

GENERAL DESCRIPTION

Spor-Klenz RTU ETO Process Packaged Cold Sterilant is an Environmental Protection Agency (EPA) registered product designed to be used as a sterilant, sporicide or as a disinfectant for cleanroom surfaces and equipment in the pharmaceutical, biotechnology, medical products manufacturing, cosmetic and nutritional manufacturing industries. Spor-Klenz RTU ETO sterilant may also be used in research facilities, including laboratory animal research facilities.

Spor-Klenz RTU ETO sterilant is a stabilized blend of peracetic acid, hydrogen peroxide and acetic acid. This chemistry provides for fast, effective microbial control, including spores.

Spor-Klenz RTU ETO sterilant may be used without dilution as a sterilant, sporicide or a disinfectant, or it may be diluted 1:49 with purified water and used as a sanitizer. Spor-Klenz RTU ETO sterilant should be used on pre-cleaned surfaces and is acceptable for use on stainless steel, plastics, glass, floors and walls. Please contact STERIS regarding substrate compatibility reports.

FEATURES

- Advanced peracetic acid/hydrogen peroxide blend

- Ready to use

- Double-bagged package, ethylene oxide (ETO) treated by a validated process and United States Pharmacopeia (USP) sterility tested

- Product may be used without dilution as a sterilant, sporicide or as a disinfectant, or it may be diluted 1:49 with purified water and used when sanitization is needed

- Reusable as a sterilant or as a disinfectant (undiluted), for up to 14 days

- 5-1/2 hour sterilant claim

- Available in 1-qt (0.95-L) container

BENEFITS

- Provides fast microbial control against a broad range of organisms, including bacteria, fungi, viruses and bacterial spores

- Saves time; eliminates labor and the need to validate preparation procedures

- Simplifies introduction into critical areas

- Flexible-use options depending on facility needs

- Proven effective and stable for extended use

- One of the fastest chemical sterilants available

- Offers versatile use for both cleanrooms and process sanitizing applications

TYPICAL PHYSICAL PROPERTIES

Form.....	Colorless liquid
Odor.....	Vinegar
Typical pH (undiluted).....	1.8 typical
Typical specific gravity (60.1°F [15.6°C]).....	1.01 typical
Sterile.....	SAL of 1 x 10 ⁻⁶

NORTH AMERICA: MICROBIAL EFFICACY DATA

SPORICIDAL PROPERTIES

Spor-Klenz RTU ETO sterilant is registered with the EPA as a sterilant. To be granted this registration, Spor-Klenz RTU ETO sterilant was tested by the Association of Official Analytical Chemists (AOAC) test method 966.04, Sporocidal Activity of Disinfectants.

Method 966.04 is a carrier method which utilizes cultures of *Bacillus subtilis* (ATCC 19659) and *Clostridium sporogenes* (ATCC 3584) to demonstrate efficacy. As per the test criteria, none of the 720 carriers evaluated in this test showed growth after a **5-1/2 hour** exposure to Spor-Klenz RTU ETO sterilant.

Spor-Klenz RTU ETO sterilant is registered with the EPA as a sporicide for use on non-porous surfaces undiluted 30 minutes at 20°C (68°F) as tested against *Bacillus subtilis* (ATCC 19659), *Clostridium sporogenes* (ATCC 3584) and *Bacillus cereus* (ATCC 14579).

Not to be used as a terminal sterilant or high level disinfectant on semi-critical or critical medical devices.

BACTERICIDAL PROPERTIES

To demonstrate that the Spor-Klenz RTU ETO sterilant meets the EPA requirements for broad-spectrum disinfectant, AOAC Use-Dilution Method 955.14 was performed. This carrier method utilizes *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442) and *Salmonella enterica* (ATCC 10708) to demonstrate efficacy. To satisfy the EPA requirements for a disinfectant claim, no more than one carrier per set of 60 may show growth under the test conditions.

Spor-Klenz RTU ETO sterilant is effective against *Mycoplasma gallisepticum* (ATCC 15302) undiluted for 10 minutes at 20°C (68°F).

Spor-Klenz RTU ETO sterilant is effective as a non-food contact surface sanitizer (*Staphylococcus aureus* [ATCC 6538] and *Klebsiella pneumoniae* [ATCC 4352]) when diluted 50x (1 part to 49 part water) for five minutes.

REUSE TESTING BY EPA PROTOCOL

To demonstrate that Spor-Klenz RTU ETO sterilant may be reused repeatedly for a 14-day period, repeated challenge testing was performed as specified by EPA guidelines (Re-Use Test Protocol Specifications). The test protocol involves daily inoculation of Spor-Klenz RTU ETO sterilant with the following organisms: *Bacillus subtilis* (ATCC 19659), *Clostridium sporogenes* (ATCC 3584), *Pseudomonas aeruginosa* (ATCC 15442) and *Staphylococcus aureus* (ATCC 6538). At days 7 and 14, a portion of Spor-Klenz RTU ETO sterilant which had been treated in this fashion was removed and tested by the aforementioned Sporicidal and Disinfectant Testing protocols. During this testing, no failed carriers were observed.

TUBERCULOCIDAL PROPERTIES

Spor-Klenz RTU ETO sterilant is effective against *Mycobacterium tuberculosis* (BCG) as tested by the AOAC Tuberculocidal Activity Test within 10 minutes at 20°C (68°F). Use fresh solutions only.

VIRUCIDAL PROPERTIES

Spor-Klenz RTU ETO sterilant was found to be effective against mouse hepatitis virus, minute virus of mice, murine norovirus, murine para influenza virus type 1 (Sendai) and Human Immunodeficiency Virus (HIV-1) when tested according to EPA guidelines undiluted for 10 minutes at 20°C (68°F) exposure. Spor-Klenz RTU ETO sterilant was found to be effective against mouse parvovirus when tested according to EPA guidelines undiluted for 25 minutes at 20°C (68°F). Treated surfaces must remain completely immersed for 25 minutes.

FUNGICIDAL PROPERTIES

Spor-Klenz RTU ETO sterilant was found to be effective against *Aspergillus niger* (ATCC 16404) undiluted five minutes at 20°C (68°F) exposure.

GERMICIDAL SPRAY

To demonstrate that Spor-Klenz RTU ETO sterilant is an effective disinfectant when sprayed onto a surface, the AOAC Germicidal Spray Products as Disinfectants test (Method 961.02) was performed. When applied as a spray, per the testing protocol, Spor-Klenz RTU ETO sterilant was found to be effective against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538) with an exposure time of 30 seconds at 20°C (68°F).

DIRECTIONS FOR USE

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

Broad-Spectrum Disinfectant

This product is not to be used as a terminal high level disinfectant or sterilant on any critical/semi-critical medical device.

For broad-spectrum disinfection of items such as equipment, walls, etc., remove any obvious debris or organic material from the surface to be disinfected. This can often be accomplished by rinsing with purified water, by mechanical action or by the use of a germicidal detergent. Apply the Spor-Klenz RTU ETO sterilant as is or as a 1:49 dilution to the clean, dry surface to be disinfected either by manual or mechanical means (i.e., spraying), in such a manner as to completely wet the surface. The surface must remain wet for a minimum of 10 minutes.

It may also be desirable to completely immerse certain items in the Spor-Klenz RTU ETO sterilant. Allowing for materials compatibility with the Spor-Klenz RTU ETO sterilant formula, this is an acceptable practice with the following provisions:

- The items to be immersed should be free of debris and organic material prior to Spor-Klenz RTU ETO sterilant exposure.
- The Spor-Klenz RTU ETO sterilant solution may be reused for a period of up to 14 days under these conditions.

Germicidal Spray

Apply Spor-Klenz RTU ETO sterilant undiluted onto pre-cleaned surfaces using a plastic spray bottle or other appropriate apparatus. Allow the surface to remain wet for 30 seconds. Allow to air dry.

Cold Sterilant

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 water, or by detergent cleaning, followed by a water rinse. Immerse the item to be sterilized with a sufficient volume of undiluted Spor-Klenz RTU ETO sterilant to cover the item and fill all passages requiring sterilization. Maintain items in the sterilizing solution for a minimum of 5-1/2 hours at 20°C (68°F) temperature. Remove items after 5-1/2 hours and rinse with sterile water until effluent reaches an acceptable residue level. The solution may be used and reused for up to 14 days in a manual system with 5-1/2 hours immersion.

Sporicide

Use only on hard, non-porous surfaces. Remove any obvious debris or organic material from the surface to be treated. This can often be accomplished by rinsing with water or by detergent cleaning followed by a water rinse. Apply product to hard, non-porous surfaces, thoroughly wetting surfaces by immersion. Treated surfaces must remain **wet** for 30 minutes. Wipe dry or allow to air dry.

Cleaner/Sanitizer (non-food contact surfaces)

Using water or mechanical action, remove heavy soil or gross filth from hard surfaces such as formica, stainless-steel or vinyl surfaces. Apply by cloth, mop or sponge so as to wet all surfaces thoroughly, a freshly made 50x dilution (1 part product to 49 part water) of Spor-Klenz RTU ETO sterilant, made using purified water, to the pre-cleaned surface or immerse pre-cleaned items to be sanitized in the solution. Allow five minutes of contact time. Let air dry or rinse with purified water, drain excess if possible and allow to dry. Spor-Klenz RTU ETO sterilant may **not** be reused as a cleaner/sanitizer.

EUROPEAN: MICROBIAL EFFICACY DATA

This testing and related claims are pertinent to Europe only and are not approved for use in the United States. For approved uses in the United States, refer to U.S. EPA approved labeling as referenced in the section above.

EN 1276:1997 Quantitative suspension test for the evaluation of bactericidal activity

Spor-Klenz RTU ETO sterilant passed the requirements of the EN 1276:1997 guidelines at all contact times tested for bactericidal activity when tested as a ready-to-use product (80% final concentration) against *Pseudomonas aeruginosa* (ATCC 15442), *Escherichia coli* (ATCC 10536), *Staphylococcus aureus* (ATCC 6538) and *Enterococcus hirae* (ATCC 10541). Testing was done under the basic obligatory conditions of EN 1276:1997, including 20°C (68°F) test temperature, five minutes and one minute +/- 10 seconds contact times, dirty conditions and using the organisms noted above.

EN 14348:2005 Quantitative suspension test for the evaluation of tuberculocidal activity

Spor-Klenz RTU ETO sterilant passed the requirements of the EN 14348:2005 guidelines at all contact times tested for tuberculocidal activity when tested as a ready-to-use product (80% final concentration) against *Mycobacterium terrae* (ATCC 15755). Testing was done under the basic obligatory conditions of EN 14348:2005, including 20°C (68°F) test temperature, 60 minutes and 10 minutes +/- 10 seconds contact times, clean conditions and using the organism noted above.

BS EN 1650:1997 Quantitative suspension test for the evaluation of fungicidal activity

Spor-Klenz RTU ETO sterilant passed the requirements of the BS EN 1650:1997 guidelines at all contact times tested for fungicidal activity when tested as a ready-to-use product (80% final concentration) against *Aspergillus niger* (ATCC 16404) and *Candida albicans* (ATCC 10231). Testing was done under the basic obligatory conditions of BS EN 1650:1997, including 20°C (68°F) test temperature, 15 minutes and five minutes +/- 10 seconds contact times, clean conditions and using the organisms noted above.

EN 14476:2005 Quantitative suspension test for the evaluation of virucidal activity

Spor-Klenz RTU ETO sterilant passed the requirements of the EN 14476-2005 guidelines at 30 minutes and 60 minutes for poliovirus Type 1 strain Sabin (NIBSC Code 06/22) virucidal activity when tested with ready-to-use product (100% final concentration). Testing was done under the basic obligatory conditions of EN 14476:2005, including 20°C (68°F) test temperature, 30 minutes and 60 minutes contact times, dirty conditions (BSA 3 g/L + sheep erythrocytes) and using the organism noted above.

UNE-EN 13704:2002 Quantitative suspension test for the evaluation of sporicidal activity

Spor-Klenz RTU ETO sterilant passed the requirements of the UNE-EN 13704:2002 guidelines when tested at a 50% dilution in hard sterile water (300 mg/kg CaCO₃) under dirty conditions (3 g/L bovine albumin) at 20°C (68°F) against *Bacillus subtilis* ATCC 6633 spores, showing a greater than 3.0 log reduction at a 10-minute contact time.

UNE-EN 13697:2002 Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity

Spor-Klenz RTU ETO sterilant passed the requirements of the UNE-EN 13697:2002 guidelines when tested using stainless steel as the hard surface and 5-minute contact time at 50% dilution in hard sterile water (300 mg/kg CaCO₃) under dirty conditions (3 g/L bovine albumin) at 20°C (68°F) is effective (greater than 4 log reduction) against *Escherichia coli* DSMZ 682, *Enterococcus hirae* ATCC 10541, *Staphylococcus aureus* CECT 239 and *Pseudomonas aeruginosa* DSMZ 939 and is fungicidal (greater than 3 log reduction) against *Aspergillus niger* DSMZ 1988 and *Candida albicans* DSMZ 1386.

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 24°C (75°F). 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

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

For ≤ 5 gallon: 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 second after the flow begins to drip. Repeat this procedure two more times.

For > 5 gallon: Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

PRECAUTIONS

Information concerning human and environmental exposure may be reviewed on the Safety Data Sheet (SDS) for the product. For additional information regarding incidents involving human and environmental exposure, call 314-535-1395.

For further information, please contact:



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