Nordic Tersus
Laboratory

Test report No. 12/2015

EVALUATION OF YEASTICIDAL AND FUNGICIDAL ACTIVITIES (EN 13624)

Name of the product:	**CHEMISEPT G**
Batch number:	LOT 69090215
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	06.04.2015
Date of registration:	06.04.2015
Test material conditions:	no specific features, sample in the manufacturers tare
Storage conditions:	in room temperature, dark
Appearance of the product:	amount 1000 ml
Contact time:	15 sec, clean and dirty conditions
Interfering substance:	3,0 g/l bovine albumin and 3,0 ml/l sheep blood erythrocytes
Test neutralizer:	polysorbate 80, 30 g/l; saponine, 30 g/l; lecithin, 3 g/l
Test organisms:	*Candida albicans* ATCC 10231
Testing method:	**EVS-EN 13624:2013** **Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area.**
Testing date:	06.04 – 10.04.2015
Results:	look at appendix 1

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Appendix 1

TEST RESULTS (yeasticidal suspension test)

Product: **CHEMISEPT G**
Dilution neutralization method; Spread plate;
Neutralizers: Polysorbate 80, 30 g/l; Saponine, 30 g/l; lecithin, 3 g/l
Test organism: *Candida albicans* ATCC 10231;
Test temperature: +20° C; Incubation temperature: +30° C
Solvents: water;
Interfering substance: 3,0 g/l bovine albumin and 3,0 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.; Date of test: 06.04 – 10.04.2015

Responsible person: Raul Raudsepp

Validation and controls

Clean conditions

Validation suspension N_{vo}			**Experimental conditions (A)**			**Neutralizer control (B)**			**Method validation (C)**		
V_{C1}	67+81=148	$\bar{x}$ = 144,5	V_{C1} 15 sek	45+65= 110	$\bar{x}$ = 124, 5	V_{C1}	71+63= 134	$\bar{x}$ = 134	V_{C1} 30 sek	45+16= 61	$\bar{x}$ = 78
V_{C2}	66+75=141		V_{C2} 15 sek	62+77= 139		V_{C2}			V_{C2} 30 sek	42+53= 95	
$30 \leq \bar{x}\ N_{vo} \leq 160$? yes X; no □			$\bar{x}$ A is $\geq 0{,}5\ \bar{x}\ N_{vo}$? yes X; no □			$\bar{x}$ **B** is $\geq 0{,}5\ \bar{x}\ N_{vo}$? yesX; no □			$\bar{x}$ **C** is $\geq 0{,}5\ \bar{x}\ N_{vo}$? yes X; no □		
Validation suspension N_{VB}			V_{C1} 59+64=123			V_{C2} 72+54=126; $\bar{x}$=124,5			$30 \leq \bar{x}\ N_{VB}/1000 \leq 160$? yes X; no □		

Test suspensioon and test

Test suspension: N *and* N_0	N	V_{C1}	V_{C2}	$\bar{x} = 2{,}0 \times 10^9$; $\log N = 9{,}30$ $N_0 = N/100$; $\log N_0 = 7{,}30$ $7{,}17 \leq \log N_0 \leq 7{,}7$; yes X; no □
	10^{-7}	**205**	**198**	
	10^{-8}	**25**	**12**	

Experimental results

Concentration of the product.%	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
RTU	-	34	17	510	2,71	4,61	15''	clean
	10x	0	0					

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions (A)			Neutralizer control (B)			Method validation (C)		
V_{C1}	67+81=148	x̄ = 144,5	V_{C1} 15 sec	78+91= 169	x̄ = 159,5	V_{C1}	69+63= 132	x̄ = 132	V_{C1}	29+40= 69	x̄ = 74
V_{C2}	66+75=141		V_{C2} 15 sec	85+65= 150		V_{C2}			V_{C2}	28+51= 79	
30 ≤ x̄ N_{vo} ≤160 ? yes X; no □			x̄ A is ≥ 0,5 x̄ N_{vo}? yes X; no □			x̄ **B** is ≥ 0,5 x̄ N_{vo}? yesX; no □			x̄ **C** is ≥ 0,5 x̄ N_{vo}? yes X; no □		
Validation suspension N_{VB}			V_{C1} 59+64=123			V_{C2} 72+54=126; x̄=124,5			30 ≤ x̄ $N_{VB}/1000$ ≤160 ? yes X; no □		

Test suspensioon and test

Test suspension: N *and* N_0	N	V_{C1}	V_{C2}	x̄ = 2,0 x 10^9; log$N$ = 9,30 $N_0 = N/100$; logN_0 = 7,30 7,17≤ logN_0≤7,7; yes X; no □
	10^{-7}	**205**	**198**	
	10^{-8}	**25**	**12**	

Experimental results

Concentration of the product.%	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
RTU	-	17	28	225	2,35	5,17	15''	dirty
	10x	0	0					
	10x	0	0					

Interpretation

Using the **EN 13624:2013** method, there was tested product **CHEMISEPT G** at the temperature conditions 20 °C ± 1 °C, with the contact time 15 seconds and the clean and dirty conditions. The dilution neutralization method has been used for the testing of product effect onto the microorganism *Candida albicans* ATCC 10231. In clean and dirty conditions (test regime) tested product was been active against the test organism in the selected contact times.

Conclusion

By the test results it can be made conclusion, that tested product **CHEMISEPT G has yeasticidal effect** at the contact time 15 seconds.

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