Nordic Tersus
Laboratory

Test report No. 168024hd

EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY IN THE MEDICAL AREA (EN 13624)

Name of the product: CHEMISEPT GEL

Batch number: 198190821/3
Date of test report: 11/06/2024

Digitally signed by Moraru Grigore
Date: 2024.10.14 11:32:16 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

EAK
EN ISO/IEC 17025
L263

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Laboratory

Test report No. 168024hd

EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY IN THE MEDICAL AREA (EN 13624)

Name of the product*:	**CHEMISEPT GEL**
Batch number*:	198190821/3
Order number:	20049
Manufacturer*:	Chemi-Pharm Ltd.
Client, representative*:	Chemi-Pharm Ltd., Tänassilma tee 11; Tänassilma küla; Saku vald 76406; ESTONIA; Siimu Rom, +37253604748
Date of delivery:	29.03.2022
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	At room temperature, darkness
Active substance – conc.*:	Ethyl alcohol 72.5% w/w, isopropyl alcohol 7.5% w/w
Appearance of the product:	Transparent, colourless liquid
Test concentration:	80.0 %, 50.0 %, 10.0 %
Contact time:	15 s
Interfering substance:	3.0 g/l bovine albumin + 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 date:	15.12.2021 – 17.12.2021
Results:	Look appendix 1
Interpretation and conclusion:	Look appendix 2

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Nele Aas-Valleriani
Laboratory Manager
Date of issue: 11.06.2024

** - Data provided by the customer*

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TEST RESULTS (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
Test organism: *Candida albicans* ATCC 10231
Test temperature: +20° C; Incubation temperature: +30 ± 1° C
Interfering substance: 3g/l bovine albumin + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 15.12.201
Responsible person: Melissa Ingela Bramanis

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions (A)			Neutralizer 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}	$\bar{x}$
91	86	88.5	92	82	87	73	63	68	69	80	74.5
$30 \leq \bar{x}\ N_{vo} \leq 160$? yes ☒; no ☐			$\bar{x}$ **A** is $\geq 0.5\ \bar{x}\ N_{vo}$? yes ☒; no ☐			$\bar{x}$ **B** is $\geq 0.0005\ \bar{x}\ N_{vB}$? yes ☒; no ☐			$\bar{x}$ **C** is $\geq 0.5\ \bar{x}\ N_{vo}$? yes ☒; no ☐		

Test suspension and test

Test suspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 3.07 \times 10^7$; $\log N = 7.49$
N and N_0	10^{-5}	**330**	**279**	$N_0 = N/10$; $\log N_0 = 6.49$
	10^{-6}	**26**	**41**	$6.17 \leq \log N_0 \leq 6.70$; yes ☒; no ☐

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	lg*Na*	*lg*R	Contact time	Conditions
80.0 %	-	<14	<14	<140	<2.15	>4.34	15 s	Dirty
50.0 %	-	<14	<14	<140	<2.15	>4.34	15 s	Dirty
10.0 %	-	>165	>165	>1650	>3.22	<3.27	15 s	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 test suspension
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*)

Interpretation:

The ready to use hand disinfection product **CHEMISEPT GEL** (batch no. 198190821/3) 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 time of 15 s. The membrane filtration method was used for testing the product's effectiveness against the reference strain *Candida albicans* ATCC 10231. Under dirty conditions, the 80.0 % solution of the tested sample of the product was effective against the reference strain *Candida albicans* within contact time tested.

Conclusion:

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

The results apply exclusively to the tested sample of the product with batch no. 198190821/3.

This is the corrected version of the test report no. 028022hd. The results of the previous test report remain valid.

This is the end of the test report.

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Nele Aas-Valleriani
Laboratory Manager
Date of issue: 11.06.2024