

1043-119

12-4-2007

17



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

DEC 04 2007

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Mr. Michael G. Sali  
Lead Specialist for,  
Steris Corporation  
P. O. Box 147  
Saint Louis, MO 63166-0147

Subject: Spor-Klenz RTU  
EPA Registration Number 1043-119  
Your Amendment Dated July 27<sup>th</sup>, 2007  
EPA Received Date August 1<sup>st</sup>, 2007

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add efficacy claims to the product labeling, is acceptable.

The submitted efficacy data (MRID Nos. 471935-02 and 471935-03) along with the previously submitted data (468271-01) support the use of the product, Spor-Klenz RTU, as a sterilant when tested against *Bacillus subtilis* and *Clostridium sporogenes* on hard, non-porous surfaces for a contact time of 30 minutes.

**EFFICACY**

The proposed label claims that the product, Spor-Klenz RTU, is an effective sterilant against *Bacillus subtilis* and *Clostridium sporogenes* on hard, non-porous surfaces for a contact time of 30 minutes. This claims is acceptable.

Since the revised 30 minute sterilant claim for hard, non-porous surfaces only is acceptable, the Agency has determined that the application in any method other than immersion is insufficient and impractical for a 30 minute contact time.

Therefore, under the Directions for Sterilization: use only on hard, non-porous surfaces, delete the application methods of cloth, mop, sponge, and sprayer. Only immersion will be allowed.

Please note that the claims for non-food contact surface sanitization at a 1:50 dilution and a 5 minute contact time are now acceptable.

**LABELING**

A listing of ATCC numbers for all organisms appearing on the product label must appear on the product labeling.

The list of ATCC numbers for the tested organisms in one of the following locations:

- on the data matrix
- on the master label with the listing of the organisms claims or
- as the final page of the master label( as optional text)

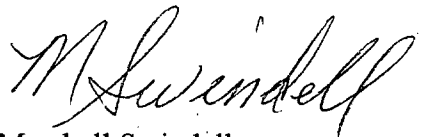
Revise the nomenclature of Salmonella choleraesuis (ATCC 10708) to read Salmonella enterica. The ATCC numbers have changed for this organism.

On the right panel of the proposed labeling, under the heading "Uses", change "counters tops" to read "counter tops".

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch I  
Antimicrobial Division(7510P)

3/7

# 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%

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1043-119

**KEEP OUT OF REACH OF CHILDREN**

**DANGER - PELIGRO**

See side panel for precautionary statements

FIRST AID	
IF INHALED	<ul style="list-style-type: none"> <li>•Move person to fresh air.</li> <li>•If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>•Call a poison control center or doctor for further treatment advice.</li> </ul>
IF ON SKIN OR ON CLOTHING	<ul style="list-style-type: none"> <li>•Take off contaminated clothing.</li> <li>•Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>•Call a poison control center or doctor for treatment.</li> </ul>
IF IN EYES	<ul style="list-style-type: none"> <li>•Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.</li> <li>•Call a poison control center or doctor for treatment advice.</li> </ul>
IF SWALLOWED	<ul style="list-style-type: none"> <li>•Call poison control center or doctor immediately for treatment advice.</li> <li>•Have person sip a glass of water if able to swallow.</li> <li>•Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>•Do not give anything by mouth to an unconscious person.</li> </ul>
<p align="center"><b>HOT LINE NUMBER</b></p> <p>For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night (800) 424-9300, (703) 527-3887.</p>	
<p>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.</p>	
<p align="center">Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

**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.:

4/7

### 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 [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
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

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5/7

**\*\*KILLS HIV- 1 ON P...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 wet 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, polypropylene, polyurethane, aceto-copolymers, polycarbonate, polysulfone, polystyrene, stainless steel.

Reuse of diluted SPOR-KLENZ Ready to Use is not recommended.

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Fungicide, and Fungicide Act as  
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1043-119

6/7

**DIRECTIONS FOR STERILIZATION**

SPOR-KLENZ Ready to 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 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. 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.

**DIRECTIONS FOR BROAD SPECTRUM**

**DISINFECTION/TUBERCULOCIDE/VIRUCIDE\* [HIV-1, Mouse hepatitis virus and Murine parainfluenza virus type 1 (Sendai)]/ 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). 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 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 m<sup>3</sup>) 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 air dry.

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7/7

**DIRECTIONS FOR USE AS A CLEANER/SANITIZER (No. 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

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