

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

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





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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

NORDIC TÉRSUS Nele Aas-Valleriani Laboratory Manager

Date of issue: 11.06.2024

* - Data provided by the customer



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CHEMISEPT GEL EVS-EN 13624:2021

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Appendix 1

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: $+20^{\circ}$ C; Incubation temperature: $+30 \pm 1^{\circ}$ 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}	Χ	V _{C1}	V_{C2}	Σ̈	V_{C1}	V_{C2}	x	V _{C1}	V_{C2}	Χ	
91	86	88.5	92	82	87	73	63	68	69	80	74.5	
3	30 ≤ x N _{vo} ≤160?			$\bar{x} \mathbf{A} \text{ is } \ge 0.5 \ \bar{x} \mathbf{N}_{vo}$?			х̄ B is ≥ 0.0005 х̄ N _{vB} ?			x̄ C is ≥ 0.5 x̄ N _{vo} ?		
yes ⊠; no □			yes ⊠; no 🗆			yes ⊠; no □			yes ⊠; no □			

Test suspension and test

Test suspension:	Ν	V _{C1}	V_{C2}	$\bar{x}_{wm} = 3.07 \times 10^7$; $\log N = 7.49$			
N	10 ⁻⁵	330	279	$N_0 = N/10$; $\log N_0 = 6.49$			
N and N₀	10 ⁻⁶	26	41	6.17 ≤ log N o≤ 6.70; yes ⊠; no □			

Experimental results

Concentration of the product %	Dilution step	V _{C1}	V _{C2}	Na (=x̄*10)	lg <i>Na</i>	<i>lg</i> 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)

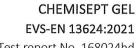
N = cfu/ml microbes in test suspension

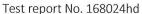
 N_0 = cfu/ml at the start of the contact time (t=0)

 N_{vo} = cfu/ml in the validation suspension (t=0)

Na =surviving microbes after the test

R = reduction factor (R= N_0/Na ; LogR=Log N_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.

Nele Aas-Valleriani aboratory Manager Date of issue: 11.06.2024