

STERI-7 ULTRA: is a market leader in the supply of specialist contamination control products to pharmaceutical, biotechnology, healthcare and medical device industries worldwide.



STERI-7 Ultra is ideal for the following applications:

- For use in all medical areas, including theatres, clinics, dental surgeries, hospital wards and for the surface disinfection of machines (X-Ray, Mammography, Ultrasound etc.) and breathing apparatus.
- Suitable for the surface disinfection of benches, shelves and laboratory equipment.
- For the disinfection of probes, transducers, centrifuges, pipettes, incubators as well as other sealed devices
- For use in all high risk areas and on most surfaces including glass, metal, ceramics, fabrics, plastic and rubber
- For use in the Clean room environment

STERI-7 Ultra is certified using BSEN, QCT1, QCT2, QCT2M and ASTM E1052 approved protocols as:

- Bactericidal
- Fungicidal
- Virucidal
- Mycobactericidal
- Sporocidal

Fully accredited:

- BS EN ISO 9001:2000 and BS EN ISO 13485:2003 accredited and holds the Medical Device Directive 93/42/EEC and the 98/8/EC Biocidal Product Directive.

STERI-7 Ultra has been tested to be effective in soiled conditions, and in the presence of blood borne diseases
STERI-7 Ultra has a shelf life of 3 years

Endoscopes:

STERI-7 Ultra can be used as an instrument disinfectant for heat labile endoscopes, which combines secure microbiological results with safety in use and rapid activity.

The product is versatile and can be used in both endoscope re-processor machines and open tank troughs.

STERI-7 contains none of the harmful characteristics of Glutaraldehyde, Phenols, Chlorine or Peracetic acid used in other disinfectants.

Tests conducted by independent laboratories and leading manufactures, show that STERI-7 will not harm sensitive instruments including the machines used to sterilise these instruments.

STERI-7 has demonstrated to equipment manufactures that:

"We have conducted tests based on immersion times of between 5 minutes and 72 hours relating to the compatibility of the material with our endoscopes only" which resulted in "There was no aggressive reaction with any of the materials tested"

"For this first round of test, EUK used a fairly harsh testing method" in which "This regime was followed for 1 week" to which "The early results have been very promising with no physical damage to occurring across any of the material types"

Richard Wolf Endoscopes 12th June 2006

Instrument disinfection:

STERI-7 High Level Instrument Disinfectant for the chemical reprocessing of thermo-sensitive surgical instruments, flexible or rigid endoscopes and devices STERI-7 Ultra can be used as an instrument disinfectant that combines secure microbiological credentials with safety in use and rapid activity.

STERI-7 Ultra is suitable for both hospital and veterinary use for the high level disinfection of surgical instruments and medical devices at a dilution of 1:50.

STERI-7 Ultra is primarily designed for open tank use but its unique flexibility also renders it suitable for other medical apparatus including ultrasonic baths.

STERI-7 Ultra is faster acting, safer to use and more economic than 2% activated alkaline glutaraldehyde.

Features of STERI-7 Ultra as a sporicide:

- Proven efficacy against a wide range of spores.
- Passes standard BSEN tests for sporicidal activity - comprehensive test data is available.
- Short contact time (5-15mins) even in conditions of heavy soiling.
- Non-toxic and non-corrosive under normal use.

STERI-7 IS A UNIQUE DUAL ACTION FORMULATION

STERI-7 is a broad spectrum high level disinfectant which has a dual action formula giving uncompromising results. The product has been in development for three years gaining the efficacy accreditation needed to bring STERI-7 to market.

STERI-7 MODE OF ACTION

STERI-7 rapidly interacts with proteins within the cell, causing an inhibition of respiration and ATP synthesis, which results in an inability to synthesize biopolymers or catabolise substrate. Growth inhibition rapidly becomes irreversible and results in cell death as essential proteins are progressively oxidized. Even before cell death occurs, the STERI-7 treated organisms are unable to synthesize either biodegradative enzymes or the exopolymers which facilitate microbial adhesion and biofilm formation.

Basically this means that STERI-7 crosses the cell wall and stops the growth processes of the microbe from within, thus killing it.

STERI-7 PACKAGING

STERI-7 is easily mixed at the point of use from the 5ltr, 1ltr and 0.5ltr containers.

STERI-7: Contains Active ingredients – Isothiazolinone blend, Benzalkonium Chloride.

STABILITY AND STORAGE

- Unopened STERI-7 will remain stable for 36 months
- Prepared or opened solution will last for 12 months (in container with sealed screw cap or lid)

OCCUPATIONAL EXPOSURE LIMITS

All constituents mentioned in the OSHA guidelines are completely within any recommendations or legislation. All the constituents are listed in the proposed European Biocides Directives annexes.

STERI-7, once diluted is in no way detrimental to the environment. The solution breaks down in water and becomes inactive. The solution once diluted can be safely discharged into disposal / drainage channels. It is non toxic, non-sensitising and under normal conditions of disposal will not present risk to aquatic life.

DIRECTIONS FOR USE

Contact times for instruments

Once STERI-7 has been diluted, instruments need only be immersed for a period of **15 MINUTES**

- Spores (inc. Clostridium difficile)
- Viruses
- Fungi
- Bacteria
- Mycobacterium Terrae

**DO NOT IMMERGE INSTRUMENTS FOR LONGER THAN 12hr PERIOD.
ALWAYS PRE-CLEAN INSTRUMENTS PRIOR TO PROCESSING**

LIFE OF PREPARED SOLUTION

STERI-7 is a Single Shot Product and should only be used as such. (STERI-7 is currently being assessed as a multi-shot product and should not be used in this manner until data is complete)

MIXING DIRECTIONS

- Dilution ratio is 1:10 to water (hard or soft).
- Replace cap on STERI-7 container and Discard.
- Pour STERI-7 solution into reservoir.
- STERI-7 solution is now ready for use. (discard gloves after use)

STERI-7 Ultra can be used in automatic endoscope re-processing machines or in cold soak troughs.

MICROBIOLOGICAL TESTS

The following test have been commissioned using STERI-7 to evaluate the products efficacy. Copies of the test papers available are as follows:

1. Spores and Mycobacteria Tests.

- Bacillus Subtilis & Bacillus Cereus Spores
(Abbott Analytical Consultant Laboratory: (D C Watson) 07.06.05
- Mycobacterium Terrae
(Abbott Analytical Consultant Laboratory: (D C Watson) 06.06.06
- Clostridium Difficile
(Abbott Analytical Consultant Laboratory: (D C Watson) 07.06.05

2. Virus Tests.

- Influenza A Virus (H1N1)
(BluScientific Laboratory: (Dr C Woodall) 09.12.05
- SARS Virus
(BluScientific Laboratory: (Dr C Woodall) 12.09.05
- HIV Virus
(BluScientific Laboratory: (Dr C Woodall) 07.03.05

3. Fungi Tests.

- Candida Albicans
(MGS Laboratories Limited :(Bob Grant) 17.06.05
- Aspergillus Niger
(Abbott Analytical Consultant Laboratory: (D C Watson) 20.02.06

4. Bacteria Tests.

- Pseudomonas Aeruginosa
(Abbott Analytical Consultant Laboratory: (D C Watson) 24.02.06
- Escherichia Coli
(Abbott Analytical Consultant Laboratory: (D C Watson) 24.02.06
- Staphylococcus Aureus
(Abbott Analytical Consultant Laboratory: (D C Watson) 24.02.06
- Enterococcus Hirae
(Abbott Analytical Consultant Laboratory: (D C Watson) 24.02.06
- Legionella Pneumophila
(Abbott Analytical Consultant Laboratory: (D C Watson) 06.03.06
- Salmonella Typhimurium
(Abbott Analytical Consultant Laboratory: (D C Watson) 22.02.06
- Methycillin Resistant Staphylococcus Aureus
(Abbott Analytical Consultant Laboratory: (D C Watson) 22.02.06