# Test Report: EN 13624:2013

Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area – Test method and requirements (phase 2, step 1)

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

**Identification of the client:** Safe Solutions (Safe4) Ltd
Wharton Green, Bostock Road, Winsford, CW7 3BD, United Kingdom

**Identification of the sample:** 19D/033

| | |
|---|---|
| Name of the product: | Safe4 Instrument Disinfectant |
| Batch number/reference and expiry date (if available): | 3558 |
| Date of delivery: | 10 April 2019 |
| 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: | Clear green 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 13624:2013 (5.5.2) |

**Experimental conditions:**

| | |
|---|---|
| Period of analysis: | 26 April 2019 to 29 April 2019 |
| Product test concentration(s): | 1:20 v/v |
| Diluent used for product test solution(s): | Hard water |
| Contact time(s): | 10 min ± 10 s |
| Test temperature(s): | 20°C ± 1°C |
| Interfering substance: | 0.3 g/l bovine albumin (clean conditions) |
| Temperature of incubation: | 30°C ± 1°C |
| Identification of the bacterial strain(s) used: | *Candida albicans* (DSM 1386) |

**Deviations:** None

**Remarks:**

1) All test conditions are as requested by the client, irrespective of whether these are in accordance with EN 13624:2013 (5.4.2) or EN 13624:2013 (5.5.1.1).

**Requirements:**

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

**Conclusion:**

According to EN 13624:2013, Safe4 Instrument Disinfectant possesses yeasticidal activity when tested at a concentration of 1:20 with a contact time of 10 minutes at 20°C under clean conditions against the referenced strain of *Candida albicans*.

**Report prepared by:**

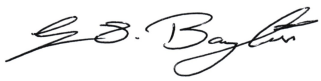
Signed: 

Name: Tony Watson

Position: General Manager

Date: 29 April 2019

**Approved by:**

Signed: 

Name: Gareth Bayliss

Position: Laboratory Manager

Date: 29 April 2019

**Results:** EN 13624:2013

| | | | |
|---|---|---|---|
| Test organism: | *Candida albicans* | | (DSM 1386) |
| Date of test: | 26 April 2019 | | |
| Test temperature: | 20°C ± 1°C | Incubation temperature: | 30°C ± 1°C |
| Dilution-neutralisation method: | Pour plate | Number of plates: | 1 / ml |
| Neutraliser: | B | Test conditions: | Clean conditions |

**Validation and controls:**

| Validation suspension ($Nv_o$) | | | Experimental conditions control (*A*) | | | Neutraliser or filtration control (*B*) | | | Method validation (*C*) Product conc.: *1:20* | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *Vc*1 | *40* | $\bar{n}$ = | *Vc*1 | *40* | $\bar{n}$ = | *Vc*1 | *39* | $\bar{n}$ = | *Vc*1 | *49* | $\bar{n}$ = |
| *Vc*2 | *43* | 41.5 | *Vc*2 | *37* | 38.5 | *Vc*2 | *45* | 42 | *Vc*2 | *39* | 44 |
| $30 \le \bar{n}$ of $Nv_o \le 160$ ? ☒ yes ☐ no | | | $\bar{n}$ of *A* $\ge 0.5 \times \bar{n}$ of $Nv_o$ ? ☒ yes ☐ no | | | $\bar{n}$ of *B* $\ge 0.5 \times \bar{n}$ of $Nv_o$ (or $Nv_B / 1000$) ? ☒ yes ☐ no | | | $\bar{n}$ of *C* $\ge 0.5 \times \bar{n}$ of $Nv_o$ ? ☒ yes ☐ no | | |
| Validation suspension ($Nv_B$) | | | *Vc*1 | *43* | $\bar{n}$ = | $30 \le \bar{n}$ of $Nv_B / 1000 \le 160$ ? ☒ yes ☐ no | | | | | |
| | | | *Vc*2 | *41* | 42 | | | | | | |

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

| *N* | *Vc*1 | *Vc*2 | $\bar{n}$ wm = $1.67 \times 10^7$ ; lg *N* = 7.22 |
|---|---|---|---|
| $10^{-5}$ | *165* | *167* | $N_o = N / 10$ ; lg $N_o$ = 6.22 |
| $10^{-6}$ | *18* | *18* | $6.17 \le \lg N_o \le 6.70$ ? ☒ yes ☐ no |

**Test:**

| Conc. of the product | Contact time | Dilution step | *Vc*1 | *Vc*2 | *Na* ($\bar{n}$ x 10 or $\bar{n}$ wm x 10) | lg *Na* | lg *R* (lg $N_o$ - lg *Na*) |
|---|---|---|---|---|---|---|---|
| *1:20* | *10 min* | $10^0$ | *2* | *1* | <140 | <2.15 | >4.07 |
| | | $10^{-1}$ | *0* | *0* | | | |

Abbott Analytical Ltd
Unit 2, Hickmans Road,
Birkenhead, CH41 1JH, United Kingdom

**T:** +44 (0)151 345 6753
**E:** enqs@abbottanalytical.co.uk
**W:** www.abbottanalytical.co.uk

**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 at the end of the contact time |
| *B* | number of survivors per ml in the neutraliser or filtration control mixture after 5 minutes |
| *C* | number of survivors per ml in the method validation mixture after 30 minutes |

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