Test report number 0721421-1 according to DIN EN 1040 (march 2006) Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antisetics - Test method and requirements (phase 1)

Identification of the test laboratory: SGS-Germany GmbH
Laboratory Services Hamburg
Weidenbaumsweg 137, 21035 Hamburg

Identification of the product:

Product name: **Bacoban ® WB**
Batch number: 2007312_WDM_konz_krei
Manufacturer: Sarastro GmbH, 66287 Quierschied-Göttelborn
Date of delivery: 2007-03-14
Storage conditions: room-temperature
Active ingredient(s): not indicated

Test method and its validation:

Method: Dilution-neutralization-method: P. aeruginosa
Membrane filtration: S. aureus
Neutralizer: 3% tween 80, 3% saponin, 0,1% histidin, 0,3 % lecithin, 0,5% na-thio. dissolved in diluent
Information about sterilization: 15 min 121°C +/- 1°C

Test conditions:

Period of analysis: 2007-05-22 - 2007-06-07
Appearance of the product: product: yellow-orange / Dilutions: light yellow
Test concentration (vol.-%) 0,75%, 1,00%
Diluent of the Dilution: distilled water
contact time: 5 min.; 15 min.
Test temperature: 20°C +/-1°C
Stability of the mixture during the procedure: no optical change
Referenced strains: ***Staphylococcus aureus*** **ATCC 6538**
Pseudomonas aeruginosa **ATCC 15442**
Temperature of incubation: 36 ± 1 °C
Counting method: pour plate

Test results: see tables 1a-c, 2a-c

Conclusion:

According DIN EN 1040 (march 2006) the product Bacoban®WB, when diluted at 0,75% in distilled water, possesses bactericidal activity in 5 min. at 20°C for referenced strains *Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538* (required reduction: 5 log).

To quality the product as a chemical disinfectant and/or an antiseptic for a determined intended use, it has to be assessed by additional normed tests, which are corresponding to the intended application.

Hamburg, 18.06.2007

i.V.
Dr. Roy Hörner (Laboratory manager)
Heidrun Globisch (Leader Microbiology)

test suspension for validation (Nv_0)			Experimental conditions (A) 5 min.			Validation of non-toxicity of the neutralizer (B)			Validation of neutralization (C) test concentration: 1,0%; 5 min.		
Vc1	43	57,5	Vc1	81	77,5	Vc1	78	80,5	Vc1	97	89,5
Vc2	72		Vc2	74		Vc2	83		Vc2	82	
$30 \leq \bar{x}$ Nv0 ≤ 160?			$\bar{x}$ A $\geq 0,5 * \bar{x}$ Nv0?			$\bar{x}$ B $\geq 0,5 * \bar{x}$ Nv0?			$\bar{x}$ C $\geq 0,5 * \bar{x}$ Nv0?		
☒ yes		☐ no	☒ yes		☐ no	☒ yes		☐ no	☒ yes		☐ no

Experimental conditions (A) 15 min.			Validation of neutralization (C) test concentration: 1,0%;15 min.		
Vc1	64	61,5	Vc1	95	86
Vc2	59		Vc2	77	
$\bar{x}$ A $\geq 0,5 * \bar{x}$ Nv0?			$\bar{x}$ C $\geq 0,5 * \bar{x}$ Nv0?		
☒ yes		☐ no	☒ yes		☐ no

Test concentration Vol.-%	N_{ao}		$N_a \bar{x} * 10$	lg Na	lg R (N_0=7,52)	contact time (min.)
	Vc1	Vc2				
0,75	0	0	<140	<2,15	>5,37	5
1,00	0	0	<140	<2,15	>5,37	5
0,75	0	0	<140	<2,15	>5,37	15
1,00	0	0	<140	<2,15	>5,37	15

Test report number 0721421-1 according to DIN EN 1040 (march 2006)

Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antisetics - Test method and requirements (phase 1)

Product: Bacoban ® WB, Period of analysis: 2007-05-22 - 2007-06-07

Test strain: S. aureus

Table 2a - Validation of the carrier test method for the test product as received

test suspension for validation (Nv_0)			Experimental conditions (A) 5 min.			Validation of the filtration (B)			Validation of neutralization (C) test concentration: 1,0%; 5 min.		
Vc1	107	107,5	Vc1	79	91,5	Vc1	64	68	Vc1	124	124
Vc2	108		Vc2	104		Vc2	72		Vc2	124	
$30 \leq \bar{x}$ Nv0 ≤ 160?			$\bar{x}$ A $\geq 0,5 * \bar{x}$ Nv0?			$\bar{x}$ B $\geq 0,5 * \bar{x}$ Nv0?			$\bar{x}$ C $\geq 0,5 * \bar{x}$ Nv0?		
☒ yes ☐ no			☒ yes ☐ no			☒ yes ☐ no			☒ yes ☐ no		
			Experimental conditions (A) 15 min.						Validation of neutralization (C) test concentration: 1,0%; 15 min.		
			Vc1	130	122				Vc1	117	113,5
			Vc2	114					Vc2	110	
			$\bar{x}$ A $\geq 0,5 * \bar{x}$ Nv0?						$\bar{x}$ C $\geq 0,5 * \bar{x}$ Nv0?		
			☒ yes ☐ no						☒ yes ☐ no		

Table 2b: Test suspension

Test suspension (N and N_0)	N	Vc1	Vc2	$\bar{x}_{wm}$ = 1,61E+08 cfu/ml
	10^{-6}	182	140	$N_0 = N/10 = \lg$ 7,21
	10^{-7}	12	10	$7,17 \leq N_0 \leq 7,70$? ☒ yes ☐ no

Table 2c: Test results

Test concentration vol.-%	N_{ao} Vc1	N_{ao} Vc2	$N_a \bar{x} * 10$	lg Na	lg R (N_0= 7,21)	contact time (min.)
0,75	1	15	<140	<2,15	>5,06	5
1,00	0	2	<140	<2,15	>5,06	5
0,75	5	1	<140	<2,15	>5,06	15
1,00	0	0	<140	<2,15	>5,06	15

Vc1; Vc2= cfu/platte

Na is the number of cells per ml in the test mixture at the end of the contact time and before neutralization or membrane-filtration. It is tenfold higher than the Vc (Vc1 + Vc2 /2) values due to the addition of neutralizer and water or the sample volume of 0,1 ml in the membrane-filtration.