

Test report no 031021sd

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 PLUS

Batch number*: 212260321

Order number: 20041

Manufacturer*: Chemi-Pharm Ltd.

Client, representative*: Chemi-Pharm Ltd., Tännassilma tee 11, Tännassilma küla, Saku vald, 76406, ESTONIA, Maris Millner, +372 5177090

Date of delivery: 02.06.2021

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

Storage conditions: At room temperature, dark

Active substance – conc.*: N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 12.5%;
Didecyl-Dimethyl-Ammonium Chloride (DDAC) 12.5%

Appearance of the product: Transparent liquid

Test concentration: 0.5% w/w

Contact time: 30 min

Interfering substance: 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: 08.06.2021 – 11.06.2021

Results: Look appendix 1-5



Melissa Ingela Bramanis
Microbiologist
Date of issue: 09.07.2021

* - Data provided by the customer

TEST RESULTS (yeasticial test)

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 g/l bovine albumin + 3 ml/l sheep blood erythrocytes

Nordic Tersus Laboratory LLC.; Date of test: 08.06.2021

Responsible person: Melissa Ingela Bramanis

Validation and controls

Validation and controls								
Validation suspension (N_{V0})			Neutralizer control (B)			Method validation (C)		
V_{C1}	92	$\bar{x} = 93$	V_{C1}	58	$\bar{x} = 61.5$	V_{C1}	71	$\bar{x} = 67$
V_{C2}	94		V_{C2}	65		V_{C2}	63	
$30 \leq \bar{x} N_{V0} \leq 160$? yes X; no ☐			$\bar{x}$ of B is $\geq 0.5 \times \bar{x}$ of N_{V0} ? (or $N_V/1000$) yesX; no ☐			$\bar{x}$ of C is $\geq 0.5 \times \bar{x}$ of N_{V0} ? yesX; no ☐		

Test suspension and test

Test-suspension (N and N_0):	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 3.08 \times 10^8$; $\log N = 8.49$ $N_0 = N/20$; $\log N_0 = 7.19$ $6.88 \leq \log N_{V0} \leq 7.40$; yesX; no ☐
	10^{-6}	270	>330	
	10^{-7}	51	27	

Drying controls

Drying control (D_{Co})	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.36 \times 10^6$; $\log T_0 = 6.38$ $5.88 \leq \log T_0 \leq 7.40$; yesX; no ☐	Dirty conditions 30 min
	10^{-5}	20	28		
	10^{-6}	2	2		
Drying control (D_{Ct})	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.86 \times 10^6$; $\log T_t = 6.27$ $5.88 \leq \log T_t \leq 7.40$; yesX; no ☐	Dirty conditions 30 min
	10^{-5}	16	20		
	10^{-6}	3	2		

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	1	3	<14	<1.15	>5.12	30 min	Dirty
	10^{-1}	0	0					

The test results apply to the tested sample only.

All the components of this test report are recognized as a portion of a complete report. The test report shall not be reproduced except in full, without approval of the laboratory.

N-7/29-V9

Test field 2 to 4 (cfu/25cm²)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} \times 5)$ cfu/25cm ²	Contact time (min)	Conditions
Ready to use	10 ⁰	0	0	0	<5	30 min	Dirty
	10 ⁻¹	0	0	0	<5		

N_w Test fields 2 to 4 (cfu/25cm²)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} \times 5)$ cfu/25cm ²	Contact time (min)	Conditions
Ready to use	10 ⁰	42	16	6	106.7	30 min	Dirty
	10 ⁻¹	6	1	1			

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 ($\log R = \log N_0 - \log N_a$)

TEST RESULTS (bactericidal test)

EVS-EN 16615:2015; Phase 2, step 2;

Neutralization method;

Rinsing liquid: -;

Test organism: *Staphylococcus aureus* ATCC 6538;

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

Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes

Nordic Tersus Laboratory LLC.; Date of test: 08.06.2021

Responsible person: Melissa Ingela Bramanis

Validation and controls

Validation and controls								
Validation suspension (N_{vo})			Neutralizer control (B)			Method validation (C)		
V_{C1}	71	$\bar{x} = 75.5$	V_{C1}	62	$\bar{x} = 58.5$	V_{C1}	47	$\bar{x} = 48$
V_{C2}	80		V_{C2}	55		V_{C2}	49	
$30 \leq \bar{x} N_{vo} \leq 160$? yes X; no ☐			$\bar{x}$ of B is $\geq 0.5 \times \bar{x}$ of N_{vo} ? (or $N_v/1000$) yesX; no ☐			$\bar{x}$ of C is $\geq 0.5 \times \bar{x}$ of N_{vo} ? yesX; no ☐		

Test suspension and test

Test-suspension (N and N_0):	N	V_{c1}	V_{c2}	$\bar{x}_{wm} = 2.71 \times 10^9$; $\log N = 9.43$ $N_0 = N/20$; $\log N_0 = 8.13$ $7.88 \leq \log N_{vo} \leq 8.40$; yesX; no ☐
	10^{-7}	273	273	
	10^{-8}	31	19	

Drying controls

Drying control (D_{co})	T_0	V_{c1}	V_{c2}	$\bar{x}_{wm} = 186 \times 10^6$; $\log T_0 = 8.27$ $6.88 \leq \log T_0 \leq 8.40$; yesX; no ☐	Dirty conditions 30 min
	10^{-5}	>330	>330		
	10^{-6}	203	169		
Drying control (D_{ct})	T_0	V_{c1}	V_{c2}	$\bar{x}_{wm} = 61.5 \times 10^6$; $\log T_t = 7.79$ $6.88 \leq \log T_t \leq 8.40$; yesX; no ☐	Dirty conditions 30 min
	10^{-5}	>330	>330		
	10^{-6}	63	60		

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	12	<14	<1.15	>6.64	30 min	Dirty
	10^{-1}	2	0					

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N-7/29-V9

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 $\bar{x}_{wm} \times 5$) cfu/25cm ²	Contact time (min)	Conditions
Ready to use	10 ⁰	0	0	0	<5	30 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 $\bar{x}_{wm} \times 5$) cfu/25cm ²	Contact time (min)	Conditions
Ready to use	10 ⁰	41	20	11	120	30 min	Dirty
	10 ⁻¹	6	2	1			

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 ($\log R = \log N_0 - \log N_a$)

Appendix 3

TEST RESULTS (bactericidal test)

EVS-EN 16615:2015; Phase 2, step 2;

Neutralization method;

Rinsing liquid: -;

Test organism: *Pseudomonas aeruginosa* ATCC 15442;

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

Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes

Nordic Tersus Laboratory LLC.; Date of test: 08.06.2021

Responsible person: Melissa Ingela Bramanis

Validation and controls

Validation and controls								
Validation suspension (N_{V0})			Neutralizer control (B)			Method validation (C)		
V_{C1}	41	$\bar{x} = 38$	V_{C1}	27	$\bar{x} = 26.5$	V_{C1}	22	$\bar{x} = 25$
V_{C2}	35		V_{C2}	26		V_{C2}	28	
$30 \leq \bar{x} N_{V0} \leq 160$? yes X; no ☐			$\bar{x}$ of B is $\geq 0.5 \times \bar{x}$ of N_{V0} ? (or $N_V/1000$) yesX; no ☐			$\bar{x}$ of C is $\geq 0.5 \times \bar{x}$ of N_{V0} ? yesX; no ☐		

Test suspension and test

Test-suspension (N and N_0):	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.63 \times 10^9$; $\log N = 9.21$ $N_0 = N/20$; $\log N_0 = 7.91$ $7.88 \leq \log N_{V0} \leq 8.40$; yesX; no ☐
	10^{-7}	159	156	
	10^{-8}	20	23	

Drying controls

Drying control (D_{Co})	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.28 \times 10^6$; $\log T_0 = 7.11$ $6.88 \leq \log T_0 \leq 8.40$; yesX; no ☐	Dirty conditions 30 min
	10^{-5}	147	108		
	10^{-6}	16	11		
Drying control (D_{Ci})	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm} = 8.90 \times 10^6$; $\log T_t = 6.94$ $6.88 \leq \log T_t \leq 8.40$; yesX; no ☐	Dirty conditions 30 min
	10^{-5}	87	92		
	10^{-6}	8	9		

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	0	0	<14	<1.15	>5.79	30 min	Dirty
	10^{-1}	0	0					

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N-7/29-V9

Test field 2 to 4 (cfu/25cm²)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} \times 5)$ cfu/25cm ²	Contact time (min)	Conditions
Ready to use	10 ⁰	0	0	0	<5	30 min	Dirty
	10 ⁻¹	0	0	0	<5		

N_w Test fields 2 to 4 (cfu/25cm²)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} \times 5)$ cfu/25cm ²	Contact time (min)	Conditions
Ready to use	10 ⁰	116	72	8	326.67	30 min	Dirty
	10 ⁻¹	43	8	0			

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 ($\log R = \log N_0 - \log N_a$)

TEST RESULTS (bactericidal test)

EVS-EN 16615:2015; Phase 2, step 2;

Neutralization method;

Rinsing liquid: -;

Test organism: *Enterococcus hirae* ATCC 10541;

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

Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes;

Nordic Tersus Laboratory LLC.; Date of test: 08.06.2021

Responsible person: Melissa Ingela Bramanis

Validation and controls

Validation and controls								
Validation suspension (N_{V0})			Neutralizer control (B)			Method validation (C)		
V_{C1}	55	$\bar{x} = 52.5$	V_{C1}	42	$\bar{x} = 39.5$	V_{C1}	36	$\bar{x} = 40$
V_{C2}	50		V_{C2}	37		V_{C2}	44	
$30 \leq \bar{x} N_{V0} \leq 160$? yes X; no ☐			$\bar{x}$ of B is $\geq 0.5 \times \bar{x}$ of N_{V0} ? (or $N_V/1000$) yesX; no ☐			$\bar{x}$ of C is $\geq 0.5 \times \bar{x}$ of N_{V0} ? yesX; no ☐		

Test suspension and test

Test-suspension (N and N_0):	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.88 \times 1^9$; $\log N = 9.27$ $N_0 = N/20$; $\log N_0 = 7.97$ $7.88 \leq \log N_{V0} \leq 8.40$; yesX; no ☐
	10^{-7}	178	172	
	10^{-8}	29	34	

Drying controls

Drying control (D_{Co})	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm} = 138.5 \times 10^6$; $\log T_0 = 8.14$ $6.88 \leq \log T_0 \leq 8.40$; yesX; no ☐	Dirty conditions 30 min
	10^{-5}	>330	>330		
	10^{-6}	130	147		
Drying control (D_{Ct})	T_0	V_{C1}	V_{C2}	$\bar{x}_{wm} = 92 \times 10^6$; $\log T_t = 7.96$ $6.88 \leq \log T_t \leq 8.40$; yesX; no ☐	Dirty conditions 30 min
	10^{-5}	>330	>330		
	10^{-6}	101	83		

Test field 1 (reduction)

Real conc. of the product %	Dilution step	V_{C1}	V_{C2}	$N_a (= \bar{x} \text{ or } \bar{x}_{wm})$	$\log N_a$	$\log R (\log T_t - \log N_a)$	Contact time (min)	Conditions
Ready to use	10^0	66	59	62.5	1.79	6.17	30 min	Dirty
	10^{-1}	4	6					

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N-7/29-V9

Test field 2 to 4 (cfu/25cm²)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} \times 5)$ cfu/25cm ²	Contact time (min)	Conditions
Ready to use	10 ⁰	0	0	0	<5	30 min	Dirty
	10 ⁻¹	0	0	0	<5		

N_w Test fields 2 to 4 (cfu/25cm²)

Real conc. of the product %	Dilution step	$V_C T_2$	$V_C T_3$	$V_C T_4$	$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} \times 5)$ cfu/25cm ²	Contact time (min)	Conditions
Ready to use	10 ⁰	22	9	7	63.3	30 min	Dirty
	10 ⁻¹	2	1	1			

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 ($\log R = \log N_0 - \log N_a$)

Appendix 5

Interpretation

The ready to use product for surface disinfection **STERISEPT PLUS** (batch no. 212260321) was tested according to the test method EVS-EN 16615:2015. The test was performed at 20 ± 1 °C, under dirty conditions during the contact time of 30 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 dirty conditions, the product was effective against all the reference strains within 30 min.

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 dirty conditions the product STERISEPT PLUS has a bactericidal and yeasticidal effect in case of surface disinfection within 30 min.**

This is the end of the test report.



Melissa Ingela Bramanis
Microbiologist
Date of issue: 09.07.2021