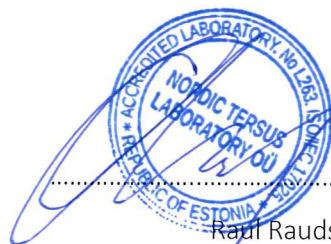


Test report No. sd3218

EVALUATION OF YEASTICIDAL AND FUNGICIDAL ACTIVITIES OF A DISINFECTANTS
AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13624)

Name of the product: CHLORINEX-60
Batch number: 230317
Order number: 18011
Manufacturer: Chemi-Pharm Ltd.
Client, representative: Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA
Maris Millner, +372-51-77-090
Date of delivery: 11.06.2018
Test material conditions: No specific features, sample in the manufacturers tare
Storage conditions: In room temperature, dark
Active substance – conc.: 1 tab = 1.5 g active chlorine if dissolved in water, thus 1 tab/1.5 l 1000 ppm active chlorine
Appearance of the product: White tablet
Test concentration: 1tab/1.5l;
Contact time: 15 min, 60 min (obligatory)
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = dirty conditions
Rinsing liquid: Sodium thiosulphate 3g/l
Neutralizer: -
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: 12.06 – 15.06.2018
Results: look appendix 1-2



Raul Raudsepp, MSc
Senior microbiologist, biochemist

Date of test report: 18.06.2018

Appendix 1

TEST RESULTS (yeastocidal suspension test)

EVS-EN 13624:2013; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: Sodium thiosulphate 3g/l;
Test organism: *Candida albicans* ATCC 10231;
Test temperature: +20° C; Incubation temperature: +30° C
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 12.06 – 15.06.2018
Responsible person: Raul Raudsepp

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions control (A)			Filtration control (B)			Method validation (C)		
V_{C1}	141	$\bar{x} = 142.5$	V_{C1}	123	$\bar{x} = 119$	V_{C1}	121	$\bar{x} = 121.5$	V_{C1}	143	$\bar{x} = 131$
V_{C2}	144		V_{C2}	115		V_{C2}	122		V_{C2}	119	
$30 \leq \bar{x} N_{vo} \leq 160$? yes X; no ☐			$\bar{x} A$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no ☐			$\bar{x} B$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no ☐			$\bar{x} C$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no ☐		

Test suspension and test

Testsuspension: N and N_0	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 4.85 \times 10^7$; $\log N = 7.69$ $N_0 = N/10$; $\log N_0 = 6.69$ $6.17 \leq \log N_0 \leq 6.70$; yes X; no ☐
	10^{-5}	>330	>330	
	10^{-6}	46	51	

Experimental results

Concentration of the product	Dilution step	V_{C1}	V_{C2}	N_a ($=\bar{x} \cdot 10$)	$\log N_a$	$\log R$	Contact time	Conditions
1 tab / 30l	-	>165	>165	>1650	>3.22	3.47	15min	Dirty
1 tab / 1.5l	-	<14	<14	<140	<2.15	4.54	15min	Dirty
5 tab / 1.5l	-	<14	<14	<140	<2.15	4.54	15min	Dirty

Explanations:

V_C = count per ml (one plate or more)

$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. duplicate)

N = cfu/ml microbes in testsuspension

N_0 = cfu/ml at the start of the contact time ($t=0$)

N_{vo} = cfu/ml in the validation suspension ($t=0$)

N_a = surviving microbes after the test

R = reduction factor ($R = N_0 / N_a$; $\log R = \log N_0 - \log N_a$)

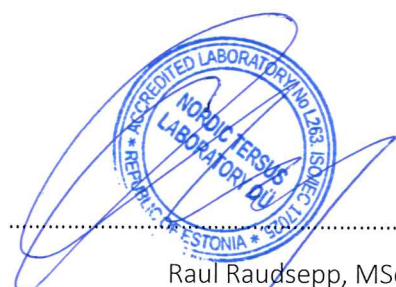
Appendix 2

Interpretation:

The product for surface disinfection CHLORINEX-60 (batch no. 230318) was tested according to the test method EVS-EN 13624:2013. The test was performed at $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$, under dirty conditions with the contact times of 15 min. The membrane filtration method was used for testing the products effectiveness against the reference strain: *Candida albicans* ATCC 10231. Under dirty conditions the tested 1tab/1.5l product's solution was effective against the reference strain within 15 min of contact time.

Conclusion:

The surviving count of yeastical reference strains showed at least 4 lg reduction meaning that under dirty conditions the 1tab/1.5l solution of product CHLORINEX-60 has a yeasticidal effect in case of surface disinfection within 15 min.



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