

SGS Germany GmbH Postfach 80 06 67 D-21006 Hamburg

ROPIMEX R. Opel GmbH
Frau Sahl / Herr Dr. Kreischer
Bildstocker Str. 12

D-66537 Neunkirchen

Test report 3307943/EN

Order-No.: 3761222
Client No.: 10089634

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SGS Germany GmbH
Weidenbaumsweg 137
21035 Hamburg

Hamburg, 2017-03-24

This test report substitutes testreport 3044608 from 2016-08-26.

Your Order/Project: Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants used in medical area; according to DIN EN 13727:2015

Your Order-No.: /
Your Order Date.: 2016-05-22

General Information

Sample-No.:	160514707
Name of the product	Bacoban WB
Batch-No.:	LOT 1605253 / 05/2018, 25.05.2016
Date of delivery of the product:	2016-06-01
Period of testing:	2016-08-04 / 2016-08-12

Comment / summary:

Results and the resulting ratings see following pages.

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i.A. Michael Pietzko / i. A. Sarah Korsch (Laboratory assistants)
i.A. Nicole Hollmann (Scientific Assistant Microbiology) /
i.V. Heidrun Globisch (Teamleader Microbiology) /
i.V. Olaf Böhmer (Teamleader Microbiology Cosmetics/Packaging)

O. Böhmer

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SGS Germany GmbH

Rödingsmarkt 16 D-20459 Hamburg www.de.sgs.com

Geschäftsführer: Stefan Steinhardt, Aufsichtsratsvorsitzender: Dirk Hellemans
Sitz der Gesellschaft: Hamburg, HRB 4951, Amtsgericht Hamburg

Die Prüfergebnisse beziehen sich auf die untersuchten Proben. Die Veröffentlichung und Vervielfältigung unserer Prüfberichte und Gutachten zu Werbezwecken sowie deren auszugsweise Verwendung in sonstigen Fällen bedürfen unserer schriftlichen Genehmigung. Alle Dienstleistungen werden auf Grundlage der anwendbaren Allgemeinen Geschäftsbedingungen der SGS, die auf Anfrage zur Verfügung gestellt werden, erbracht.
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Disinfectant sample

Name of the product:	Bacoban WB
Batch-No:	LOT 1605253 / 05/2018, 25.05.2016
Manufacturer:	ROPIMEX R. Opel GmbH, Bildstocker Str. 12, 66538 Neunkirchen
Storage condition:	room temperature
Appearance of the product:	yellow liquid
Active ingredients in 100 g of the product:	<20 % Diethylene glycol <10 % Inorganic-organic polymer, made from silanes with EINECS registration 26 % Benzalkonium chloride 2,5% Pyridine-2-thio-1-oxide, sodium salt < 2 % Perfume mix

Experimental conditions

Method:	dilution-neutralization-method
Neutralizer:	3% polysorbate 80 +3% saponine + 0,3% lecithin + 0,1% histidine + 0,5% sodium thiosulphate dissolved in dilution-solution
Counting method:	pour plate process
Conditions:	
Contact times:	5 and 60 min +/- 10 s
Test concentrations:	3 %; 1 %; 0,5 %
Test temperature:	20 °C +/- 1°C
Interfering substance:	0,3 % bovine serum albumin + 0,3 % sheep blood erythrocytes (dirty conditions)
Test organisms:	<i>Staphylococcus aureus</i> ATCC 6538 <i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Enterococcus hirae</i> ATCC 10541
Incubation temperature:	37 °C +/- 1°C
Stability of the product in the test:	the product testing solutions were bright and clear

Conclusion:

According to DIN EN 13727:2015 the product **Bacoban WB** with the batch 1605253 possesses bactericidal activity for a disinfectant, when diluted to 1,0 % (v/v) during the test at 20°C +/- 1°C, 5 min +/- 10s contact time and dirty conditions for the above mentioned test organisms (required reduction: log 5).

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Test organism: *Staphylococcus aureus*
Test temperature: 20 °C +/- 1 °C
Test date: 2016-08-04 / 2016-08-10
Interfering: 0,3 % bovine serum albumin + 0,3% sheep blood erythrocytes (dirty conditions)

Table 1a - Verification of the methodology and validation of the neutralization method

Validation suspension (Nv ₀)			Experimental conditions control (A) 5 min			Neutralizer control (B)			Method validation (C) product conc.: 3% 5 min		
Vc1	32	31	Vc1	38	37	Vc1	33	32,5	Vc1	0	0
Vc2	30		Vc2	36		Vc2	32		Vc2	0	
30 ≤ x of Nv0 ≤ 160? ☒ yes ☐ no			x of A is ≥ 0,5 * x of Nv0? ☒ yes ☐ no			x of B is ≥ 0,5 * x of Nv0? ☒ yes ☐ no			x of C is ≥ 0,5 * x of Nv0? ☐ yes ☒ no		
			Experimental conditions control (A) 60 min						Method validation (C) product conc.: 3% 60 min		
			Vc1	47	44				Vc1	0	0
			Vc2	41					Vc2	0	
			x of A is ≥ 0,5 * x of Nv0? ☒ yes ☐ no						x of C is ≥ 0,5 * x of Nv0? ☐ yes ☒ no		

Table 1b: Test suspension

Test suspension (N and N ₀)	N	Vc1	Vc2	Nx _{wm} 1,33E+08
	10 ⁻⁶	123	143	N ₀ = N/10 = 7,12 lg
	10 ⁻⁷	12	12	7,17 ≤ N ₀ ≤ 7,70 ? ☐ yes ☒ no

Table 1c - Verification of the methodology and validation of the neutralization method

Validation suspension (Nv ₀)			Method validation (C) product conc.: 0,5 % 5 min		
Vc1	50	47	Vc1	32	32,5
Vc2	44		Vc2	33	
30 ≤ x of Nv0 ≤ 160? ☒ yes ☐ no			x of C is ≥ 0,5 * x of Nv0? ☒ yes ☐ no		
			Method validation (C) product conc.: 0,5 % 60 min		
			Vc1	67	68,5
			Vc2	70	
			x of C is ≥ 0,5 * x of Nv0? ☒ yes ☐ no		

Table 1d: Test suspension

Test suspension (N and N ₀)	N	Vc1	Vc2	Nx _{wm} 2,17E+08
	10 ⁻⁶	241	194	N ₀ = N/10 = 7,34 lg
	10 ⁻⁷	22	20	7,17 ≤ N ₀ ≤ 7,70 ? ☒ yes ☐ no

Explanations:

Vc = count per ml

$\bar{x}$ = average of Vc1 and Vc2

(1.+2.duplicate)

$\bar{x}_{wm}$ = weighted mean of $\bar{x}$

R = reduction (lgR = lg N₀ - lg N_a)

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Test organism: *Staphylococcus aureus*
Test temperature: 20 °C +/- 1°C
Test date: 2016-08-04 / 2016-08-10
Interfering: 0,3 % bovine serum albumin + 0,3% sheep blood erythrocytes (dirty conditions)

Table 1e: Test

Conc. of the product during the test (v/v)	Dilution	Na ₀		Na ₀ x * 10	lg Na	lg R (N ₀ =7,12/7,36)	contact time (min)
		Vc ₁	Vc ₂				
3,0	10 ⁰	0	0	<140	<2,15	>4,97	5
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
1,0	10 ⁰	0	0	<140	<2,15	>4,97	5
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
0,5	10 ⁰	0	0	<140	<2,15	>5,19	5
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
3,0	10 ⁰	0	0	<140	<2,15	>4,97	60
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
1,0	10 ⁰	0	0	<140	<2,15	>4,97	60
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
0,5	10 ⁰	0	0	<140	<2,15	>5,19	60
	10 ⁻¹	0	0				
	10 ⁻²	0	0				

Explanations:

Vc = count per ml

$\bar{x}$ = average of Vc1 and Vc2

(1.+2.duplicate)

$\bar{x}_{wm}$ = weighted mean of $\bar{x}$

R = reduction (lgR = lg N₀ - lgNa)

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Test organism: *Enterococcus hirae*
Test temperature: 20 °C +/- 1°C
Test date: 2016-08-04 / 2016-08-10
Interfering: 0,3 % bovine serum albumin + 0,3% sheep blood erythrocytes (dirty conditions)

Table 2a - Verification of the methodology and validation of the neutralization method

Validation suspension (Nv ₀)			Experimental conditions control (A) 5 min			Neutralizer control (B)			Method validation (C) product conc.: 3% 5 min		
Vc1	101	105,5	Vc1	98	111	Vc1	112	113	Vc1	0	0
Vc2	110		Vc2	124		Vc2	114		Vc2	0	
30 ≤ x of Nv0 ≤ 160?			x of A is ≥ 0,5 * x of Nv0?			x of B is ≥ 0,5 * x of Nv0?			x of C is ≥ 0,5 * x of Nv0?		
☒ yes ☐ no			☒ yes ☐ no			☒ yes ☐ no			☐ yes ☒ no		
			Experimental conditions control (A) 60 min						Method validation (C) product conc.: 3% 60 min		
Vc1	108	105,5	Vc1	108					Vc1	0	0
Vc2	103		Vc2	103					Vc2	0	
x of A is ≥ 0,5 * x of Nv0?									x of C is ≥ 0,5 * x of Nv0?		
☒ yes ☐ no									☐ yes ☒ no		

Table 2b: Test suspension

Test suspension (N and N ₀)	N	Vc1	Vc2	Nx _{wm} 4,80E+08
	10 ⁻⁶	>330	>330	N ₀ = N/10 = 7,68 lg
	10 ⁻⁷	48	48	7,17 ≤ N ₀ ≤ 7,70 ? ☒ yes ☐ no

Table 2c - Verification of the methodology and validation of the neutralization method

Validation suspension (Nv ₀)			Method validation (C) product conc.: 0,5 % 5 min		
Vc1	79	78,5	Vc1	101	98
Vc2	78		Vc2	95	
30 ≤ x of Nv0 ≤ 160?			x of C is ≥ 0,5 * x of Nv0?		
☒ yes ☐ no			☒ yes ☐ no		
			Method validation (C) product conc.: 0,5 % 60 min		
Vc1	72	72,5	Vc1	72	72,5
Vc2	73		Vc2	73	
			x of C is ≥ 0,5 * x of Nv0?		
			☒ yes ☐ no		

Table 2d: Test suspension

Test suspension (N and N ₀)	N	Vc1	Vc2	Nx _{wm} 4,45E+08
	10 ⁻⁶	>330	>330	N ₀ = N/10 = 7,65 lg
	10 ⁻⁷	44	45	7,17 ≤ N ₀ ≤ 7,70 ? ☒ yes ☐ no

Explanations:

Vc = count per ml
x̄ = average of Vc1 and Vc2
(1.+2.duplicate)

$\bar{x}_{wm}$ = weighted mean of $\bar{x}$
R = reduction (lgR = lg N₀ - lg N_a)

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Test organism: *Enterococcus hirae*
Test temperature: 20 °C +/- 1°C
Test date: 2016-08-04
Interfering: 0,3 % bovine serum albumin + 0,3% sheep blood erythrocytes (dirty conditions)

Table 2e: Test

Conc. of the product during the test (v/v)	Dilution	Na ₀		Na ₀ x * 10	lg Na	lg R (N ₀ =7,68)	contact time (min)
		Vc ₁	Vc ₂				
3,0	10 ⁰	0	0	<140	<2,15	>5,53	5
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
1,0	10 ⁰	0	0	<140	<2,15	>5,53	5
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
0,5	10 ⁰	0	0	<140	<2,15	>5,53	5
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
3,0	10 ⁰	0	0	<140	<2,15	>5,53	60
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
1,0	10 ⁰	0	0	<140	<2,15	>5,53	60
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
0,5	10 ⁰	0	0	<140	<2,15	>5,53	60
	10 ⁻¹	0	0				
	10 ⁻²	0	0				

Explanations:

Vc = count per ml

$\bar{x}$ = average of Vc1 and Vc2

(1.+2.duplicate)

$\bar{x}_{wm}$ = weighted mean of $\bar{x}$

R = reduction (lgR = lg N₀ - lgNa)

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Test organism: *Pseudomonas aeruginosa*
Test temperature: 20 °C +/- 1°C
Test date: 2016-08-04
Interfering: 0,3 % bovine serum albumin + 0,3% sheep blood erythrocytes (dirty conditions)

Table 3a - Verification of the methodology and validation of the neutralization method

Validation suspension (Nv ₀)			Experimental conditions control (A) 5 min			Neutralizer control (B)			Method validation (C) product conc.: 3% 5 min		
Vc1	29	30,5	Vc1	25	24	Vc1	29	32,5	Vc1	30	31
Vc2	32		Vc2	23		Vc2	36		Vc2	32	
30 ≤ x of Nv0 ≤ 160? ☒ yes ☐ no			x of A is ≥ 0,5 * x of Nv0? ☒ yes ☐ no			x of B is ≥ 0,5 * x of Nv0? ☒ yes ☐ no			x of C is ≥ 0,5 * x of Nv0? ☒ yes ☐ no		
			Experimental conditions control (A) 60 min						Method validation (C) product conc.: 3% 60 min		
			Vc1	20	21				Vc1	20	24
			Vc2	22					Vc2	28	
			x of A is ≥ 0,5 * x of Nv0? ☒ yes ☐ no						x of C is ≥ 0,5 * x of Nv0? ☒ yes ☐ no		

Table 3b: Test suspension

Test suspension (N and N ₀)	N	Vc1	Vc2	Nx _{wm} 1,56E+08
	10 ⁻⁶	171	140	N ₀ = N/10 = 7,19 lg
	10 ⁻⁷	11	17	7,17 ≤ N ₀ ≤ 7,70 ? ☒ yes ☐ no

Explanations:

Vc = count per ml
x̄ = average of Vc1 and Vc2
(1.+2.duplicate)

$\bar{x}_{wm}$ = weighted mean of $\bar{x}$
R = reduction (lgR = lg No - lgNa)

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Test organism: *Pseudomonas aeruginosa*
Test temperature: 20 °C +/- 1 °C
Test date: 2016-08-04
Interfering: 0,3 % bovine serum albumin + 0,3% sheep blood erythrocytes (dirty conditions)

Table 3c: Test

Conc. of the product during the test (v/v)	Dilution	Na ₀		Na ₀ x * 10	lg Na	lg R (N ₀ =7,19)	contact time (min)
		Vc ₁	Vc ₂				
3,0	10 ⁰	0	0	<140	<2,15	>5,04	5
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
1,0	10 ⁰	0	0	<140	<2,15	>5,04	5
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
0,5	10 ⁰	36	21	285	2,45	4,74	5
	10 ⁻¹	1	2				
	10 ⁻²	0	0				
3,0	10 ⁰	0	0	<140	<2,15	>5,04	60
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
1,0	10 ⁰	0	0	<140	<2,15	>5,04	60
	10 ⁻¹	0	0				
	10 ⁻²	0	0				
0,5	10 ⁰	0	0	<140	<2,15	>5,04	60
	10 ⁻¹	0	0				
	10 ⁻²	0	0				

Explanations:

Vc = count per ml

$\bar{x}$ = average of Vc1 and Vc2

(1.+2.duplicate)

$\bar{x}_{wm}$ = weighted mean of $\bar{x}$

R = reduction (lgR = lg N₀ - lgNa)