

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

**B. Braun Medical AG**

**Seesatz**

**6204 Sempach**

**Schweiz / Switzerland**

CUSTOMER NUMBER  
324

DATE  
June 02, 2016

**REPORT A 16141**

**MELISEPTOL RAPID**

**BACTERICIDAL AND YEASTICIDAL ACTIVITY**

**(EN 13697)**

## Purpose

The bactericidal and yeasticidal activity of **Meliseptol rapid** (B. Braun Medical AG, Sempach, Switzerland) should be evaluated in accordance with the **EN 13697 (2015)**.

## Test description

|                               |  |            |            |           |
|-------------------------------|--|------------|------------|-----------|
| Manufacturer:                 | B. Braun Medical AG, Sempach, Switzerland  |            |            |           |
| Product name:                 | Meliseptol rapid   |            |            |           |
| Batch number:                 | 15022M02   |            |            |           |
| Sample number:                | P 162511   |            |            |           |
| Storage conditions:           | Room temperature   |            |            |           |
| Date of order:                | May 02, 2015   |            |            |           |
| Date of delivery:             | May 09, 2015   |            |            |           |
| Test date:                    | May 24, 2015 – June 02, 2015   |            |            |           |
| Basis:                        | EN 13697 (2015): 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 solutions:               | 100 %, 50 %, 25 %, 5 %   |            |            |           |
| Active ingredients in 100 ml: | 50 % Propan-1-ol<br>< 0.25 % Didecyltrimethylammoniumchloride  |            |            |           |
| Odour:                        | alcoholic  |            |            |           |
| Appearance:                   | colourless, clear liquid   |            |            |           |
| Appearance of dilution:       | colourless, clear liquids  |            |            |           |
| pH value (pH-meter):          | 100 %: 6.97  | 50 %: 6.68 | 25 %: 6.10 | 5 %: 5.97 |
|                               | WFI: 5.61  |            |            |           |
| pH value (pH-stripes):        | 100 %: 5   |            |            |           |
| Neutralizer:                  | 4 % Tween 80 + 3 % Saponin + 0.4 % Lecithin + 0.5 % SDS<br>(neutralizer XXIII)   |            |            |           |
| Contact time:                 | 1 min and 5 min, additionally 15 min for C. albicans   |            |            |           |
| Interfering substance:        | 0.3 % albumin (dirty conditions)   |            |            |           |
| Test temperature:             | 20 ± 1 °C  |            |            |           |
| Incubation temperature:       | 30 ± 1 °C  |            |            |           |
| Incubation temperature:       | 36 ± 1 °C (bacteria) or 30 ± 1 °C (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). Validation and control procedures are therefore carried out in accordance with that standard.

Small metal plates ( $\varnothing$  20 mm, stainless steel according to EN 10088-1/-2) 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 A. dest. 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.

For the test, 0.05 ml of the test suspension including the interfering substance were pipetted and spread on 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 sterile TSB with neutralizer and glass beads. These tubes were then vortexed for 2 min to release the remaining viable test organisms from the test surfaces. Aliquots of the resulting test-neutralisation-solution and its dilutions were plated in duplicate using the pour-plate technique. The number of viable test organisms still remaining on the carrier after that recovery procedure ( $N_{15}$ ) was also assayed.

The reduction (ME) is calculated in relation to a test surface treated with water instead of the test product ( $N_0$ ). 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 ( $20 \pm 1$  °C) using *Staphylococcus aureus*, *Enterococcus hirae*, *Pseudomonas aeruginosa*, *Escherichia coli* and *Candida albicans* as test-organisms. The test organisms are incubated at  $36 \pm 1$  °C (bacteria) or  $30 \pm 1$  °C (yeast). Results are presented in tables 1 – 5.


## Results

According to the EN 13697 (2015), the batch 15022M02 of the product **Meliseptol rapid** possesses **bactericidal** and **yeasticidal efficacy** ( $\log_{10}$  RF  $\geq 4$  or  $\log_{10}$  RF  $\geq 3$ , respectively) under **dirty conditions** in 1 min at a product concentration of at least 25 % for reference strains *S. aureus*, *E. hirae*, *P. aeruginosa*, *E. coli* and *C. albicans* (Tab. 1 – 5).

Results are validated in accordance with the requirements of the EN 13697 (2015).

Greifswald, June 02, 2016

  
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- General Manager -

  
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- MD for Hygiene and Environmental Medicine -

**Table 1: Results of the quantitative carrier test according to EN 13697 (2015)**

|                            |  |                   |           |
|----------------------------|--|-------------------|-----------|
| Date:                      | May 26, 2016                           | Order number:     | A 16141   |
| Product:                   | Meliseptol rapid                       | Sample number:    | P 162511  |
| Test organism:             | <i>S. aureus</i>                       | Batch number:     | 15022M02  |
| Interfering substance:     | 0.3 % albumin                          |                   |           |
| Incubation temperature:    | 36 ± 1 °C                              | Neutralizer:      | XXIII     |
| Incubation time:           | 24 h - 48 h                            | Test temperature: | 20 ± 1 °C |
| Test suspension (N):       | 3.02*10 <sup>8</sup> cfu/ml (8.48 log) | Rel. Humidity:    | 49.3 %    |
| Test suspension (carrier): | 1.51*10 <sup>7</sup> cfu/ml (7.18 log) | Drying time:      | 50 min    |

| contact time: 1 min              |                          |                  |                  |       |       |                |        |                 |
|----------------------------------|--------------------------|------------------|------------------|-------|-------|----------------|--------|-----------------|
| concentration                    | dilution                 | cfu /<br>plate 1 | cfu /<br>plate 2 | a     | a'    | N <sub>d</sub> | ME     | N <sub>is</sub> |
| 100 %                            | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | < 2.15         | > 4.57 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
| 50 %                             | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | 2.15           | 4.57   | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
| 25 %                             | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | 2.15           | 4.57   | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
| 5 %                              | 1 ml (10 <sup>0</sup> )  | > 330            | > 330            | > 330 | > 330 |                |        | > 330           |
|                                  | 1 ml (10 <sup>-1</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | > 330            | > 330            | > 330 | > 330 | > 5.52         | < 1.20 |                 |
| WSH-Control<br>(N <sub>c</sub> ) | 1 ml (10 <sup>-1</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        | > 330           |
|                                  | 1 ml (10 <sup>-2</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        |                 |
|                                  | 1 ml (10 <sup>-3</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        |                 |
|                                  | 1 ml (10 <sup>-4</sup> ) | 51               | 53               | 51    | 53    | 6.72           |        |                 |

| contact time: 5 min              |                          |                  |                  |       |       |                |        |                 |
|----------------------------------|--------------------------|------------------|------------------|-------|-------|----------------|--------|-----------------|
| concentration                    | dilution                 | cfu /<br>plate 1 | cfu /<br>plate 2 | a     | a'    | N <sub>d</sub> | ME     | N <sub>is</sub> |
| 100 %                            | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | < 2.15         | > 4.56 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
| 50 %                             | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | < 2.15         | > 4.56 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
| 25 %                             | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | < 2.15         | > 4.56 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
| 5 %                              | 1 ml (10 <sup>0</sup> )  | > 330            | > 330            | > 330 | > 330 |                |        | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 41               | 44               | 41    | 44    | 4.63           | 2.08   |                 |
| WSH-Control<br>(N <sub>c</sub> ) | 1 ml (10 <sup>-1</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        | > 330           |
|                                  | 1 ml (10 <sup>-2</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        |                 |
|                                  | 1 ml (10 <sup>-3</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        |                 |
|                                  | 1 ml (10 <sup>-4</sup> ) | 49               | 53               | 49    | 53    | 6.71           |        |                 |

Table 1; continued: Results of the quantitative carrier test according to EN 13697 (2015)

|                            |  |                   |           |
|----------------------------|--|-------------------|-----------|
| Date:                      | May 26, 2016                           | Order number:     | A 16141   |
| Product:                   | Meliseptol rapid                       | Sample number:    | P 162511  |
| Test organism:             | <i>S. aureus</i>                       | Batch number:     | 15022M02  |
| Interfering substance:     | 0.3 % albumin                          | Neutralizer:      | XXIII     |
| Incubation temperature:    | 36 ± 1 °C                              | Test temperature: | 20 ± 1 °C |
| Incubation time:           | 24 h - 48 h                            | Rel. Humidity:    | 49.3 %    |
| Test suspension (N):       | 3.02*10 <sup>8</sup> cfu/ml (8.48 log) | Drying time:      | 50 min    |
| Test suspension (carrier): | 1.51*10 <sup>7</sup> cfu/ml (7.18 log) |                   |           |

| Validation and Controls:  |                          |               |               |   |                    |
|---|--------------------------|---------------|---------------|---|--------------------|
| Neutralisation control (T)<br>(Product concentration:<br>100 %) | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>T</sub>  | log N <sub>T</sub> |
|   | 1 ml (10 <sup>-3</sup> ) | > 330         | > 330         |   |                    |
|   | 1 ml (10 <sup>-4</sup> ) | <u>34</u>     | <u>36</u>     | 3.50E+06  | 6.54               |
|   |                          |               |               | N <sub>c</sub> - N <sub>T</sub> ≤ ± 0.3 log<br><div><input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</div> |                    |
| Neutralisation control (T)<br>(Product concentration:<br>50 %)  | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>T</sub>  | log N <sub>T</sub> |
|   | 1 ml (10 <sup>-3</sup> ) | > 330         | > 330         |   |                    |
|   | 1 ml (10 <sup>-4</sup> ) | <u>66</u>     | <u>45</u>     | 5.55E+06  | 6.74               |
|   |                          |               |               | N <sub>c</sub> - N <sub>T</sub> ≤ ± 0.3 log<br><div><input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</div> |                    |
| Non-toxicity (C)  | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>c</sub>  | log N <sub>c</sub> |
|   | 1 ml (10 <sup>-3</sup> ) | > 330         | > 330         |   |                    |
|   | 1 ml (10 <sup>-4</sup> ) | <u>31</u>     | <u>25</u>     | 2.80E+06  | 6.45               |
|   |                          |               |               | N - N <sub>c</sub> ≤ 2 log<br><div><input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</div>                  |                    |
|   |                          |               |               | N - N <sub>c</sub> (WSH-Control) ≤ 2 log<br><div><input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</div>    |                    |



**Table 2: Results of the quantitative carrier test according to EN 13697 (2015)**

|                            |  |                  |           |
|----------------------------|--|------------------|-----------|
| Date:                      | May 26, 2016                           | Order number:    | A 16141   |
| Product:                   | Meliseptol rapid                       | Sample number:   | P 162511  |
| Test organism:             | <i>E. hirae</i>                        | Batch number:    | 15022M02  |
| Interfering substance:     | 0.3 % albumin                          | Neutralizer:     | XXIII     |
| Incubation temperature:    | 36 ± 1 °C                              | Test temperature | 20 ± 1 °C |
| Incubation time:           | 24 h - 48 h                            | Rel. Humidity:   | 49.3 %    |
| Test suspension (N):       | 1.89*10 <sup>8</sup> cfu/ml (8.28 log) | Drying time:     | 50 min    |
| Test suspension (carrier): | 9.45*10 <sup>6</sup> cfu/ml (6.98 log) |                  |           |

| contact time: 1 min              |                          |                  |                  |       |       |                |        |                 |
|----------------------------------|--------------------------|------------------|------------------|-------|-------|----------------|--------|-----------------|
| concentration                    | dilution                 | cfu /<br>plate 1 | cfu /<br>plate 2 | a     | a'    | N <sub>d</sub> | ME     | N <sub>is</sub> |
| 100 %                            | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | < 2.15         | > 4.64 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
| 50 %                             | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | < 2.15         | > 4.64 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
| 25 %                             | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | < 2.15         | > 4.64 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
| 5 %                              | 1 ml (10 <sup>0</sup> )  | > 330            | > 330            | > 330 | > 330 |                |        | > 330           |
|                                  | 1 ml (10 <sup>-1</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | > 330            | > 330            | > 330 | > 330 | > 5.52         | < 1.27 |                 |
| WSH-Control<br>(N <sub>c</sub> ) | 1 ml (10 <sup>-1</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        | > 330           |
|                                  | 1 ml (10 <sup>-2</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        |                 |
|                                  | 1 ml (10 <sup>-3</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        |                 |
|                                  | 1 ml (10 <sup>-4</sup> ) | 61               | 62               | 61    | 62    | 6.79           |        |                 |

| contact time: 5 min              |                          |                  |                  |      |      |                |        |                 |
|----------------------------------|--------------------------|------------------|------------------|------|------|----------------|--------|-----------------|
| concentration                    | dilution                 | cfu /<br>plate 1 | cfu /<br>plate 2 | a    | a'   | N <sub>d</sub> | ME     | N <sub>is</sub> |
| 100 %                            | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14 | < 14 | < 2.15         | > 4.73 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
| 50 %                             | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14 | < 14 | < 2.15         | > 4.73 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
| 25 %                             | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14 | < 14 | < 2.15         | > 4.73 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
| 5 %                              | 1 ml (10 <sup>0</sup> )  | 62               | 47               | 62   | 47   | 2.74           | 4.14   | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 5                | 8                | < 14 | < 14 |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 2                | 0                | < 14 | < 14 |                |        |                 |
| WSH-Control<br>(N <sub>c</sub> ) | 1 ml (10 <sup>-1</sup> ) | >330             | >330             | >330 | >330 |                |        | > 330           |
|                                  | 1 ml (10 <sup>-2</sup> ) | >330             | >330             | >330 | >330 |                |        |                 |
|                                  | 1 ml (10 <sup>-3</sup> ) | >330             | >330             | >330 | >330 |                |        |                 |
|                                  | 1 ml (10 <sup>-4</sup> ) | 72               | 77               | 72   | 77   | 6.87           |        |                 |

Table 2; continued: Results of the quantitative carrier test according to EN 13697 (2015)

|                            |  |                  |           |
|----------------------------|--|------------------|-----------|
| Date:                      | May 26, 2016                           | Order number:    | A 16141   |
| Product:                   | Meliseptol rapid                       | Sample number:   | P 162511  |
| Test organism:             | <i>E. hirae</i>                        | Batch number:    | 15022M02  |
| Interfering substance:     | 0.3 % albumin                          | Neutralizer:     | XXIII     |
| Incubation temperature:    | 36 ± 1 °C                              | Test temperature | 20 ± 1 °C |
| Incubation time:           | 24 h - 48 h                            | Rel. Humidity:   | 49.3 %    |
| Test suspension (N):       | 1.89*10 <sup>8</sup> cfu/ml (8.28 log) | Drying time:     | 50 min    |
| Test suspension (carrier): | 9.45*10 <sup>6</sup> cfu/ml (6.98 log) |                  |           |

| Validation and Controls:  |                          |               |               |   |                    |
|---|--------------------------|---------------|---------------|---|--------------------|
| Neutralisation control (T)<br>(Product concentration:<br>100 %) | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>T</sub>  | log N <sub>T</sub> |
|   | 1 ml (10 <sup>-3</sup> ) | > 330         | > 330         |   |                    |
|   | 1 ml (10 <sup>-4</sup> ) | 62            | 62            | 6.20E+06  | 6.79               |
|   |                          |               |               | N <sub>c</sub> – N <sub>T</sub> ≤ ± 0.3 log<br><div><input checked="" type="checkbox"/> X YES <input type="checkbox"/> NO</div> |                    |
| Neutralisation control (T)<br>(Product concentration:<br>50 %)  | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>T</sub>  | log N <sub>T</sub> |
|   | 1 ml (10 <sup>-3</sup> ) | > 330         | > 330         |   |                    |
|   | 1 ml (10 <sup>-4</sup> ) | 90            | 68            | 7.90E+06  | 6.90               |
|   |                          |               |               | N <sub>c</sub> – N <sub>T</sub> ≤ ± 0.3 log<br><div><input checked="" type="checkbox"/> X YES <input type="checkbox"/> NO</div> |                    |
| Non-toxicity (C)  | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>c</sub>  | log N <sub>c</sub> |
|   | 1 ml (10 <sup>-3</sup> ) | > 330         | > 330         |   |                    |
|   | 1 ml (10 <sup>-4</sup> ) | 71            | 66            | 6.85E+06  | 6.84               |
|   |                          |               |               | N – N <sub>c</sub> ≤ 2 log<br><div><input checked="" type="checkbox"/> X YES <input type="checkbox"/> NO</div>                  |                    |
|   |                          |               |               | N – N <sub>c</sub> (WSH-Control) ≤ 2 log<br><div><input checked="" type="checkbox"/> X YES <input type="checkbox"/> NO</div>    |                    |

**Table 3.1: Results of the quantitative carrier test according to EN 13697 (2015)**

|                            |  |                  |           |
|----------------------------|--|------------------|-----------|
| Date:                      | May 26, 2016                           | Order number:    | A 16141   |
| Product:                   | Meliseptol rapid                       | Sample number:   | P 162511  |
| Test organism:             | <i>P. aeruginosa</i>                   | Batch number:    | 15022M02  |
| Interfering substance:     | 0.3 % albumin                          | Neutralizer:     | XXIII     |
| Incubation temperature:    | 36 ± 1 °C                              | Test temperature | 20 ± 1 °C |
| Incubation time:           | 24 h - 48 h                            | Rel. Humidity:   | 49.3 %    |
| Test suspension (N):       | 1.96*10 <sup>8</sup> cfu/ml (8.29 log) | Drying time:     | 50 min    |
| Test suspension (carrier): | 9.80*10 <sup>6</sup> cfu/ml (6.99 log) |                  |           |

| contact time: 1 min           |                          |               |               |       |       |                |        |                 |
|-------------------------------|--------------------------|---------------|---------------|-------|-------|----------------|--------|-----------------|
| concentration                 | dilution                 | cfu / plate 1 | cfu / plate 2 | a     | a'    | N <sub>d</sub> | ME     | N <sub>ts</sub> |
| 100 %                         | 1 ml (10 <sup>0</sup> )  | > 330         | > 330         | > 330 | > 330 |                | *      | 55              |
|                               | 1 ml (10 <sup>-1</sup> ) | > 330         | > 330         | > 330 | > 330 |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 12            | 13            | 14    | 14    |                |        |                 |
| 50 %                          | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 4.33 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 25 %                          | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 4.33 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 5 %                           | 1 ml (10 <sup>0</sup> )  | > 330         | > 330         | > 330 | > 330 |                |        | > 330           |
|                               | 1 ml (10 <sup>-1</sup> ) | > 330         | > 330         | > 330 | > 330 |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | > 330         | > 330         | > 330 | > 330 | > 5.52         | < 0.95 |                 |
| WSH-Control (N <sub>c</sub> ) | 1 ml (10 <sup>-1</sup> ) | > 330         | > 330         | > 330 | > 330 |                |        | > 330           |
|                               | 1 ml (10 <sup>-2</sup> ) | > 330         | > 330         | > 330 | > 330 |                |        |                 |
|                               | 1 ml (10 <sup>-3</sup> ) | 307           | 301           | 307   | 301   | 6.48           |        |                 |
|                               | 1 ml (10 <sup>-4</sup> ) | 30            | 28            | 30    | 28    | 6.46           |        |                 |

\* implausible 7 invalid result - see table 3.2 for verification

| contact time: 5 min           |                          |               |               |       |       |                |        |                 |
|-------------------------------|--------------------------|---------------|---------------|-------|-------|----------------|--------|-----------------|
| concentration                 | dilution                 | cfu / plate 1 | cfu / plate 2 | a     | a'    | N <sub>d</sub> | ME     | N <sub>ts</sub> |
| 100 %                         | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 4.24 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 50 %                          | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 4.24 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 25 %                          | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 4.24 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 5 %                           | 1 ml (10 <sup>0</sup> )  | > 330         | > 330         | > 330 | > 330 |                |        | > 330           |
|                               | 1 ml (10 <sup>-1</sup> ) | > 330         | > 330         | > 330 | > 330 |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 43            | 59            | 43    | 59    | 4.71           | 1.68   |                 |
| WSH-Control (N <sub>c</sub> ) | 1 ml (10 <sup>-1</sup> ) | >330          | >330          | >330  | >330  |                |        | > 330           |
|                               | 1 ml (10 <sup>-2</sup> ) | >330          | >330          | >330  | >330  |                |        |                 |
|                               | 1 ml (10 <sup>-3</sup> ) | 188           | 284           | 188   | 284   | 6.37           |        |                 |
|                               | 1 ml (10 <sup>-4</sup> ) | 24            | 27            | 24    | 27    | 6.41           |        |                 |



Table 3.1; continued:

## Results of the quantitative carrier test according to EN 13697 (2015)

Date: May 26, 2016  
 Product: Meliseptol rapid  
 Test organism: *P. aeruginosa*  
 Interfering substance: 0.3 % albumin  
 Incubation temperature:  $36 \pm 1$  °C  
 Incubation time: 24 h - 48 h  
 Test suspension (N):  $1.96 \cdot 10^8$  cfu/ml (8.29 log)  
 Test suspension (carrier):  $9.80 \cdot 10^6$  cfu/ml (6.99 log)

Order number: A 16141  
 Sample number: P 162511  
 Batch number: 15022M02  
 Neutralizer: XXIII  
 Test temperature:  $20 \pm 1$  °C  
 Rel. Humidity: 49.3 %  
 Drying time: 50 min

| Validation and Controls:  |                          |               |               |   |                    |
|---|--------------------------|---------------|---------------|---|--------------------|
| Neutralisation control (T)<br>(Product concentration:<br>100 %) | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>T</sub>  | log N <sub>T</sub> |
|   | 1 ml (10 <sup>-3</sup> ) | <u>260</u>    | <u>255</u>    | 2.58E+06  | 6.41               |
|   | 1 ml (10 <sup>-4</sup> ) | <u>2</u>      | <u>1</u>      |   |                    |
|   |                          |               |               | N <sub>c</sub> - N <sub>T</sub> ≤ ± 0.3 log<br><div><input checked="" type="checkbox"/> X YES <input type="checkbox"/> NO</div> |                    |
| Neutralisation control (T)<br>(Product concentration:<br>50 %)  | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>T</sub>  | log N <sub>T</sub> |
|   | 1 ml (10 <sup>-3</sup> ) | > 330         | > 330         |   |                    |
|   | 1 ml (10 <sup>-4</sup> ) | <u>38</u>     | <u>28</u>     | 3.30E+06  | 6.52               |
|   |                          |               |               | N <sub>c</sub> - N <sub>T</sub> ≤ ± 0.3 log<br><div><input checked="" type="checkbox"/> X YES <input type="checkbox"/> NO</div> |                    |
| Non-toxicity (C)  | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>c</sub>  | log N <sub>c</sub> |
|   | 1 ml (10 <sup>-3</sup> ) | <u>299</u>    | <u>234</u>    | 2.67E+06  | 6.40               |
|   | 1 ml (10 <sup>-4</sup> ) | <u>30</u>     | <u>17</u>     | 2.35E+06  |                    |
|   |                          |               |               | N - N <sub>c</sub> ≤ 2 log<br><div><input checked="" type="checkbox"/> X YES <input type="checkbox"/> NO</div>                  |                    |
|   |                          |               |               | N - N <sub>c</sub> (WSH-Control) ≤ 2 log<br><div><input checked="" type="checkbox"/> X YES <input type="checkbox"/> NO</div>    |                    |

**Table 3.2: Results of the quantitative carrier test according to EN 13697 (2015)**

|                            |  |                  |           |
|----------------------------|--|------------------|-----------|
| Date:                      | June 02, 2016                          | Order number:    | A 16141   |
| Product:                   | Meliseptol rapid                       | Sample number:   | P 162511  |
| Test organism:             | <i>P. aeruginosa</i>                   | Batch number:    | 15022M02  |
| Interfering substance:     | 0.3 % albumin                          | Neutralizer:     | XXIII     |
| Incubation temperature:    | 36 ± 1 °C                              | Test temperature | 20 ± 1 °C |
| Incubation time:           | 24 h - 48 h                            | Rel. Humidity:   | 59.0 %    |
| Test suspension (N):       | 1.62*10 <sup>8</sup> cfu/ml (8.21 log) | Drying time:     | 50 min    |
| Test suspension (carrier): | 8.60*10 <sup>6</sup> cfu/ml (6.91 log) |                  |           |

| contact time: 1 min              |                          |                  |                  |       |       |                |      |                 |
|----------------------------------|--------------------------|------------------|------------------|-------|-------|----------------|------|-----------------|
| concentration                    | dilution                 | cfu /<br>plate 1 | cfu /<br>plate 2 | a     | a'    | N <sub>d</sub> | ME   | N <sub>ts</sub> |
| 100 %                            | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | 2.15           | 4.65 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |      |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |      |                 |
| 50 %                             | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | 2.15           | 4.65 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |      |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |      |                 |
| WSH-Control<br>(N <sub>c</sub> ) | 1 ml (10 <sup>-1</sup> ) | > 330            | > 330            | > 330 | > 330 |                |      | > 330           |
|                                  | 1 ml (10 <sup>-2</sup> ) | > 330            | > 330            | > 330 | > 330 |                |      |                 |
|                                  | 1 ml (10 <sup>-3</sup> ) | > 330            | > 330            | > 330 | > 330 |                |      |                 |
|                                  | 1 ml (10 <sup>-4</sup> ) | 61               | 64               | 61    | 64    | 6.80           |      |                 |

**Table 4: Results of the quantitative carrier test according to EN 13697 (2015)**

|                            |  |                  |           |
|----------------------------|--|------------------|-----------|
| Date:                      | May 26, 2016                           | Order number:    | A 16141   |
| Product:                   | Meliseptol rapid                       | Sample number:   | P 162511  |
| Test organism:             | <i>E. coli</i>                         | Batch number:    | 15022M02  |
| Interfering substance:     | 0.3 % albumin                          | Neutralizer:     | XXIII     |
| Incubation temperature:    | 36 ± 1 °C                              | Test temperature | 20 ± 1 °C |
| Incubation time:           | 24 h - 48 h                            | Rel. Humidity:   | 52.0 %    |
| Test suspension (N):       | 1.90*10 <sup>8</sup> cfu/ml (8.28 log) | Drying time:     | 60 min    |
| Test suspension (carrier): | 9.50*10 <sup>6</sup> cfu/ml (6.98 log) |                  |           |

| contact time: 1 min              |                          |                  |                  |       |       |                |        |                 |
|----------------------------------|--------------------------|------------------|------------------|-------|-------|----------------|--------|-----------------|
| concentration                    | dilution                 | cfu /<br>plate 1 | cfu /<br>plate 2 | a     | a'    | N <sub>d</sub> | ME     | N <sub>ts</sub> |
| 100 %                            | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | < 2.15         | > 4.12 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
| 50 %                             | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14  | < 14  | < 2.15         | > 4.12 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
| 25 %                             | 1 ml (10 <sup>0</sup> )  | 1                | 1                | < 14  | < 14  | < 2.15         | > 4.12 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14  | < 14  |                |        |                 |
| 5 %                              | 1 ml (10 <sup>0</sup> )  | > 330            | > 330            | > 330 | > 330 |                |        | 34              |
|                                  | 1 ml (10 <sup>-1</sup> ) | 205              | 198              | 205   | 198   | 4.30           | 1.92   |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 23               | 25               | 23    | 25    | 4.38           |        |                 |
| WSH-Control<br>(N <sub>c</sub> ) | 1 ml (10 <sup>-1</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        | > 330           |
|                                  | 1 ml (10 <sup>-2</sup> ) | > 330            | > 330            | > 330 | > 330 |                |        |                 |
|                                  | 1 ml (10 <sup>-3</sup> ) | 189              | 176              | 189   | 176   | 6.26           |        |                 |
|                                  | 1 ml (10 <sup>-4</sup> ) | 17               | 20               | 17    | 20    | 6.27           |        |                 |

| contact time: 5 min              |                          |                  |                  |      |      |                |        |                 |
|----------------------------------|--------------------------|------------------|------------------|------|------|----------------|--------|-----------------|
| concentration                    | dilution                 | cfu /<br>plate 1 | cfu /<br>plate 2 | a    | a'   | N <sub>d</sub> | ME     | N <sub>ts</sub> |
| 100 %                            | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14 | < 14 | < 2.15         | > 3.93 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
| 50 %                             | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14 | < 14 | < 2.15         | > 3.93 | 0               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
| 25 %                             | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14 | < 14 | < 2.15         | > 3.93 | 1               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
| 5 %                              | 1 ml (10 <sup>0</sup> )  | 0                | 0                | < 14 | < 14 | < 2.15         | > 3.93 | 1               |
|                                  | 1 ml (10 <sup>-1</sup> ) | 0                | 0                | < 14 | < 14 |                |        |                 |
|                                  | 1 ml (10 <sup>-2</sup> ) | 1                | 0                | < 14 | < 14 |                |        |                 |
| WSH-Control<br>(N <sub>c</sub> ) | 1 ml (10 <sup>-1</sup> ) | >330             | >330             | >330 | >330 |                |        | > 330           |
|                                  | 1 ml (10 <sup>-2</sup> ) | >330             | >330             | >330 | >330 |                |        |                 |
|                                  | 1 ml (10 <sup>-3</sup> ) | 99               | 100              | 99   | 100  | 6.00           |        |                 |
|                                  | 1 ml (10 <sup>-4</sup> ) | 12               | 15               | 14   | 15   | 6.16           |        |                 |

Table 4; continued: Results of the quantitative carrier test according to EN 13697 (2015)

|                            |  |                   |           |
|----------------------------|--|-------------------|-----------|
| Date:                      | May 26, 2016                           | Order number:     | A 16141   |
| Product:                   | Meliseptol rapid                       | Sample number:    | P 162511  |
| Test organism:             | <i>E. coli</i>                         | Batch number:     | 15022M02  |
| Interfering substance:     | 0.3 % albumin                          | Neutralizer:      | XXIII     |
| Incubation temperature:    | 36 ± 1 °C                              | Test temperature: | 20 ± 1 °C |
| Incubation time:           | 24 h - 48 h                            | Rel. Humidity:    | 52.0 %    |
| Test suspension (N):       | 1.90*10 <sup>8</sup> cfu/ml (8.28 log) | Drying time:      | 60 min    |
| Test suspension (carrier): | 9.50*10 <sup>6</sup> cfu/ml (6.98 log) |                   |           |

| Validation and Controls:  |                          |               |               |   |                    |
|---|--------------------------|---------------|---------------|---|--------------------|
| Neutralisation control (T)<br>(Product concentration:<br>100 %) | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>T</sub>  | log N <sub>T</sub> |
|   | 1 ml (10 <sup>-3</sup> ) | <u>34</u>     | <u>35</u>     | 3.45E+05  | 5.54               |
|   | 1 ml (10 <sup>-4</sup> ) | 4             | 3             |   |                    |
|   |                          |               |               | N <sub>c</sub> - N <sub>T</sub> ≤ ± 0.3 log<br><div><input checked="" type="checkbox"/> X YES <input type="checkbox"/> NO</div> |                    |
| Neutralisation control (T)<br>(Product concentration:<br>50 %)  | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>T</sub>  | log N <sub>T</sub> |
|   | 1 ml (10 <sup>-3</sup> ) | <u>35</u>     | <u>31</u>     | 3.30E+05  | 5.52               |
|   | 1 ml (10 <sup>-4</sup> ) | 1             | 4             |   |                    |
|   |                          |               |               | N <sub>c</sub> - N <sub>T</sub> ≤ ± 0.3 log<br><div><input checked="" type="checkbox"/> X YES <input type="checkbox"/> NO</div> |                    |
| Non-toxicity (C)  | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>c</sub>  | log N <sub>c</sub> |
|   | 1 ml (10 <sup>-3</sup> ) | <u>38</u>     | <u>46</u>     | 4.20E+05  | 5.62               |
|   | 1 ml (10 <sup>-4</sup> ) | 3             | 4             |   |                    |
|   |                          |               |               | N - N <sub>c</sub> ≤ 2 log<br><div><input checked="" type="checkbox"/> (X) YES* <input type="checkbox"/> NO</div>               |                    |
|   |                          |               |               | N - N <sub>c</sub> (WSH-Control) ≤ 2 log<br><div><input checked="" type="checkbox"/> (X) YES <input type="checkbox"/> NO</div>  |                    |

\* This not due to problems with the neutralizer – it's due to the well known problem of *E. coli* not taking the drying time on the carrier very well

**Table 5: Results of the quantitative carrier test according to EN 13697 (2015)**

|                            |  |                  |           |
|----------------------------|--|------------------|-----------|
| Date:                      | May 26, 2016                           | Order number:    | A 16141   |
| Product:                   | Meliseptol rapid                       | Sample number:   | P 162511  |
| Test organism:             | <i>C. albicans</i>                     | Batch number:    | 15022M02  |
| Interfering substance:     | 0.3 % albumin                          | Neutralizer:     | XXIII     |
| Incubation temperature:    | 30 ± 1 °C                              | Test temperature | 20 ± 1 °C |
| Incubation time:           | 48 h                                   | Rel. Humidity:   | 52.0 %    |
| Test suspension (N):       | 1.96*10 <sup>7</sup> cfu/ml (7.29 log) | Drying time:     | 60 min    |
| Test suspension (carrier): | 9.80*10 <sup>5</sup> cfu/ml (5.99 log) |                  |           |

| contact time: 1 min           |                          |               |               |       |       |                |        |                 |
|-------------------------------|--------------------------|---------------|---------------|-------|-------|----------------|--------|-----------------|
| concentration                 | dilution                 | cfu / plate 1 | cfu / plate 2 | a     | a'    | N <sub>d</sub> | ME     | N <sub>ts</sub> |
| 100 %                         | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 3.32 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 50 %                          | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 3.32 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 25 %                          | 1 ml (10 <sup>0</sup> )  | 4             | 4             | < 14  | < 14  | < 2.15         | > 3.32 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 5 %                           | 1 ml (10 <sup>0</sup> )  | > 330         | > 330         | > 330 | > 330 |                |        | 1               |
|                               | 1 ml (10 <sup>-1</sup> ) | > 330         | > 330         | > 330 | > 330 |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 93            | 74            | 93    | 74    | 4.92           | 0.55   |                 |
| WSH-Control (N <sub>c</sub> ) | 1 ml (10 <sup>0</sup> )  | > 330         | > 330         | > 330 | > 330 |                |        | > 330           |
|                               | 1 ml (10 <sup>-1</sup> ) | > 330         | > 330         | > 330 | > 330 |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 297           | 301           | 297   | 301   | 5.48           |        |                 |
|                               | 1 ml (10 <sup>-3</sup> ) | 28            | 30            | 28    | 30    | 5.46           |        |                 |

| contact time: 5 min           |                          |               |               |       |       |                |        |                 |
|-------------------------------|--------------------------|---------------|---------------|-------|-------|----------------|--------|-----------------|
| concentration                 | dilution                 | cfu / plate 1 | cfu / plate 2 | a     | a'    | N <sub>d</sub> | ME     | N <sub>ts</sub> |
| 100 %                         | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 2.93 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 50 %                          | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 2.93 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 25 %                          | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 2.93 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 5 %                           | 1 ml (10 <sup>0</sup> )  | > 330         | > 330         | > 330 | > 330 |                |        | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | > 330         | > 330         | > 330 | > 330 |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 188           | 215           | 188   | 215   | 5.30           | -0.23  |                 |
| WSH-Control (N <sub>c</sub> ) | 1 ml (10 <sup>0</sup> )  | > 330         | > 330         | > 330 | > 330 |                |        | > 330           |
|                               | 1 ml (10 <sup>-1</sup> ) | > 330         | > 330         | > 330 | > 330 |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 102           | 97            | 102   | 97    | 5.00           |        |                 |
|                               | 1 ml (10 <sup>-3</sup> ) | 14            | 11            | < 14  | < 14  | 5.15           |        |                 |



Table 5; continued: Results of the quantitative carrier test according to EN 13697 (2015)

|                            |  |                   |           |
|----------------------------|--|-------------------|-----------|
| Date:                      | May 26, 2016                           | Order number:     | A 16141   |
| Product:                   | Meliseptol rapid                       | Sample number:    | P 162511  |
| Test organism:             | <i>C. albicans</i>                     | Batch number:     | 15022M02  |
| Interfering substance:     | 0.3 % albumin                          | Neutralizer:      | XXIII     |
| Incubation temperature:    | 30 ± 1 °C                              | Test temperature: | 20 ± 1 °C |
| Incubation time:           | 48 h                                   | Rel. Humidity:    | 52.0 %    |
| Test suspension (N):       | 1.96*10 <sup>7</sup> cfu/ml (7.29 log) | Drying time:      | 60 min    |
| Test suspension (carrier): | 9.80*10 <sup>5</sup> cfu/ml (5.99 log) |                   |           |

| contact time: 15 min          |                          |               |               |       |       |                |        |                 |
|-------------------------------|--------------------------|---------------|---------------|-------|-------|----------------|--------|-----------------|
| concentration                 | dilution                 | cfu / plate 1 | cfu / plate 2 | a     | a'    | N <sub>d</sub> | ME     | N <sub>ts</sub> |
| 100 %                         | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 2.83 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 50 %                          | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 2.83 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 25 %                          | 1 ml (10 <sup>0</sup> )  | 0             | 0             | < 14  | < 14  | < 2.15         | > 2.83 | 0               |
|                               | 1 ml (10 <sup>-1</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 0             | 0             | < 14  | < 14  |                |        |                 |
| 5 %                           | 1 ml (10 <sup>0</sup> )  | > 330         | > 330         | > 330 | > 330 |                |        | 330             |
|                               | 1 ml (10 <sup>-1</sup> ) | > 330         | > 330         | > 330 | > 330 |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 107           | 89            | 107   | 89    | 4.99           | -0.02  |                 |
| WSH-Control (N <sub>c</sub> ) | 1 ml (10 <sup>0</sup> )  | > 330         | > 330         | > 330 | > 330 |                |        | > 330           |
|                               | 1 ml (10 <sup>-1</sup> ) | > 330         | > 330         | > 330 | > 330 |                |        |                 |
|                               | 1 ml (10 <sup>-2</sup> ) | 65            | 61            | 65    | 61    | 4.80           |        |                 |
|                               | 1 ml (10 <sup>-3</sup> ) | 3             | 9             | 14    | 14    | 5.15           |        |                 |

| Validation and Controls:  |                          |               |               |   |                    |
|---|--------------------------|---------------|---------------|---|--------------------|
| Neutralisation control (T)<br>(Product concentration:<br>100 %) | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>T</sub>  | log N <sub>T</sub> |
|   | 1 ml (10 <sup>-2</sup> ) | 94            | 92            | 9.30E+04  | 4.97               |
|   | 1 ml (10 <sup>-3</sup> ) | 12            | 12            |   |                    |
|   |                          |               |               | N <sub>c</sub> - N <sub>T</sub> ≤ ± 0.3 log<br><div><input checked="" type="checkbox"/> X YES <input type="checkbox"/> NO</div> |                    |
| Neutralisation control (T)<br>(Product concentration:<br>50 %)  | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>T</sub>  | log N <sub>T</sub> |
|   | 1 ml (10 <sup>-2</sup> ) | 80            | 72            | 7.60E+04  | 4.88               |
|   | 1 ml (10 <sup>-3</sup> ) | 10            | 6             |   |                    |
|   |                          |               |               | N <sub>c</sub> - N <sub>T</sub> ≤ ± 0.3 log<br><div><input checked="" type="checkbox"/> X YES <input type="checkbox"/> NO</div> |                    |
| Non-toxicity (C)  | dilution                 | cfu / plate 1 | cfu / plate 2 | N <sub>c</sub>  | log N <sub>c</sub> |
|   | 1 ml (10 <sup>-2</sup> ) | 106           | 99            | 1.03E+05  | 5.01               |
|   | 1 ml (10 <sup>-3</sup> ) | 13            | 12            |   |                    |
|   |                          |               |               | N - N <sub>c</sub> ≤ 2 log<br><div><input checked="" type="checkbox"/> (X) YES* <input type="checkbox"/> NO</div>               |                    |
|   |                          |               |               | N - N <sub>c</sub> (WSH-Control) ≤ 2 log<br><div><input checked="" type="checkbox"/> (X) YES <input type="checkbox"/> NO</div>  |                    |

\* This not due to problems with the neutralizer – it's due to the well known problem of *C. albicans* not taking the drying time on the carrier very well



## Legend:

|           |   |                      |
|-----------|---|----------------------|
| MW        | = | average value        |
| x         | = | average value        |
| $\bar{x}$ | = | average value        |
| RF        | = | reduction factor     |
| R         | = | reduction factor     |
| ME        | = | reduction factor     |
| > 330     | = | not countable        |
| > 660     | = | not countable        |
| n.d.      | = | not determined       |
| WFI       | = | water for injections |