



NORBAK
Nordic Biotside Arenduse ja Kontrolli Laboratoorium

OXISEPT
EVS-EN 17126:2018



EVS-EN 17126:2018
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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 713

1. Client:

ZHIVAS LTD
14 Assen Jordanov Blvd. 1592 Sofia, Bulgaria
2022/02/08

2. Identification of sample

Name of the product: **OXISEPT**
Batch number: **the sample**
Manufacturer: **ZHIVAS LTD**
Date of delivery: **2022/01/31**

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Ljudmila Shljapnikova
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Storage conditions:
Appearance of the product:
Recommended diluent:
Active substance and concentration

room temperature and darkness
white powder
hard water
Sodium percarbonate: 30 – 50 %;
TAED: 15 – 25 %

3. Test conditions

Test period: 2022/03/03 – 2022/03/11
Date of test: 2022/03/03; 2022/03/08
Product test concentrations: 2,0 %
Exposure time: 30 min
Test temperature: 19,5 ± 0,5°C
Temperature of incubation: 36,5 ± 0,5°C
Organic load: 0,3 g/l bovine albumine for low-level soiling
Neutralizer: Polysorbate 80, 30 g/l, Lecithin, 3 g/l, Sodium thiosulfate, 5 g/l
Test organisms: Bacillus subtilis ATCC 6633, Bacillus cereus CIP 105151
dilution neutralisation
see annex

4. Method

5. Results

6. Conclusion

In accordance with EVS-EN 17126:2018, the product OXISEPT (the sample) with concentration 2,0 % possesses sporicidal activity in suspension test in 30 min at 20 °C under clean condition for reference strains Bacillus subtilis ATCC 6633 and Bacillus cereus CIP 105151. The product OXISEPT (the sample) demonstrates at least than 4 logarithms of reduction.

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

Total 6 pages

Annex on 4 pages

Tallinn, 2022/03/11

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Annex 1

VALIDATION AND CONTROLS

Test organism	Validation suspension N _{vo} -1			Validation suspension N _{vb} -3			Experimental conditions control A			Neutralizer control B -2			Method validation C Concentration 2,0 %		
	30 ≤ \bar{X} of N _{vo} ≤ 160			30 ≤ \bar{X} of N _{vb} / 1000 ≤ 160			\bar{X} of A is ≥ 0.5 \bar{X} of N _{vo}			\bar{X} of A is ≥ 0.5 \bar{X} of N _{vo}			\bar{X} of A is ≥ 0.5 \bar{X} of N _{vo}		
	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}	V _{c1}	V _{c2}	\bar{X}
Bacillus subtilis ATCC 6633	38	44	41	44	34	39	35	43	39	36	35	36	42	39	41
Bacillus cereus CIP 105151	57	63	60	72	68	70	59	52	56	59	66	63	40	38	39

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Annex 2

TEST SUSPENSION

Test organism	Dilution range	Vc1	Vc2	N, No
Bacillus subtilis ATCC 6633	-5 -6	>200 17	>200 22	$N = 1,95 \times 10^7 = \lg 7,29$ $No = N / 10 = \lg 6,29$ $6,17 \leq \lg No \leq 6,70$
Bacillus cereus CIP 105151	-5 -6	>300 34	>300 41	$N = 3,75 \times 10^7 = \lg 7,57$ $No = N / 10 = \lg 6,57$ $6,17 \leq \lg No \leq 6,70$

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Annex 3

TEST

Test organism	Dilution range	Vc1	Vc2	Na x 10	Ig Na	Ig R	Concentration	Contact time
Bacillus subtilis ATCC 6633	1	0	0	<140	<2,15	>4,14	2,0 %	30 min
	-1	0	0					
	-2	0	0					
	-3	0	0					
Bacillus cereus CIP 105151	1	0	0	<140	<2,15	>4,42	2,0 %	30 min
	-1	0	0					
	-2	0	0					
	-3	0	0					

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Annex 4

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

$$N_0 = N / 10$$

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

$$R = \lg N_0 - \lg N_a$$

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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