

Test report No. sd1819

EVALUATION OF THE ANTIBACTERIAL AND – FUNGAL PROTECTION OF A
DISINFECTANT ON NONPOROUS SURFACE (EN 13697)

Name of the product:	STERISEPT WIPES
Batch number:	14300818W
Order number:	18014
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, Estonia, Maris Millner, +372-51-77-090
Date of delivery:	04.10.2018
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 0.45%; Didecyl- Dimethyl-Ammonium Chloride (DDAC)0.45%
Appearance of the product:	Transparent liquid
Test concentration:	Ready to use
Contact time:	60 s
Interfering substance:	8.5 g/l skim milk for <i>Pseudomonas aeruginosa</i> ; 0.3 g/l bovine albumin for all the other organisms
Test neutralizer:	Polysorbate 80: 30g/l; saponin 30g/l; lecithin, 3g/l
Test organisms:	<i>Staphylococcus aureus</i> ATCC 6538 <i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Enterococcus hirae</i> ATCC 10541 <i>Escherichia coli</i> ATCC 10536 <i>Candida albicans</i> ATCC 10231
Testing method base:	EVS-EN 13697:2015 -Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.
Testing date:	19.11.2018 – 21.11.2018
Results:	look appendix 1-2



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Allar Laaneleht
Chief specialist

Date of test report: 15.01.2019

Appendix 1

TEST RESULTS

EVS-EN 13697:2015; Phase 2, step 2;

Product: STERISEPT WIPES

Contact/neutralization method; surface;

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

Test organisms: *Staphylococcus aureus* ATCC 6538; *Pseudomonas aeruginosa* ATCC 15442;

Enterococcus hirae ATCC 10541; *Escherichia coli* ATCC 10536; *Candida albicans* ATCC 10231;

Test temperature: +20° ±1° C; Incubation temperatures: +37° ±1° C for bacteria and +30° ±1° C for fungi;

Solvents: water;

Interfering substances: 8.5 g/l skim milk for *Pseudomonas aeruginosa*; 0.3 g/l bovine albumin for all the other organisms

Nordic Tersus Laboratory LLC.

Table 1. Data counted and calculated; clean conditions; 60 s

Test organisms	Test suspension N	Test validation		Water control Nc	Test procedure concentration RTU
		NT	NC		
<i>Staphylococcus aureus</i> ATCC 6538	10 ⁻⁶ : 242;236	10 ⁻³ :>330;>330	10 ⁻³ : >330;>330	10 ⁻³ : >330;>330	10 ⁰ : 0;0
	10 ⁻⁷ : 21;27	10 ⁻⁴ : 69;75	10 ⁻⁴ : 54;50	10 ⁻⁴ :83;91	10 ⁻¹ : 0;0
	N: 6.78	10 ⁻⁵ :6;9	10 ⁻⁵ :5;5	10 ⁻⁵ :7;11	10 ⁻² : 0;0
		NT: 6.86	NT: 6.72	Nc: 6.94	Nd: <0.10
				Nts:>330	Nts: <1
					R: >6.84
<i>Pseudomonas aeruginosa</i> ATCC 15442	10 ⁻⁶ : 168;178	10 ⁻³ :>330;>330	10 ⁻³ : >330;>330	10 ⁻³ : >330;>330	10 ⁰ : 1;0
	10 ⁻⁷ : 19;15	10 ⁻⁴ :49;36	10 ⁻⁴ :57;68	10 ⁻⁴ : 70;81	10 ⁻¹ : 0;0
	N: 6.64	10 ⁻⁵ :3;8	10 ⁻⁵ :8;5	10 ⁻⁵ : 7;7	10 ⁻² : 0;0
		NT: 6.68	NT: 6.80	Nc: 6.88	Nd: <0.10
				Nts:>330	Nts: <1
					R: >6.78

<i>Enterococcus hirae</i> ATCC 10541	10 ⁻⁶ : 152;164	10 ⁻³ : >330;>330	10 ⁻³ : >330;>330	10 ⁻³ : >330;>330	10 ⁰ : 0;1
	10 ⁻⁷ : 14;16	10 ⁻⁴ : 70;79	10 ⁻⁴ : 104;113	10 ⁻⁴ :94;99	10 ⁻¹ : 0;0
	N: 6.59	10 ⁻⁵ :6;9	10 ⁻⁵ :13;11	10 ⁻⁵ : 10;6	10 ⁻² : 0;0
		NT: 6.87	NT: 7.04	Nc: 6.98	Nd: >0.10
				Nts:>330	Nts: <1
					R: >6.88
<i>Escherichia coli</i> ATCC 10636	10 ⁻⁶ : 204;221	10 ⁻³ : >330;>330	10 ⁻³ : >330;>330	10 ⁻³ : >330;>330	10 ⁰ : 0;0
	10 ⁻⁷ : 21;25	10 ⁻⁴ : 59;72	10 ⁻⁴ : 68;48	10 ⁻⁴ : 83;87	10 ⁻¹ : 0;0
	N: 6.73	10 ⁻⁵ :4;8	10 ⁻⁵ :4;5	10 ⁻⁵ : 9;7	10 ⁻² : 0;0
		NT: 6.82	NT: 6.76	Nc: 6.93	Nd: <0.10
				Nts:>330	Nts: <1
					R: >6.83
<i>Candida albicans</i> ATCC 10231	10 ⁻⁵ : 262;278	10 ⁻³ : 244;219	10 ⁻³ : 193;208	10 ⁻³ : 225;232	10 ⁰ : 0;0
	10 ⁻⁶ : 30;24	10 ⁻⁴ : 22;24	10 ⁻⁴ : 15;21	10 ⁻⁴ : 24;20	10 ⁻¹ : 0;0
	N: 5.83	10 ⁻⁵ :2;1	10 ⁻⁵ :3;1	10 ⁻⁵ : 2;2	10 ⁻² : 0;0
		NT: 6.36	NT: 6.30	Nc: 6.36	Nd: <0.10
				Nts:>330	Nts: <1
					R: >6.26

Table 2. Data counted and calculated; dirty conditions; 5 min (obligatory contact time for bacteria)

Test organisms	Test suspension N	Test validation		Water control Nc	Test procedure concentration
		NT	NC		RTU
<i>Staphylococcus aureus</i> ATCC 6538	10 ⁻⁶ : 242;236	10 ⁻³ :>330;>330	10 ⁻³ : >330;>330	10 ⁻³ : >330;>330	10 ⁰ : 0;0
	10 ⁻⁷ : 21;27	10 ⁻⁴ : 69;75	10 ⁻⁴ : 54;50	10 ⁻⁴ :83;91	10 ⁻¹ : 0;0
	N: 6.78	10 ⁻⁵ :6;9	10 ⁻⁵ :5;5	10 ⁻⁵ :7;11	10 ⁻² : 0;0
		NT: 6.86	NT: 6.72	Nc: 6.94	Nd: <0.10
				Nts:>330	Nts: <1
					R: >6.84
<i>Pseudomonas aeruginosa</i> ATCC 15442	10 ⁻⁶ : 168;178	10 ⁻³ :>330;>330	10 ⁻³ : >330;>330	10 ⁻³ : >330;>330	10 ⁰ : 1;0
	10 ⁻⁷ : 19;15	10 ⁻⁴ :49;36	10 ⁻⁴ :57;68	10 ⁻⁴ : 70;81	10 ⁻¹ : 0;0
	N: 6.64	10 ⁻⁵ :3;8	10 ⁻⁵ :8;5	10 ⁻⁵ : 7;7	10 ⁻² : 0;0
		NT: 6.68	NT: 6.80	Nc: 6.88	Nd: <0.10
				Nts:>330	Nts: <1
					R: >6.78

<i>Enterococcus hirae</i> ATCC 10541	10 ⁻⁶ : 152;164	10 ⁻³ : >330;>330	10 ⁻³ : >330;>330	10 ⁻³ : >330;>330	10 ⁰ : 0;1
	10 ⁻⁷ : 14;16	10 ⁻⁴ : 70;79	10 ⁻⁴ : 104;113	10 ⁻⁴ :94;99	10 ⁻¹ : 0;0
	N: 6.59	10 ⁻⁵ :6;9	10 ⁻⁵ :13;11	10 ⁻⁵ : 10;6	10 ⁻² : 0;0
		NT: 6.87	NT: 7.04	Nc: 6.98	Nd: >0.10
				Nts:>330	Nts: <1
					R: >6.88
<i>Escherichia coli</i> ATCC 10636	10 ⁻⁶ : 204;221	10 ⁻³ : >330;>330	10 ⁻³ : >330;>330	10 ⁻³ : >330;>330	10 ⁰ : 0;1
	10 ⁻⁷ : 21;25	10 ⁻⁴ : 59;72	10 ⁻⁴ : 68;48	10 ⁻⁴ : 83;87	10 ⁻¹ : 0;0
	N: 6.73	10 ⁻⁵ :4;8	10 ⁻⁵ :4;5	10 ⁻⁵ : 9;7	10 ⁻² : 0;0
		NT: 6.82	NT: 6.76	Nc: 6.93	Nd: <0.10
				Nts:>330	Nts: <1
					R: >6.83

Table 3. Data counted and calculated; clean conditions; 15 min (obligatory contact time for yeast)

Test organisms	Test suspension N	Test validation		Water control Nc	Test procedure concentration RTU
		NT	NC		
<i>Candida albicans</i> ATCC 10231	10 ⁻⁵ : 262;278	10 ⁻³ : 244;219	10 ⁻³ : 193;208	10 ⁻³ : 225;232	10 ⁰ : 0;1
	10 ⁻⁶ : 30;24	10 ⁻⁴ : 22;24	10 ⁻⁴ : 15;21	10 ⁻⁴ : 24;20	10 ⁻¹ : 0;0
	N: 5.83	10 ⁻⁵ :2;1	10 ⁻⁵ :3;1	10 ⁻⁵ : 2;2	10 ⁻² : 0;0
		NT: 6.36	NT: 6.30	Nc: 6.36	Nd: <0.10
				Nts:>330	Nts: <1
					R: >6.26

Appendix 2

Conclusion

A product STERISEPT WIPES (Batch No. 14300818W) was tested according to the EN 13697 standard at $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, with the contact time 60 s, under clean conditions. The method was used for testing the product's efficacy against the microorganisms: *Staphylococcus aureus* ATCC 6538; *Pseudomonas aeruginosa* ATCC 9027; *Enterococcus hirae* ATCC 10541; *Escherichia coli* ATCC 8739 and *Candida albicans* ATCC 1023. Under clean conditions (test regime) the tested product was active against all the testorganisms within the contact time tested.

Summary

The surviving microbial count showed at least 4lg reduction for bacteria and 3lg reduction for yeast, meaning that STERISEPT WIPES is bactericidal and yeasticidal under clean conditions within 60s.



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