

Test report No. 123023sd

EVALUATION OF THE BACTERICIDAL AND YEASTICIDAL AND/OR FUNGICIDAL
ACTIVITY OF CHEMICAL DISINFECTANTS ON A NON-POROUS SURFACE (EN
17387)

Name of the product*: STERISEPT WIPES

Batch number*: 14250522

Order number: 20077

Manufacturer*: Chemi-Pharm Ltd.

Client, representative*: Chemi-Pharm Ltd., Tännassilma tee 11; Tännassilma küla; Saku vald
76406; ESTONIA; Siimu Rom, +37253604748.

Date of delivery: 06.06.2022

Test material conditions: No specific features, sample in the manufacturers tare

Storage conditions: At room temperature, darkness

Active substance – conc.*: Didecyl-Dimethyl-Ammonium Chloride (DDAC) 0,45g/100g;
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 0,45g/100g.

Appearance of the product: Transparent, colourless liquid

Test concentration: RTU

Contact time: 3 min

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

Test neutralizer: Polysorbate 80, 30 g/l; saponin, 30 g/l; lecithin, 3 g/l

Test surface: Stainless steel 304 discs (2 cm diameter), grade 2b finish

Repetitions: 1 repetition

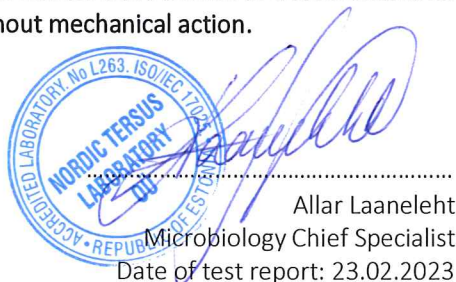
Test organisms: *Staphylococcus aureus* ATCC 6538
Pseudomonas aeruginosa ATCC 15442
Enterococcus hirae ATCC 10541
Candida albicans ATCC 10231

Testing method base: EVS-EN 17387:2021 - Chemical disinfectants and antiseptics –
Quantitative test for the evaluation of bactericidal and yeasticidal
and/or fungicidal activity of chemical disinfectants in the medical area
on non-porous surfaces without mechanical action.

Testing date: 12.07.2022 – 11.08.2022

Results: Look appendix 1

Interpretation and conclusion: Look appendix 2.



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Allar Laaneleht
Microbiology Chief Specialist
Date of test report: 23.02.2023

* - Data provided by the customer

Appendix 1

TEST RESULTS

EVS-EN 17387:2021; Phase 2, step 2; Contact/neutralization method; Neutralizers: Polysorbate 80: 30g/l; lecithin: 3g/l; Test organisms: *Staphylococcus aureus* ATCC 6538; *Pseudomonas aeruginosa* ATCC 15442; *Enterococcus hirae* ATCC 10541; *Candida albicans* ATCC 10231; Test temperature: +20° ±1° C; Incubation temperatures: +37° ±1° C for bacteria and +30° ±1° C for fungi; Solvents: glass-distilled water; Interfering substances: 3.0 g/l bovine albumin and 3.0 ml/l sheep erythrocytes (dirty conditions), Nordic Tersus Laboratory LLC. Responsible person: Melissa Ingela Bramanis, Kerda Treksler

Table 1. Data counted and calculated; dirty conditions; 3 min

Test organisms	Test suspension			Test validation						Water control Nc			Test procedure concentration								
				NT			NC						100%			50%			10%		
<i>Pseudomonas aeruginosa</i> ATCC 15442	10 ⁻⁷	330	330	10 ⁻⁴	81	77	10 ⁻⁴	67	78	10 ⁻⁴	102	113	10 ⁰	0	0	10 ⁰	330	330	10 ⁰	330	330
	10 ⁻⁸	73	56	10 ⁻⁵	6	8	10 ⁻⁵	10	11	10 ⁻⁵	11	9	10 ⁻¹	0	0	10 ⁻¹	88	86	10 ⁻¹	254	262
		log No	7.94	10 ⁻⁶	0	0	10 ⁻⁶	1	0	10 ⁻⁶	1	0	10 ⁻²	0	0	10 ⁻²	7	10	10 ⁻²	22	37
	10 ⁻⁷			0	0	10 ⁻⁷	0	0	10 ⁻⁷	0	0	Nd	<0.70	Nd	3.94	Nd	4.42				
	NT			6.89	NC	6.88	NC	7.03	Nts	0	Nts	67	Nts	>100	R	2.39	R	2.61			
<i>Candida albicans</i> ATCC 10231	10 ⁻⁶	170	156	10 ⁻³	60	59	10 ⁻³	80	97	10 ⁻³	122	115	10 ⁰	0	0	10 ⁰	4	0	10 ⁰	330	330
	10 ⁻⁷	23	19	10 ⁻⁴	8	5	10 ⁻⁴	3	9	10 ⁻⁴	13	12	10 ⁻¹	0	0	10 ⁻¹	0	0	10 ⁻¹	134	169
		log No	6.62	10 ⁻⁵	0	0	10 ⁻⁵	2	2	10 ⁻⁵	0	1	10 ⁻²	0	0	10 ⁻²	0	0	10 ⁻²	22	23
	10 ⁻⁶			0	0	10 ⁻⁶	0	1	10 ⁻⁶	0	0	Nd	<0.70	Nd	<0.70	Nd	4.20				
	NT			5.79	NC	5.82	NC	6.09	Nts	0	Nts	0	Nts	>5.39	R	>5.39	R	>100	1.89		

Test organisms	Test suspension			Test validation						Test procedure concentration																
				NT			NC			Water control Nc						100%			50%			10%				
Staphylococcus aureus ATCC 6538	10 ⁻⁷	280	276	10 ⁻⁴	330	330	330	10 ⁻⁴	330	330	330	10 ⁻⁴	330	10 ⁰	20	16	10 ⁰	330	330	10 ⁰	330	330	330	330	330	330
	10 ⁻⁸	33	27	10 ⁻⁵	97	91	92	10 ⁻⁵	75	92	91	10 ⁻⁵	56	10 ⁻¹	2	2	10 ⁻¹	242	252	10 ⁻¹	330	330	330	330	330	
	log N ₀	7.85	10 ⁻⁶	14	5	7	10 ⁻⁶	11	7	9	10 ⁻⁶	10	9	10 ⁻²	0	0	10 ⁻²	35	45	10 ⁻²	199	199	199	199	199	
			10 ⁻⁷	0	0	0	10 ⁻⁷	0	0	0	10 ⁻⁷	0	0	Nd	2.38	Nd	4.42	Nd	5.3	Nd	>100	2.58				
			NT	7.97			NC	7.92	NC	7.88	Nts	0	Nts	5.5	R	3.46	R									
Enterococcus hirae ATCC 10541	10 ⁻⁷	325	330	10 ⁻⁴	330	330	328	10 ⁻⁴	324	328	330	10 ⁻⁴	330	10 ⁰	0	0	10 ⁰	54	49	10 ⁰	330	330	330	330		
	10 ⁻⁸	142	33	10 ⁻⁵	37	33	35	10 ⁻⁵	45	35	38	10 ⁻⁵	47	10 ⁻¹	0	0	10 ⁻¹	5	1	10 ⁻¹	330	330	330	330		
	Log N ₀	7.92	10 ⁻⁶	3	5	3	10 ⁻⁶	0	3	6	10 ⁻⁶	2	6	10 ⁻²	0	0	10 ⁻²	0	0	10 ⁻²	330	330	330	330		
			10 ⁻⁷	0	0	0	10 ⁻⁷	0	0	1	10 ⁻⁷	0	1	Nd	<0.70	Nd	2.71	Nd	>5.52	Nd	>100	<1.41				
			NT	7.55			NC	7.6	NC	7.63	Nts	0	Nts	>100	R	>6.93	R	4.22	R							

Appendix 2

Conclusion

A surface disinfection product **STERISEPT WIPES** (Batch no. 14250522) was tested according to the EN 17387 standard at 20°C ± 1°C, with the contact time of 3 min for bacteria and *Candida albicans* under dirty conditions. The method was used for testing the product's efficacy against the microorganisms: *Staphylococcus aureus* ATCC 6538; *Pseudomonas aeruginosa* ATCC 15442; *Enterococcus hirae* ATCC 10541 and *Candida albicans* ATCC 10231. Under dirty conditions, the tested sample of the product was active against bacteria and yeast. The product on the surface cannot be wiped or otherwise influenced before the contact time of 3 min has elapsed.

Summary

The surviving microbial count did show at least 5 lg reduction for bacteria and 4 lg reduction for yeast, meaning that the sample of **STERISEPT WIPES** is **bactericidal and yeasticidal under dirty conditions within 3 min.**

This is the end of the test report.



Allar Laaneleht
Microbiology Chief Specialist
23.02.2023