

SGS INSTITUT FRESENIUS GmbH · Postfach 1261 · 65220 Taunusstein

Biodyozon GmbH
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Sample: 210332491
Order: 5722676
Client: 10197738



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Cosmetics & Hygiene – BioServices

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Taunusstein, 07.05.2021

Report 5722676-02-V1

This (e)report is a free translation of (e)report 5722676-01-V1. In the event of any contradiction between both texts, the German text prevails.

Quantitative suspension test of bactericidal activity according to EN 1276:2019

Sample entry: 30.03.2021
Sample designation: Biodyozon 500ppm
Test period: 13.04.2021 – 16.04.2021

Summary:

The results show that the product meets the required bactericidal activity according to standard EN 1276 since a 5 log reduction was achieved under the given conditions. Detailed conclusion is found on page 5, evaluation.

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Scope of test

Evaluation of bactericidal activity for **Biodyozon 500ppm** according to **EN 1276:2019** *Chemical disinfectant and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1).*

Identification of sample

| | |
|---|--|
| Name of product | Biodyozon 500ppm |
| Batch no. | - |
| Production date | - |
| Expiry date | - |
| Active compound (s) | >500 ppm active chlorine/hypochlorous acid |
| Appearance, odour | Colorless, clear, product specific |
| pH-values | Undiluted: <5.0 (20 °C) |
| Storage conditions | Room temperature |
| The sample was used like handed by the costumer | |

Test conditions:

| | |
|--------------------------|--|
| Test organism(s) | <i>Escherichia coli</i> K12 NCTC 10538 <i>Enterococcus hirae</i> ATCC 10541 <i>Staphylococcus aureus</i> ATCC 6538 <i>Pseudomonas aeruginosa</i> ATCC 15442 |
| Test suspension | 1.5 – 5.0 x 10 ⁸ cfu/mL |
| Incubation | Caso agar plates for 48 h at 36 ± 1 °C |
| Test method | Dilution-Neutralization-Method |
| Neutralization | 3% Polysorbate 80, 0.3% Lecithin, 0.1% Histidine, 0.5% Na-thiosulfate, 3% Saponin |
| Temperature | 20 °C |
| Contact time | 30 seconds |
| Product concentration | Undiluted (80%) 50% 1% |
| Interfering substance(s) | Clean (0.03% albumin) |

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Results

Table 1: Validation using pour plate method

| Test organism | Bacteria suspension | | Validation | | |
|---|---------------------|-------------------------------------|-----------------------------------|-----------------------------|--------------------------|
| | | | Experimental conditions A | Control of neutralization B | Process Validation C |
| Validation criteria | N: | $1.5 \times 10^8 - 5.0 \times 10^8$ | $\geq 0.5 \times N_{v0}$ | $\geq 0.5 \times N_{v0}$ | $\geq 0.5 \times N_{v0}$ |
| | N ₀ : | $1.5 \times 10^7 - 5.0 \times 10^7$ | | | |
| | N _v : | $3.0 \times 10^2 - 1.6 \times 10^3$ | | | |
| | N _{v0} : | $3.0 \times 10^1 - 1.6 \times 10^2$ | | | |
| <i>Escherichia coli</i> K12 (NCTC 10538) | N: | 2.48×10^8 | 70 | 81 | 69 |
| | N ₀ : | 2.48×10^7 | | | |
| | N _v : | 7.60×10^2 | | | |
| | N _{v0} : | 8.90×10^1 | | | |
| <i>Enterococcus hirae</i> (ATCC 10541) | N: | 4.55×10^8 | 148 | 124 | 162 |
| | N ₀ : | 4.55×10^7 | | | |
| | N _v : | 1.49×10^3 | | | |
| | N _{v0} : | 1.50×10^2 | | | |
| <i>Staphylococcus aureus</i> (ATCC 6538) | N: | 2.72×10^8 | 46 | 39 | 44 |
| | N ₀ : | 2.72×10^7 | | | |
| | N _v : | 5.05×10^2 | | | |
| | N _{v0} : | 4.95×10^1 | | | |
| <i>Pseudomonas aeruginosa</i> (ATCC 15442) | N: | 1.55×10^8 | 56 | 47 | 48 |
| | N ₀ : | 1.55×10^7 | | | |
| | N _v : | 4.70×10^2 | | | |
| | N _{v0} : | 4.30×10^1 | | | |
| colony forming units = cfu | | | | | |
| N cfu per ml test suspension | | | A cfu per ml (WSH control) | | |
| N ₀ cfu per ml test suspension N/10 | | | B cfu per ml (method control) | | |
| N _v cfu per ml validation suspension | | | C cfu per ml (process validation) | | |
| N _{v0} cfu per ml validation suspension N _v /10 | | | | | |

The results show that the validation criteria are according EN 1276 chapter 5.7.3

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Table 2: Test results using pour plate method

| Test organism | Contact time: 30 seconds, Interfering substance(s): clean (0.03% albumin) | | | | | | |
|--|--|-------------------------|---|-------------------------|---|-------------------------|------|
| | | 80 % | | 50% | | 1% | |
| <i>Escherichia coli K12</i> (NCTC 10538) No: 2.48 x 10 ⁷ | V _c (10 ⁰): | 0 | 0 | 0 | 0 | >330 | >330 |
| | V _c (10 ⁻¹): | 0 | 0 | 0 | 0 | >330 | >330 |
| | V _c (10 ⁻²): | 0 | 0 | 0 | 0 | >330 | >330 |
| | N _a : | <140 | | <140 | | >3.30 x 10 ⁵ | |
| | R: | >1.77 x 10 ⁵ | | >1.77 x 10 ⁵ | | <7.52 x 10 ¹ | |
| | R (log): | >5.26 | | >5.26 | | <1.88 | |
| <i>Enterococcus hirae</i> (ATCC 10541) No: 4.55 x 10 ⁷ | V _c (10 ⁰): | 0 | 0 | 0 | 0 | >330 | >330 |
| | V _c (10 ⁻¹): | 0 | 0 | 0 | 0 | >330 | >330 |
| | V _c (10 ⁻²): | 0 | 0 | 0 | 0 | >330 | >330 |
| | N _a : | <140 | | <140 | | >3.30 x 10 ⁵ | |
| | R: | >3.25 x 10 ⁵ | | >3.25 x 10 ⁵ | | <1.38 x 10 ² | |
| | R (log): | >5.51 | | >5.51 | | <2.14 | |
| <i>Staphylococcus aureus</i> (ATCC 6538) No: 2.72 x 10 ⁷ | V _c (10 ⁰): | 0 | 0 | 0 | 0 | >330 | >330 |
| | V _c (10 ⁻¹): | 0 | 0 | 0 | 0 | >330 | >330 |
| | V _c (10 ⁻²): | 0 | 0 | 0 | 0 | >330 | >330 |
| | N _a : | <140 | | <140 | | >3.30 x 10 ⁵ | |
| | R: | >1.94 x 10 ⁵ | | >1.94 x 10 ⁵ | | <8.24 x 10 ¹ | |
| | R (log): | >5.29 | | >5.29 | | <1.92 | |
| <i>Pseudomonas aeruginosa</i> (ATCC 15442) No: 1.55 x 10 ⁷ | V _c (10 ⁰): | 0 | 0 | 0 | 0 | >330 | >330 |
| | V _c (10 ⁻¹): | 0 | 0 | 0 | 0 | >330 | >330 |
| | V _c (10 ⁻²): | 0 | 0 | 0 | 0 | >330 | >330 |
| | N _a : | <140 | | <140 | | >3.30 x 10 ⁵ | |
| | R: | >1.11 x 10 ⁵ | | >1.11 x 10 ⁵ | | <4.70 x 10 ¹ | |
| | R (log): | >5.05 | | >5.05 | | <1.67 | |

colony forming units = cfu

V_c Viable bacterial count per dilution

N_a Total viable count per test mixture (cfu per ml)

R Reduction of bacterial count (N₀/N_a)

bold = required 5 log reduction according EN 1276 achieved

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Evaluation:

The results show that the product **Biodyozon 500ppm** meets the required bactericidal activity according to EN 1276 since a reduction of 5 log was achieved for all tested microorganisms under following conditions:

≥ 50% product concentration – 30 seconds contact time – clean conditions (0.03% albumin)

SGS INSTITUT FRESENIUS GmbH



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