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Sample: 200679058 Order: 5434588 Client: 10089634



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Taunusstein, 23.10.2020

Report 5434588-07

Quantitative suspension test of yeasticidal activity according to DIN EN 1650:2019

Sample entry: 09.07.2020

Sample designation: Bacoban WB

LOT: 2005159

Active substance: 26.0 g benzalkonium chloride

2.5 g sodium pyrithione

Sample storage: Room temperature





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EN 1650

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Test conditions:

EN 1650: Chemical disinfectant and antiseptics - Quantitative suspension test for the

evaluation of fungicidal and yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test

method and requirements (phase 2, step 1) - EN1650:2019

Test organisms: Candida albicans ATCC 10231

Test suspension: $1.5 - 5.0 \times 10^7 \text{ cfu/mL}$

Contact time: 5 min

20 °C Temperature:

Product concentration: 1%

> 0.5 % 0.05%

Protein contamination: dirty (0.3% albumin)

Test method: Dilution-Neutralization-Method

Membrane filtration

Neutralization: 3% Polysorbate 80, 0.3% Lecithin, 0.1% Histidine,

0.5% Na-thiosulfate, 3% Saponin

Incubation: Malt agar plates for 48 h at 36 ± 1 °C

Test period: 31.08.2020 - 03.09.2020

02.10.2020 - 05.10.2020

Requirement: 4-log (99.99%) reduction of fungi



Sample:



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Table 1: Test results using pour plate and membrane filtration method according to DIN EN 1650 (Sample number 200679058)

	Validation					Contact time: 5 min, Protein load: dirty			
Test organism	Fungi suspension	Experimental conditions	Control of neutralization	Process validation	Fungi test suspension		1 % ⁽¹⁾	0.5 %	0.05 %
Candida albicans (ATCC 10231)	$\begin{array}{c} V_c (10^{-1}): 112/108 \\ V_c (10^{-2}): 9/10 \\ N_v: 1.10 \times 10^3 \\ V_c (10^{-1}): 100/112 \\ V_c (10^{-2}): 12/17 \\ N_v: 1.26 \times 10^3 \end{array}$	V _c : 112/118 A = 115 V _c : 126/120 A _{80%} = 123	V _c : 135/148 B = 142 V _c : 100/120 B _{80%} = 110	V _c : 136/80 C = 108	10 ⁻⁵ : >330/>330 10 ⁻⁶ : 37/35 N: 3.60 x 10 ⁷ 10 ⁻⁵ : >165/>165 10 ⁻⁶ : 44/34 N: 3.90 x 10 ⁷	V _c (10 ⁻¹): V _c (10 ⁻²):	0/0 0/0 0/0 <140 >2.79 x 10 ⁴ > 4.45	n.a. 38/41 3/4 3.95 x 10 ³ 9.11 x 10 ² 2.96	>330/>330 >330/>330 >330/>330 >3.30 x 10 ⁵ <1.09 x 10 ¹ <1.04
V _c N R N _a	Viable fungi count (colony forming units = cfu) cfu per ml fungi test suspension Reduction of fungi count cfu per ml test mixture			N _v cfu per ml fungi suspension A cfu per ml (WSH control) B cfu per ml (method control) C cfu per ml (process validation)					

⁽¹⁾The Dilution-Neutralization-Method was not suitable, therefore Membrane filtration was performed for 1% product concentration.

n.a.= not applicable





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Evaluation:

The results show that the product Bacoban WB meets the required yeasticidal activity according to standard EN 1650 since a reduction of 4 log was achieved for Candida albicans at a contact time of 5 min under the given conditions:

1 % product concentration - 5 min - dirty conditions

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i. V. Sebastian Vogel **GROUP LEADER BIOSERVICE** CUSTOMER SERVICE CONSULTANT

The test results refer exclusively to the examined test items and the date of the test under the test specifications.

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