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Biodyozon GmbH
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Sample: 210332491
Order: 5722676
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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)	*Escherichia coli K12* NCTC 10538 *Enterococcus hirae* ATCC 10541 *Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* 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)

Results

Table 1: Validation using pour plate method

Test organism	Validation: Bacteria suspension		Validation: Experimental conditions A	Validation: Control of neutralization B	Validation: Process Validation C
Validation criteria	N:	$1.5 \times 10^8 – 5.0 \times 10^8$	≥ 0.5 x N_{v0}	≥ 0.5 x N_{v0}	≥ 0.5 x 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}:	$3.0 \times 10^1 – 1.6 \times 10^2$			
Escherichia coli 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			
Enterococcus hirae (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			
Staphylococcus aureus (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			
Pseudomonas aeruginosa (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		
N_0	cfu per ml test suspension N/10	A	cfu per ml (WSH control)
N_v	cfu per ml validation suspension	B	cfu per ml (method control)
N_{v0}	cfu per ml validation suspension N_v/10	C	cfu per ml (process validation)

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

Table 2: Test results using pour plate method

Test organism		Contact time: 30 seconds, Interfering substance(s): clean (0.03% albumin)					
		80 %		50%		1%	
Escherichia coli K12 (NCTC 10538) N_0: 2.48×10^7	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		$>3.30 \times 10^5$	
	R:	$>1.77 \times 10^5$		$>1.77 \times 10^5$		$<7.52 \times 10^1$	
	R (log):	**>5.26**		**>5.26**		<1.88	
Enterococcus hirae (ATCC 10541) N_0: 4.55×10^7	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		$>3.30 \times 10^5$	
	R:	$>3.25 \times 10^5$		$>3.25 \times 10^5$		$<1.38 \times 10^2$	
	R (log):	**>5.51**		**>5.51**		<2.14	
Staphylococcus aureus (ATCC 6538) N_0: 2.72×10^7	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		$>3.30 \times 10^5$	
	R:	$>1.94 \times 10^5$		$>1.94 \times 10^5$		$<8.24 \times 10^1$	
	R (log):	**>5.29**		**>5.29**		<1.92	
Pseudomonas aeruginosa (ATCC 15442) N_0: 1.55×10^7	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		$>3.30 \times 10^5$	
	R:	$>1.11 \times 10^5$		$>1.11 \times 10^5$		$<4.70 \times 10^1$	
	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 (N_0/ N_a)

bold = required 5 log reduction according EN 1276 achieved

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)

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-End of Report-