Use for a minimum of 30 minutes" to read "Leave surfaces **completely immersed** in undiluted Spor-Klenz Ready to Use for a minimum of 30 minutes".
 - On page 4, under **DIRECTIONS FOR STERILIZATION**, add the word "Use" after "Spor-Klenz Ready to". In addition, in the statement that begins "This product in not..." remove the word "in" and replace with the word "is".
 - On page 4, under **DIRECTIONS FOR USE AS A SPORACIDE**, change "Apply product to hard, non porous surfaces, thoroughly wetting surfaces by immersion. Treated surfaces must remain wet for 30 minutes" to read, "**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".

- On page 4, under the **DIRECTIONS FOR BROAD SPECTRUM** section, change the statement “(For mouse parovirus, contact time is 25 minutes)” to read “(For mouse parvovirus, keep surfaces completely immersed for 25 minutes)”.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFFA sec. (6(e). Your release for shipment of the product constitutes acceptance of these conditions. Please submit two copies of your final printed labeling before you release the product for shipment. A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,



Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

SPOR-KLENZ® RTU
COLD STERILANT

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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%

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 1643-119

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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with COMMENTS
EPA Letter Date:

PRECAUTIONARY STATEMENTS

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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.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, this product is registered under EPA Reg. No. 1043-119

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 [S. aureus (ATCC 6538), S. enterica (ATCC 10708)] 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)	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. *completely immersed*

CONTACT TIME: Leave surfaces ~~soiled~~ with undiluted SPOR-KLENZ Ready to Use for a minimum of 30 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

Triple rinse empty container with water. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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, *EPA Label Dated:*

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with COMMENTS
EPA Label Dated:

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Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1043-119

polypropylene, polyethylene, acetate-copolymers, polycarbonate, polystyrene, stainless steel.
Reuse of diluted SPOR-KLENZ Ready to Use is not recommended.

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DIRECTIONS FOR STERILIZATION

SPOR-KLENZ Ready to Use ^{use} This product ^{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 5 1/2 hours at 20°C temperature (68°F). Remove items after 5 1/2 hours and rinse with sterile water until rinse water shows levels of 10 ppm or less. The solution ~~may~~ ^{can} be used and reused for up to 14 days in a manual system with 5 1/2 hours immersion.

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended for the pesticide, registered under EPA Reg. No. 1043-119

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. ~~Apply product to hard, non-porous surfaces, thoroughly wetting surfaces by immersion.~~ Treated surfaces ~~must~~ remain wet for 30 minutes. Wipe dry or allow to air dry.

OK Immersed

DIRECTIONS FOR BROAD SPECTRUM

DISINFECTION/TUBERCULOCIDE/VIRUCIDE* [HIV-1, Mouse hepatitis virus Murine parainfluenza virus type 1 (Sendai) and Mouse parvovirus]/ 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, ~~contact time is 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.

OK

FOGGING AS AN ADJUNCT TO REGULAR CLEANING AND DISINFECTING:

This product ~~may~~ be used in fogging as an adjunct either preceding 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 seconds. Let air dry or rinse with purified water, drain off excess water if possible and allow to dry.

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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. ~~It~~ not be reused as a cleaner/sanitizer.

OK

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

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