

Test report No. hd6019

EVALUATION OF BASIC FUNGICIDAL OR BASIC YEASTICIDAL ACTIVITY (EN 1275)

Name of the product: CHEMISEPT MED  
Batch number: 196291118  
Order number: 19008  
Manufacturer: Chemi-Pharm Ltd..  
Client, representative: Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA  
Maris Millner, +372-51-77-090  
Date of delivery: 10.02.2019  
Test material conditions: No specific features, sample in the manufacturers tare  
Storage conditions: In room temperature, dark  
Active substance – conc.: Ethyl alcohol 72.5% wt; isopropyl alcohol 7.5% wt  
Appearance of the product: Transparent liquid  
Test concentration: Ready to use  
Product diluent: -  
Contact time: 30 s, 60 s, 15 min (obligatory contact time)  
Neutralizer: -  
Rinsing liquid: Tryptone 1 g/l + NaCl 8.5 g/l  
Test organisms: *Candida albicans* ATCC 10231  
*Aspergillus brasiliensis* ATCC 16404  
Testing method: EVS-EN 1275:2006  
Chemical disinfectants and antiseptics – Quantitative suspension test  
for the evaluation of basic fungicidal or basic yeasticidal activity of  
chemical disinfectants and antiseptics – Test method and  
requirements (phase 1)  
Testing date: 25.02.2019 – 28.02.2019  
Results: look appendix 1-3



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Allar Laaneleht  
Chief specialist  
Date of test report: 28.02.2019

Appendix 1

**TEST RESULTS (yeasticidal suspension test)**

EVS-EN 1275:2006; Phase 1, step 1;  
Membrane filtration method;  
Rinsing liquid: Tryptone 1 g/l + NaCl 8.5 g/l;  
Test organism: *Candida albicans* ATCC 10231;  
Test temperature: +20° C; Incubation temperature: +30 °C  
Nordic Tersus Laboratory LLC.;  
Date of test: 25.02.2019  
Responsible person: Allar Laaneleht

**Validation and controls**

Validation suspension $N_{vo}$			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
$V_{C1}$	63	$\bar{x} = 56.5$	$V_{C1}$	49	$\bar{x} = 50.5$	$V_{C1}$	37	$\bar{x} = 41$	$V_{C1}$	61	$\bar{x} = 57$
$V_{C2}$	50		$V_{C2}$	52		$V_{C2}$	45		$V_{C2}$	53	
$30 \leq \bar{x} N_{vo} \leq 160$ ? yes X; no <input type="checkbox"/>			$\bar{x} A$ is $\geq 0.5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>			$\bar{x} B$ is $\geq 0.5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>			$\bar{x} C$ is $\geq 0.5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>		

**Test suspension and test**

Testsuspension:  $N$ and $N_0$	$N$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 1.74 \times 10^9$ ; $\log N = 7.24$ $N_0 = N/10$ ; $\log N_0 = 6.24$ $6.17 \leq \log N_0 \leq 7.70$ ; yes X; no <input type="checkbox"/>
	$10^{-5}$	180	163	
	$10^{-6}$	19	21	

**Experimental results**

Concentration of the product %	$V_{C1}$	$V_{C2}$	Na (= $\bar{x} \cdot 10$ )	lgNa	lgR	Contact time
Ready to use	<14	<14	<140	<2.15	>4.09	30 s
Ready to use	<14	<14	<140	<2.15	>4.09	60 s
Ready to use	<14	<14	<140	<2.15	>4.09	15 min

**Explanations:**

$V_C$  = count per ml (one plate or more)  
 $\bar{x}$  = average of  $V_{C1}$  and  $V_{C2}$  (1. + 2. Duplicate)  
 $\bar{x}_{wm}$  = weighter mean of  $\bar{x}$   
R = reduction factor ( $R = N_0 / Na$ ;  $\log R = \log N_0 - \log Na$ )

Appendix 2

**TEST RESULTS (fungicidal suspension test)**

EVS-EN 1275:2006; Phase 1, step 1;  
Membrane filtration method;  
Rinsing liquid: Tryptone 1 g/l + NaCl 8.5 g/l;  
Test organism: *Aspergillus brasiliensis* ATCC 16404;  
Test temperature: +20° C; Incubation temperature: +30 °C  
Nordic Tersus Laboratory LLC.;  
Date of test: 25.02.2019  
Responsible person: Allar Laaneleht

**Validation and controls**

Validation suspension $N_{vo}$			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
$V_{C1}$	47	$\bar{x} = 51.5$	$V_{C1}$	32	$\bar{x} = 33.5$	$V_{C1}$	43	$\bar{x} = 41.5$	$V_{C1}$	45	$\bar{x} = 47.5$
$V_{C2}$	56		$V_{C2}$	35		$V_{C2}$	40		$V_{C2}$	50	
$30 \leq \bar{x} N_{vo} \leq 160$ ? yes X; no <input type="checkbox"/>			$\bar{x} A$ is $\geq 0.5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>			$\bar{x} B$ is $\geq 0.5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>			$\bar{x} C$ is $\geq 0.5 \bar{x} N_{vo}$ ? yes X; no <input type="checkbox"/>		

**Test suspension and test**

Test suspension:  $N$ and $N_0$	$N$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 1.76 \times 10^7$ ; $\log N = 7.25$ $N_0 = N/10$ ; $\log N_0 = 6.25$ $6.17 \leq \log N_0 \leq 7.70$ ; yes X; no <input type="checkbox"/>
	$10^{-5}$	<b>178</b>	<b>166</b>	
	$10^{-6}$	<b>24</b>	<b>19</b>	

**Experimental results**

Concentration of the product %	$V_{C1}$	$V_{C2}$	Na (= $\bar{x} \times 10$ )	lgNa	lgR	Contact time
Ready to use	<14	<14	<140	<2.15	>4.10	30 s
Ready to use	<14	<14	<140	<2.15	>4.10	60 s
Ready to use	<14	<14	<140	<2.15	>4.10	15 min

**Explanations:**

$V_C$  = count per ml (one plate or more)  
 $\bar{x}$  = average of  $V_{C1}$  and  $V_{C2}$  (1. + 2. Duplicate)  
 $\bar{x}_{wm}$  = weighter mean of  $\bar{x}$   
R = reduction factor ( $R = N_0 / Na$ ;  $\log R = \log N_0 - \log Na$ )

Appendix 3

**Interpretation:**

The product CHEMISEPT MED (batch no. 196291118) was tested according to the test method EVS-EN 1275:2006. The test was performed at 20 °C ± 1 °C, within the contact times of 30s, 60s and obligatory 15min. The membrane filtration method was used for testing the product's effectiveness against the reference strains: *Candida albicans* ATCC 10231 and *Aspergillus brasiliensis* ATCC 16404. The tested product was effective against both reference strains within the contact times tested.

**Conclusion:**

The surviving count of reference strains showed at least 4lg reduction meaning that the ready to use product CHEMISEPT MED has a basic yeasticidal and fungicidal effect within 30 s.

  
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Allar Laaneleht  
Chief Specialist  
28.02.2019