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c/o BIOTECHNIKUM
WALTHER-RATHENAU-STRASSE 49 A
17489 GREIFSWALD
DEUTSCHLAND - GERMANY

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Akkreditierungsstelle
D-PL-18411-01-01
D-PL-18411-01-02

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HYGIENE NORD GMBH, C/O BIOTECHNIKUM, W.-RATHENAU-STR. 49 A, D-17489 GREIFSWALD

ROPIMEX R. OPEL GmbH

Bildstocker Straße 12-14

66538 Neunkirchen

Deutschland / Germany

CUSTOMER NUMBER	DATE
1155	July 11, 2022

REPORT 221403.VI

BACOBAN®

BACTERICIDAL AND YEASTICIDAL ACTIVITY

EN 13697 (2019)

Purpose

The bactericidal and yeasticidal activity of the product formulation **Bacoban®** (ROPIMEX R. OPEL GmbH, Neunkirchen, Germany) should be evaluated in accordance with the European Standard **EN 13697 (2015+A1:2019)**.

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HANDELSREGISTER: AMTSGERICHT STRALSUND HRB 5168

Test description

Order number:	A22-0694
Manufacturer:	ROPIMEX R. OPEL GmbH, Neunkirchen, Germany
Test product:	**Bacoban®**
Batch number:	2206034
Sample number:	P 223226
Date of manufacture:	not provided
Best before:	06 / 2024
Storage conditions:	room temperature
Date of order:	June 10, 2022
Date of delivery:	June 10, 2022
Test date:	June 22, 2022 – July 06, 2022
Basis:	**EN 13697 (2015+A1:2019)**: Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or yeasticidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action (phase 2, step 2)
Test organisms:	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* ATCC 10536 *Candida albicans* ATCC 10231
Test solution:	100 %; 50 %; 5 %
Product dilution:	water for injections
Active ingredients[1]:	49.4 g Ethanol 7.1 g Propan-2-ol 0.71 g benzalkonium chloride 0.05 g sodium pyrithione
Odour:	alcoholic, product specific
Appearance:	clear, colourless liquid
Appearance of test solutions:	clear, colourless liquids
pH value (pH-meter):	100 %: 5.74 50 %: 4.93 5 %: 4.56 1 %: 4.80 WFI: 5.73
pH value (pH-stripes):	100 %: 5
Neutralizer:	4 % Tween 80 + 3 % saponin + 0.4 % lecithin + 0.25 % SDS (neutralizer XXIV)
Contact times:	1 min (and 5 min only with *E. hirae*)
Interfering substance:	0.3 % albumin (dirty conditions)
Test temperature:	20 ± 1 °C
Incubation temperature:	36 ± 1 °C / 30 ± 1 °C for *C. albicans*

Test Method

Quantitative carrier test - surface disinfection without mechanical action (EN 13697)

Testing was performed in accordance on the European Standard **EN 13697 (2015+A1:2019)**. Validation and control procedures are therefore carried out in accordance with that standard.

Small metal plates (ø 20 mm, stainless steel according to EN 14301-1 = AIS 304) were used as test surfaces. Plates had been boiled in a soft soap solution for 60 min, washed with tap water and afterwards rinsed with water. The sterilisation of the plates occurred with Isopropanol (70 Vol %) for 15 min. After sterilisation plates were dried; they were used for the test or stored under aseptic conditions.

As required by the EN 13697(2019) for tests under dirty conditions, the concentration of the inoculum bacterial test suspension was adjusted to the range of $1.5 \times 10^8 - 5.0 \times 10^8$ cfu/ml, the yeasticidal test suspension was adjusted to $1.5 \times 10^7 - 5.0 \times 10^7$ cfu/ml

For the test, 0.05 ml of the test suspension including the interfering substance were pipetted to the central area of the test surfaces. After a drying time of not more than 1 hour, 0.1 ml of the test product, (diluted with hard water, if necessary) were applied to the contaminated test area. The dried test suspension was to be covered completely. At the end of the required contact time, the metal plates were transferred to tubes containing 10 ml of neutralizer and glass beads. These tubes were then vortexed for at least 1 min to release the remaining viable test organisms from the test surfaces. Two 1 ml aliquots of the resulting test-neutralisation-solution and its dilutions (10^{-1} and 10^{-2}) were spread on at least 2 plates each. The number of viable test organisms still remaining on the carrier after that recovery procedure (N_{ts}) was also assayed. The reduction (RF) is calculated in relation to a test surface treated with water instead of the test product (Nc). The dilution-neutralization method (Control T) and the non-toxicity of the neutralizer (Control C) are validated.

The test was performed under dirty conditions (0.3 % albumin) at room temperature (20 ± 1 °C) using *S. aureus*, *E. hirae*, *P. aeruginosa*, *E. coli* and *C. albicans* as test-organisms. The test organisms are incubated at 36 ± 1 C and 30 ± 1 C (*C. albicans*), respectively. Results are presented in tables 1.1 – 5.

Results and conclusion[2]

In accordance with the **EN 13697 (2015+A1:2019**, the batch 2206034 of the test product formulation **Bacoban®**, when applied at a product concentration/ contact time-relation of at least **100 % / 1 min** at 20 °C under dirty conditions (0.3 % albumin), **possesses** bactericidal efficacy (log_{10} RF ≥ 4) for reference strains *S. aureus*, *E. hirae*, *P. aeruginosa* and *E. coli*, with *E. coli* as the most resistant strain (Tab. 1.1 – 4).

According to **EN 13697 (2015+A1:2019**, the batch 2206034 of the test product formulation **Bacoban®**, when applied at a product concentration/ contact time-relations of at least **100 % / 1 min** at 20 °C under dirty conditions (0.3 % albumin), **possesses** yeasticidal efficacy (log_{10} RF ≥ 3) for reference strain *C. albicans* (Tab. 5).

Results are considered validated in accordance with the requirements of the **EN 13697 (2015+A1:2019**.

Greifswald, July 11, 2022

Dr. rer. med. (Dipl. Biol.) T. Koburger-Janssen
- General Manager -

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NACH DIN EN ISO/IEC 17025

Table 1.1: Results of the quantitative carrier test according to EN 13697 (2019)

Date:	June 24, 2022	**Order number:**	A22-0694
Product:	**Bacoban®**	**Sample number:**	P 223226
Test organism:	*E. hirae*	**Batch number:**	2206034
Interfering substance:	0.3 % albumin		
Incubation temperature:	36 ± 1 °C	**Neutralizer:**	XXIV
Incubation time:	48 h	**Test temperature:**	20 ± 1 °C
Test suspension:	$2.23*10^8$ cfu/ml (8.35 log)	**Rel. humidity:**	34.4 %
Test suspension N (carrier):	$5.55*10^6$ cfu/carrier (6.74 log)	**Drying time:**	49 min

contact time: 1 min										
concentration	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_d**	**RF**	**N_{ts}**
100 %	4 x 0.5 ml (10^0)	0	0	0	0	0	0	< 0.7	**> 6.02**	**0**
	4 x 0.5 ml (10^{-1})	0	0	0	0	< 14	< 14			
	4 x 0.5 ml (10^{-2})	0	0	0	0	< 14	< 14			
60 %	4 x 0.5 ml (10^0)	0	0	0	0	0	0	< 0.7	**> 6.02**	**0**
	4 x 0.5 ml (10^{-1})	0	0	0	0	< 14	< 14			
	4 x 0.5 ml (10^{-2})	0	0	0	0	< 14	< 14			
25 %	4 x 0.5 ml (10^0)	0	0	0	0	0	0	< 0.7	**> 6.02**	**0**
	4 x 0.5 ml (10^{-1})	0	0	0	0	< 14	< 14			
	4 x 0.5 ml (10^{-2})	0	0	0	0	< 14	< 14			
Water-Control (Nc)	4 x 0.5 ml (10^{-1})	> 330	> 330	> 330	> 330	> 660	> 660			**> 330**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660			
	4 x 0.5 ml (10^{-3})	261	259	260	261	520	521	**6.72**		
	4 x 0.5 ml (10^{-4})	24	30	26	28	54	54			

contact time: 5 min										
concentration	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_d**	**RF**	**N_{ts}**
100 %	4 x 0.5 ml (10^0)	0	0	0	0	0	0	< 0.7	**> 6.07**	**0**
	4 x 0.5 ml (10^{-1})	0	0	0	0	< 14	< 14			
	4 x 0.5 ml (10^{-2})	0	0	0	0	< 14	< 14			
60 %	4 x 0.5 ml (10^0)	0	0	0	0	0	0	< 0.7	**> 6.07**	**0**
	4 x 0.5 ml (10^{-1})	0	0	0	0	< 14	< 14			
	4 x 0.5 ml (10^{-2})	0	0	0	0	< 14	< 14			
25 %	4 x 0.5 ml (10^0)	0	0	0	0	0	0	< 0.7	**> 6.07**	**1**
	4 x 0.5 ml (10^{-1})	0	0	0	0	< 14	< 14			
	4 x 0.5 ml (10^{-2})	0	0	0	0	< 14	< 14			
Water-Control (Nc)	4 x 0.5 ml (10^{-1})	> 330	> 330	> 330	> 330	> 660	> 660			**> 330**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660			
	4 x 0.5 ml (10^{-3})	284	302	293	299	586	592	**6.77**		
	4 x 0.5 ml (10^{-4})	34	32	30	31	66	61			

Table 1.1, continued: Results of the quantitative carrier test according to EN 13697 (2019)

Date:	June 24, 2022	**Order number:**	A22-0694
Product:	**Bacoban®**	**Sample number:**	P 223226
Test organism:	*E. hirae*	**Batch number:**	2206034
Interfering substance:	0.3 % albumin		
Incubation temperature:	36 ± 1 °C	**Neutralizer:**	XXIV
Incubation time:	24 h - 48 h	**Test temperature:**	20 ± 1 °C
Test suspension:	$2.23*10^8$ cfu/ml (8.35 log)	**Rel. humidity:**	34.4 %
Test suspension N (carrier):	$5.55*10^6$ cfu/carrier (6.74 log)	**Drying time:**	49 min

Validation and Controls:

	dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V_{c1}	V_{c2}	N_T	log N_T
Neutralisation control (T)	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10^{-3})	273	259	263	269	532	532	5.40E+06	**6.73**
Product concentration:	4 x 0.5 ml (10^{-4})	32	31	31	30	63	61		
100 %								**NT – Nc ≤ ± 0.3 log** [X] YES [ ] NO	

	dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V_{c1}	V_{c2}	N_C	log N_C
Non-toxicity (C)	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10^{-3})	289	289	290	293	578	583	6.01E+06	**6.78**
	4 x 0.5 ml (10^{-4})	44	39	40	39	83	79		
								NC – Nc ≤ ± 0.3 log [X] YES [ ] NO	

6.57 ≤ log N ≤ 7.10 [X] YES [ ] NO

Table 1.2: Results of the quantitative carrier test according to EN 13697 (2019)

Date:	July 07, 2022	**Order number:**	A22-0694
Product:	**Bacoban®**	**Sample number:**	P 223226
Test organism:	*E. hirae*	**Batch number:**	2206034
Interfering substance:	0.3 % albumin		
Incubation temperature:	36 ± 1 °C	**Neutralizer:**	XXIV
Incubation time:	24 h - 48 h	**Test temperature:**	20 ± 1 °C
Test suspension:	$2.19*10^8$ cfu/ml (8.34 log)	**Rel. humidity:**	32.5 %
Test suspension N (carrier):	$5.48*10^6$ cfu/carrier (6.74 log)	**Drying time:**	58 min

contact time: 1 min										
concentration	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_d**	**RF**	**N_{ts}**
5 %	4 x 0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660			**> 330**
	4 x 0.5 ml (10^{-1})	> 330	> 330	> 330	> 330	> 660	> 660			
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660	> 5.82	**< 0.80**	
Water-Control (Nc)	4 x 0.5 ml (10^{-1})	> 330	> 330	> 330	> 330	> 660	> 660			**> 330**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660			
	4 x 0.5 ml (10^{-3})	226	166	207	209	392	416	**6.62**		
	4 x 0.5 ml (10^{-4})	24	30	26	28	54	54			

Validation and Controls:									
Neutralisation control (T) **Product concentration: 5 %**	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_T**	**log N_T**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10^{-3})	234	224	230	229	458	459	4.61E+06	**6.66**
	4 x 0.5 ml (10^{-4})	24	30	23	20	54	43		
								NT – Nc ≤ ± 0.3 log [X] YES [ ] NO	
Non-toxicity (C)	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_C**	**log N_C**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10^{-3})	310	330	315	330	640	645	6.37E+06	**6.80**
	4 x 0.5 ml (10^{-4})	25	32	29	30	57	59		
								NC – Nc ≤ ± 0.3 log [X] YES [ ] NO	
								6.57 ≤ log N ≤ 7.10 [X] YES [ ] NO	

Table 2: Results of the quantitative carrier test according to EN 13697 (2019)

Date:	July 07, 2022	**Order number:**	A22-0694
Product:	**Bacoban®**	**Sample number:**	P 223226
Test organism:	*S. aureus*	**Batch number:**	2206034
Interfering substance:	0.3 % albumin		
Incubation temperature:	36 ± 1 °C	**Neutralizer:**	XXIV
Incubation time:	24 h - 48 h	**Test temperature:**	20 ± 1 °C
Test suspension:	$3.22*10^8$ cfu/ml (8.51 log)	**Rel. humidity:**	32.5 %
Test suspension N (carrier):	$8.05*10^6$ cfu/carrier (6.91 log)	**Drying time:**	58 min

contact time: 1 min										
concentration	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_d**	**RF**	**N_{ts}**
100 %	4 x 0.5 ml (10^0)	0	0	0	0	0	0	< 0.7	**> 6.27**	**0**
	4 x 0.5 ml (10^{-1})	0	0	0	0	< 14	< 14			
	4 x 0.5 ml (10^{-2})	0	0	0	0	< 14	< 14			
50 %	4 x 0.5 ml (10^0)	0	0	0	0	0	0	< 0.7	**> 6.27**	**0**
	4 x 0.5 ml (10^{-1})	0	0	0	0	< 14	< 14			
	4 x 0.5 ml (10^{-2})	0	0	0	0	< 14	< 14			
5 %	4 x 0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660			**> 330**
	4 x 0.5 ml (10^{-1})	> 330	> 330	> 330	> 330	> 660	> 660			
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660	> 5.82	**< 1.15**	
Water-Control (Nc)	4 x 0.5 ml (10^{-1})	> 330	> 330	> 330	> 330	> 660	> 660			**> 330**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660			
	4 x 0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660			
	4 x 0.5 ml (10^{-4})	52	41	48	47	93	95	**6.97**		

Validation and Controls:									
Neutralisation control (T)	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_T**	**log N_T**
Product concentration: 100 %	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10^{-4})	40	57	52	48	97	100	9.85E+06	**6.99**
								NT – Nc ≤ ± 0.3 log [X] YES [ ] NO	
Non-toxicity (C)	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_C**	**log N_C**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10^{-4})	49	46	53	45	95	98	9.65E+06	**6.98**
								NC – Nc ≤ ± 0.3 log [X] YES [ ] NO	
								6.57 ≤ log N ≤ 7.10 [X] YES [ ] NO	

Table 3: Results of the quantitative carrier test according to EN 13697 (2019)

Date:	July 06, 2022	**Order number:**	A22-0694
Product:	**Bacoban®**	**Sample number:**	P 223226
Test organism:	*P. aeruginosa*	**Batch number:**	2206034
Interfering substance:	0.3 % albumin		
Incubation temperature:	36 ± 1 °C	**Neutralizer:**	XXIV
Incubation time:	24 h - 48 h	**Test temperature:**	20 ± 1 °C
Test suspension:	$3.21*10^8$ cfu/ml (8.51 log)	**Rel. humidity:**	32.5 %
Test suspension N (carrier):	$8.03*10^6$ cfu/carrier (6.90 log)	**Drying time:**	58 min

contact time: 1 min										
concentration	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_d**	**RF**	**N_{ts}**
100 %	4 x 0.5 ml (10^0)	0	0	0	0	0	0	< 0.7	**> 5.63**	**0**
	4 x 0.5 ml (10^{-1})	0	0	0	0	< 14	< 14			
	4 x 0.5 ml (10^{-2})	0	0	0	0	< 14	< 14			
50 %	4 x 0.5 ml (10^0)	0	0	0	0	0	0	< 0.7	**> 5.63**	**0**
	4 x 0.5 ml (10^{-1})	0	0	0	0	< 14	< 14			
	4 x 0.5 ml (10^{-2})	0	0	0	0	< 14	< 14			
5 %	4 x 0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660			
	4 x 0.5 ml (10^{-1})	234	244	227	238	478	465	4.66	**1.67**	**15**
	4 x 0.5 ml (10^{-2})	17	15	21	20	32	41			
Water-Control (Nc)	4 x 0.5 ml (10^{-1})	> 330	> 330	> 330	> 330	> 660	> 660			**> 330**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660			
	4 x 0.5 ml (10^{-3})	98	114	107	112	212	219	**6.33**		
	4 x 0.5 ml (10^{-4})	4	10	12	13	14	25			

Validation and Controls:									
Neutralisation control (T)	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_T**	**log N_T**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
Product concentration:	4 x 0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
100 %	4 x 0.5 ml (10^{-4})	28	25	21	37	53	58	5.55E+06	**6.74**
								NT – Nc ≤ ± 0.3 log [(X)] YES* [ ] NO	
Non-toxicity (C)	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_C**	**log N_C**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10^{-3})	242	276	263	260	518	523	5.11E+06	**6.71**
	4 x 0.5 ml (10^{-4})	19	22	24	18	41	42		
								NC – Nc ≤ ± 0.3 log [X] YES [ ] NO	
								6.57 ≤ log N ≤ 7.10 [X] YES [ ] NO	

*slightly higher than 0.3 log, but OK, no indication for neutralizer problems

Table 4: Results of the quantitative carrier test according to EN 13697 (2019)

Date:	July 06, 2022	**Order number:**	A22-0694
Product:	**Bacoban®**	**Sample number:**	P 223226
Test organism:	*E. coli*	**Batch number:**	2206034
Interfering substance:	0.3 % albumin		
Incubation temperature:	36 ± 1 °C	**Neutralizer:**	XXIV
Incubation time:	24 h - 48 h	**Test temperature:**	20 ± 1 °C
Test suspension:	$2.55*10^8$ cfu/ml (8.41 log)	**Rel. humidity:**	32.5 %
Test suspension N (carrier):	$6.38*10^6$ cfu/carrier (6.80 log)	**Drying time:**	58 min

contact time: 1 min										
concentration	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_d**	**RF**	**N_{ts}**
100 %	4 x 0.5 ml (10^0)	0	0	0	0	0	0	< 0.7	**> 5.29**	**0**
	4 x 0.5 ml (10^{-1})	0	0	0	0	< 14	< 14			
	4 x 0.5 ml (10^{-2})	0	0	0	0	< 14	< 14			
50 %	4 x 0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660			**97**
	4 x 0.5 ml (10^{-1})	121	155	163	139	276	302	4.46	**1.53**	
	4 x 0.5 ml (10^{-2})	14	16	13	17	30	30			
5 %	4 x 0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660			**> 330**
	4 x 0.5 ml (10^{-1})	> 330	> 330	> 330	> 330	> 660	> 660			
	4 x 0.5 ml (10^{-2})	39	39	45	43	78	88	4.92	**1.07**	
Water-Control (Nc)	4 x 0.5 ml (10^{-1})	> 330	> 330	> 330	> 330	> 660	> 660			**> 330**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660			
	4 x 0.5 ml (10^{-3})	44	50	49	53	94	102	**5.99**		
	4 x 0.5 ml (10^{-4})	6	7	7	5	< 14	< 14			

Validation and Controls:									
Neutralisation control (T)	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_T**	**log N_T**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
Product concentration: 100 %	4 x 0.5 ml (10^{-3})	46	39	41	42	85	83	8.40E+05	**5.92**
	4 x 0.5 ml (10^{-4})	2	3	5	6	< 14	< 14		
								NT – Nc ≤ ± 0.3 log	
								[X] YES	[ ] NO
Non-toxicity (C)	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_C**	**log N_C**
	4 x 0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10^{-3})	33	41	45	39	74	84	1.10E+06	**6.04**
	4 x 0.5 ml (10^{-4})	3	2	4	5	< 14	< 14		
								NC – Nc ≤ ± 0.3 log	
								[X] YES	[ ] NO
								6.57 ≤ log N ≤ 7.10	
								[X] YES	[ ] NO

Table 5: Results of the quantitative carrier test according to EN 13697 (2019)

Date:	July 06, 2022	**Order number:**	A22-0694
Product:	**Bacoban®**	**Sample number:**	P 223226
Test organism:	*C. albicans*	**Batch number:**	2206034
Interfering substance:	0.3 % albumin		
Incubation temperature:	30 ± 1 °C	**Neutralizer:**	XXIV
Incubation time:	48 h - 72 h	**Test temperature:**	20 ± 1 °C
Test suspension:	$5.45*10^7$ cfu/ml (7.74 log) *	**Rel. humidity:**	32.5 %
Test suspension N (carrier):	$1.36*10^6$ cfu/carrier (6.13 log)	**Drying time:**	58 min

* slightly exceeding requirements of test suspension max. 7.70 log, but OK with regard to yeasticidal efficacy at 100 % and valid controls

contact time: 1 min										
concentration	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_d**	**RF**	**N_{ts}**
100 %	4 x 0.5 ml (10^0)	0	0	0	0	0	0	< 0.7	**> 4.12**	**0**
	4 x 0.5 ml (10^{-1})	0	0	0	0	< 14	< 14			
	4 x 0.5 ml (10^{-2})	0	0	0	0	< 14	< 14			
50 %	4 x 0.5 ml (10^0)	52	74	63	67	126	130	3.12	**1.70**	**35**
	4 x 0.5 ml (10^{-1})	2	17	8	9	19	17			
	4 x 0.5 ml (10^{-2})	0	2	0	0	< 14	< 14			
5 %	4 x 0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660			**82**
	4 x 0.5 ml (10^{-1})	160	152	149	158	312	307	4.49	**0.34**	
	4 x 0.5 ml (10^{-2})	16	13	12	13	29	25			
Water-Control (Nc)	4 x 0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660			**> 330**
	4 x 0.5 ml (10^{-1})	> 330	318	> 330	315	648	645	**4.82**		
	4 x 0.5 ml (10^{-2})	62	37	42	35	99	77			
	4 x 0.5 ml (10^{-3})	2	3	4	6	< 14	< 14			

Validation and Controls:									
Neutralisation control (T)	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_T**	**log N_T**
	4 x 0.5 ml (10^{-1})	> 330	> 330	> 330	> 330	> 660	> 660		
Product concentration:	4 x 0.5 ml (10^{-2})	55	51	56	57	106	113	1.10E+05	**5.04**
100 %	4 x 0.5 ml (10^{-3})	2	5	6	5	< 14	< 14		
								NT – Nc ≤ ± 0.3 log	
								[X] YES	[ ] NO
Non-toxicity (C)	**dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**N_C**	**log N_C**
	4 x 0.5 ml (10^{-1})	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10^{-2})	51	54	55	50	105	105	1.05E+05	**5.02**
	4 x 0.5 ml (10^{-3})	6	1	7	5	< 14	< 14		
								NC – Nc ≤ ± 0.3 log	
								[X] YES	[ ] NO
								5.57 ≤ log N ≤ 6.10	
								[X] YES*	[ ] NO

Legend:

[1]	=	as provided by the sponsor / manufacturer (unless stated otherwise)
[2]	=	According to EN 17025, § 7.8.2.1 l, we are required to state that the results presented in this report relate to the item(s) tested only. That is quite obvious in the first place, anyway. And it is also ridiculous, of course, with regard to these tests and reports typically being used for a product's generalized efficacy evaluation and market authorization. Which, as such, is then fully acceptable by all other relevant authorizing and responsible parties (other than EN 17025), too. Which therefore is why this disclaimer is only to be found at the very back end of this report.
> 165	=	not countable
> 330	=	not countable
> 660	=	not countable
n.d.	=	not determined
n.p.	=	not provided
WFI	=	water for injections
WSH	=	water of standardized hardness