

1043-120

01-28-2011

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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 28, 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,

A handwritten signature in cursive script that reads "M Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

314

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:

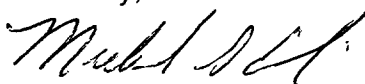
- Application for Pesticide (EPA Form 8570-1)
- Labeling –size (1 copy)

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

ACCEPTED

JAN 28 2011



SPOR-KLENZ Concentrate

Cold Sterilant

Reorder Number: 6520-26 Net Contents: 0.946 L (1 qt.)

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.

Table with 2 columns: Active Ingredients (Hydrogen Peroxide, Peroxyacetic Acid) and Inert Ingredients, with percentages.

KEEP OUT OF REACH OF CHILDREN DANGER - PELIGRO See side panel for precautionary statements.

Table with 2 columns: FIRST AID (If inhaled, If on skin, If in eyes, If swallowed) and HOT LINE NUMBER (For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night (800) 424-9300, (703) 527-3887).

LOT: MFD: EXP: EPA Reg. No. C43-120 EPA Est. No. 52252-MN-01

Barcode and vertical text: (01)00724995 041403

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.

*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.

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.

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.

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 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/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. 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:

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 surface or immerse items to be sanitized in the solution. Product may be applied by 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 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 Escherichia 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 disposed 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. 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.

Manufactured for: STERIS Corporation ■ 7501 Page Avenue St. Louis, MO 63133 ■ USA ■ 800-548-4873 ■ www.steris.com 6520-21H(110) 67199-501A 61224 Product Made in U.S.A.

Handwritten initials: JFC