



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., Tännassilma tee 11; Tännassilma 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.*: Troclosen 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 antiseptics - 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
Microbiology Chief Specialist
Date of issue: 09.08.2023

* - Data provided by the customer

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 albumin + 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}	\bar{x}	V_{C1}	V_{C2}	\bar{x}	V_{C1}	V_{C2}	\bar{x}	V_{C1}	V_{C2}	\bar{x}
48	56	52	81	59	70	70	52	61	64	39	51.5
$30 \leq \bar{x} N_{vo} \leq 160$? yes x; no <input type="checkbox"/>			$\bar{x} A \geq 0.5 \bar{x} N_{vo}$? yes x; no <input type="checkbox"/>			$\bar{x} B \geq 0.5 \bar{x} N_{vo}$? yes x; no <input type="checkbox"/>			$\bar{x} C \geq 0.5 \bar{x} N_{vo}$? yes x; no <input type="checkbox"/>		

Test suspension and test

Test suspension: N and N_0	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.70 \times 10^7$; $\log N = 7.23$ $N_0 = N/10$; $\log N_0 = 6.23$ $6.17 \leq \log N_0 \leq 6.70$; yes x; no <input type="checkbox"/>
	10^{-5}	139	196	
	10^{-6}	14	24	

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	N_a ($=\bar{x} \cdot 10$)	$\lg N_a$	$\lg R$	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) N_a = surviving microbes after the test
 R = reduction factor ($R = N_0 / N_a$; $\log R = \log N_0 - \log N_a$)

The test results apply to the tested sample only.

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N-7/29-V9



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.



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