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 3308045/EN**
Order-No.: 3761222
Client No.: 10089634

Nicole Hollmann
Michael Pietzko
Telefon +49 4088309-414
Fax +49 4088309-170
nicole.hollmann@sgs.com
michael.pietzko@sgs.com
Agriculture, Food

SGS Germany GmbH
Weidenbaumsweg 137
21035 Hamburg

DAkkS Deutsche Akkreditierungsstelle D-PL-11020-04-02

Durch die DAkkS nach DIN EN ISO/IEC 17025 akkreditiertes Prüflaboratorium. Die Akkreditierung gilt für die in der Urkunde aufgeführten Prüfverfahren.

Hamburg, 2017-03-24
This test report substitutes test report 3090658 from 08.12.2016.

Your Order/Project: Quantitative carrier test for the evaluation of yeasticidal activity for instruments used in the medical area following DIN EN 14562:2006

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: | 2016-08-25 / 2016-09-19 |

**Comment / summary:**

Results and the resulting ratings see following pages.

SGS Germany GmbH

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)

**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<br><10% inorganic organic polymer,<br>prepared from silanes with EINECS registration<br>26 % benzalkonium chloride<br>2.5% pyridine-2-thio-1-oxide, sodium salt<br><2% perfume mixture |

**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 time:** | 5 und 60 min +/- 10 s |
| **Test concentrations:** | 3 %; 1 % and 0,5 % |
| **Test temperatures:** | 20°C +/- 1°C |
| **Interfering substances:** | 0,3 % bovine serum albumin + 0,3 % sheep blood erythrocyte(dirty conditions) |
| **Test organism:** | *Candida albicans* ATCC 10231 |
| **Incubation temperature:** | 30 °C +/- 1°C |
| **Stability of the product in the test:** | The product testing solutions were bright and clear |

**Conclusion**

Following DIN EN 14562:2006 the product **Bacoban WB** with the batch 1605253 possesses yeasticidal activity, when diluted to 0,5 % (v/v) during the test at 20°C +/- 1°C, 60 min +/- 10s contact time and dirty conditions for the above mentioned test organism (required reduction: log 4).

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)

**Test organism:** *Candida albicans*
**Test temperature:** 20 °C +/- 1°C
**Test date:** 2016-08-25
**Interfering:** 0,3 % bovine serum albumin + 0,3 % sheep blood erythrocyte (dirty conditions)

**Table 1a: Validation and control**

| Validation suspension (Nv0) | | | Experimental conditions control (A) | | | Neutralizer control (B) | | | Method validation (C) product conc.: 1% 5 min | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Vc1 | 90 | 93 | Vc1 | 87 | 93,5 | Vc1 | 89 | 81 | Vc1 | 82 | 75 |
| Vc2 | 96 | | Vc2 | 100 | | Vc2 | 73 | | Vc2 | 68 | |
| 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 |

**Table 1b: Testsuspension**

| Testsuspension (N) | N | Vc1 | Vc2 | $Nx_{wm}$ = 4,10E+08 |
|---|---|---|---|---|
| | $10^{-6}$ | >330 | >330 | lg N = 8,61 (8,17 ≤ N ≤ 8,70 ?) |
| | $10^{-7}$ | 40 | 42 | ☒ yes ☐ no |

**Table 1c: Testcontrol with water**

| Testcontrol with water ($N_w$) Contact time: 5 min | N | Vc1 | Vc2 | $N_w x_{wm}$ x 10 = 5,05E+06 |
|---|---|---|---|---|
| | $10^{-3}$ | >330 | >330 | 7,15 ≤ lg $N_w$ = 6,70 ≤ (lg N - 1,30) |
| | $10^{-4}$ | 52 | 49 | ☒ yes ☐ no |

**Table 1d: Test**

| Conc. of the product during the test (v/v) | Dilution | $Na_o$ $Vc_1$ | $Na_o$ $Vc_2$ | $Na_o x$ * 10 | lg Na = lg (x or $x_{wm}$) +1 | lg R ($N_0$= 6,70) | Contact time (min +/- 10s) |
|---|---|---|---|---|---|---|---|
| 3 | $10^0$ | 76 | 74 | 790 | 2,90 | 3,80 | 5 |
| | $10^{-1}$ | 8 | 15 | | | | |
| | $10^{-2}$ | 0 | 0 | | | | |
| | $10^{-3}$ | 0 | 0 | | | | |
| 1 | $10^0$ | >330 | >330 | 30600 | 4,49 | 2,21 | 5 |
| | $10^{-1}$ | 305 | 304 | | | | |
| | $10^{-2}$ | 33 | 32 | | | | |
| | $10^{-3}$ | 1 | 2 | | | | |
| 0,5 | $10^0$ | >330 | >330 | 32200 | 4,51 | 2,19 | 5 |
| | $10^{-1}$ | 322 | 323 | | | | |
| | $10^{-2}$ | 35 | 28 | | | | |
| | $10^{-3}$ | 3 | 3 | | | | |

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 No - lgNa)

**Test organism:** *Candida albicans*
**Test temperature:** 20 °C +/- 1°C
**Test date:** 2016-08-25
**Interfering:** 0,3 % bovine serum albumin + 0,3 % sheep blood erythrocyte (dirty conditions)

**Table 2a: Validation and control**

| Validation suspension (Nv0) | | | Experimental conditions control (A) | | | Neutralizer control (B) | | | Method validation (C) product conc.: 1 % 60 min | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Vc1 | 90 | 93 | Vc1 | 98 | 97 | Vc1 | 89 | 81 | Vc1 | 66 | 71,5 |
| Vc2 | 96 | | Vc2 | 96 | | Vc2 | 73 | | Vc2 | 77 | |
| 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 |

**Table 2b: Testsuspension**

| Testsuspension (N) | N | Vc1 | Vc2 | $Nx_{wm}$ = 4,10E+08 |
|---|---|---|---|---|
| | $10^{-6}$ | >330 | >330 | lg N = 8,61 (8,17 ≤ N ≤ 8,70 ?) |
| | $10^{-7}$ | 40 | 42 | ☒ yes ☐ no |

**Table 2c: Testcontrol with water**

| Testcontrol with water ($N_w$) Contact time: 60 min | N | Vc1 | Vc2 | $N_w x_{wm}$ x 10 = 8,45E+05 |
|---|---|---|---|---|
| | $10^{-3}$ | 86 | 83 | 7,15 ≤ lg $N_w$ = 5,93 ≤ (lg N - 1,30) |
| | $10^{-4}$ | 4 | 8 | ☐ yes ☒ no |

**Table 2d: Test**

| Conc. of the product during the test (v/v) | Dilution | $Na_o$ $Vc_1$ | $Na_o$ $Vc_2$ | $Na_o x$ * 10 | lg Na = lg (x or $x_{wm}$) +1 | lg R ($N_0$= 5,93) | Contact time (min +/- 10s) |
|---|---|---|---|---|---|---|---|
| 3 | $10^0$ | 0 | 0 | <140 | <2,15 | >3,78 | 60 |
| | $10^{-1}$ | 0 | 0 | | | | |
| | $10^{-2}$ | 0 | 0 | | | | |
| | $10^{-3}$ | 0 | 0 | | | | |
| 1 | $10^0$ | 0 | 0 | <140 | <2,15 | >3,78 | 60 |
| | $10^{-1}$ | 0 | 0 | | | | |
| | $10^{-2}$ | 0 | 0 | | | | |
| | $10^{-3}$ | 0 | 0 | | | | |
| 0,5 | $10^0$ | 0 | 0 | <140 | <2,15 | >3,78 | 60 |
| | $10^{-1}$ | 0 | 0 | | | | |
| | $10^{-2}$ | 0 | 0 | | | | |
| | $10^{-3}$ | 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 No - lgNa)

**Test organism:** *Candida albicans*
**Test temperature:** 20 °C +/- 1°C
**Test date:** 2016-08-25
**Interfering:** 0,3 % bovine serum albumin + 0,3 % sheep blood erythrocyte (dirty conditions)

**Table 3a: Testsuspension**

| Testsuspension (N) | N | Vc1 | Vc2 | $Nx_{wm}$ = 9,30E+08 |
|---|---|---|---|---|
| | $10^{-6}$ | >330 | >330 | lg N = 8,59 (8,17 ≤ N ≤ 8,70 ?) |
| | $10^{-7}$ | 41 | 37 | ☒ yes ☐ no |

**Table 3b: Testcontrol with water**

| Testcontrol with water ($N_w$) Contact time: 60 min | N | Vc1 | Vc2 | $N_w x_{wm}$ x 10 = 1,21E+06 |
|---|---|---|---|---|
| | $10^{-3}$ | 115 | 123 | 7,15 ≤ lg $N_w$ = 6,08 ≤ (lg N - 1,30) |
| | $10^{-4}$ | 14 | 17 | ☐ yes ☒ no |

**Table 3c: Test**

| Conc. of the product during the test (v/v) | Dilut-ion | $Na_o$ | | $Na_o x$ * 10 | lg Na = lg (x or $x_{wm}$) +1 | lg R ($N_0$= 6,08) | Contact time (min +/- 10s) |
|---|---|---|---|---|---|---|---|
| | | $Vc_1$ | $Vc_2$ | | | | |
| 0,5 | $10^0$ | 0 | 0 | <100* | <2,00 | >4,08 | 60 |
| | $10^{-1}$ | 0 | 0 | | | | |
| | $10^{-2}$ | 0 | 0 | | | | |
| | $10^{-3}$ | 0 | 0 | | | | |

*= The detection limit of the Na test was set to <100 KbE / ml, whereby a log reduction of> 4.08 lg could be calculated.

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 No - lgNa)