**Report:** ALH.20H042.SB **Issued:** 24 September 2020 **Page:** 1 of 8

# Test Report: EN 13697:2015+A1:2019

Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 2)

| | |
|---|---|
| **Identification of the test laboratory:** | Abbott Analytical Ltd<br>Unit 2, Hickmans Road, Birkenhead, CH41 1JH, United Kingdom |
| **Identification of the client:** | Allied Hygiene Systems Ltd<br>5 Centurion Way, Erith, DA18 4AF, United Kingdom |
| **Identification of the sample:** | 20H/042 |
| Name of the product: | Sanisafe 3 Wipes |
| Batch number/reference and expiry date (if available): | N/A |
| Date of delivery: | 06 August 2020 |
| 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: | White wipes from which was squeezed 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 13697:2015+A1:2019 (5.5.2) |

**Experimental conditions:**

| | |
|---|---|
| Period of analysis: | 18 September 2020 to 21 September 2020 |
| Product test concentration(s): | Neat liquid squeezed from wipes |
| Diluent used for product test solution(s): | N/A |
| Contact time(s): | 5 min ± 10 s |
| Test temperature(s): | 20°C ± 1°C |
| Interfering substance: | 3.0 g/l bovine albumin (dirty conditions) |
| Temperature of incubation: | 36°C ± 1°C |
| Identification of the bacterial strain(s) used: | *Pseudomonas aeruginosa* (NCIMB 10421)<br>*Escherichia coli* (NCTC 10418)<br>*Staphylococcus aureus* (NCTC 10788)<br>*Enterococcus hirae* (NCIMB 8192) |

**Deviations:** None

**Remarks:**

1) All test conditions are as requested by the client, irrespective of whether these are in accordance with EN 13697:2015+A1:2019 (5.4.2) or EN 13697:2015+A1:2019 (5.5.1).

**Requirements:**

The product shall demonstrate at least a 4 decimal log (lg) reduction against every test organism.

**Conclusion:**

According to EN 13697:2015+A1:2019, the liquid squeezed from this sample of Sanisafe 3 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 5 minutes at 20°C under dirty conditions.

**Report prepared by:**

Signed: 

Name: Karl Cumings

Position: Microbiologist

Date: 24 September 2020

**Approved by:**

Signed: 

Name: Tony Watson

Position: General Manager

Date: 24 September 2020

**Results:** EN 13697:2015+A1:2019

RST 012 (Issue 4)

| | | | |
|---|---|---|---|
| Test organism: | *Pseudomonas aeruginosa* | | (NCIMB 10421) |
| Date of test: | 18 September 2020 | Test temperature: | 20°C ± 1°C |
| Interfering substance: | 3.0 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:**

| Test and validation suspension (*N*) | | | Neutraliser toxicity control (*NC*) | | | Method validation (*NT*) Product conc.: *Neat** | | |
|---|---|---|---|---|---|---|---|---|
| | *Vc*1 | *Vc*2 | | *Vc*1 | *Vc*2 | | *Vc*1 | *Vc*2 |
| $10^{-6}$ | *264* | *248* | $10^{-3}$ | *259* | *238* | $10^{-3}$ | *232* | *241* |
| $10^{-7}$ | *23* | *22* | $10^{-4}$ | *27* | *29* | $10^{-4}$ | *23* | *26* |
| | | | $10^{-5}$ | *2* | *4* | $10^{-5}$ | *2* | *2* |
| lg *N* = 6.80 | | | lg *NC* = 6.40 | | | lg *NT* = 6.38 | | |
| 6.57 ≤ lg *N* ≤ 7.10 ? ☒ yes ☐ no | | | -0.3 ≤ lg *NC* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no | | | -0.3 ≤ lg *NT* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no | | |

**Water control (*Nc*):**

| *Nc* | *Vc*1 | *Vc*2 | |
|---|---|---|---|
| $10^{-3}$ | *240* | *240* | lg *Nc* = 6.38 |
| $10^{-4}$ | *28* | *22* | |
| $10^{-5}$ | *4* | *3* | |
| *Nts* | *9* | | |

**Test:**

| Conc. of the product | Contact time | Dilution step | *Vc*1 | *Vc*2 | lg *Nd* | lg *R* (lg *Nc* - lg *Nd*) |
|---|---|---|---|---|---|---|
| *Neat** | *5 min* | $10^{0}$ | *0* | *0* | <0.10 | >6.28 |
| | | $10^{-1}$ | *0* | *0* | | |
| | | $10^{-2}$ | *0* | *0* | | |
| | | *Nts* | *0* | | | |

*Neat liquid squeezed from wipes

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**Results:** EN 13697:2015+A1:2019

RST 012 (Issue 4)

| | | | |
|---|---|---|---|
| Test organism: | *Escherichia coli* | | (NCTC 10418) |
| Date of test: | 18 September 2020 | Test temperature: | 20°C ± 1°C |
| Interfering substance: | 3.0 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:**

| Test and validation suspension (*N*) | | | Neutraliser toxicity control (*NC*) | | | Method validation (*NT*) Product conc.: *Neat** | | |
|---|---|---|---|---|---|---|---|---|
| | *Vc*1 | *Vc*2 | | *Vc*1 | *Vc*2 | | *Vc*1 | *Vc*2 |
| $10^{-6}$ | *224* | *232* | $10^{-3}$ | *247* | *255* | $10^{-3}$ | *239* | *245* |
| $10^{-7}$ | *22* | *21* | $10^{-4}$ | *25* | *29* | $10^{-4}$ | *24* | *27* |
| | | | $10^{-5}$ | *2* | *4* | $10^{-5}$ | *2* | *3* |
| lg *N* = 6.75 | | | lg *NC* = 6.40 | | | lg *NT* = 6.39 | | |
| 6.57 ≤ lg *N* ≤ 7.10 ? ☒ yes ☐ no | | | -0.3 ≤ lg *NC* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no | | | -0.3 ≤ lg *NT* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no | | |

**Water control (*Nc*):**

| *Nc* | *Vc*1 | *Vc*2 | |
|---|---|---|---|
| $10^{-3}$ | *256* | *250* | lg *Nc* = 6.41 |
| $10^{-4}$ | *30* | *28* | |
| $10^{-5}$ | *3* | *3* | |
| *Nts* | *5* | | |

**Test:**

| Conc. of the product | Contact time | Dilution step | *Vc*1 | *Vc*2 | lg *Nd* | lg *R* (lg *Nc* - lg *Nd*) |
|---|---|---|---|---|---|---|
| *Neat** | *5 min* | $10^{0}$ | *0* | *0* | <0.10 | >6.31 |
| | | $10^{-1}$ | *0* | *0* | | |
| | | $10^{-2}$ | *0* | *0* | | |
| | | *Nts* | *0* | | | |

*Neat liquid squeezed from wipes

**Results:** EN 13697:2015+A1:2019

RST 012 (Issue 4)

| | | | |
|---|---|---|---|
| Test organism: | *Staphylococcus aureus* | | (NCTC 10788) |
| Date of test: | 18 September 2020 | Test temperature: | 20°C ± 1°C |
| Interfering substance: | 3.0 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:**

| Test and validation suspension (*N*) | | | Neutraliser toxicity control (*NC*) | | | Method validation (*NT*) Product conc.: *Neat** | | |
|---|---|---|---|---|---|---|---|---|
| | *Vc*1 | *Vc*2 | | *Vc*1 | *Vc*2 | | *Vc*1 | *Vc*2 |
| $10^{-6}$ | *288* | *288* | $10^{-3}$ | *249* | *268* | $10^{-3}$ | *264* | *259* |
| $10^{-7}$ | *28* | *26* | $10^{-4}$ | *28* | *30* | $10^{-4}$ | *27* | *25* |
| | | | $10^{-5}$ | *3* | *3* | $10^{-5}$ | *2* | *2* |
| lg *N* = 6.85 | | | lg *NC* = 6.42 | | | lg *NT* = 6.42 | | |
| 6.57 ≤ lg *N* ≤ 7.10 ? ☒ yes ☐ no | | | -0.3 ≤ lg *NC* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no | | | -0.3 ≤ lg *NT* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no | | |

**Water control (*Nc*):**

| *Nc* | *Vc*1 | *Vc*2 | |
|---|---|---|---|
| $10^{-3}$ | *256* | *288* | lg *Nc* = 6.44 |
| $10^{-4}$ | *32* | *28* | |
| $10^{-5}$ | *2* | *4* | |
| *Nts* | *12* | | |

**Test:**

| Conc. of the product | Contact time | Dilution step | *Vc*1 | *Vc*2 | lg *Nd* | lg *R* (lg *Nc* - lg *Nd*) |
|---|---|---|---|---|---|---|
| *Neat** | *5 min* | $10^{0}$ | *0* | *0* | <0.10 | >6.34 |
| | | $10^{-1}$ | *0* | *0* | | |
| | | $10^{-2}$ | *0* | *0* | | |
| | | *Nts* | *0* | | | |

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**Results:** EN 13697:2015+A1:2019

RST 012 (Issue 4)

| | | | |
|---|---|---|---|
| Test organism: | *Enterococcus hirae* | | (NCIMB 8192) |
| Date of test: | 18 September 2020 | Test temperature: | 20°C ± 1°C |
| Interfering substance: | 3.0 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:**

| Test and validation suspension (*N*) | | | Neutraliser toxicity control (*NC*) | | | Method validation (*NT*) Product conc.: *Neat** | | |
|---|---|---|---|---|---|---|---|---|
| | *Vc*1 | *Vc*2 | | *Vc*1 | *Vc*2 | | *Vc*1 | *Vc*2 |
| $10^{-6}$ | *184* | *192* | $10^{-3}$ | *242* | *249* | $10^{-3}$ | *232* | *240* |
| $10^{-7}$ | *15* | *17* | $10^{-4}$ | *24* | *23* | $10^{-4}$ | *28* | *26* |
| | | | $10^{-5}$ | *2* | *2* | $10^{-5}$ | *3* | *3* |
| lg *N* = 6.67 | | | lg *NC* = 6.39 | | | lg *NT* = 6.38 | | |
| 6.57 ≤ lg *N* ≤ 7.10 ? ☒ yes ☐ no | | | -0.3 ≤ lg *NC* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no | | | -0.3 ≤ lg *NT* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no | | |

**Water control (*Nc*):**

| *Nc* | *Vc*1 | *Vc*2 | |
|---|---|---|---|
| $10^{-3}$ | *256* | *240* | lg *Nc* = 6.39 |
| $10^{-4}$ | *22* | *24* | |
| $10^{-5}$ | *4* | *2* | |
| *Nts* | *5* | | |

**Test:**

| Conc. of the product | Contact time | Dilution step | *Vc*1 | *Vc*2 | lg *Nd* | lg *R* (lg *Nc* - lg *Nd*) |
|---|---|---|---|---|---|---|
| *Neat** | *5 min* | $10^{0}$ | *0* | *0* | <0.10 | >6.29 |
| | | $10^{-1}$ | *0* | *0* | | |
| | | $10^{-2}$ | *0* | *0* | | |
| | | *Nts* | *0* | | | |

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**Explanations:**

| | |
|---|---|
| *Vc* | count per ml (one plate or more) |
| *N* | number of cells per 0.025 ml in the test suspension |
| *Nd* | number of survivors per surface at the end of the contact time (before neutralisation) |
| *Nc* | number of survivors per water control surface |
| *R* | reduction (lg *R* = lg *Nc* - lg *Nd*) |
| *NC* | number of survivors per neutraliser toxicity control surface |
| *NT* | number of survivors per method validation control surface |

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