Nordic Tersus
Laboratory

Test report no. 171024sd

EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY OF DISINFECTANTS AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13624)

Name of the product: BACTICID AF
Batch number: 197050124
Date of test report: 14/06/2024

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

EAK
EN ISO/IEC 17025
L263

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EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY OF DISINFECTANTS AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13624)

Name of the product*:	BACTICID AF
Batch number*:	197050124
Order number:	20307
Manufacturer*:	Chemi-Pharm Ltd.
Client, representative*:	Chemi-Pharm Ltd., Tänassilma tee 11; Tänassilma küla; Saku vald 76406; ESTONIA; Siimu Rom, +37253604748.
Date of delivery:	11.06.2024
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.*:	Ethanol 57g/100g, isopropanol 6g/100g
Appearance of the product:	Transparent, colourless liquid
Test concentration:	80%, 50%, 10%
Contact time:	15 seconds and 30 seconds
Interfering substance:	3 g/l bovine albumin solution + 3 ml/l sheep blood erythrocytes (dirty conditions)
Neutralizer:	-
Rinsing liquid:	Tryptone 1 g/l + NaCl, 9 g/l
Test organisms:	*Candida albicans* ATCC 10231
Testing method:	EVS-EN 13624:2021 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)
Testing period:	12.06.2024 – 14.06.2024
Results:	look appendix 1
Interpretation and conclusion:	look appendix 2

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Kerda Treksler
Microbiologist
Date of test report: 14.06.2024

** - Data provided by the customer*

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Appendix 1

TEST RESULTS (yeasticidal suspension test)

EVS-EN 13624:2021; Phase 2, step 1
Membrane filtration method
Product diluent: Glass-Distilled water
Appearance of product solutions: Transparent, colourless liquid
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l
Test organism: *Candida albicans* ATCC 10231
Test temperature: +20° C; Incubation temperature: +30 °C
Interfering substance: 3 g/l bovine albmin solution + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 12.06.2024
Responsible person: Kerda Treksler

Validation and controls

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$
44	52	48	63	49	56	45	45	45	52	69	60.5
$30 \leq \bar{x}\ N_{vo} \leq 160$? yes X; no □			$\bar{x}$ A is $\geq 0.5\ \bar{x}\ N_{vo}$? yes X; no □			$\bar{x}$ B is $\geq 0.5\ \bar{x}\ N_{vo}$? yes X; no □			$\bar{x}$ C is $\geq 0.5\ \bar{x}\ N_{vo}$? yes X; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.91 \times 10^7$; $\log N = 7.28$
N and N_0	10^{-5}	190	203	$N_0 = N/10$; $\log N_0 = 6.28$
	10^{-6}	18	10	$6.17 \leq \log N_0 \leq 6.70$; yes X; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	< 2.15	> 4.13	15 sec	Dirty
50.0%	-	>165	>165	>1650	> 3.22	< 3.06	15 sec	Dirty
10.0%	-	>165	>165	>1650	> 3.22	< 3.06	15 sec	Dirty
80.0%	-	<14	<14	<140	< 2.15	> 4.13	30 sec	Dirty
50.0%	-	>165	>165	>1650	> 3.22	< 3.06	30 sec	Dirty
10.0%	-	>165	>165	>1650	> 3.22	< 3.06	30 sec	Dirty

Explanations:

V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 2

Interpretation:

The ready to use product **BACTICID AF** (batch no. 197050124) was tested according to the test method EVS-EN 13624:2021. The test was performed at 20 °C ± 1 °C under dirty conditions with the contact times of 15 seconds and 30 seconds. The membrane filtration method was used for testing the product's effectiveness against the reference strain *Candida albicans* ATCC 10231. Under dirty conditions the tested product was effective against *Candida albicans* within 15 seconds.

Conclusion:

The surviving count of reference strain showed at least 4lg reduction meaning that **according to EVS-EN 13624:2021 under dirty conditions the sample of the ready to use product BACTICID AF is effective against *Candida albicans* within 15 seconds.**

The results apply exclusively to the tested sample of the product with batch no. 197050124.

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Kerda Treksler
Microbiologist
Date of test report: 14.06.2024