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Bode Chemie GmbH
Melanchthonstraße 27

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Germany

Bad Bocklet, 24 November 2014

Test report
(Version 01)

Sample: Sterillium med **L+S-Code: 0244490**

Order: Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants following EN 14348

Order of	31.07.2014
Period of testing	30.09.2014 – 21.10.2014

Material and Method

Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants following EN 14348 (phase 2/step 1; date: April 2005)

1. Identification of the testing laboratory

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2. Identification of the sample

Product name:	Sterillium med
Identification of the sample:	VP 579/3E (Lot: 2673140217)
Active substances per 100 g:	85.0 g ethanol
Appearance of the product:	liquid, colourless, clear
pH-value (100%):	8.30
Storage conditions:	room temperature

3. Quantitative suspension test following EN 14348

Test strains:	*Mycobacterium (M.) terrae*	ATCC 15755
	Mycobacterium (*M.*) *avium*	ATCC 15769
Test concentrations:	97%, 80% and 10%	
Contact times*:	15 sec, 30 sec and 60 sec	

* Efficacy testing of the above mentioned hand disinfectant was performed at short contact times up to a max. of 60 sec. Therefore the neutralisation time within testing was only 10 sec.

Test temperature:	20°C ± 1°C
Organic loading:	0.03% albumin
Conditions of incubation:	21 days, 37°C ± 1°C

4. Test method and its validation

Test method: dilution neutralisation

Inactivation combination: 1.0% Tween 80, 3.0% saponin, 0.5% sodium-thiosulfat, 0.1% histidin in M/15 buffered phosphate

The results of the validation tests A and B proved the validity of the method in all cases. In the validation tests C an incomplete inactivation was detected in the undiluted mixtures of the neutralisation control, as well as the test neutralisation mixture of the test solutions. Accordingly, the dilution which demonstrated adequate inactivation – and thus valid results – was used in the calculation for microbial count reduction.

5. Requirements

According to EN 14348 a log reduction of > 4.0 log against mycobateria is required.

6. Results

The results are stated in tables A (overview) and 1 - 2.

The results from the quantitative suspension test following EN 14348 with the product **Sterillium med** at test concentrations of 97%, 80% and 10% after contact times of 15, 30 and 60 seconds under clean conditions are stated in table A. Results, which passed the required criteria of > 4.0 log are given in bold numbers (for detailed results see tables 1 - 2).

Table A: Overview about the log-reductions of the quantitative suspension test

Product: Sterillium med Test strain: *M. terrae* Organic loading: 0.03% albumin			
Contact time/Concentration	97%	80%	10%
15 sec	**> 5.15**	**> 5.28**	< 1.61
30 sec	**> 5.15**	**> 5.28**	< 1.61
60 sec	**> 5.15**	**> 5.28**	< 1.61
Product: Sterillium med Test strain: *M. avium* Organic loading: 0.03% albumin			
Contact time/Concentration	97%	80%	10%
15 sec	**> 5.18**	3.60	< 1.70
30 sec	**> 5.18**	**> 5.37**	< 1.70
60 sec	**> 5.18**	**> 5.37**	< 1.70

7. Conclusion

In accordance with the requirements of the EN 14348 the product **Sterillium med** showed the required microbial reduction of > 4.0 log at a test temperature of 20°C with reference to the test strains *M. terrae* and *M. avium* at the below mentioned concentration-time relations.

Effective concentration-time relations are:

Clean conditions (0.03% albumin):

97%	15 sec contact time
97% and 80%	30 sec contact time
97% and 80%	60 sec cntact time

The controls demonstrated the validity of the test procedure.

We recommend the following usage:

Mycobactericidal efficacy at clean conditions (0.03% albumin) undiluted at 15 sec contact time

24. NOV. 2014

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