

1043-119

7/7/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUL 07 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Michael G. Sarli
Lead Regulatory 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 March 10th, 2009
EPA Received Date March 13th, 2009

The amendment referred to above, submitted in connection with under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to include product claims and directions supported by the enclosed efficacy data and revise the container disposal language as per PR Notice 2007-4, is acceptable.

The submitted efficacy data (MRID No. 477009-01) support the use of the product, Spor-Klenz RTU, as a disinfectant with bactericidal activity against *Pseudomonas aeruginosa* on hard, non-porous surfaces when used undiluted at 20 degrees Celcius for 9 minutes contact time.

The submitted efficacy data (MRID No. 477009-02) support the use of the product, Spor-Klenz RTU, as a disinfectant with virucidal activity against Murine Norovirus on hard, non-porous surfaces in the presence of a 5% organic soil load (serum) for a contact time of 10 minutes when used undiluted at 20 degrees Celcius.

The proposed label claims that the product, Spor-Klenz RTU, is an effective disinfectant against *Pseudomonas aeruginosa* and Murine Norovirus on hard, non-porous surfaces when used undiluted, for a contact time of 10 minutes at 20 degrees Celcius, are supported by the submitted efficacy data.

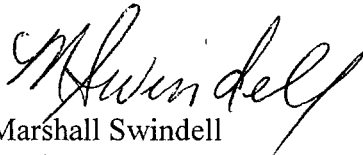
A stamped copy of the labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration /reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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

Sincerely,



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

SPOR-KLENZ® R
COLD STERILANT

3087

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

ACCEPTED
with **COMMENTS**
EPA Letter Dated:

Exp. Date:

Lot No.:

JUL - 7 2009

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

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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 the 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.

ACCEPTED with COMMENTS EPA Letter Dated: JUL - 7 2009 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1043-119

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 novovirus (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

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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.

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.

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

ACCEPTED
with COMMENTS
EPA Letter Dated:
1/17/2009

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 less. The solution may be used and reused for up to 14 days in a manual system with 5½ hours immersion. 6007

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 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 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, vinyl, or vinyl surfaces. Apply by cloth, mop or sponge so as to wet all surfaces. Dilute with purified water to a 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. 7 of 7

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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