

Expert Opinion

DIN EN 14563:2009

Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area (phase 2, step 2)

	Report Number	:	SM2019065GATn-00
a)	Identification of the test laboratory	:	Microbiology Department Schülke & Mayr GmbH D – 22840 Norderstedt
b)	Identification of the sample		
	Name of the product	:	thermosept® ED
	Batch number	:	1330352
	Manufacturer	:	Schülke & Mayr GmbH
	Date of supply	:	17.06.2019
	Storage conditions	:	room temperature (dark)
	Diluent recommended by the manufacturer	:	water
	Active substance(s) and its concentration(s)	:	100 g solution contains 20 g glutaraldehyde
c)	Test procedure and its validation		
	Procedure	:	Dilution-Neutralisation
	Neutraliser	:	3% polysorbate 80, 0.3% lecithin, 2% L-histidine, 2% glycine ("TLH-Glycine")

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d) Test conditions

Period of the test	: 09.08.-02.09.2019
Appearance of the product and its dilutions	: clear liquids
Concentrations of the test product	: 0.5%, 1%, 1.5%
Test temperature	: 55°C ± 1°C
Diluent for the product	: sterile hard water
Contact time	: 5 min
Load substances	: 0.3 g/l bovine serum albumin (clean cond.)
Stability of the test products	: no precipitates
Incubation temperature	: 36°C ± 1°C
Bacterial strains used	: <i>Mycobacterium avium</i> (ATCC 15769) <i>Mycobacterium terrae</i> (ATCC 15755)

e) Test results

See Annex in test report

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f) Conclusion

In accordance with DIN EN 14563:2009, the formulation thermosept® ED (batch 1330352) displays a **mycobactericidal** effect against tested mycobacterial species *Mycobacterium avium* and *Mycobacterium terrae* at **55°C** under conditions of **low organic soiling** (0.3 g/l bovine serum albumin) at the following concentration-time relation:

0.5% - 5 min

Norderstedt, 30.09.2019

Schülke & Mayr GmbH

Research & Regulatory Affairs



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