



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 24, 2018

Jenifer Pavlovsky
Manager, Regulatory Affairs
Steris Corporation
7501 Page Avenue
St. Louis, MO 63133

Subject: Notification per PRN 98-10 – To update label language
Product Name: SPOR-KLENZ Ready to use Disinfectant Wipes
EPA Registration Number: 1043-131
Application Date: July 25, 2018
Decision Number: 543168

Dear Ms. Pavlovsky:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, you may contact Emilia Oiguenblik by phone at 703-347-0199, or via email at Oiguenblik.emilia@epa.gov or Zeno Bain by phone at 703-347-8102, or via email at bain.zeno@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Zeno Bain".

Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

NOTIFICATION

1043-131

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

10/24/2018

[Front Label]

SPOR-KLENZ® Ready-To-Use Disinfectant Wipes

Gamma Process Package

For Use in Pharmaceutical, Medical Device, Biotech and Cosmetic Manufacturing Facilities

Bactericidal, Tuberculocidal, Fungicidal, *Virucidal

Uses: Primarily intended for disinfection of: stainless steel, plastic items and **hard nonporous** surfaces, **hard surfaces** e.g. counter tops, floors, walls, glass, vinyl.

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Active Ingredients:

Hydrogen Peroxide 1.00%
Peroxyacetic Acid 0.08%

Inert Ingredients:

98.92%

Total

100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

NOT TO BE USED AS A BABY WIPE

See back panel for additional precautionary statements

FIRST AID	
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.•Call a poison control center or doctor for 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 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 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.	

LOT: *Net Weight:* 1 lb. 1 oz. (478.5 g)
MFD: *Contents:* 15 Wipes
EXP: (9x9in.) (22.9x22.9cm)

[Back label]

PRECAUTIONARY STATEMENTS
Hazard to Humans and Domestic Animals.

Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin. Do not get in eyes, on skin, or on clothing. Avoid contact with skin. Wear protective eye-wear such as goggles, or face shield. Wash thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing 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.

[Insert]

****KILLS HIV- 1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODILY FLUIDS** in 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 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 disinfectant.

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 wet with SPOR-KLENZ Ready-To-Use Disinfectant Wipes for a minimum of 10 minutes.

[Back of Label]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

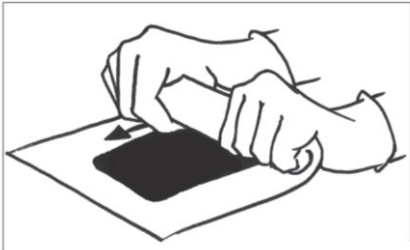
DIRECTIONS FOR BROAD SPECTRUM DISINFECTION/TUBERCULOCIDE/VIRUCIDE*

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. Roll outer pouch to release liquid onto the wipe material. Peel back the label. Remove wetted wipes from pouch. Use as many wipes as needed to thoroughly wet surfaces for 10 minutes. Wear gloves when handling wipes. After use, discard pouch and any unused wipes.

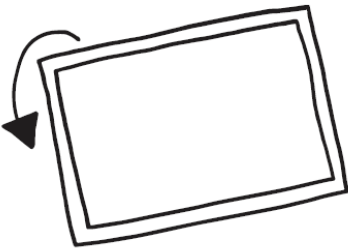
Spor-Klenz Ready-To-Use Disinfectant Wipes require saturation of the dry wipes contained in the package at point of use.

Preparation of wipes:

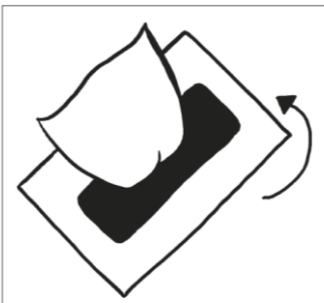
1. Ensure package opening is facing up. Use two hands to roll one end of the pouch and apply pressure until you feel the inner packet containing the Spor-Klenz Ready-To-Use Disinfectant Wipes release the disinfectant solution.



2. Invert pouch until wipes are fully saturated.



3. Using the resealable cover, remove wipes. Reseal once desired number of wipes have been removed.



Product that has been saturated must be discarded daily.

(Note to Reviewer: These are representative images/descriptions that may appear on the label with the appropriate package.)

DO NOT USE AFTER EXPIRATION DATE. Do not allow SPOR-KLENZ Ready-To-Use Disinfectant Wipes to mix with alkaline substances such as bleach (Sodium Hypochlorite) or other oxidizing agents. Use purified water (e.g. deionized) for cleaning and rinsing. Some materials may be incompatible with SPOR-KLENZ Ready-To-Use Disinfectant Wipes. Test material prior to use. Spor-Klenz Ready-To-Use Disinfectant Wipes have been shown to be compatible with Polyvinyl chloride, polypropylene, polyurethane, aceto-copolymers, polycarbonate, polysulfone, polystyrene, stainless steel.

[Insert]

PRODUCT CLAIMS	
Broad Spectrum Disinfectant [<i>Staphylococcus aureus</i> (ATCC 6538), <i>Pseudomonas aeruginosa</i> (ATCC 15442)] Tuberculocidal (<i>Mycobacterium bovis</i> BCG) (Clinical Isolate) <i>Mycoplasma gallisepticum</i> (ATCC 15302) <i>Trichophyton interdigitale</i> (ATCC 9533) *HIV-1** (Clinical Isolate) *Murine parainfluenza virus type 1 (Sendai) (ATCC VR-907) *Mouse hepatitis virus (Clinical Isolate) *Murine norovirus (Clinical Isolate) <i>Aspergillus niger</i> (ATCC 16404)	10 minutes 20°C

[Back Label]

<p>STORAGE AND DISPOSAL</p> <p>Do not contaminate water, food or feed by storage or disposal.</p> <p>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.</p> <p>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.</p> <p>Container Disposal: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.</p> <p>Wipes Disposal: Nonreusable one time use container. Discard used and unused wipes in trash. Do not flush wipes down toilet.</p>

(Optional Label Text)

See product insert for additional product information.

[Front or Back of Label]

EPA Reg. No. 1043-XXX EPA Est. No. 94998-NC-1

Manufactured for:
STERIS Corporation
7501 Page Avenue
St. Louis, MO 63133 U.S.A.
800-548-4873

Product Made in U.S.A.