



Test report No. 15419hd

EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY IN FOOD, INDUSTRIAL,
DOMESTIC AND INSTITUTIONAL AREAS (EN 1650)

Name of the product: CHEMISEPT MED

Batch number: 196300919

Date of test report: 25/11/2019

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

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Name of the product: CHEMISEPT MED
Batch number: 196300919
Order number: 19033
Manufacturer: Chemi-Pharm Ltd.
Client, representative: Chemi-Pharm Ltd., Tännassilma tee 11, Tännassilma, 76406 Harju maakond, Estonia
Maris Millner, +372-51-77-090
Date of delivery: 04.10.2019
Test material conditions: No specific features, sample in the manufacturers tare
Storage conditions: In room temperature, dark
Active substance – conc.: Ethyl alcohol 72.5% w/w, isopropyl alcohol 7.5% w/w
Appearance of the product: Transparent liquid
Test concentration: 80%; 50%; 10%
Contact time: 15 s
Interfering substance: 3.0 g/l bovine albumin = dirty conditions
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l
Neutralizer: -
Test organisms: *Candida albicans* ATCC 10231
Testing method: EVS-EN 1650:2019
Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.
Testing date: 07.10.2019 – 09.10.2019
Results: look appendix 1-2




Nete Aas-Valleriani
Microbiologist

Date of test report: 25.11.2019

Appendix 1

TEST RESULTS (suspension test)

EVS-EN 1650:2019; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l;
Test organism: *Candida albicans* ATCC 10231;
Test temperature: +20° C; Incubation temperature: +30 ± 1° C
Interfering substance: 3.0 g/l bovine albumin = dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 07.10.2019
Responsible person: Nele Aas-Valleriani

Validation and controls

Dirty conditions

| 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} |
| 147 | 150 | 148.5 | 141 | 134 | 137.5 | 134 | 116 | 125 | 122 | 125 | 123.5 |
| $30 \leq \bar{x} N_{vo} \leq 160$? yes X; no <input type="checkbox"/> | | | $\bar{x} A$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no <input type="checkbox"/> | | | $\bar{x} B$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no <input type="checkbox"/> | | | $\bar{x} C$ is $\geq 0.5 \bar{x} N_{vo}$? yes X; no <input type="checkbox"/> | | |

Test suspension and test

| | | | | |
|------------------|-----------|----------|----------|--|
| Test suspension: | N | V_{C1} | V_{C2} | $\bar{x}_{wm} = 5.00 \times 10^7$; $\log N = 7.70$ $N_0 = N/10$; $\log N_0 = 6.70$ $6.17 \leq \log N_0 \leq 6.70$; yes X; no <input type="checkbox"/> |
| N and N_0 | 10^{-5} | 485 | 489 | |
| | 10^{-6} | 58 | 68 | |

Experimental results

| Concentration of the product | Dilution step | V_{C1} | V_{C2} | N_a ($=\bar{x} \cdot 10$) | $\log N_a$ | $\log R$ | Contact time | Conditions |
|------------------------------|---------------|----------|----------|-------------------------------|------------|----------|--------------|------------|
| 10% | - | >165 | >165 | >1650 | >3.22 | <3.48 | 15 s | Dirty |
| 50% | - | 44 | 106 | 750 | 2.88 | 3.82 | 15 s | Dirty |
| 80% | - | 18 | 24 | 210 | 2.32 | 4.38 | 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 testsuspension
 N_0 = cfu/ml at the start of the contact time (t=0)
 N_{vo} = cfu/ml in the validation suspension (t=0)
 N_a = surviving microbes after the test
 R = reduction factor ($R = N_0 / N_a$; $\log R = \log N_0 - \log N_a$)

Appendix 2

Interpretation:

The ready to use product CHEMISEPT MED (batch no. 196300919) was tested according to the test method 1650:2019. The test was performed at $20\text{ °C} \pm 1\text{ °C}$, under dirty conditions during 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 tested product was effective against the reference strain within contact time tested.

Conclusion:

The surviving count of the reference strains showed at least 4 lg reduction meaning that the ready to use product CHEMISEPT MED is effective against *C.albicans* ATCC 10231 under dirty conditions within 15 s.




Nele Aas-Valleriani
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25.11.2019