

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., Tännasilma tee 11, Tännasilma 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

\* - Data provided by the customer

### TEST RESULTS (yeastcidal 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 ( $N_{vo}$ )			Neutralizer control (B)			Method validation (C)		
$V_{c1}$	75	$\bar{x} = 67.5$	$V_{c1}$	58	$\bar{x} = 54.5$	$V_{c1}$	55	$\bar{x} = 57$
$V_{c2}$	60		$V_{c2}$	51		$V_{c2}$	59	
30 ≤ $\bar{x} N_{vo}$ ≤ 160? yes X; no □			$\bar{x}$ of B is ≥ 0.5 × $\bar{x}$ of $N_{vo}$ ? (or $N_v/1000$ ) yesX; no □			$\bar{x}$ of C is ≥ 0.5 × $\bar{x}$ of $N_{vo}$ ? yesX; no □		

### Test suspension and test

Test-suspension ( $N$ and $N_0$ ):	$N$	$V_{c1}$	$V_{c2}$	$\bar{x}_{wm} = 2.13 \times 10^8$ ; $\log N = 8.33$ $N_0 = N/20$ ; $\log N_0 = 7.03$ $6.88 \leq \log N_{vo} \leq 7.40$ ; yesX; no □
	$10^{-6}$	204	216	
	$10^{-7}$	22	26	

### Drying controls

Drying control ( $D_{c0}$ )	$T_0$	$V_{c1}$	$V_{c2}$	$\bar{x}_{wm} = 5.25 \times 10^6$ ; $\log T_0 = 6.72$ $5.88 \leq \log T_0 \leq 7.40$ ; yesX; no □	Dirty conditions 1 min
	$10^{-3}$	>330	>330		
	$10^{-4}$	55	50		

### Drying controls

Drying control ( $D_{ct}$ )	$T_0$	$V_{c1}$	$V_{c2}$	$\bar{x}_{wm} = 5.45 \times 10^6$ ; $\log T_t = 6.74$ $5.88 \leq \log T_t \leq 7.40$ ; yesX; no □	Dirty conditions 1 min
	$10^{-3}$	>330	>330		
	$10^{-4}$	64	45		

### 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	$10^0$	3	7	<14	<1.15	>5.59	1 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.

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**Test field 2 to 4 (cfu/25cm<sup>2</sup>)**

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 <sup>2</sup>	Contact time (min)	Conditions
Ready to use	10 <sup>0</sup>	1	0	0	<5	1 min	Dirty
	10 <sup>-1</sup>	0	0	0	<5		

**$N_W$  Test fields 2 to 4 (cfu/25cm<sup>2</sup>)**

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 <sup>2</sup>	Contact time (min)	Conditions
Ready to use	10 <sup>0</sup>	>330	>330	>330	2383.33	1 min	Dirty
	10 <sup>-1</sup>	71	52	19			

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: 22.03.2021

Responsible person: Allar Laaneleht, Melissa Ingela Bramanis

### Validation and controls

Validation suspension ( $N_{V0}$ )			Neutralizer control (B)			Method validation (C)		
$V_{C1}$	93	$\bar{x} = 96$	$V_{C1}$	56	$\bar{x} = 60$	$V_{C1}$	69	$\bar{x} = 60$
$V_{C2}$	99		$V_{C2}$	64		$V_{C2}$	51	
$30 \leq \bar{x} N_{V0} \leq 160$ ? yes X; no <input type="checkbox"/>			$\bar{x}$ of B is $\geq 0.5 \times \bar{x}$ of $N_{V0}$ ? (or $N_V/1000$ ) yesX; no <input type="checkbox"/>			$\bar{x}$ of C is $\geq 0.5 \times \bar{x}$ of $N_{V0}$ ? yesX; no <input type="checkbox"/>		

### Test suspension and test

Test-suspension ( $N$ and $N_0$ ):	$N$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 2.60 \times 10^9$ ; $\log N = 9.41$ $N_0 = N/20$ ; $\log N_0 = 8.11$ $6.88 \leq \log N_{V0} \leq 7.40$ ; yesX; no <input type="checkbox"/>
	$10^{-7}$	244	272	
	$10^{-8}$	26	31	

### Drying controls

Drying control ( $D_{C0}$ )	$T_0$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 5.80 \times 10^7$ ; $\log T_0 = 7.76$ $6.88 \leq \log T_0 \leq 8.40$ ; yesX; no <input type="checkbox"/>	Dirty conditions 1 min
	$10^{-4}$	>330	>330		
	$10^{-5}$	50	66		

### Drying controls

Drying control ( $D_{Ct}$ )	$T_t$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 7.20 \times 10^7$ ; $\log T_t = 7.86$ $6.88 \leq \log T_t \leq 8.40$ ; yesX; no <input type="checkbox"/>	Dirty conditions 1 min
	$10^{-4}$	>330	>330		
	$10^{-5}$	61	83		

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**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	$10^0$	4	10	<14	<1.15	>6.71	1 min	Dirty
	$10^{-1}$	0	0					

**Test field 2 to 4 (cfu/25cm<sup>2</sup>)**

Real conc. of the product %	Dilution step	$V_{CT2}$	$V_{CT3}$	$V_{CT4}$	$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} \times 5)$ cfu/25cm <sup>2</sup>	Contact time (min)	Conditions
Ready to use	$10^0$	1	0	0	<5	1 min	Dirty
	$10^{-1}$	0	0	0	<5		

**$N_w$  Test fields 2 to 4 (cfu/25cm<sup>2</sup>)**

Real conc. of the product %	Dilution step	$V_{CT2}$	$V_{CT3}$	$V_{CT4}$	$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} \times 5)$ cfu/25cm <sup>2</sup>	Contact time (min)	Conditions
Ready to use	$10^0$	>330	>330	>330	5083.33	1 min	Dirty
	$10^{-1}$	162	93	50			

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: 22.03.2021

Responsible person: Allar Laaneleht, Melissa Ingela Bramanis

**Validation and controls**

Validation suspension ( $N_{V0}$ )			Neutralizer control (B)			Method validation (C)		
$V_{C1}$	107	$\bar{x} = 104$	$V_{C1}$	85	$\bar{x} = 82.5$	$V_{C1}$	76	$\bar{x} = 73$
$V_{C2}$	101		$V_{C2}$	80		$V_{C2}$	70	
$30 \leq \bar{x} N_{V0} \leq 160$ ? yes X; no <input type="checkbox"/>			$\bar{x}$ of B is $\geq 0.5 \times \bar{x}$ of $N_{V0}$ ? (or $N_V/1000$ ) yesX; no <input type="checkbox"/>			$\bar{x}$ of C is $\geq 0.5 \times \bar{x}$ of $N_{V0}$ ? yesX; no <input type="checkbox"/>		

**Test suspension and test**

Test-suspension ( $N$ and $N_0$ ):	$N$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 2.79 \times 10^9$ ; $\log N = 9.45$ $N_0 = N/20$ ; $\log N_0 = 8.14$ $6.88 \leq \log N_{V0} \leq 7.40$ ; yesX; no <input type="checkbox"/>
	$10^{-7}$	262	297	
	$10^{-8}$	25	30	

**Drying controls**

Drying control ( $D_{C0}$ )	$T_0$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 4.60 \times 10^7$ ; $\log T_0 = 7.66$ $6.88 \leq \log T_0 \leq 8.40$ ; yesX; no <input type="checkbox"/>	Dirty conditions 1 min
	$10^{-4}$	>330	>330		
	$10^{-5}$	45	47		

**Drying controls**

Drying control ( $D_{Ct}$ )	$T_t$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 5.25 \times 10^7$ ; $\log T_t = 7.72$ $6.88 \leq \log T_t \leq 8.40$ ; yesX; no <input type="checkbox"/>	Dirty conditions 1 min
	$10^{-4}$	>330	>330		
	$10^{-5}$	42	62		

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**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	$10^0$	2	2	<14	<1.15	>6.57	1 min	Dirty
	$10^{-1}$	0	0					

**Test field 2 to 4 (cfu/25cm<sup>2</sup>)**

Real conc. of the product %	Dilution step	$V_{CT2}$	$V_{CT3}$	$V_{CT4}$	$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} \times 5)$ cfu/25cm <sup>2</sup>	Contact time (min)	Conditions
Ready to use	$10^0$	2	0	0	<5	1 min	Dirty
	$10^{-1}$	0	0	0	<5		

**$N_w$  Test fields 2 to 4 (cfu/25cm<sup>2</sup>)**

Real conc. of the product %	Dilution step	$V_{CT2}$	$V_{CT3}$	$V_{CT4}$	$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} \times 5)$ cfu/25cm <sup>2</sup>	Contact time (min)	Conditions
Ready to use	$10^0$	>330	>330	>330	1633.33	1 min	Dirty
	$10^{-1}$	49	32	17			

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: 22.03.2021

Responsible person: Allar Laaneleht, Melissa Ingela Bramanis

### Validation and controls

Validation suspension ( $N_{V0}$ )			Neutralizer control (B)			Method validation (C)		
$V_{C1}$	49	$\bar{x} = 45.5$	$V_{C1}$	36	$\bar{x} = 37.5$	$V_{C1}$	30	$\bar{x} = 35.5$
$V_{C2}$	42		$V_{C2}$	39		$V_{C2}$	41	
$30 \leq \bar{x} N_{V0} \leq 160$ ? yes X; no <input type="checkbox"/>			$\bar{x}$ of B is $\geq 0.5 \times \bar{x}$ of $N_{V0}$ ? (or $N_V/1000$ ) yes X; no <input type="checkbox"/>			$\bar{x}$ of C is $\geq 0.5 \times \bar{x}$ of $N_{V0}$ ? yes X; no <input type="checkbox"/>		

### Test suspension and test

Test-suspension ( $N$ and $N_0$ ):	$N$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 1.68 \times 10^9$ ; $\log N = 9.23$ $N_0 = N/20$ ; $\log N_0 = 7.92$ $6.88 \leq \log N_{V0} \leq 7.40$ ; yes X; no <input type="checkbox"/>
	$10^{-7}$	162	173	
	$10^{-8}$	19	16	

### Drying controls

Drying control ( $D_{C0}$ )	$T_0$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 3.70 \times 10^7$ ; $\log T_0 = 7.57$ $6.88 \leq \log T_0 \leq 8.40$ ; yes X; no <input type="checkbox"/>	Dirty conditions 1 min
	$10^{-4}$	>330	>330		
	$10^{-5}$	36	38		

### Drying controls

Drying control ( $D_{Ct}$ )	$T_t$	$V_{C1}$	$V_{C2}$	$\bar{x}_{wm} = 4.10 \times 10^7$ ; $\log T_t = 7.61$ $6.88 \leq \log T_t \leq 8.40$ ; yes X; no <input type="checkbox"/>	Dirty conditions 1 min
	$10^{-4}$	>330	>330		
	$10^{-5}$	40	42		

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**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	$10^0$	9	4	<14	<1.15	>6.46	1 min	Dirty
	$10^{-1}$	0	0					

**Test field 2 to 4 (cfu/25cm<sup>2</sup>)**

Real conc. of the product %	Dilution step	$V_{CT2}$	$V_{CT3}$	$V_{CT4}$	$V_{T2to4} (= \bar{x} \text{ or } \bar{x}_{wm} \times 5)$ cfu/25cm <sup>2</sup>	Contact time (min)	Conditions
Ready to use	$10^0$	0	0	0	<5	1 min	Dirty
	$10^{-1}$	0	0	0	<5		

**$N_w$  Test fields 2 to 4 (cfu/25cm<sup>2</sup>)**

Real conc. of the product %	Dilution step	$V_{CT2}$	$V_{CT3}$	$V_{CT4}$	$V_{NWT2to4} (= \bar{x} \text{ or } \bar{x}_{wm} \times 5)$ cfu/25cm <sup>2</sup>	Contact time (min)	Conditions
Ready to use	$10^0$	>330	>330	>330	>16500	1 min	Dirty
	$10^{-1}$	>330	>330	>330			

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 **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  $20 \pm 1$  °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

Date of issue: 29.03.2021