

Test report No. 158023sd

EVALUATION OF SPORICIDAL ACTIVITY IN THE MEDICAL AREA (EN 17126)

Name of the product: CHLORINEX-60

Batch number: 812103073

Date of test report: 09/08/2023

Client, representative: Chemi-Pharm Ltd. Tänassilma tee 11 Tänassilma küla Saku vald 76406 ESTONIA



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EVALUATION OF SPORICIDAL ACTIVITY IN THE MEDICAL AREA (EN 17126)

Name of the product*:

CHLORINEX-60

Batch number*:

812103073

Order number:

20051

Manufacturer*:

Chemi-Pharm Ltd.

Client, representative*:

Chemi-Pharm Ltd., Tänassilma tee 11; Tänassilma küla; Saku vald

76406; ESTONIA; Siimu Rom, +37253604748.

Date of delivery:

10.01.2022

Test material conditions:

No specific features, sample in the manufacturers tare

Storage conditions:

At room temperature, darkness

Active substance - conc.*:

Troclosene sodium 75g/100 product

Appearance of the product:

White granules

Test concentration:

4 tbl/1.5L; 1 tbl/1.5L; 0.2 tbl/1.5L

Contact time:

15 min

Interfering substance:

3 g/l bovine albmin + 3 ml/l sheep blood erythrocytes (dirty

conditions)

Neutralizer:

Rinsing liquid:

Sodium thiosulfate, 3 g/L

Test organisms:

Clostridium difficile NCTC 13366

Testing method:

EVS-EN 17126:2018 - Chemical disinfectants and antisepticas -

Quantitative suspension test for the evaluation of sporicidal activity in the medical area – Test method and requirements (phase 2, step 1)

Testing period:

09.06.2022 - 14.06.2022

Results:

look appendix 1

Interpretation and conclusion: look appendix 2

Nele Aas-Valleriani obiology Chief Specialist Date of issue: 09.08.2023

* - Data provided by the customer

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Appendix 1

TEST RESULTS (bactericidal suspension test)

EVS-EN 17126:2018; Phase 2, step 1;

Membrane filtration method; Product diluent: Hard water;

Appearance of product solutions: Transparent, colourless liquid;

Test organism: Clostridium difficile NCTC 13366;

Test temperature: +20°C; Incubation temperature: +37°C

Interfering substance: 3 g/l bovine albmin + 3 ml/l sheep blood erythrocytes (dirty conditions)

Nordic Tersus Laboratory LLC.; Date of test: 09.06.2022

Responsible person: Melissa-Ingela Bramanis, Kerda Treksler

Validation and controls Dirty conditions

Validation suspension N_{vo}			Experimental conditions (A)			Neutralizer control (B)			Method validation (C)			
V _{C1}	V_{C2}	x	V_{C1}	V_{C2}	x	V _{C1}	V_{C2}	x	V _{C1}	V_{C2}	x	
48	56	52	81	59	70	70	52	61	64	39	51.5	
30	30 ≤ x̄ N _{vo} ≤160?			$\bar{x} \mathbf{A} \text{is} \ge 0.5 \bar{x} \mathbf{N}_{vo}$?			$\bar{x} \mathbf{B} \text{is} \ge 0.5 \bar{x} N_{vo}$?			x̄ C is ≥ 0.5 x̄ N _{vo} ?		
yes x; no □			yes x; no □			yes x; no □			yes x; no □			

Test suspension and test

Test suspension:	N	V _{C1}	V _{C2}	$\bar{x}_{wm} = 1.70 \times 10^7$; $\log N = 7.23$
N and N₀	10 ⁻⁵	139	196	$N_0 = N/10$; $\log N_0 = 6.23$
IV UIIU IVO	10 ⁻⁶	14	24	6.17 ≤ log N ₀ ≤ 6.70; yes x; no □

Experimental results

Concentration of the product %	Dilution step	V _{C1}	V _{C2}	Na (=x̄*10)	lgNa	lg <i>R</i>	Contact time	Conditions
4 tbl/1.5L	-	<14	<14	<140	<2.15	>4.08	15min	Dirty
1 tbl/1.5L	-	>165	>165	>1650	>3.22	<3.01	15min	Dirty
0.2 tbl/1.5L	-	>165	>165	>1650	>3.22	<3.01	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 test suspension

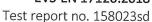
 N_0 = cfu/ml at the start of the contact time (t=0)

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

Na = surviving microbes after the test

R = reduction factor (R= N_0/Na ; LogR=Log N_0 - Log Na)







Appendix 2

Interpretation:

The surface disinfection product **CHLORINEX-60** (batch no. 812103073) was tested according to the test method EVS-EN 17126:2018. The test was performed at $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions with the contact time of 15 min. The membrane filtration method was used for testing the product's effectiveness against the reference strain *Clostridium difficile* NCTC 13366. Under dirty conditions the 4 tbl/1.5L solution of the tested sample of the product was effective against the reference strain within 15 minutes.

Conclusion:

The surviving count of *Clostridium difficile* strain showed at least 4lg reduction meaning that **according** to EVS-EN 17126:2018 under dirty conditions the 4 tbl/1.5L solution of surface disinfection product CHLORINEX-60 has a sporicidal effect against *Clostridium difficile* within 15 minutes.

This is the end of the test report.

NORDIC TERSUS LABORATORY Nele Aas-Valleriani
Microbiology Chief Specialist

Uc Date of issue: 09.08.2023

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