



EVS-EN 17126:2018
INTERFLO OÜ
LABORATORY
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Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area (phase 2, step 1)

TEST REPORT no 703

1. Client:

Date of order:

2. Identification of sample

Name of the product:

Batch number:

Manufacturer:

Date of delivery:

Storage conditions:

Microbiologist

Ljudmila Shljapnikova

Ph.D.

Head of the Laboratory

ZHIVAS LTD
14 Assen Jordanov Blvd. 1592 Sofia, Bulgaria
2022/01/27

OXISEPT
the sample

ZHIVAS LTD

ure and darkness





Appearance of the product:

Recommended diluent:

Active substance

3. Test conditions

Test period:

Date of test:

Product test concentrations:

Exposure time:

Test temperature:

Temperature of incubation

Organic load:

Neutralizer:

Test organisms:

4. Method

5. Results

6. Conclusion

In accordance with EVS-EN 17126:2018, the product OXISEPT (the sample) with concentration 1,0 % in 30 min and with concentration 2,0 % in 15 min possesses sporicidal activity in suspension test at 20 °C under clean condition for referenced strain Clostridium difficile (R027) DSM 27147. The product OXISEPT (sample) shows a reduction of at least 4 lg.

The conclusion is true only for the studied sample of the product OXISEPT (the sample).

Total 6 pages

Annex on 4 pages

Tallinn, 2022/02/07

white crystalline powder

water

Peracetic acid

2022/02/03 – 2022/02/07

2022/02/03

1,0 %; 2,0 %

15 min; 30 min

19,5 ± 0,5°C

36,5 ± 0,5°C

0,3 g/l bovine albumine for low-level soiling

Polysorbate 80, 30 g/l, Lecithin, 3 g/l, Sodium thiosulfate, 5 g/l

Clostridium difficile (R027) DSM 27147

dilution neutralisation

see annex

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Annex I

VALIDATION AND CONTROLS

Test organism	Validation suspension Nvo -1			Validation suspension Nvb -3			Experimental conditions control A			Neutralizer control B -2			Method validation C Concentration 2,0 %		
	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}	Vc1	Vc2	\bar{X}
	64	70	67	88	75	82	60	67	64	63	70	67	44	51	48
Clostridium difficile (R027) DSM 27147															
	$30 \leq \bar{X} \text{ of } Nvo \leq 160$			$30 \leq \bar{X} \text{ of } Nvb / 1000 \leq 160$			$\bar{X} \text{ of } A \text{ is } \geq 0.5 \bar{X} \text{ of } Nvo$			$\bar{X} \text{ of } A \text{ is } \geq 0.5 \bar{X} \text{ of } Nvo$			$\bar{X} \text{ of } A \text{ is } \geq 0.5 \bar{X} \text{ of } Nvo$		

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Annex 2

TEST SUSPENSIONS

Test organism	Dilution range	Vc1	Vc2	N, No
Clostridium difficile (R027) DSM 27147	-5 -6	>200 18	>200 22	$N = 2,0 \times 10^7 = \lg 7,3$ $No = N / 10 = \lg 6,3$ $6,17 \leq \lg No \leq 6,70$

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Annex 3

TEST

Test organism	Dilution range	Vc1	Vc2	Na x 10	lg Na	lg R	Concentration	Contact time
Clostridium difficile (R027) DSM 27147	1	0	0	<140	<2.15	>4,15	1,0 %	30 min
	-1	0	0					
	-2	0	0					
	-3	0	0					
	1	7	10	<140	<2.15	>4,15	2,0 %	15 min
	-1	0	0					
	-2	0	0					
	-3	0	0					

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Annex 4

$$N = c / (n1 + 0,1 n2) \times 10^{-6}$$

$$No = N / 10$$

$$Na = c \times 10 / n$$

$$R = \lg No - \lg Na$$

N – is the number of colonies for 1 ml test suspension
Vc1, Vc2 - is the number of colonies for 1 ml sample
n – is the number of Vc-values taken into account
R – reduction

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