



EVS-EN 13624:2013
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Quantitative suspension test for the evaluation of yeasticidal and fungicidal 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: 2014-11-24 - 2015-02-02
Date of tests: 2014-11-24; 2015-01-29
Concentration of the product: 1,5 %; 1,75 %
Product diluent: hard water (35°C)
Test temperature: 19,5 ± 0,5°C

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Temperature of incubation: $29,5 \pm 0,5^{\circ}\text{C}$

Interfering substances: 0,3 g/l bovine albumin for clean conditions; 3,0 g/l bovine albumin plus 3,0 ml/l erythrocytes for dirty conditions

Contact-time: $1\text{min} \pm 5\text{ s.}$, $3\text{ min} \pm 10\text{ s.}$, $5\text{ min} \pm 10\text{ s.}$ (additional contact times) for *Candida albicans* ATCC 10231;

$15\text{min} \pm 10\text{ s.}$ (additional contact times) for *Aspergillus brasiliensis* (former „A. niger”) ATCC 16404

Test-organisms: *Candida albicans* ATCC 10231; *Aspergillus brasiliensis* (former „A. niger”) ATCC 16404

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 4 lg.

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

Test results: See annex.

CONCLUSION:

In accordance with EN 13624:2013 product CHEMIDES PULVER (batch number: 140903), the yeasticidal concentration for instrument or surface disinfection determined according to the EN 13624 Standard under dirty conditions with 1 min contact time is:

1,5% (w/v)

The reduction with *Candida albicans* ATCC 10231 were tested once and showed a 4,11 lg or more.

In accordance with EN 13624:2013 product CHEMIDES PULVER (batch number: 140903), the fungicidal concentration for instrument or surface disinfection determined according to the EN 13624 Standard under dirty and clean conditions with 15 min contact time is:

1,75% (w/v)

The reduction with *Aspergillus brasiliensis* ATCC 16404 were tested once and showed a 4,03 lg or more.

Total 8 pages

Annex on 6 pages

Maardu, 2015-02-02

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Handwritten signature and blue circular stamp of Baltiachemi. The stamp contains the text: "EESTI VABARIK", "00", "Baltiachemi", and "REG. KOOD 10965881".

Annex 1

Validation and controls 1

Test organism	Validation suspension Nvo 10 -1			Experimental conditions control A			Neutralizer or filtration control B			Metod validation C Product conc.: 1,5%		
Candida albicans ATCC 10231	Vc1	77	X =76	Vc1	54	X = 53	Vc1	46	X = 49	Vc1	40	X = 42
	Vc2	74		Vc2	51		Vc2	51		Vc2	43	
	45≤ X of Nvo ≤160			X of A≥0,5X of Nvo			X of B ≥0,5X of Nvo			X of C≥0,5X of Nvo		

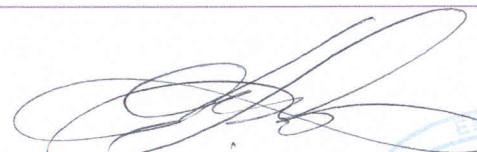
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Annex 2

Validation and controls 2

Test organism	Validation suspension N _{vo} 10 -1			Experimental conditions control A			Neutralizer or filtration control B			Metod validation C Product conc.: 1,75 %		
Aspergillus brasiliensis ATCC 16404	Vc1	55	X =58	Vc1	40	X = 39	Vc1	35	X = 36	Vc1	37	X = 34
	Vc2	61		Vc2	38		Vc2	36		Vc2	30	
	45≤ X of N _{vo} ≤160			X of A≥0,5X of N _{vo}			X of B ≥0,5X of N _{vo}			X of C≥0,5X of N _{vo}		

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Annex 3

Test suspensions (N and No)

Test organisms	Dilution step	Vc1	Vc2	Test - suspension N and No
Candida albicans ATCC 10231	-5	184	170	N=1,8 x 10 ⁷ lgN=7,26 No = N / 10 lg No= 6,26 6.17 ≤ lg No ≤ 6,70
	-6	17	25	
Aspergillus brasiliensis ATCC 16404	-5	144	125	N=1,5 x 10 ⁷ lgN=7,18 No = N / 10 lg No= 6,18 6.17 ≤ lg No ≤ 6,70
	-6	22	29	

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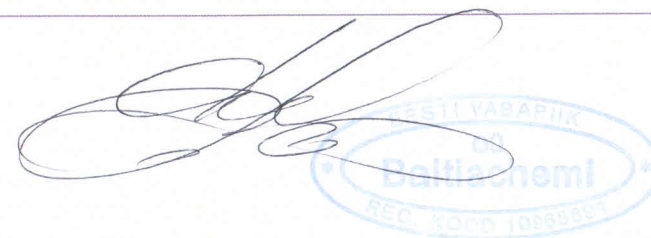

Annex 4

Test 1

Candida albicans ATCC 10231

Concentration of the product	Dilution step	Vc1	Vc2	Na	lg Na	lg R	Dirty conditions
							Contact time
1,5 %	1	0	0	< 140	< 2,15	>4,11	1 min
	-1	0	0				
	-2	0	0				
	1	0	0	< 140	< 2,15	>4,11	3 min
	-1	0	0				
	-2	0	0				
	1	0	0	< 140	< 2,15	>4,11	5 min
	-1	0	0				
	-2	0	0				

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Annex 5

Test 2

Aspergillus brasiliensis ATCC 16404

Concentration of the product 1,75 %	Dilution step	Vc1	Vc2	Na	lg Na	lg R	Contact time
Conditions							
Clean	1	0	0	<140	<2,15	>4.03	15 min
	-1	0	0				
	-2	0	0				
Dirty	1	0	0	<140	<2,15	>4.03	15 min
	-1	0	0				
	-2	0	0				

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Annex 6

$$N = \frac{\sum V_c}{(n_1 + 0,1 n_2) \times 10^{-5}}$$

$$N_0 = N / 10$$

$$N_{vo} = c / n$$

$$N_a = c \times 10 / 2,2 \times 10^z$$

$$A, B, C = \frac{V_c}{n}$$

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

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