



SteriTech
SPECIALIST INFECTION PROTECTION

STERI101 COLD STERILANT



Where access to an approved, regularly maintained and tested autoclave is available, the autoclave should always be considered the primary means of sterilisation.



For additional information about this product, or to give product feedback to the manufacturer, please scan this QR code.

PPE REQUIREMENTS

Latex or nitrile gloves and chemical splash goggles, however OSH requires the use of good ventilation when mixing, handling or discarding chemical disinfectants.

HIGH LEVEL INSTRUMENT DISINFECTANT

INTENDED USE

Disinfection of pre-cleaned thermo-sensitive instruments. Disinfection of pre-cleaned instruments where a functional calibrated autoclave is unavailable. **Note: Recommended for immersible instruments and equipment only - repeated use on pleather and some white plastics may cause permanent discolouration.**

ACTIVE INGREDIENTS

12.75% Isopropanol; 2.25% Ethanol; 0.5% Bis (3-amino-propyl) dodecylamine; 0,36%] Didecylidimethylammonium chloride; 0.02% Alkyldimethylbenzylammonium chloride; 0.02% Alkyldimethylethylbenzylammonium chloride; Corrosion Inhibitor; Surfactant.

PACKAGING VARIANTS

25L, 5L, 1L

PRODUCT CHARACTERISTICS

Dilution Form: Ready to use
Physical Form: Translucent blue liquid
Odour: Mild chemical fragrance (Fragrance-Free)
pH: 9.5-10.5
Tray Life: 21-28 days
Incompatibilities: Anionic detergents, Natural Soaps, Strong oxidisers
Environmental Concerns: Biodegradable
Optional Accessories: Minimum Effective Concentration Test Strips

REGULATORY INFORMATION

NRCS Registration no.: NRCS/8054/242613/501
SAHPRA Medical Device Registration Number: Awaiting
Class Registration Call-up
Risk Classification: C / IIb
GMDN Code: 47631
GMDN Descriptor: Medical device disinfection agent



INSTRUCTIONS FOR USE



Decant the required amount of undiluted Steri101 Cold Sterilant into a clean, dry, covered stainless steel or HDPE receptacle. Completely immerse thoroughly disassembled, pre-cleaned, rinsed & dried instruments / devices in the liquid, ensuring that any hinges or joints are in the open position. Allow a contact time as per your desired efficacy – see below efficacy table. Remove the instruments / devices from the liquid using sterile forceps, rinse and follow the post-sterilisation procedure of the facility. Tray-life of the liquid should be tested weekly using M.E.C. strips. As soon as the test indicates that the active level has fallen below the minimum effective level (1000ppm), the liquid should be discarded. The product should have a tray-life of between 21 & 28 days, should the strips prove a shorter life, check your instrument cleaning process. Steri101 Cold Sterilant should not be subjected to heating under any circumstances, including use in an autoclave, statum, automated washer and or any other heat-generating equipment.



EFFICACY TESTING:



| | Tested To: | Time: (mins) | Dilution: | Conditions: |
|---------------------------------|---|--------------|-----------|-------------|
| Bactericidal Efficacy | SANS 51276 (EN 1276): Enterococcus hirae, Escherichia coli, Pseudomonas aeruginosa & Staphylococcus aureus | 5 | NEAT | Clean |
| | SANS 53727 (EN 13727): Enterococcus hirae, Pseudomonas aeruginosa, Staphylococcus aureus, Klebsiella pneumoniae & Listeria monocytogenes | 2 5 | | |
| | EN 14561 (SANS 54561): Enterococcus hirae, Pseudomonas aeruginosa & Staphylococcus aureus | 30 | | |
| Fungicidal & Yeastidal Efficacy | SANS 51650 (EN 1650): Aspergillus brasiliensis & Candida albicans | 15 | NEAT | Clean |
| | SANS 53624 (EN 13624): Aspergillus brasiliensis & Candida albicans | 20 | | |
| | EN 14562 (SANS 54562): Aspergillus brasiliensis & Candida albicans | 30 | | |
| Virucidal Efficacy | EN 13610 (SANS 53610): Lactococcus lactis P001 & Lactococcus lactis P008 | 15 | NEAT | Clean |
| | EN 14476 (SANS 54776): Human coronavirus & murine norovirus | 15 & 30 | | |
| Sporocidal Efficacy | SANS 53704 (EN 13704): Bacillus subtilis & Clostridium difficile | 20; 5 | NEAT | Clean |
| Mycobactericidal Efficacy | EN 14348 (SANS 54348): Mycobacterium terrae EN 14563 (SANS 54563): Mycobacterium terrae | 60 30 | NEAT | Clean |
| Corrosivity | SANS 636 (In-house): Non-corrosive up to 1 hour. Do not exceed a 60 minute exposure time. | | | |
| Dermal irritation | OECD 439: Category 2 Irritant. | | | |
| Cytotoxicity | ISO 10993-5: Cytotoxic potential. Do not apply to broken skin, open wounds or cell-culture containers. | | | |