TECHNICAL **DATA SHEET**

TRISTEL DUO ULT DISINFECTANT

DESCRIPTION

Tristel Duo ULT is chlorine dioxide in a foam, designed specifically for the cleaning and high-level disinfection of endo-cavity ultrasound probes; it offers speed, safety, efficacy and excellent material compatibility.

Through its powerful oxidising action, it destroys all types of microorganisms and eliminates the possibility of cross-contamination between patients. Tristel Duo is sporicidal, mycobactericidal, virucidal, fungicidal and bactericidal in 30 seconds.

TECHNICAL SPECIFICATION

Chemistry	Chlorine Dioxide (produced by combining a Citric Acid base solution with a Sodium Chlorite activator solution.
Shelf Life	2 Years Unopened, From Manufacture Date
Recommended Uses	Non-lumened endo-cavity ultrasound probes and non-invasive medical devices such as: bladder scanners, transabdominal probes and blood pressure cuffs.
Size	250ml Bottle (Made up of 2 x 125ml tubes)
Carton Qty	2 x 250ml Bottles
Efficacy	Sporicidal, mycobactericidal, virucidal, fungicidal, and bactericidal in 30 seconds.

QUALITY STANDARDS

Tristel Duo for Ultrasound is CE marked as a Class IIb Medical Device in accordance with the European Medical Devices Directive 93/42/EEC and the 2007/47/EC amendments.

The product has been independently tested and meets the require-ments set out by European Norms including EN 14885.

Sporicidal efficacy according to EN 17126:2018 is also demonstrated.

FEATURES

- Chlorine Dioxide Foam
- For High-Level Disinfection of Non-Lumened, Non-Invasive Medical Devices
- Each bottle is made up of 2 x 125ml tubes
- Each bottle dispenses 250ml active product
- Destroys all types of micro-organisms (see page 2 for efficacy data)

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MICROBIOLOGICAL EFFICACY SUMMARY

Testing was performed in accordance with European Standard EN14885:2022 and the latest regulatory efficacy requirements for disinfectants used in the medical area.

ORGANISM	TEST METHOD	TEST TYPE	CONDITIONS
SPORICIDAL			
Bacillus subtilis	EN17126	Suspension	Clean 1 & Dirty 1
Bacillus cereus			
Clostridioides difficile			
MYCOBACTERICIDAL/TUBERCULOCIDAL			
Mycobacterium terrae	EN14348	Suspension	Clean 1 & Dirty 1
Mycobacterium avium			
VIRUCIDAL			
Poliovirus Type 1	EN14476	Suspension	Clean 1 & Dirty 1
Adenovirus Type 5			
Murine Norovirus			
FUNGICIDAL/YEASTICIDAL			
Candida albicans	EN 16615	Surface with mechanical action	Clean 1 & Dirty 1
Aspergillus brasiliensis	EN13624	Suspension	Clean 1 & Dirty 1
Candida albicans			
BACTERICIDAL			
Staphylococcus aureus	EN 16615	Surface with mechanical action	Clean 1 & Dirty 1
Enterococcus hirae			
Pseudomonas aeruginosa			
Staphylococcus aureus	EN13727	Suspension	Clean 1 & Dirty 1
Enterococcus hirae			
Pseudomonas aeruginosa			

MICROBIOLOGICAL EFFICACY SUMMARY

Additional testing

TEST METHOD
DNA/RNA
Polyacrylamide gel electrophoresis (PAGE)

ORGANISM	TEST METHOD	TEST TYPE	CONDITIONS
PROTOZOA			
Acanthamoeba castellanii cysts	Bespoke Test	Suspension	Clean 1
SPORES			
Clostridioides difficile	prEN 17846	Surface with mechanical action	Clean 1 & Dirty 1
Bacillus cereus	EN 13704	Suspension	Dirty 1
Bacillus subtilis var niger	Babb JR, Bradely CR & Ayliffe GAJ (J. of Hosp. Inf. 1980 1:63-75)	Suspension	Clean 1 & Dirty 3
MYCOBACTERIA			
Mycobacterium terrae	EN 16615	Surface with mechanical action	Dirty 1
Mycobacterium avium			
Mycobacterium terrae	EN 14563	Carrier	Clean 1 & Dirty 2
Mycobacterium avium			
Mycobacterium terrae	DGHM	Carrier	Dirty 1
Mycobacterium avium			
Mycobacterium terrae	Griffiths et al. (J. of Hosp. Inf. 1998 38:183-92)	Suspension	Clean 1 & Dirty 4

MICROBIOLOGICAL EFFICACY SUMMARY

Additional testing

ORGANISM	TEST METHOD	TEST TYPE	CONDITIONS
VIRUSES			
Bovine Coronavirus	EN 16615	Surface with mechanical action	Dirty 1
Murine Norovirus			Clean 1 & Dirty 1
Adenovirus Type 5			Dirty 1
Human Papillomavirus (HPV) Type 16	Meyers et al (J Med Virol. 2020; 92: 1298–1302.)	Simulated-use Test	Dirty 2
Human Papillomavirus (HPV) Type 18			
Poliovirus Type 1	ASTM E-1053	Surface without mechanical action	Dirty 2
Adenovirus Type 5			
Feline Calicivirus			
Hepatitis B Virus (HBV)			
Herpes Simplex Virus (HSV) Type 1			
Human Immunodeficiency Virus (HIV)			
Influenza A Virus (H1N1)			
Parvovirus (Using Minute Virus of Mice (MVM) surrogate)	DVV/RKI	Suspension	Dirty 3
Poliovirus Type 1			Clean 2 & Dirty 3
Adenovirus Type 5			
Murine Norovirus			
Human Papillomavirus (HPV) (Using Polyomavirus SV40 surrogate)			
Vaccinia Virus			
Influenza A Virus (H1N1)	EN 14476	Suspension	Dirty 1

MICROBIOLOGICAL EFFICACY SUMMARY

Additional testing

ORGANISM	TEST METHOD	TEST TYPE	CONDITIONS
FUNGI/YEAST			
Aspergillus brasiliensis	EN 16615	Surface with mechanical action	Clean 1 & Dirty 1
Candida albicans	EN 13697	Surface without mechanical action	Clean 1
Aspergillus brasiliensis	EN 14562	Carrier	Clean 1
Candida albicans			Clean 1
Candida auris			Dirty 2
Candida albicans	AOAC Use-Dilution Method	Carrier	Dirty 2
Candida albicans	DGHM	Carrier	Dirty 1
Fusarium solani	EN 13624	Suspension	Clean 1
Aspergillus sydowii			
BACTERIA			
Proteus vulgaris	EN 16615	Surface with mechanical action	Dirty 1
Methicillin-resistant *Staphylococcus aureus* (MRSA)			
Neisseria gonorrhoeae			Clean 1
Gardnerella vaginalis			
Streptococcus agalactiae			
Streptococcus pyogenes			
Staphylococcus aureus	EN 13697	Surface without mechanical action	Clean 1
Enterococcus hirae			
Pseudomonas aeruginosa			
Escherichia coli			

MICROBIOLOGICAL EFFICACY SUMMARY

Additional testing

ORGANISM	TEST METHOD	TEST TYPE	CONDITIONS
BACTERIA (continued)			
Staphylococcus aureus	EN 14561	Carrier	Clean 1
Enterococcus hirae			
Pseudomonas aeruginosa			
Carbapenem-resistant Enterobacteriaceae (CRE) *Klebsiellapneumoniae*			
Vancomycin-resistant Enterococci (VRE) *Enterococcus faecium*			
Multidrug-resistant *Acinetobacter baumannii* (MDRAB)			Dirty 2
Extended Spectrum Beta-Lactamase *Klebsiella pneumoniae* (ESBL)			
Methicillin-resistant *Staphylococcus aureus* (MRSA)			
Staphylococcus aureus	VAH 2015	Carrier & Suspension	Dirty 1
Enterococcus hirae			
Pseudomonas aeruginosa			
Methicillin-resistant *Staphylococcus aureus* (MRSA)	EN 13727	Suspension	Dirty 1

Conditions Key:
Clean 1: 0.3g/l Bovine albumin
Clean 2: Aqua bidest
Dirty 1: 3g/l Bovine albumin + 3ml/l Blood erythrocytes
Dirty 2: 5% Blood Serum
Dirty 3: 10% Blood Serum
Dirty 4: 1% Blood Serum