STERIS®

SPOR-KLENZ® READY-TO-USE COLD STERILANT TECHNICAL DATA

GENERAL DESCRIPTION

Spor-Klenz Ready-To-Use (RTU) Cold Sterilant is an Environmental Protection Agency (EPA) registered product designed to be used as a sterilant, sporicide or as a high-level disinfectant for cleanroom surfaces and equipment in the pharmaceutical, biotechnology, medical products, cosmetics and nutritionals industries. Spor-Klenz RTU sterilant may also be used in research facilities, including laboratory animal research facilities.

Spor-Klenz RTU 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 sterilant may be used without dilution as a sterilant, sporicide or a high-level disinfectant, or it may be diluted 1:50 with purified water and used as a sanitizer. Spor-Klenz RTU sterilant should be used on pre-cleaned surfaces and is safe for use on stainless steel, plastics, glass, floors and walls. Please contact STERIS regarding substrate compatibility reports.

FEATURES	BENEFITS
Advanced peracetic acid/hydrogen peroxide blend	Provides fast microbial control against a broad range of organisms, including bacteria, fungi, viruses and bacterial spores
Ready to use	Saves time; eliminates labor and the need to validate preparation procedures
Product may be used without dilution as a sterilant, sporicide or as a high-level disinfectant, or it may be diluted 1:50 with purified water and used when sanitization is needed	Flexible-use options depending on facility needs
Reusable as a sterilant or as a high-level disinfectant (undiluted), for up to 14 days	Proven effective and stable for extended use
5-1/2 hour sterilant claim	One of the fastest chemical sterilants available
Available in 1-gal (3.78-L), 1-qt (0.95-L), and 55-gal (208-L) containers	Offers versatile use options for both cleanrooms and process sanitizing applications

TYPICAL PHYSICAL PROPERTIES

Form.....Colorless liquid

Odor.....Vinegar

Typical pH (undiluted).....1.8 typical

Typical specific gravity (77°F [25°C]).....1.01 typical

NORTH AMERICA: MICROBIAL EFFICACY DATA

SPORICIDAL PROPERTIES

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

Spor-Klenz RTU 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) *and Clostridium sporogenes* (ATCC 3584).

BACTERICIDAL PROPERTIES

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

Spor-Klenz RTU 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 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 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 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 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 sterilant was found to be effective against mouse hepatitis, minute virus of mice, murine novovirus, 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 sterilant was found to be effective against mouse parvovirus when tested according to EPA guildlines undiluted for 25 minutes at 20°C (68°F). Treated surfaces must remain completely immersed for 25 minutes.

FUNGICIDAL PROPERTIES

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

GERMICIDAL SPRAY

To demonstrate that Spor-Klenz RTU 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 sterilant was found to be effective against *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella cholerasuis* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538) with an exposure time of 30 seconds at 20°C (68°F).

DIRECTIONS FOR USE

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

Broad-Spectrum Disinfectant

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 sterilant as is or as a 1:50 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 sterilant. Allowing for materials compatibility with the Spor-Klenz RTU 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 sterilant exposure.
- The Spor-Klenz RTU sterilant solution may be reused for a period of up to 14 days under these conditions.

Germicidal Spray

Apply Spor-Klenz RTU 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

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 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 sterilized. 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 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 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 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 aeureus* (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 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 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.

STORAGE AND DISPOSAL

Storage

Store this product in its shipping carton. Do not expose to direct sunlight. Maintain temperature below 24°C (75°F). Avoid contact with combustible materials. Store this product in its original closed container. For chemical emergency, spill, leak, fire, exposure or accident, call Chemtrec, day or night (800) 424-9300 or (703) 527-3887.

Prohibitions

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

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 or mixture of rinsate is a violation of Federal Law. If these wastes cannot be disposed of according to the 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, burning, or by other procedures approved by state and local authorities. If burned, stay out of smoke.

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 Material Safety Data Sheet (MSDS) 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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