# Test Report: EN 1276:2019

Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1)

**Identification of the test laboratory:** Abbott Analytical Ltd
Unit 2, Hickmans Road, Birkenhead, CH41 1JH, Great Britain

**Identification of the client:** IPS Group A/S
Hejreskovvej 22A, DK-3490 Kvistgård, Denmark

**Identification of the sample:** 21G/019

| | |
|---|---|
| Name of the product: | 7100HA |
| Batch number/reference and expiry date (if available): | N/A |
| Date of delivery: | 05 July 2021 |
| Storage conditions: | Room temperature in darkness |
| Product diluent recommended by the manufacturer for use: | Not disclosed |
| Active substance(s) and their concentrations (s) (optional): | Not disclosed |
| Appearance of the product: | Blue wipes from which was extracted a clear colourless liquid |

**Notes:**

1) The test results in this report relate only to the sample(s) tested.
2) This test report may not be reproduced except in full, adapted, altered or used to create a derivative work, without written approval from Abbott Analytical Ltd.

**Test method and its validation:**

| | |
|---|---|
| Method: | Dilution-neutralisation |
| Neutraliser: | 100.0 g/l Polysorbate 80 + 30.0 g/l Lecithin + 30.0 g/l Tryptone Soya Broth + 5.0 g/l Sodium thiosulphate + 1.0 g/l L-histidine (Neutraliser B) |
| Neutraliser validation: | Validated in accordance with EN 1276:2019 (5.5.2) |

**Experimental conditions:**

| | |
|---|---|
| Period of analysis: | 21 July 2021 to 23 July 2021 |
| Product test concentration(s): | Neat liquid extracted from wipes |
| Diluent used for product test solution(s): | Hard water |
| Contact time(s): | 60 s ± 5 s |
| Test temperature(s): | 20°C ± 1°C |
| Interfering substance: | 0.3 g/l bovine albumin (clean conditions) |
| Temperature of incubation: | 36°C ± 1°C |
| Identification of the bacterial strain(s) used: | *Pseudomonas aeruginosa* (DSM 939)<br>*Escherichia coli* (NCTC 10418)<br>*Staphylococcus aureus* (NCTC 10788)<br>*Enterococcus hirae* (DSM 3320) |

**Deviations:** None

**Remarks:**

1) All test conditions are as requested by the client, irrespective of whether these are in accordance with EN 1276:2019 (5.4.2) or EN 1276:2019 (5.5.1.1).
2) Products can only be tested at a concentration of 80% or less as some dilution is always produced by adding the test organisms and interfering substance.

**Requirements:**

The product shall demonstrate at least a 5 decimal log (lg) reduction against every test organism.

**Conclusion:**

According to EN 1276:2019, the liquid extracted from this sample of 7100HA wipes possesses bactericidal activity against all of the referenced strains of *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus* and *Enterococcus hirae*, when tested neat with a contact time of 60 seconds at 20°C under clean conditions.

**Approved by:**

Signed: 

Name: Tony Watson

Position: General Manager

Date: 23 July 2021

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**Results:** EN 1276:2019

RST 002 (Issue 5)

| | | | |
|---|---|---|---|
| Test organism: | *Pseudomonas aeruginosa* | | (DSM 939) |
| Date of test: | 21 July 2021 | Test temperature: | 20°C ± 1°C |
| Interfering substance: | 0.3 g/l bovine albumin | | |
| Dilution-neutralisation method: | Pour plate | Number of plates: | 1 / ml |
| Neutraliser: | B | Incubation temperature: | 36°C ± 1°C |

**Validation and controls:**

| Validation suspension ($Nv_o$) | | | Experimental conditions control (*A*) | | | Neutraliser or filtration control (*B*) | | | Method validation (*C*) Product conc.: *Neat** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Vc*1 | *64* | $\bar{n}$ = | *Vc*1 | *65* | $\bar{n}$ = | *Vc*1 | *53* | $\bar{n}$ = | *Vc*1 | *57* | $\bar{n}$ = |
| *Vc*2 | *70* | 67 | *Vc*2 | *61* | 63 | *Vc*2 | *60* | 56.5 | *Vc*2 | *69* | 63 |
| $30 \le \bar{n}$ of $Nv_o \le 160$ ? | | | $\bar{n}$ of $A \ge 0.5 \times \bar{n}$ of $Nv_o$ ? | | | $\bar{n}$ of $B \ge 0.5 \times \bar{n}$ of $Nv_o$ ? | | | $\bar{n}$ of $C \ge 0.5 \times \bar{n}$ of $Nv_o$ ? | | |
| ☒ yes ☐ no | | | ☒ yes ☐ no | | | ☒ yes ☐ no | | | ☒ yes ☐ no | | |

**Test suspension (*N* and $N_o$):**

| *N* | *Vc*1 | *Vc*2 | | |
|---|---|---|---|---|
| $10^{-6}$ | *188* | *172* | $\bar{n}$ wm = $1.79 \times 10^{8}$ ; | lg *N* = 8.25 |
| $10^{-7}$ | *16* | *18* | $N_o = N / 10$ ; | lg $N_o$ = 7.25 |
| | | | $7.17 \le \lg N_o \le 7.70$ ? | ☒ yes ☐ no |

**Test:**

| Conc. of the product | Contact time | *Vc*1 | *Vc*2 | *Na* ($\bar{n} \times 10$) | lg *Na* | lg *R* (lg $N_o$ - lg *Na*) |
|---|---|---|---|---|---|---|
| *Neat** | *60 s* | *0* | *0* | <140 | <2.15 | >5.10 |

*Neat liquid extracted from wipes

**Results:** EN 1276:2019

RST 002 (Issue 5)

| | | | |
|---|---|---|---|
| Test organism: | *Escherichia coli* | | (NCTC 10418) |
| Date of test: | 21 July 2021 | Test temperature: | 20°C ± 1°C |
| Interfering substance: | 0.3 g/l bovine albumin | | |
| Dilution-neutralisation method: | Pour plate | Number of plates: | 1 / ml |
| Neutraliser: | B | Incubation temperature: | 36°C ± 1°C |

**Validation and controls:**

| Validation suspension ($Nv_o$) | | | Experimental conditions control (*A*) | | | Neutraliser or filtration control (*B*) | | | Method validation (*C*) Product conc.: *Neat** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Vc*1 | *56* | $\overline{n}$ = | *Vc*1 | *89* | $\overline{n}$ = | *Vc*1 | *57* | $\overline{n}$ = | *Vc*1 | *60* | $\overline{n}$ = |
| *Vc*2 | *60* | 58 | *Vc*2 | *91* | 90 | *Vc*2 | *62* | 59.5 | *Vc*2 | *60* | 60 |
| $30 \le \overline{n}$ of $Nv_o \le 160$ ? | | | $\overline{n}$ of $A \ge 0.5 \times \overline{n}$ of $Nv_o$ ? | | | $\overline{n}$ of $B \ge 0.5 \times \overline{n}$ of $Nv_o$ ? | | | $\overline{n}$ of $C \ge 0.5 \times \overline{n}$ of $Nv_o$ ? | | |
| ☒ yes ☐ no | | | ☒ yes ☐ no | | | ☒ yes ☐ no | | | ☒ yes ☐ no | | |

**Test suspension (*N* and $N_o$):**

| *N* | *Vc*1 | *Vc*2 | | | |
|---|---|---|---|---|---|
| $10^{-6}$ | *288* | *296* | $\overline{n}$ wm = $2.94 \times 10^{8}$ ; | lg *N* = | 8.47 |
| $10^{-7}$ | *34* | *29* | $N_o = N / 10$ ; | lg $N_o$ = | 7.47 |
| | | | $7.17 \le \lg N_o \le 7.70$ ? | ☒ yes | ☐ no |

**Test:**

| Conc. of the product | Contact time | *Vc*1 | *Vc*2 | *Na* ($\overline{n} \times 10$) | lg *Na* | lg *R* (lg $N_o$ - lg *Na*) |
|---|---|---|---|---|---|---|
| *Neat** | *60 s* | *0* | *0* | <140 | <2.15 | >5.32 |

*Neat liquid extracted from wipes

**Results:** EN 1276:2019

RST 002 (Issue 5)

| | | | |
|---|---|---|---|
| Test organism: | *Staphylococcus aureus* | | (NCTC 10788) |
| Date of test: | 21 July 2021 | Test temperature: | 20°C ± 1°C |
| Interfering substance: | 0.3 g/l bovine albumin | | |
| Dilution-neutralisation method: | Pour plate | Number of plates: | 1 / ml |
| Neutraliser: | B | Incubation temperature: | 36°C ± 1°C |

**Validation and controls:**

| Validation suspension ($Nv_o$) | | | Experimental conditions control (*A*) | | | Neutraliser or filtration control (*B*) | | | Method validation (*C*) Product conc.: *Neat** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Vc*1 | *55* | $\overline{n}$ = | *Vc*1 | *54* | $\overline{n}$ = | *Vc*1 | *46* | $\overline{n}$ = | *Vc*1 | *42* | $\overline{n}$ = |
| *Vc*2 | *49* | 52 | *Vc*2 | *55* | 54.5 | *Vc*2 | *62* | 54 | *Vc*2 | *47* | 44.5 |
| $30 \le \overline{n}$ of $Nv_o \le 160$ ? | | | $\overline{n}$ of $A \ge 0.5 \times \overline{n}$ of $Nv_o$ ? | | | $\overline{n}$ of $B \ge 0.5 \times \overline{n}$ of $Nv_o$ ? | | | $\overline{n}$ of $C \ge 0.5 \times \overline{n}$ of $Nv_o$ ? | | |
| ☒ yes ☐ no | | | ☒ yes ☐ no | | | ☒ yes ☐ no | | | ☒ yes ☐ no | | |

**Test suspension (*N* and $N_o$):**

| *N* | *Vc*1 | *Vc*2 | | | |
|---|---|---|---|---|---|
| $10^{-6}$ | *224* | *183* | $\overline{n}$ wm = $2.08 \times 10^{8}$ ; | lg *N* = | 8.32 |
| $10^{-7}$ | *25* | *26* | $N_o = N / 10$ ; | lg $N_o$ = | 7.32 |
| | | | $7.17 \le \lg N_o \le 7.70$ ? | ☒ yes | ☐ no |

**Test:**

| Conc. of the product | Contact time | *Vc*1 | *Vc*2 | *Na* ($\overline{n} \times 10$) | lg *Na* | lg *R* (lg $N_o$ - lg *Na*) |
|---|---|---|---|---|---|---|
| *Neat** | *60 s* | *0* | *0* | <140 | <2.15 | >5.17 |

*Neat liquid extracted from wipes

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**Results:** EN 1276:2019

RST 002 (Issue 5)

| | | | |
|---|---|---|---|
| Test organism: | *Enterococcus hirae* | | (DSM 3320) |
| Date of test: | 21 July 2021 | Test temperature: | 20°C ± 1°C |
| Interfering substance: | 0.3 g/l bovine albumin | | |
| Dilution-neutralisation method: | Pour plate | Number of plates: | 1 / ml |
| Neutraliser: | B | Incubation temperature: | 36°C ± 1°C |

**Validation and controls:**

| Validation suspension ($Nv_o$) | | | Experimental conditions control (*A*) | | | Neutraliser or filtration control (*B*) | | | Method validation (*C*) Product conc.: *Neat** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Vc*1 | *73* | $\overline{n}$ = | *Vc*1 | *84* | $\overline{n}$ = | *Vc*1 | *71* | $\overline{n}$ = | *Vc*1 | *67* | $\overline{n}$ = |
| *Vc*2 | *71* | 72 | *Vc*2 | *68* | 76 | *Vc*2 | *64* | 67.5 | *Vc*2 | *63* | 65 |
| $30 \le \overline{n}$ of $Nv_o \le 160$ ? | | | $\overline{n}$ of $A \ge 0.5 \times \overline{n}$ of $Nv_o$ ? | | | $\overline{n}$ of $B \ge 0.5 \times \overline{n}$ of $Nv_o$ ? | | | $\overline{n}$ of $C \ge 0.5 \times \overline{n}$ of $Nv_o$ ? | | |
| ☒ yes ☐ no | | | ☒ yes ☐ no | | | ☒ yes ☐ no | | | ☒ yes ☐ no | | |

**Test suspension (*N* and $N_o$):**

| *N* | *Vc*1 | *Vc*2 | | | |
|---|---|---|---|---|---|
| $10^{-6}$ | *>330* | *>330* | $\overline{n}$ wm = $3.45 \times 10^8$ ; | lg *N* = | 8.54 |
| $10^{-7}$ | *34* | *35* | $N_o = N / 10$ ; | lg $N_o$ = | 7.54 |
| | | | $7.17 \le \lg N_o \le 7.70$ ? | ☒ yes | ☐ no |

**Test:**

| Conc. of the product | Contact time | *Vc*1 | *Vc*2 | *Na* ($\overline{n} \times 10$) | lg *Na* | lg *R* (lg $N_o$ - lg *Na*) |
|---|---|---|---|---|---|---|
| *Neat** | *60 s* | *0* | *0* | <140 | <2.15 | >5.39 |

*Neat liquid extracted from wipes

**Explanations:**

| | |
|---|---|
| *Vc* | count per ml (one plate or more) |
| $\overline{\nu}$ | average of *Vc*1 and *Vc*2 (1 + 2 duplicate) |
| $\overline{\nu}$ wm | weighted mean of $\overline{\nu}$ |
| *N* | number of cells per ml in the test suspension |
| $N_o$ | number of cells in the test mixture at the beginning of the contact time ($N_o = N / 10$) |
| *Na* | number of survivors per ml in the test mixture at the end of the contact time (before neutralisation or filtration) |
| *R* | reduction ($\lg R = \lg N_o - \lg Na$) |
| *Nv* | number of cells per ml in the validation suspension |
| $Nv_o$ | number of cells in the validation mixtures at the beginning of the contact time ($Nv_o = Nv / 10$) |
| *A* | number of survivors per ml in the experimental conditions control mixture |
| *B* | number of survivors per ml in the neutraliser or filtration control mixture |
| *C* | number of survivors per ml in the method validation mixture |

All test results have an associated uncertainty of measurement, details of which are available on request.

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