

GENERAL DESCRIPTION

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

Spor-Klenz Concentrate Cold 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 Concentrate Cold Sterilant is economically formulated to be used at a 1% v/v dilution as a sterilant or as a broad spectrum disinfectant. Spor-Klenz Concentrate Cold Sterilant, at a 1% v/v dilution, should be used on precleaned surfaces and is acceptable for use on stainless steel, plastics, glass, floors and walls.

FEATURES

Advanced peracetic acid/hydrogen peroxide blend

Diluted from concentrate at a 1% v/v dilution with purified water

Product may be used as a sterilant with a contact time of 11 hours, or as a disinfectant with a contact time of 10 minutes

Reusable as a disinfectant, for up to seven days after dilution

BENEFITS

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

Economical use-dilution provides for cost savings

Flexible use options depending upon facility needs

Proven effective and stable for extended use

PHYSICAL PROPERTIES

Form.....	Colorless liquid
Odor.....	Vinegar
Specific gravity (25°C [77°F]).....	1.13 typical
pH (undiluted).....	1.0 typical
pH (1% v/v).....	3.2 typical

BACTERICIDAL PROPERTIES

To demonstrate that the Spor-Klenz Concentrate Cold Sterilant (1%) meets the EPA requirements for a broad spectrum disinfectant, Association of Official Analytical Chemists (AOAC) Use-Dilution Method 955.14 was performed. This is a carrier method which utilizes *Staphylococcus aureus* (ATCC 6538), *Salmonella choleraesuis* (ATCC 10708) and *Pseudomonas aeruginosa* (ATCC 15442) 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 Concentrate Cold Sterilant met this criterion, as no carriers showed growth when used at a contact time of 10 minutes at 20°C (68°F). Additionally, Spor-Klenz Concentrate Cold Sterilant has demonstrated efficacy against non-tuberculous mycobacterium (*Chelonae abscessus*) within 10 minutes at 20°C (68°F).

Spor-Klenz Concentrate Cold Sterilant is effective as a non-food contact sanitizer (*Staphylococcus aureus* [ATCC 6538] and *Klebsiella pneumonia* [ATCC 43521]) when diluted 32x (1 part to 31 part water) for ten minutes.

Spor-Klenz Concentrate Cold Sterilant is effective as a food contact sanitizer (*Staphylococcus aureus* [ATCC 6538] and *Escherichia coli* [ATCC 11229]) when diluted 320x (1 part to 319 part water) for one minute at 20°C (68°F).

SPORICIDAL PROPERTIES

Spor-Klenz Concentrate Cold Sterilant is registered with the U.S. Environmental Protection Agency (EPA) as a sterilant. In order to be granted this registration, Spor-Klenz Concentrate Cold Sterilant was tested by the 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 an **11 hour** exposure to Spor-Klenz Concentrate Cold Sterilant.

DIRECTIONS FOR USE

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 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, mechanical action or by the use of a germicidal detergent. Apply the Spor-Klenz Concentrate Cold Sterilant at a 1% v/v 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 Concentrate Cold Sterilant dilution. Allowing for materials compatibility with the diluted Spor-Klenz Concentrate Cold Sterilant, this is an acceptable practice with the following provisions. The items to be immersed should be free of debris and organic material prior to exposure to Spor-Klenz Concentrate Cold Sterilant. The Spor-Klenz Concentrate Cold Sterilant dilution may be reused for a period of up to seven days under these conditions.

Cold Sterilant

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

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. 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 Cold Sterilant 1% v/v with purified water. Do not store diluted Spor-Klenz Concentrate Cold Sterilant for use as a sterilant; once diluted, use immediately. Immerse the item to be sterilized in a sufficient volume of diluted Spor-Klenz Concentrate Cold Sterilant 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 reaches an acceptable residue level.

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 32x dilution (1 part product to 31 part water) of Spor-Klenz Concentrate Cold Sterilant, made using purified water, to the precleaned surface or immerse precleaned items to be sanitized in the solution. Allow ten minutes of contact time. Let air dry or rinse with purified water, drain excess if possible and allow to dry. Spor-Klenz Concentrate Cold Sterilant may **not** be reused as a cleaner/sanitizer.

Cleaner/Sanitizer (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. Rinse with potable water. Remove any food products or packaging materials from the room or cover completely. Dilute Spor-Klenz Concentrate Cold Sterilant at 2 oz/5 gal 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 one minute at 25°C (77°F). Allow to drain well. Do not rinse. Blow or air dry.

STORAGE AND DISPOSAL

Storage

Do not contaminate water, food or feed by storage or disposal. Store in shipping carton. Do not expose to direct sunlight. Maintain temperature below 24°C (75°F). 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.

Disposal

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on-site by dilution 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: Triple rinse empty container with water, then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

For chemical emergency, spill, leak, fire, exposure or accident, call 314-535-1395 (STERIS); 800-424-9300 (CHEMTREC).

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:



STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-444-9009
www.STERISLifeSciences.com