

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JAN 28 2011

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

Attention: Michael Sarli Regulatory Manager

Subject:

SPOR-KLENZ Concentrate

EPA Reg. No. 1043-120

Amendment Dated December 13, 2010

This will acknowledge receipt of your notification under the provisions of FIFRA Section 3(c) (9). Based on a review of the submitted material, the following apply:

• Minor Corrections/Additions to last accepted label

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been made a part of your file.

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)

EPA United StatesEnvironmental Protection Ages Washington, DC 20460			gency		stration ndment	OPP Identifier Number	
	Ap	plication for	Pesticide - Sec		<u> </u>		
1. Company/Product Number 1043-120			2. EPA Product	2. EPA Product Manager Marshall Swindell  3. Proposed Classification			
4. Company/Product (Name) SPOR-KLENZ Cond		ncentrate	PM# 33		X Noi	ne Restricted	
5. Name and Address of Applicant (include Zip Code)						on 3(c)(3)(b)(i), my product	
STERIS Corporation P.O. Box 147			EPA Reg. No.	is similar or identical in composition and labeling to:  EPA Reg. No.			
St. Louis, MO 63166-0147  Check if this is a new address			Product Name	Product Name			
		Sect	tion - II				
Amendment - Explain B Resubmission in respon: X Notification - Explain b	se to Agency letter dated		Final printed label "Me Too" Applica Other – Explain b	aton	gency letter dated		
Explanation: Notification of Submission of printer's proof label with minor additions as per PR Notice 98-10 "This notification is consistent with the provisions of PR Notice 98-10 and EPA Regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."							
		Sect	ion - III				
1. Material This Product will be			W. 0111 B 1		5 TS 6 C 1 :		
Child-Resistant Packaging Yes* X No *Certification must be	Unit Packaging Yes No X If "Yes" Unit Packaging wgt.	No. per container	Yes No X  If "Yes" Package wgt	Metal Plastic Glass "Yes" No. per Paper		c X	
submitted	Ome rackaging wge,	container	i dekage wgt	Container	Other (Specify)		
3. Location of Net Contents Info	rmation	4. Size(s) Retail C	ontainer		ion of Label Directi	ons	
Label X Container				On Label X On Labeling accompanying product			
6. Manner in Which Label is Affixed to Product		Lithograph Paper glued Stenciled	Paper glued X			( (	
		Soct	ion - IV			CCCC	
1. Contact Point (Complete items	directly below for identificat			ry, to process this	application.)		
Name Michael G. Sarli		Title Manager Regulatory Affairs			Telephone No. (Include Area Code)		
Certification  I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.  (Stamped)							
2. Signature	3. Title						
Mull Sch		Manager Regulatory Affairs				t	
4. Typed Name		5. Date					
Michael G. Sarli		12/28/10					
EPA Form 8570-1	-						

# STERIS®



December 28, 2010

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Regulatory Management Branch I
Antimicrobials Division (7510C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
Attn: Marshall Swindell, PM Team 33

Re: Notification for SPOR-KLENZ Concentrate (EPA Reg. No. 1043-120) – Submission of Printer's Proof Label - Minor Additions

Dear Mr. Swindell:

Enclosed in support of the subject action, please find the following:

- Application for Pesticide (EPA Form 8570-1)
- Labeling -size (1 copy)

The enclosed printer's proof includes the following minor additions/correction to the last EPA approved label:

-The label submitted under notification on 11/12/09 and acknowledged by EPA on 12/10/09 erroneously placed the claim in the "Product Claim" section for non-tuberculosis mycobacterium. The correct associated conditions of use for non-tuberculosis mycobacterium are a 100x dilution with a 10 minute contact time as supported by previously submitted efficacy data. The enclosed printer proof has been corrected.

Please provide a stamped approved copy that we will use in support of state registrations. If you have any questions I can be reached at 314-290-4704 or at mike\_sarli@steris.com.

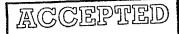
Sincerely,

Michael G. Sarli

Manager Regulatory Affairs

STERIS Corporation

**Enclosures** 



JAN 28 2011 Fungicide, and d, for the

STERIS\* The Technology of Clean®

## SPOR-KLENZ® Concentrate

Cold Sterilant

Reorder Number 6520-26

Net Contents: 0.946 L (1 at.)

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

For use in the following locations:

Industrial Laboratories Pharmaceutical Manufacturers Medical Products Manufacturers **Electrical Utility Companies** Dairies and Pasteurizing Facilities Beverage and Food Processing Plants

Hospitals University Laboratories Semi Conductor Manufacturers Cosmetic Manufacturers Bio Tech Companies 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:	00.00/
Hydrogen Peroxide	. 22.0%
Peroxyacetic Acid	. 4.5%
Inert Ingredients	. 73.5%
TOTAL	.100.00%

### KEEP OUT OF REACH OF CHILDREN DANGER - PELIGRO

See side panel for precautionary statements.

	FIRST AID		
If inhaled	<ul> <li>Move person to fresh air. It 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.</li> </ul>		
lf on skin or on clothing	<ul> <li>Take off contaminated clothing. 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> <li>Hold eye open and rinse slowly and gently with water for 15-20 minutes. Pernove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye. Call a poison control center or doctor for treatment advice.</li> </ul>		
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 Chemtrac at

1-800-424-9300 for emergency medical treatment information. NOTE TO PHYSICIAN COM

Probable mucosal damage may contraindicate the use of pastric lavage.







EPA Reg. No. (1043-120) EPA Est. No. 52252-MN-01

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 Trands 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

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 discharque 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.

\*KILS 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.

GENERAL 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 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.

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: Vinvl Surfaces: Formica Surfaces: Glass

DIRECTIONS FOR STERILIZATION

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 any obvious debris or organic material from the surface to be sterilized. This can often be accomplished by inising 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 accéptable levels.

This product may be used to preclean or decontaminate critical/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 (scissors. clamps) etc. This product is not to be used as a terminal high level disinfectant on any critical ciamps) etc. I his 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 disinfection. Add it the disinfection solution for a minimum of the 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. This product may be used to preclean or decontaminate critical/semi-critical medical devices prior to sterilization or high level disinfection.

FOGGING AS AN ADJUNCT TO REGULAR CLEANING AND DISINFECTING:

POGING 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. For 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 surface or immerse items to be sanitized in the solution. Product may be applied by climop 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 fillers, 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.

PRODUCT CLAIMS

 Sterilant; Sporicidal; Bactericidal; Virucidal (Hepatitis B, HIV-1\*); Fungicidal (100X) dilution 11 hours 20°C • Non-tuberculosis mycobacterium (chelonae abscessus); Hospital Disinfectant; Pseudomonacidal; Broad Spectrum Disinfectant; Germicidal Spray disinfectant (100X) dilution 10 min. 20°C • Cleaner/Sanitizer (non-food contact surfaces) (32X) dilution 10 min. 20°C • Cleaner/Sanitizer (food contact surfaces - Staphylococcus aureus and Escerichia coli) (320X) dilution 1 min. (20°C).

#### 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 pressures Store in original closed container. NEVER TAMPER WITH VENT.

Pesticide Disposal: Wastes resulting from the use of this product may be dispos

on-site by diluting in a sanitary sewer or at an approved waste disposal facility. Pest 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. Offe 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 1/4 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.

> Manufactured for: STERIS Corporation ■ 7501 Page Avenue St. Louis. MO 63133 ■ USA ■ 800-548-4873 ■ www.steris.com

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Product Made in U.S.A

