



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

EPA Reg. Number:
1043-120

Date of Issuance:
SEP 26 2005

NOTICE OF PESTICIDE:
 Registration
 Re-registration

Term of Issuance:
CONDITIONAL

Name of Pesticide Product:
Spor-Klenz Concentrate

(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. 1043-120.

Signature of Approving Official:

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

Date:

SEP 26 2005

page 2
EPA Reg. No. 1043-120

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. Prolonged or frequent repeated skin contact may cause an allergic reaction in some individuals. 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 EFFICACY

• Sterilant	100X dilution, 11 hours 20°C
• Sporicidal	100X dilution, 11 hours 20°C
• Bactericidal	100X dilution, 11 hours 20°C
• Virucidal	100X dilution, 11 hours 20°C
• Hepatitis B HIV-1*	100X dilution, 11 hours 20°C
• Fungicidal	100X dilution, 11 hours 20°C
• Effective against non-tuberculous mycobacterium (cheek abscesses)	100X dilution, 10 min., 20°C
• Cleaner/Sanitizer (Non-food contact surfaces) (Food contact surfaces Staphylococcus aureus and Bacterioid coli)	32X dilution, 10 min., 20°C 320X dilution, 1 min., 20°C
• Hospital Disinfectant Pseudomonas	100X dilution, 10 min., 20°C
• Broad Spectrum Disinfectant	100X dilution, 10 min., 20°C
• Germicidal Spray Disinfectant	100X dilution, 10 min., 20°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 of 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 human immunodeficiency virus Type 1 (HIV-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 bloody or body fluids are disposable latex gloves, masks or eye coverings.
CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before 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 for 11 hours.

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. Avoid contamination from any source, including metals, dust, etc. Such contamination may cause rapid decomposition, generation of large quantities of oxygen gas and high pressure. Store in original closed container. NEVER TAMPER WITH VENT.

Pesticide Disposal

Wastes resulting from the use of this product may be disposed of on-site by diluting 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, incinerate, or, if allowed by state and local authorities, dispose of by burning. If burned, stay clear of the smoke.

**SPOR-KLENZ
 CONCENTRATE
 COLD STERILANT**

For the sterilization and disinfection of hard surfaces and non-porous food contact surfaces.

For use in the following locations:

- | | |
|-------------------------------------|------------------------------|
| Industrial Laboratories | Hospitals |
| Pharmaceutical Manufacturers | University Laboratories |
| Medical Products Manufacturers | Semi Conductor Manufacturers |
| Electrical Utility Companies | Cosmetic Manufacturers |
| Dairies and Pasteurizing Facilities | Rio Tech Companies |
| Beverage and Food Processing Plants | Breweries/Wineries |

Read the SPOR-KLENZ Concentrate label before using this product.

Failure to follow directions for use may result in user injury.

This product must be diluted with purified water prior to use.

Active Ingredients:		
Hydrogen Peroxide	22.0%	
Peroxyacetic Acid	4.5%	
Inert Ingredients:	73.5%	
Total	100.0%	

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

See side panel for additional precautionary statements

FIRST AID	
IF INHALED:	• 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:	• 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:	• 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:	• 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:

Lot No:

Exp. Date:

**ACCEPTED
 with COMMENTS
 EPA Letter Dated:**

STERIS Corp.
 7501 Page Avenue
 St. Louis, MO 63131 **SEP 26 2005**

EPA Reg. No. 1043-333

EPA Reg. No. 52252-MN-01

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

1043-120

MINERAL OILS - FLUOROPOLYMER

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 Concentrate to mix with alkaline substances such as bleach (Sodium Hypochlorite). If spilled, flush away with large quantities of water. Use purified water when diluting SPOR-KLENZ Concentrate. SPOR-KLENZ Concentrate is a single-use product not intended for reuse. Fresh sanitizing solution should be prepared daily or more often if the solution becomes diluted or soiled.

DIRECTIONS FOR STERILIZATION

For use on hard, non-porous surfaces such as plastics, stainless steel objects or containers, or glass used by laboratories and manufacturers of pharmaceuticals, medical products, and cosmetics. Examples include glassware, laboratory instruments, containers, non-invasive dental/medical instruments such as forceps, scissors, clamps, etc. 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 purified water; mechanical action or by detergent cleaning followed by a water rinse. Dilute SPOR-KLENZ Concentrate 100X (1 part SPOR-KLENZ Concentrate plus 99 parts purified water). Do not store diluted SPOR-KLENZ Concentrate for use as a sterilant; once diluted, use immediately. Immerse the item to be sterilized in a sufficient volume of diluted SPOR-KLENZ Concentrate to cover the item and fill all passages requiring sterilization. Hold in the sterilizing solution for a minimum of 11 hours at 20°C (68°F). Remove items after 11 hours and rinse with sterile water until effluent testing shows acceptable levels.

This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

DIRECTIONS FOR HOSPITAL DISINFECTION

SPOR-KLENZ Concentrate is to be used on hard, non-porous surfaces such as plastic, glass, or stainless steel in settings such as hospitals, clinics or physician's offices. Examples include counters, bed rails, bathroom fixtures, bedpans, non-invasive medical instruments (sensors, clamps) 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 be accomplished by rinsing with purified water, mechanical action or by detergent cleaning followed by a water rinse. Dilute SPOR-KLENZ Concentrate 100X (1 part SPOR-KLENZ Concentrate plus 99 parts purified water). Once diluted, the solution must be used within seven (7) days. Immerse the item to be disinfected in sufficient volume of diluted SPOR-KLENZ Concentrate to cover the item and fill all passages requiring disinfecting. Hold in the disinfecting solution for a minimum of 10 minutes. Remove items after 10 minutes and rinse with sterile water until effluent reaches acceptable levels when tested with Spor-Klenz Concentrate Test Strips.

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 a 0.30% SPOR-KLENZ Concentrate solution. Allow surfaces to dry thoroughly before operations are resumed. Note: Once diluted, the solution must be used within 7 days. Discard any unused diluted solution.

DIRECTIONS FOR USE AS A GERMICIDAL DISINFECTANT SPRAY

For use as a germicidal spray on hard surfaces such as floors, walls, bathroom fixtures, vinyl or Formica surfaces. Dilute 100X with purified water. Note: Once diluted, the solution must be used within 7 days. Discard any unused diluted solution. Spray onto surfaces using a plastic spray bottle. Allow to remain on surface for 10 minutes. 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)

For use on hard, non-porous surfaces such as plastics, stainless steel objects or Formica. Examples include counter tops, walls, floors, bedrails, bathroom fixtures etc. Using water or mechanical action, remove heavy soil and gross filth from hard surfaces such as Formica, stainless steel or plastic. Dilute 32X with purified water. Note: Once diluted, the solution must be used within 7 days. Discard any unused diluted solution. Fresh solution should be prepared daily or more often if the solution becomes diluted or soiled. Apply solution to surface or immerse items to be sanitized in the solution. Product may be applied by cloth, mop or sponge. Allow 10 minutes of contact time. Rinse with purified water, drain excess, if possible, and allow to air dry.

DIRECTIONS FOR USE AS A CLEANER/SANITIZER (FOOD CONTACT SURFACES)

SPOR-KLENZ Concentrate may be used to sanitize hard, non-porous surfaces such as glass or stainless steel used in filters, pipelines, silos, processing vats, bulk tanks and utensils used in dairies, food processing plants, wineries and breweries. Using water or mechanical action, remove heavy soil, gross food particles or gross filth from hard surfaces such as Formica, stainless steel, glass or plastic. Using an appropriate detergent or cleaner, wash surfaces or objects. Rinse with potable water. Remove any food products or packaging materials from the room or cover completely. Dilute SPOR-KLENZ Concentrate at 2 ounces to 5 gallons of water. Use fresh solution with each use. Fresh sanitizing solution should be prepared daily or more often if the solution becomes diluted or soiled. Dip, spray, brush or fill equipment with solution and allow to sit at least 1 minute at 75°F (25°C). Allow to drain well. Do not rinse, blow or air dry.

USES

- Primarily intended for use with surfaces such as:
- Plastic Items
- Stainless Steel Objects or containers e.g. bedpans, tanks
- Hard Surfaces e.g. counters, sinks, bulk tanks etc.
- Floors
- Walls
- Bathroom Fixtures
- Vinyl Surfaces
- Formica Surfaces
- Glass

373