

1043-119

9-26-2005

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA Reg. Number:
1043-119

Date of Issuance:
SEP 26 2005

Term of Issuance:
CONDITIONAL

Name of Pesticide Product:
Spor-Klenz RTU

NOTICE OF PESTICIDE:
 X Registration
 Re-registration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP code):

Steris Corporation
7501 Page Avenue
Saint Louis, MO 63133

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/re-registered under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA Section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA Section 4, or as required by registration review under FIFRA Section 3(g).
2. Make the following labeling changes:
 - a. Revise the EPA Registration Number to read, EPA Reg. No.1043-119.

Signature of Approving Official:

Marshall Swindell, Product Manager, Team 33,
Regulatory Management Branch I, Antimicrobials Division

Date:

SEP 26 2005

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3. Submit three copies of a final printed production label.

If these 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 constitutes acceptance of these conditions.

A stamped copy of the accepted label 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 1
Antimicrobial Division(7510C)

Enclosure

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)

Handiers 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.

**SPOR-KLENZ®
READY TO USE
COLD STERILANT**

For Use in Health Care Environments

Active Ingredients:		
Hydrogen Peroxide	1.00%	
Peroxyacetic Acid	0.00%	
Inert Ingredients:	28.92%	
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.

Exp. Date: Lot No:

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

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

DIRECTIONS FOR STERILIZATION (In any application other than a health care setting/hospital). 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 3 1/2 hours at 20°C temperature (68°F). Remove items after 3 1/2 hours and rinse with sterile water until rinse water shows levels of 10 ppm or less when tested with Spor-Klenz Residual Test Strips. The solution may be used and reused for up to 14 days in a manual system with 3 1/2 hours immersion.

DIRECTIONS FOR BROAD-SPECTRUM DISINFECTION
For broad spectrum disinfection of items such as external surfaces of counters, bathroom fixtures, etc. 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. Immerse the item to be disinfected in sufficient volume of undiluted SPOR-KLENZ Ready to Use solution to cover the item and/or where appropriate by filling all passages requiring disinfection. Hold item in contact with the disinfecting solution for a minimum of 10 minutes at 20°C temperature (68°F). Remove items after 10 minutes and rinse with purified water until effluent shows acceptable levels when tested with Spor-Klenz Residual Test Strips. The solution may be used and reused for up to 14 days in a manual system with 10 minutes immersion. For tuberculocidal activity at 20°C with fresh, undiluted solution, immerse completely for 10 minutes. Remove items and rinse thoroughly. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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
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.

USES

Primarily intended for sterilization, or disinfection of:
Stainless Steel
Plastic Items and surfaces

Hard Surfaces e.g. counters tops
Floors
Walls
Bathroom Fixtures
Glass
Formica
Vinyl
Materials Compatibility: Polyvinyl chloride, polypropylene, polyurethane, aceto-copolymers, polycarbonate, polysulfone, polystyrene, stainless steel.

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

SEP 26 2005

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

1043-119

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.

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