Nordic Tersus
Laboratory

Test report no. sd1319-2

EVALUATION OF BACTERICIDAL AND YEASTICIDAL ACTIVITY ON NON-POROUS SURFACES WITH MECHANICAL ACTION EMPLOYING WIPES IN THE MEDICAL AREA (EN 16615)

Name of the product: STERISEPT WIPES
Batch number: 14300818W
Date of test report: 09.01.2024

Digitally signed by Moraru Grigore
Date: 2025.12.17 16:00:46 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

Nordic Tersus
Laboratory

Test report No. sd1319-2

EVALUATION OF BACTERICIDAL AND YEASTICIDAL ACTIVITY ON NON-POROUS SURFACES WITH MECHANICAL ACTION EMPLOYING WIPES IN THE MEDICAL AREA (EN 16615)

Name of the product:	**STERISEPT WIPES**
Batch number:	14300818W
Order number:	18014
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Tänassilma tee 11; Tänassilma küla; Saku vald 76406; ESTONIA; Siimu Rom, +37253604748.
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:	White wipes
Test concentration:	Ready to use
Contact time:	1 min
Interfering substance:	3.0 g/l bovine albumin = clean conditions; 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = dirty conditions
Rinsing liquid:	-
Neutralizer:	Polysorbate 80 30g/l; saponin 30 g/l, lecithin 3 g/l
Test organisms:	*Candida albicans* ATCC 10231 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541 *Staphylococcus aureus* ATCC 6538
Testing method:	**EVS-EN 16615:2015** **Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) (Phase 2, step 2)**
Testing date:	07.02.2019 – 10.02.2019
Results:	look appendix 1-5

ACCREDITED LABORATORY No L263, ISO/IEC 17025:2017 NORDIC TERSUS LABORATORY OÜ REPUBLIC OF ESTONIA

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Kerda Treksler
Microbiologist
Date of issue: 09.01.2024

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TEST RESULTS

EVS-EN 16615:2015; Phase 2, step 2;
Neutralization method;
Rinsing liquid: -;
Test organism: *Candida albicans* ATCC 10231;
Test temperature: +20° C; Incubation temperature: +30° C
Interfering substance: 3.0 g/l bovine albumin = clean conditions; 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 08.02.2019
Responsible person: Allar Laaneleht

Validation and controls

Validation suspension (N_{V0})			Neutralizer control (B)			Method validation (C)		
V_{C1}	41	$\bar{x}$ = 38	V_{C1}	31	$\bar{x}$ = 28.5	V_{C1}	33	$\bar{x}$ = 35.5
V_{C2}	35		V_{C2}	26		V_{C2}	38	
30 ≤ $\bar{x}$ N_{V0} ≤160? yes X; no □			$\bar{x}$ of *B* is ≥ 0.5 x $\bar{x}$ of N_{V0}? (or N_V/1000) yesX; no □			$\bar{x}$ of *C* is ≥ 0.5 x $\bar{x}$ of N_{V0}? yesX; no □		

Test suspension and test

Test-suspension (*N and N0*):	*N*	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 1.57 x 10^8; log*N* = 8.20 N_0 = *N*/20; logN_0 = 6.89 6.88≤ logN_{V0}≤7.40; yesX; no □
	10^{-6}	153	160	
	10^{-7}	16	16	

Drying controls

	T_0	V_{C1}	V_{C2}		
Drying control (D_{C0})	10^{-4}	103	95	$\bar{x}_{wm}$ = 0.97 x 10^6; logT_0 = 5.99 5.88≤ logT_0≤7.40; yesX; no □	Clean conditions
	10^{-5}	10	7		
	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 1.15 x 10^6; logT_0 = 6.06 5.88≤ logT_0≤7.40; yesX; no □	Dirty conditions
	10^{-4}	121	109		
	10^{-5}	13	10		

Drying controls

	T_0	V_{C1}	V_{C2}		
Drying control (D_{Ct})	10^{-4}	120	94	$\bar{x}_{wm}$ = 1.05 x 10^6; logT_t = 6.02 5.88≤ logT_t≤7.40; yesX; no □	Clean conditions
	10^{-5}	9	9		
	T_0	V_{C1}	V_{C2}		
	10^{-4}	116	130	$\bar{x}_{wm}$ = 1.21 x 10^6; logT_t = 6.08 5.88≤ logT_t≤7.40; yesX; no □	Dirty conditions
	10^{-5}	8	12		

Test field 1 (reduction)

Real conc. of the product %	Dilution step	V_{C1}	V_{C2}	N_a (=$\bar{x}$ or $\bar{x}_{wm}$)	log N_a	log R (log T_t - log N_a)	Contact time (min)	Conditions
Ready to use	10^0	19	24	21.5	1.33	4.69	1 min	Clean
	10^{-1}	2	2					
Ready to use	10^0	42	46	44	1.64	4.44	1 min	Dirty
	10^{-1}	4	6					

Test field 2 to 4 (cfu/25cm^2)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	V_{T2to4} (=$\bar{x}$ or $\bar{x}_{wm}$ x 5) cfu/25cm^2	Contact time (min)	Conditions
Ready to use	10^0	1	1	0	<5	1 min	Clean
Ready to use	10^{-1}	0	0	0	<5	1 min	Dirty

N_W Test fields 2 to 4 (cfu/25cm^2)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	$V_{NWT2to4}$ (=$\bar{x}$ or $\bar{x}_{wm}$ x 5) cfu/25cm^2	Contact time (min)	Conditions
Ready to use	10^0	>660	>660	>660	>16500	1 min	Clean
	10^{-1}	>660	>660	>660			
Ready to use	10^0	>660	>660	>660	>16500	1 min	Dirty
	10^{-1}	>660	>660	>660			

Explanations:
V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. duplicate)
$\bar{x}_{wm}$ = weighted mean of $\bar{x}$
R = reduction (logR = log N_0 – log N_a)

Appendix 2

TEST RESULTS

EVS-EN 16615:2015; Phase 2, step 2;
Neutralization method;
Rinsing liquid: -;
Test organism: *Staphylococcus aureus* ATCC 6538;
Test temperature: +20° C; Incubation temperature: +30° C
Interfering substance: 3.0 g/l bovine albumin = clean conditions; 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.; Date of test: 07.02.2019
Responsible person: Allar Laaneleht

Validation and controls

Validation suspension (N_{V0})			Neutralizer control (B)			Method validation (C)		
V_{C1}	84	$\bar{x}$ = 79.5	V_{C1}	62	$\bar{x}$ = 64	V_{C1}	72	$\bar{x}$ = 68
V_{C2}	75		V_{C2}	66		V_{C2}	64	
30 ≤ $\bar{x}$ N_{V0} ≤160? yes X; no □			$\bar{x}$ of *B* is ≥ 0.5 x $\bar{x}$ of N_{V0}? (or N_V/1000) yesX; no □			$\bar{x}$ of *C* is ≥ 0.5 x $\bar{x}$ of N_{V0}? yesX; no □		

Test suspension and test

Test-suspension (*N and N0*):	*N*	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.35 \times 10^9$; log*N* = 9.37 $N_0 = N/20$; logN_0 = 8.07 7.88≤ logN_{V0}≤8.40; yesX; no □
	10^{-7}	241	226	
	10^{-8}	25	25	

Drying controls

Drying control (D_{C0})	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.21 \times 10^7$; log$T_0$ = 7.35 6.88≤ logT_0≤8.40; yesX; no □	Clean conditions
	10^{-5}	238	211		
	10^{-6}	19	19		
	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.41 \times 10^7$; log$T_0$ = 7.38 6.88≤ logT_0≤8.40; yesX; no □	Dirty conditions
	10^{-5}	252	227		
	10^{-6}	26	26		

Drying controls

Drying control (D_{Ct})	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.90 \times 10^7$; $\log T_t = 7.28$ $6.88 \leq \log T_t \leq 8.40$; yesX; no □	Clean conditions
	10^{-5}	207	173		
	10^{-6}	21	16		
	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.16 \times 10^7$; $\log T_t = 7.34$ $6.88 \leq \log T_t \leq 8.40$; yesX; no □	Dirty conditions
	10^{-5}	223	211		
	10^{-6}	19	23		

Test field 1 (reduction)

Real conc. of the product %	Dilution step	V_{C1}	V_{C2}	N_a (=$\bar{x}$ or $\bar{x}_{wm}$)	log N_a	log R (log T_t - log N_a)	Contact time (min)	Conditions
Ready to use	10^0	12	17	14.5	1.16	6.12	1 min	Clean
	10^{-1}	1	1					
Ready to use	10^0	19	25	22	1.34	5.99	1 min	Dirty
	10^{-1}	2	2					

Test field 2 to 4 (cfu/25cm²)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	V_{T2to4} (=$\bar{x}$ or $\bar{x}_{wm}$ x 5) cfu/25cm²	Contact time (min)	Conditions
Ready to use	10^0	1	0	0	<5	1 min	Clean
	10^{-1}	0	0	0	<5		
Ready to use	10^0	2	1	0	<5	1 min	Dirty
	10^{-1}	0	0	0	<5		

N_W Test fields 2 to 4 (cfu/25cm²)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	$V_{NWT2to4}$ (=$\bar{x}$ or $\bar{x}_{wm}$ x 5) cfu/25cm²	Contact time (min)	Conditions
Ready to use	10^0	>660	>660	>660	>16500	1 min	Clean
	10^{-1}	>660	>660	>660			
Ready to use	10^0	>660	>660	>660	>16500	1 min	Dirty
	10^{-1}	>660	>660	>660			

Explanations:
V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. duplicate)
$\bar{x}_{wm}$ = weighted mean of $\bar{x}$
R = reduction (logR = log N_0 – log N_a)

Appendix 3

TEST RESULTS

EVS-EN 16615:2015; Phase 2, step 2;
Neutralization method;
Rinsing liquid: -;
Test organism: *Pseudomonas aeruginosa* ATCC 15442;
Test temperature: +20° C; Incubation temperature: +30° C
Interfering substance: 3.0 g/l bovine albumin = clean conditions; 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.; Date of test: 07.02.2019
Responsible person: Allar Laaneleht

Validation and controls

Validation suspension (N_{V0})			Neutralizer control (B)			Method validation (C)		
V_{C1}	42	$\bar{x}$ = 44.5	V_{C1}	29	$\bar{x}$ = 32.5	V_{C1}	34	$\bar{x}$ = 35.5
V_{C2}	47		V_{C2}	36		V_{C2}	37	
30 ≤ $\bar{x}$ N_{V0} ≤160? yes X; no □			$\bar{x}$ of *B* is ≥ 0.5 x $\bar{x}$ of N_{V0}? (or N_V/1000) yesX; no □			$\bar{x}$ of *C* is ≥ 0.5 x $\bar{x}$ of N_{V0}? yesX; no □		

Test suspension and test

Test-suspension (*N and N0):*	*N*	V_{C1}	V_{C2}	
	10^{-7}	154	172	$\bar{x}_{wm}$ = 1.63 x 10^9; log*N* = 9.21 N_0 = *N*/20; logN_0 = 7.91 7.88≤ logN_{V0}≤8.40; yesX; no □
	10^{-8}	16	17	

Drying controls

	T_0	V_{C1}	V_{C2}		
Drying control (D_{C0})	10^{-5}	138	166	$\bar{x}_{wm}$ = 1.53 x 10^7; logT_0 = 7.19 6.88≤ logT_0≤8.40; yesX; no □	Clean conditions
	10^{-6}	18	15		
	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 1.43 x 10^7; logT_0 = 7.16 6.88≤ logT_0≤8.40; yesX; no □	Dirty conditions
	10^{-5}	140	151		
	10^{-6}	13	11		

Drying controls

	T_0	V_{C1}	V_{C2}		
Drying control (D_{Ct})	10^{-5}	127	155	$\bar{x}_{wm}$ = 1.42 x 10^7; logT_t = 7.15 6.88≤ logT_t≤8.40; yesX; no □	Clean conditions
	10^{-6}	14	17		
	T_0	V_{C1}	V_{C2}		
	10^{-5}	166	143	$\bar{x}_{wm}$ = 1.54 x 10^7; logT_t = 7.19 6.88≤ logT_t≤8.40; yesX; no □	Dirty conditions
	10^{-6}	12	17		

Test field 1 (reduction)

Real conc. of the product %	Dilution step	V_{C1}	V_{C2}	N_a (=$\bar{x}$ or $\bar{x}_{wm}$)	log N_a	log R (log T_t - log N_a)	Contact time (min)	Conditions
Ready to use	10^0	16	22	19	1.28	5.87	1 min	Clean
	10^{-1}	1	1					
Ready to use	10^0	33	40	36.5	1.56	5.62	1 min	Dirty
	10^{-1}	3	3					

Test field 2 to 4 (cfu/25cm²)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	V_{T2to4} (=$\bar{x}$ or $\bar{x}_{wm}$ x 5) cfu/25cm²	Contact time (min)	Conditions
Ready to use	10^0	2	0	0	<5	1 min	Clean
	10^{-1}	0	0	0	<5		
Ready to use	10^0	3	1	0	<5	1 min	Dirty
	10^{-1}	0	0	0	<5		

N_W Test fields 2 to 4 (cfu/25cm²)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	$V_{NWT2to4}$ (=$\bar{x}$ or $\bar{x}_{wm}$ x 5) cfu/25cm²	Contact time (min)	Conditions
Ready to use	10^0	>660	>660	>660	>16500	1 min	Clean
	10^{-1}	>660	>660	>660			
Ready to use	10^0	>660	>660	>660	>16500	1 min	Dirty
	10^{-1}	>660	>660	>660			

Explanations:
V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. duplicate)
$\bar{x}_{wm}$ = weighted mean of $\bar{x}$
R = reduction (logR = log N_0 – log N_a)

Appendix 4

TEST RESULTS

EVS-EN 16615:2015; Phase 2, step 2;
Neutralization method;
Rinsing liquid: -;
Test organism: *Enterococcus hirae* ATCC 10541;
Test temperature: +20° C; Incubation temperature: +30° C
Interfering substance: 3.0 g/l bovine albumin = clean conditions; 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = dirty conditions;
Nordic Tersus Laboratory LLC.; Date of test: 07.02.2019
Responsible person: Allar Laaneleht

Validation and controls

Validation suspension (N_{V0})			Neutralizer control (B)			Method validation (C)		
V_{C1}	65	$\bar{x}$ = 60	V_{C1}	33	$\bar{x}$ = 37.5	V_{C1}	58	$\bar{x}$ = 52.5
V_{C2}	55		V_{C2}	42		V_{C2}	47	
30 ≤ $\bar{x}$ N_{V0} ≤160? yes X; no □			$\bar{x}$ of *B* is ≥ 0.5 x $\bar{x}$ of N_{V0}? (or N_V/1000) yesX; no □			$\bar{x}$ of *C* is ≥ 0.5 x $\bar{x}$ of N_{V0}? yesX; no □		

Test suspension and test

Test-suspension (*N and N0):*	*N*	V_{C1}	V_{C2}	
	10^{-7}	209	226	$\bar{x}_{wm}$ = 2.17 x 10^9; log*N* = 9.34 N_0 = *N*/20; logN_0 = 8.04 7.88≤ logN_{V0}≤8.40; yesX; no □
	10^{-8}	19	24	

Drying controls

	T_0	V_{C1}	V_{C2}		
Drying control (D_{C0})	10^{-5}	191	177	$\bar{x}_{wm}$ = 1.84 x 10^7; logT_0 = 7.26 6.88≤ logT_0≤8.40; yesX; no □	Clean conditions
	10^{-6}	22	14		
	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 1.96 x 10^7; logT_0 = 7.29 6.88≤ logT_0≤8.40; yesX; no □	Dirty conditions
	10^{-5}	202	187		
	10^{-6}	22	20		

Drying controls

	T_0	V_{C1}	V_{C2}		
Drying control (D_{Ct})	10^{-5}	203	182	$\bar{x}_{wm}$ = 1.94 x 10^7; logT_t = 7.29 6.88≤ logT_t≤8.40; yesX; no □	Clean conditions
	10^{-6}	24	18		
	T_0	V_{C1}	V_{C2}		
	10^{-5}	192	225	$\bar{x}_{wm}$ = 2.06 x 10^7; logT_t = 7.31 6.88≤ logT_t≤8.40; yesX; no □	Dirty conditions
	10^{-6}	16	20		

Test field 1 (reduction)

Real conc. of the product %	Dilution step	V_{C1}	V_{C2}	N_a (=$\bar{x}$ or $\bar{x}_{wm}$)	log N_a	log R (log T_t - log N_a)	Contact time (min)	Conditions
Ready to use	10^0	14	19	16.5	1.22	6.07	1 min	Clean
	10^{-1}	1	1					
Ready to use	10^0	24	30	27	1.43	5.88	1 min	Dirty
	10^{-1}	3	3					

Test field 2 to 4 (cfu/25cm²)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	V_{T2to4} (=$\bar{x}$ or $\bar{x}_{wm}$ x 5) cfu/25cm²	Contact time (min)	Conditions
Ready to use	10^0	0	0	0	<5	1 min	Clean
	10^{-1}	0	0	0	<5		
Ready to use	10^0	1	1	0	<5	1 min	Dirty
	10^{-1}	0	0	0	<5		

N_W Test fields 2 to 4 (cfu/25cm²)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	$V_{NWT2to4}$ (=$\bar{x}$ or $\bar{x}_{wm}$ x 5) cfu/25cm²	Contact time (min)	Conditions
Ready to use	10^0	>660	>660	>660	>16500	1 min	Clean
	10^{-1}	>660	>660	>660			
Ready to use	10^0	>660	>660	>660	>16500	1 min	Dirty
	10^{-1}	>660	>660	>660			

Explanations:
V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. duplicate)
$\bar{x}_{wm}$ = weighted mean of $\bar{x}$
R = reduction (logR = log N_0 – log N_a)

Interpretation

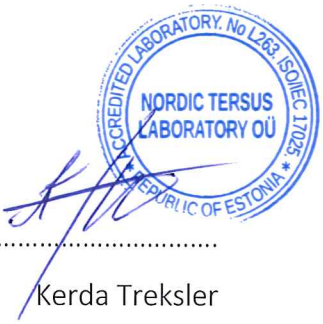
The ready-to-use product for surface disinfection **STERISEPT WIPES** (batch no. 14300818W) was tested according to the test method EVS-EN 16615:2015. The test was performed at 20 ± 1 °C, under clean and dirty conditions during the contact time of 1 min. The dilution – neutralization method was used for testing the product's effectiveness against the reference strains: *Candida albicans* ATCC 10231; *Pseudomonas aeruginosa* ATCC 15442; *Enterococcus hirae* ATCC 10541 and *Staphylococcus aureus* ATCC 6538. Under clean and dirty conditions, the product was effective against all the reference strains within 1 min of contact time.

Conclusion

The surviving count of bacterial reference strains showed at least 5 lg and yeast reference strain showed at least 4 lg reduction meaning that **under clean and dirty conditions the product STERISEPT WIPES has a bactericidal and yeasticidal effect in case of surface disinfection within 1 min**.

The results apply exclusively to the tested sample of the product with batch no. 14300818W.

This is a corrected version of the test report no sd1319 and supersedes the previous version of the test report.



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Kerda Treksler
Microbiologist
Date of test report: 09.01.2024