

Test report No 19021sd

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*: BACTICID AF

Batch number*: 197271120

Order number: 20042

Manufacturer*: Chemi-Pharm Ltd.

Client, representative*: Chemi-Pharm Ltd., Tänassilma tee 11, Tänassilma küla, Saku

vald, 76406, ESTONIA, Maris Millner, +372 5177090

Date of delivery: 15.01.2021

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

Storage conditions: In room temperature, dark

Active substance – conc.*: Ethyl alcohol 57.0% wt, isopropyl alcohol 6.0% wt

Appearance of the product: Transparent liquid

Test concentration: Ready to use

Contact time: 1 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: 22.03.2021 – 25.03.2021

Results: look appendix 1-5

Allar Laaneleht Chief specialist

Date of issue: 29.03.2021

E-mail: info@ntl.ee

Test report No. 19021sd

Appendix 1

TEST RESULTS (yeasticidal 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: 22.03.2021 Responsible person: Allar Laaneleht, Melissa Ingela Bramanis

Validation and controls

Validation suspension (N _{V0})			Neutralizer control (B)			Method validation (C)			
V _{C1}	75	5 - 67 F	V _{C1}	58	5 - E4 E	V _{C1}	55	5. F7	
V _{C2}	60	$\bar{x} = 67.5$	V_{C2}	51	$\ddot{x} = 54.5$	V_{C2}	59	x = 57	
30 ≤	x̄ N vo ≤160? yes X	(; no □	\bar{x} of B is $\geq 0.5 \times \bar{x}$ of N_{vo} ? (or $N_V/1000$) yesX; no \Box			\bar{x} of C is $\geq 0.5 \times \bar{x}$ of N_{vo} ? yesX; no \Box			

Test suspension and test

Test-suspension	N	V _{C1}	V _{C2}	$\bar{x}_{wm} = 2.13 \times 10^8$; $\log N = 8.33$
(N and N0):	10 ⁻⁶	204	216	$N_0 = N/20$; $\log N_0 = 7.03$
	10-7	22	26	6.88≤ log <i>N_{v0}</i> ≤7.40; yesX; no □

Drying controls

Drying	T ₀	V _{C1}	V _{C2}		,
control	10-3	>330	>330	$\bar{x}_{wm} = 5.25 \times 10^6$; $\log T_0 = 6.72$ 5.88 \le $\log T_0 \le 7.40$; yesX; no	Dirty conditions 1 min
(D _{co})	10-4	55	50	3.005 1081057.40, yesh, 110 L	

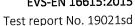
Drying controls

Drying	To	V _{C1}	V _{C2}	- FAF 406 L T 674	
control	10 ⁻³	>330	>330	$\bar{x}_{wm} = 5.45 \times 10^6$; $\log T_t = 6.74$ 5.88 $\leq \log T_t \leq 7.40$; yesX; no \Box	Dirty conditions 1 min
(D _{Ct})	10 ⁻⁴	64	45	3.005 log 1t57.40, yesh, 110 L	

Test field 1 (reduction)

Real conc. of the product %	Dilution step	V _{C1}	V _{C2}	N_a (= \bar{x} or \bar{x}_{wm})	log Na	log R (log T _t - log N _a)	Contact time (min)	Conditions
Ready to	10 ⁰	3	7	<14	√1 1E	>5.59	1 min	Dirty
use	10 ⁻¹	0	0	14	<1.15	/5.59	T [[]	Dirty

The test results apply to the tested sample only.





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	10 ⁰	1	0	0	<5	1 min	Dirty
use	10-1	0	0	0	<5	T 1[11]	Dirty

Nw Test fields 2 to 4 (cfu/25cm²)

TYPE I COL TICIOS				1		T	
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	10 ⁰	>330	>330	>330	2383.33	1 min	Dirty
use	10-1	10 ⁻¹ 71 52 19		2363.33		Direy	

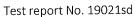
Explanations:

 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 2

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: 22.03.2021 Responsible person: Allar Laaneleht, Melissa Ingela Bramanis

Validation and controls

Valid	Validation suspension (N _{VO})			Neutralizer control (B)			Method validation (C)		
V _{C1}	93	- 06	V _{C1}	56	B - CO	V _{C1}	69	x = 60	
V _{C2}	99	x̄ = 96	V _{C2}	64	$\bar{x} = 60$	V_{C2}	51		
30 ≤ x̄ N _{vo} ≤160? yes X; no □			\bar{x} of B is $\geq 0.5 \times \bar{x}$ of N_{vo} ? (or $N_v/1000$) yesX; no \Box			\bar{x} of C is $\geq 0.5 \times \bar{x}$ of N_{vo} ? yesX; no \Box			

Test suspension and test

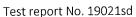
Test-suspension	N	V _{C1}	V _{C2}	$\bar{x}_{wm} = 2.60 \times 10^9$; $\log N = 9.41$
(N and NO):	10 ⁻⁷	244	272	$N_0 = N/20$; $\log N_0 = 8.11$
	10-8	26	31	6.88≤ log <i>N_{vo}</i> ≤7.40; yesX; no □

Drying controls

Drying control	T ₀	V c1 >330	<i>V_{c2}</i> >330	$\bar{x}_{wm} = 5.80 \times 10^7; \log T_0 = 7.76$	Dirty conditions 1 min
(D _{C0})	10 ⁻⁵	50	66	6.88≤ logT ₀ ≤8.40; yesX; no □	•

Drying controls

Γ	Drying	T _t	V _{C1}	V _{C2}	- 7.00 40 ⁷ la -T 7.00	
	control	10 ⁻⁴	>330	>330	$\bar{x}_{wm} = 7.20 \times 10^7$; $\log T_t = 7.86$ 6.88 \leq \log T_t \leq 8.40; yes X; no \pi	Dirty conditions 1 min
	(D _{Ct})	10 ⁻⁵	61	83	0.005 1081t50.40, yesh, 110 11	





Test field 1 (reduction)

Real conc. of the product %	Dilution step	V _{C1}	V _{C2}	N_a (= \bar{x} or \bar{x}_{wm})	log Na	log R (log T _t - log N _a)	Contact time (min)	Conditions
Ready to	10 ⁰	4	10	<14	<1.15	>6.71	1 min	Dirty
use	10 ⁻¹	0	0	\14	<1.13	Z0.71	T 111111	Dirty

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	10 ⁰	1	0	0	<5	1 min	Dirty
use	10-1	0	0	0	<5	1 min	Dirty

Nw 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/25cm ²	Contact time (min)	Conditions
Ready to	10 ⁰	>330	>330	>330	5083.33	1 min	Dirty
use	10-1	162	93	50	3063.33	T 1[1]]]	Dirty

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}

 $R = reduction (log R = log N_o - log N_a)$

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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: 22.03.2021 Responsible person: Allar Laaneleht, Melissa Ingela Bramanis

Validation and controls

Valid	dation suspension	(N _{VO})	Neutralizer control (B)			Method validation (C)			
V _{C1}	107	- 104	V _{C1}	85	□ _ 02 E	V_{C1}	76	x̄ = 73	
V _{C2}	101	$\bar{x} = 104$	V _{C2}	80	$\ddot{x} = 82.5$	V_{C2}	70	X = 73	
30 ≤	x̄ N νο ≤160? yes X	⁄; no □			B is ≥ 0.5 x \bar{x} of N _{vo} ? N _v /1000) yesX; no \Box		\bar{x} of C is $\geq 0.5 \times \bar{x}$ of N_{vo} ? yesX; no \Box		

Test suspension and test

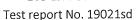
Test-suspension	N	V _{C1}	V _{C2}	$\bar{x}_{wm} = 2.79 \times 10^9$; $\log N = 9.45$
(N and N0):	10 ⁻⁷	262	297	$N_0 = N/20$; $\log N_0 = 8.14$
	10-8	25	30	6.88≤ log <i>N_{vo}</i> ≤7.40; yesX; no □

Drying controls

Drying	To	V _{C1}	V_{C2}	- ACO 407 L. T. 7.66	
control	10-4	>330	>330	$\bar{x}_{wm} = 4.60 \times 10^7$; $\log T_0 = 7.66$ 6.88 \leq \log T_0 \leq 8.40; yesX; no	Dirty conditions 1 min
(D _{co})	10 ⁻⁵	45	47	0.865 1081058.40, yesh, 110 L	

Drying controls

Drying	T _t	V _{C1}	V_{C2}		
control	10-4	>330	>330	$\bar{x}_{wm} = 5.25 \times 10^7$; $\log T_t = 7.72$ 6.88 \leq \log T_t \leq 8.40; yesX; no	Dirty conditions :
(D _{Ct})	10 ⁻⁵	42	62	0.002 10g1t20.40, yes/, 110 L	





Test field 1 (reduction)

Real conc. of the product %	Dilution step	V _{C1}	V _{C2}	N_a (= \bar{x} or \bar{x}_{wm})	log Na	log R (log T _t - log N _a)	Contact time (min)	Conditions
Ready to	10 ⁰	2	2	<14	<1.15	>6.57	1 min	Dirty
use	10-1	0	0	\14	\1.15	/0.57	T [1][][Dirty

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	10 ⁰	2	0	0	<5	1 min	Dirty
use	10-1	0	0	0	<5	1 min	Dirty

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/25cm ²	Contact time (min)	Conditions
Ready to	10 ⁰	>330	>330	>330	1633.33	1 min	Dirty
use	10-1	49	32	17	1033.33	T 111111	Difty

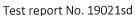
Explanations:

 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 4

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: 22.03.2021 Responsible person: Allar Laaneleht, Melissa Ingela Bramanis

Validation and controls

Valid	Validation suspension (N_{VO})			Neutralizer control (B)			Method validation (C)		
V _{C1}	49	5 _ 4F F	V_{C1}	36	5 - 27 F	V_{C1}	30	5-255	
V _{C2}	42	x̄ = 45.5	V _{C2}	39	$\bar{x} = 37.5$	V_{C2}	41	x = 35.5	
30 ≤	30 ≤ x̄ N _{vo} ≤160? yes X; no □		\bar{x} of B is $\geq 0.5 \times \bar{x}$ of N_{vo} ? (or $N_V/1000$) yesX; no \Box			\bar{x} of C is $\geq 0.5 \times \bar{x}$ of N_{vo} ? yesX; no \Box			

Test suspension and test

Test-suspension	N	V _{C1}	V _{C2}	$\bar{x}_{wm} = 1.68 \times 10^9$; $\log N = 9.23$
(N and NO):	10 ⁻⁷	162	173	$N_0 = N/20$; $\log N_0 = 7.92$
	10-8	19	16	6.88≤ log <i>N_{vo}</i> ≤7.40; yesX; no □

Drying controls

Drying	To	V _{C1}	V _{C2}	- 0.70 407 7.77	
control	10-4	>330	>330	$\bar{x}_{wm} = 3.70 \times 10^7$; $\log T_0 = 7.57$ 6.88 \leq \log T_0 \leq 8.40; yesX; no	Dirty conditions 1 min
(D _{co})	10 ⁻⁵	36	38	0.005 10g1050.40, yesh, 110 L	

Drying controls

Drying	T _t	<i>V</i> _{C1}	V _{C2}	- 440 40 ⁷ L T 7.64	
control	10-4	>330	>330	$\bar{x}_{wm} = 4.10 \times 10^7$; $\log T_t = 7.61$ 6.88 \leq \log T_t \leq 8.40; yesX; no	Dirty conditions 1 min
(D _{Ct})	10 ⁻⁵	40	42	0.865 10g1t56.40, yesh, 110 ti	



Test field 1 (reduction)

Real conc. of the product %	Dilution step	V _{C1}	V _{C2}	N_a (= \bar{x} or \bar{x}_{wm})	log Na	log R (log T _t - log N _a)	Contact time (min)	Conditions
Ready to	10 ⁰	9	4	-11	∠1 1E	> 6.46	1 min	Dirty
use	10-1	0	0	<14	<1.15	>6.46	1 min	Dirty

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	10 ⁰	0	0	0	<5	1	Dieta
use	10-1	0	0	0	<5	1 min	Dirty

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/25cm ²	Contact time (min)	Conditions
Ready to	10 ⁰	>330	>330	>330	>16500	1 min	Dieta
use	10-1	>330	>330	>330	>16500	1 min	Dirty

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}

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



3t Teport 110: 130213d

Appendix 5

Interpretation

The ready to use product for surface disinfection **BACTICID AF** (batch no.197271120) was tested according to the test method EVS-EN 16615:2015. The standard wipes were soaked with 16 ml of the product. The test was performed at 20 ± 1 °C, under 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 dirty conditions, the product was effective against all the reference strains within 1 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 BACTICID AF has a bactericidal and yeasticidal effect in case of surface disinfection within 1 min.

This is the end of the test report.

Allar Laaneleht Chief specialist