



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

TEST REPORT no 767

1. General information and material

Client:

MEDISEPT SP. ZOO
Reg. 946001016, ul. Ludwika Spiessa 4, 20 270 Lublin
2022/12/28

Date of order:

2. Identification of sample

Name of the product:

VIRUTON PULVER
220902 4, LOT 20250902

Batch number:

Manufacturer:

MEDISEPT SP. ZOO

Date of delivery:

2022/11/21

Storage conditions:

room temperature and darkness

Microbiologist
Ljudmila Shljapnikova
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Head of the Laboratory

Apperance of the product: white powder with blue granules
Recommended diluent: water 30 °C, testing 15 min after dilution
Active substance and concentration: Sodium percarbonate – 44 %; TAED – 26 %

3. Test conditions

Test period: 2023/01/17 – 2023/02/09
Date of test: 2023/01/17; 2023/02/06
Product test concentrations: 1,5 %; 2,0 %
Exposure time: 30 min, 60 min
Test temperature: 19,5 ± 0,5°C
Temperature of incubation: 36,5 ± 0,5°C
Organic load: 3,0 g/l bovine albumin and 3,0 ml/l sheep erythrocytes for high-level soiling
Neutralizer: Polysorbate 80, 30 g/l, Sodium thiosulphate, 5 g/l, Lecithin, 3 g/l
Test organisms: Bacillus cereus ATCC 12826, Bacillus subtilis ATCC 6633

4. Methods

Test method and its validation: dilution neutralisation

5. Results

see annex

6. Conclusion

In accordance with EN 17126:2018, product VIRUTON PULVER (220902 4, LOT 20250902) with concentration 2,0 % under dirty conditions at 30 min and 60 min possesses sporicidal activity in suspension test at 20 °C for referenced strains Bacillus cereus ATCC 12826 and Bacillus subtilis ATCC 6633. The product VIRUTON PULVER (220902 4, LOT 20250902) demonstrates at least a 4 lg reduction for referenced strains Bacillus cereus ATCC 12826 and Bacillus subtilis ATCC 6633.

The conclusion is true only for the studied sample of the product VIRUTON PULVER (220902 4, LOT 20250902).

Total 7 pages

Annex on 4 pages

Maardu, 2023/02/09

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Annex 1

VALIDATION AND CONTROLS

Test organism	Validation suspension N _{vo} Dilution range -1			Validation suspension N _{vb} Dilution range -3			Experimental conditions control A			Neutralizer control B Dilution range -2			Method validation C Concentration 2,0 %		
	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 cereus ATCC 12826	49	56	53	39	35	37	51	47	49	42	37	40	58	50	54
Bacillus subtilis ATCC 6633	58	64	61	44	39	42	54	60	57	40	36	38	50	53	52

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Annex 2

TEST SUSPENSIONS

Test organism	Dilution range	Vc1	Vc2	N, No
Bacillus cereus ATCC 12826	-6	35	30	$N = 3,41 \times 10^7 = \lg 7,53$ No 6,53 $6,17 \leq \lg No \leq 6,70$
	-7	5	5	
Bacillus subtilis ATCC 6633	-5	266	252	$N = 261,8 \times 10^5 = \lg 7,42$ No 6,42 $6,17 \leq \lg No \leq 6,70$
	-6	25	33	

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Annex 3

TEST 1

Test organism	Dilution range	Vc1	Vc2	Na x 10	lg Na	lg R	Concentrations	Conditions	Contact time
Bacillus cereus ATCC 12826	1	>300	>300	5545	3,74	2,79	1,5%	Dirty	30 min
	-1	45	57						
	-2	10	10						
	-3	1	0						
	1	140	153	1463,6	3,17	3,36	1,5 %	Dirty	60 min
	-1	12	17						
	-2	0	0						
	-3	0	0						
	1	12	14	130	2,11	4,42	2,0 %	Dirty	30 min
	-1	0	0						
	-2	0	0						
	-3	0	0						
	1	0	0	<140	<2,15	>4,38	2,0 %	Dirty	60 min
	-1	0	0						
	-2	0	0						
	-3	0	0						

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Annex 4

TEST 2

Test organism	Dilution range	Vc1	Vc2	Na x 10	lg Na	lg R	Concentrations	Conditions	Contact time
Bacillus subtilis ATCC 6633	1	0	0	<140	<2,15	>4,27	2,0%	Dirty	30 min
	-1	0	0						
	-2	0	0						
	-3	0	0						
	1	0	0	<140	<2,15	>4,27	2,0 %	Dirty	60 min
	-1	0	0						
	-2	0	0						
	-3	0	0						

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Annex 5

$$N = c / (n_1 + 0,1 n_2) \times 10^{-z}$$

$$N_0 = N / 10$$

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

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

N – is the number of colonies for 1 ml test suspension

Vc1, Vc2 - is the is number of colonies for 1 ml sample

n – is the number of Vc-values taken into account

z – is the dilution factor corresponding to the lower dilution

R – reduction

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