



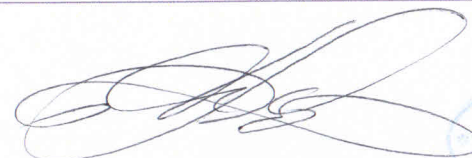
EVS-EN 13727:2012+A1:2013
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Quantitative suspension test for the evaluation of bactericidal activity

TEST REPORT

Name of the product: CHEMIDES PULVER
Batch number: 140903
Manufacturer: AS Chemi-Pharm
Date of delivery: 2014-11-14
Storage conditions: Room temperature and darkness
Active substance and its concentration: Peracetic acid in reaction mixture
Test method and its validation: dilution neutralisation
Neutralizer: Polysorbate 80, 30 g/l, Sodium thiosulphate 4 g/l, Lecithin, 3 g/l
Period of testing: 2014-11-26 – 2014-11-28
Concentration of the product: 1,5 %
Product diluent: hard water (35°C)
Date of test: 2014-11-26
Apperance product dilutions: clear solution
Interfering substances: bovine albumin 3,0 g/l and sheep erythrocytes 3 ml/ l for dirty conditions
Test temperature: 19,5 ± 0,5°C

Microbiologist
Ljudmila Shljapnikova
Biol.Ph.D.
Head of the Laboratory




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Contact-time: 1 min $\pm$ 5 s., 3 min $\pm$ 10 s., 5 min $\pm$ 10 s.

Temperature of incubation: 36,5 $\pm$ 0,5°C

Test organisms: Staphylococcus aureus ATCC 6538
Pseudomonas aeruginosa ATCC 15442
Enterococcus hirae ATCC 10541

Special remarks regarding the results: 1. All controls and validation were within the basic limits.

2. At least one concentration of the product demonstrated a lg reduction of less than 5 lg.

3. No precipitate during the test procedure (test mixtures were homogeneous).

Test results: See annex.

Conclusion:

For the product CHEMIDES PULVER (batch number: 140903), the bactericidal concentration for instrument and surface disinfection determined according to the EN 13727 Standard under dirty conditions at 20 °C within 1 min is:

1,5 % (w/v)

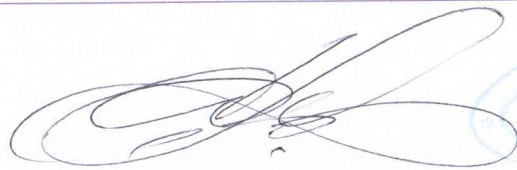
The reduction with test organisms Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442 and Enterococcus hirae ATCC 10541 were tested once and showed a 5 lg and more.

Total 8 pages

Annex on 6 pages

Maardu, 2014-11-28

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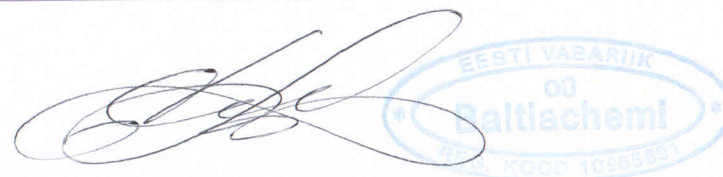
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Annex 1

Validation and controls

Test organisms	Vc	Validation suspension Nvo	Experimental conditions control A	Neutralizer control B	Method validation C Prod.conc. 1,5 %
Staphylococcus aureus ATCC 6538	Vc1/Vc2	46/41	35/34	30/35	28/36
	X	43	35	33	32
Pseudomonas aeruginosa ATCC 15442	Vc1/Vc2	82/96	55/51	65/54	51/53
	X	89	53	60	52
Enterococcus hirae ATCC 10541	Vc1/Vc2	115/91	78/70	67/77	66/74
	X	103	74	72	70

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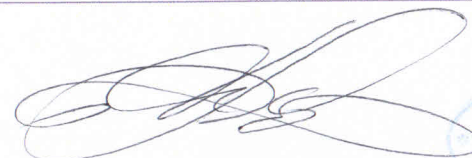
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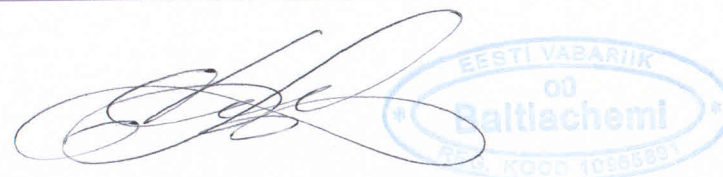
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Annex 2

Test suspensions

Test organisms	Dilution step	Vc1	Vc2	No
Staphylococcus aureus ATCC 6538	-6	178	165	N= 1,7 x 10 ⁸ ; lgN 8,23 No = N / 10 = lg 7,23 6,17 ≤ No ≤ 6,70
	-7	14	18	
Pseudomonas aeruginosa ATCC 15442	-6	164	145	N= 1,55 x 10 ⁸ ; lgN 8,19 No = N / 10 = lg 7,19 6,17 ≤ No ≤ 6,70
	-7	21	12	
Enterococcus hirae ATCC 10541	-6	184	172	N= 1,8 x 10 ⁸ = lg 8,26 No = N / 10 = lg 7,26 6,17 ≤ No ≤ 6,70
	-7	27	13	

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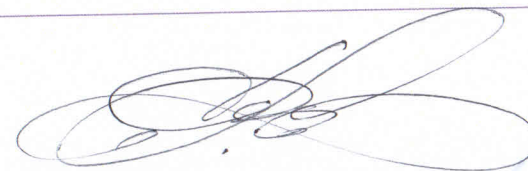

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Annex 3

Test 1

Test organism	Real concentration of the product	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Staphylococcus aureus ATCC 6538	1,5 %	1	3	4	< 140	< 2,15	>5,08	1 min
		-1	0	0				
		-2	0	0				
		1	1	1	< 140	< 2,15	>5,08	3 min
		-1	0	0				
		-2	0	0				
		1	0	0	< 140	< 2,15	>5,08	5 min
		-1	0	0				
		-2	0	0				

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Annex 4

Test 2

Test organism	Real concentration of the product	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Pseudomonas aeruginosa ATCC 15442	1,5 %	1	0	0	< 140	< 2,15	>5,04	1 min
		-1	0	0				
		-2	0	0				
		1	0	0	< 140	< 2,15	>5,04	3 min
		-1	0	0				
		-2	0	0				
		1	0	0	< 140	< 2,15	>5,04	5 min
		-1	0	0				
		-2	0	0				

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Annex 5

Test 3

Test organism	Real concentration of the product	Dilution step	Vc1	Vc2	Na x 10	lg Na	lg R	Contact time
Enterococcus hirae ATCC 10541	1,5 %	1	0	0	< 140	< 2,15	>5,11	1 min
		-1	0	0				
		-2	0	0				
		1	0	0	< 140	< 2,15	>5,11	3 min
		-1	0	0				
		-2	0	0				
		1	0	0	< 140	< 2,15	>5,11	5 min
		-1	0	0				
		-2	0	0				

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Annex 6

$$N = \frac{C}{(n1 + 0.1 n2) \times 10^{-6}}$$

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

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

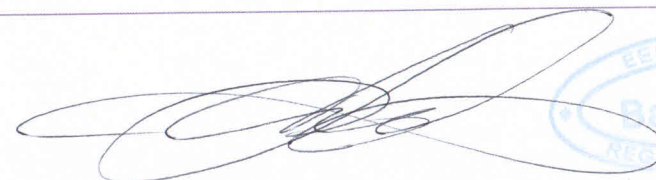
Vc1, Vc2 - is the number of colonies for 1 ml sample

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

R – reduction

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

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