

**Report:** SSL.20H048.MB-HR

**Issued:** 24 September 2020

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**Test Report:**

**EN 13727:2012+A2:2015**

Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal 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:**

20H/048

Name of the product:

Hand Sanitiser Alcohol Based

Batch number/reference and  
expiry date (if available):

4735

Date of delivery:

07 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:

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.

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**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 13727:2012+A2:2015 (5.5.2)

**Experimental conditions:**

Period of analysis: 18 September 2020 to 21 September 2020

Product test concentration(s): Neat

Diluent used for product test solution(s): N/A

Contact time(s): 30 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* (NCIMB 10421)  
*Escherichia coli* K12 (NCIMB 10083)  
*Staphylococcus aureus* (NCTC 10788)  
*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 13727:2012+A2:2015 (5.4.2) or EN 13727:2012+A2:2015 (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.

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**Requirements:**

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

**Conclusion:**

According to EN 13727:2012+A2:2015, this sample of Hand Sanitiser Alcohol Based possesses bactericidal activity against all of the referenced strains of *Pseudomonas aeruginosa*, *Escherichia coli* K12, *Staphylococcus aureus* and *Enterococcus hirae*, when tested neat with a contact time of 30 seconds at 20°C under clean 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

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Results: EN 13727:2012+A2:2015

RST 004 (Issue 4)

Test organism:	<i>Pseudomonas aeruginosa</i>	(NCIMB 10421)
Date of test:	18 September 2020	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 ( $N_{V_0}$ )			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: <i>Neat</i>		
Vc1	52	$\bar{x} =$	Vc1	54	$\bar{x} =$	Vc1	55	$\bar{x} =$	Vc1	54	$\bar{x} =$
Vc2	56	54	Vc2	57	55.5	Vc2	52	53.5	Vc2	50	52
30 ≤ $\bar{x}$ of $N_{V_0}$ ≤ 160 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x}$ of A ≥ 0.5 x $\bar{x}$ of $N_{V_0}$ ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x}$ of B ≥ 0.5 x $\bar{x}$ of $N_{V_0}$ ? (or $N_{V_B} / 1000$ ) ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x}$ of C ≥ 0.5 x $\bar{x}$ of $N_{V_0}$ ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		
Validation suspension ( $N_{V_B}$ )											
Vc1	55	$\bar{x} =$									
Vc2	51	53									
30 ≤ $\bar{x}$ of $N_{V_B} / 1000$ ≤ 160 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no											

**Test suspension ( $N$  and  $N_0$ ):**

$N$	Vc1	Vc2	$\bar{x}$ wm = 2.53 x 10 <sup>8</sup> ; $N_0 = N / 10$ ; 7.17 ≤ lg $N_0$ ≤ 7.70 ?
10 <sup>-6</sup>	264	248	lg $N$ = 8.40 lg $N_0$ = 7.40
10 <sup>-7</sup>	23	22	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

**Test:**

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	$Na$ ( $\bar{x} \times 10$ or $\bar{x}$ wm x 10)	lg $Na$	lg $R$ (lg $N_0$ - lg $Na$ )
<i>Neat</i>	30 s	10 <sup>0</sup>	0	0	<140	<2.15	>5.25
		10 <sup>-1</sup>	0	0			

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Results: EN 13727:2012+A2:2015

RST 004 (Issue 4)

Test organism:	<i>Escherichia coli</i> K12	(NCIMB 10083)
Date of test:	18 September 2020	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 ( $N_{V_0}$ )			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: <i>Neat</i>		
Vc1	45	$\bar{x} =$	Vc1	49	$\bar{x} =$	Vc1	53	$\bar{x} =$	Vc1	46	$\bar{x} =$
Vc2	54	49.5	Vc2	57	53	Vc2	50	51.5	Vc2	49	47.5
30 ≤ $\bar{x}$ of $N_{V_0}$ ≤ 160 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x}$ of A ≥ 0.5 x $\bar{x}$ of $N_{V_0}$ ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x}$ of B ≥ 0.5 x $\bar{x}$ of $N_{V_0}$ ? (or $N_{V_B} / 1000$ ) ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x}$ of C ≥ 0.5 x $\bar{x}$ of $N_{V_0}$ ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		
Validation suspension ( $N_{V_B}$ )											
Vc1	50	$\bar{x} =$									
Vc2	47	48.5									
30 ≤ $\bar{x}$ of $N_{V_B} / 1000$ ≤ 160 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no											

**Test suspension ( $N$  and  $N_0$ ):**

$N$	Vc1	Vc2	$\bar{x}$ wm = 2.53 x 10 <sup>8</sup> ;	lg $N$ = 8.40
10 <sup>-6</sup>	264	248	$N_0 = N / 10$ ;	lg $N_0$ = 7.40
10 <sup>-7</sup>	23	22	7.17 ≤ lg $N_0$ ≤ 7.70 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	

**Test:**

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	$Na$ ( $\bar{x} \times 10$ or $\bar{x}$ wm x 10)	lg $Na$	lg $R$ (lg $N_0$ - lg $Na$ )
<i>Neat</i>	30 s	10 <sup>0</sup>	0	0	<140	<2.15	>5.25
		10 <sup>-1</sup>	0	0			

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Results: EN 13727:2012+A2:2015

RST 004 (Issue 4)

Test organism:	<i>Staphylococcus aureus</i>	(NCTC 10788)
Date of test:	18 September 2020	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 ( $N_{V_0}$ )			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: <i>Neat</i>		
Vc1	56	$\bar{x} =$	Vc1	50	$\bar{x} =$	Vc1	55	$\bar{x} =$	Vc1	54	$\bar{x} =$
Vc2	54	55	Vc2	53	51.5	Vc2	52	53.5	Vc2	50	52
30 ≤ $\bar{x}$ of $N_{V_0}$ ≤ 160 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x}$ of A ≥ 0.5 × $\bar{x}$ of $N_{V_0}$ ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x}$ of B ≥ 0.5 × $\bar{x}$ of $N_{V_0}$ ? (or $N_{V_B} / 1000$ ) ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x}$ of C ≥ 0.5 × $\bar{x}$ of $N_{V_0}$ ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		
Validation suspension ( $N_{V_B}$ )											
Vc1	52	$\bar{x} =$									
Vc2	57	54.5									
30 ≤ $\bar{x}$ of $N_{V_B} / 1000$ ≤ 160 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no											

**Test suspension ( $N$  and  $N_0$ ):**

$N$	Vc1	Vc2	$\bar{x}$ wm = 2.86 × 10 <sup>8</sup> ; $N_0 = N / 10$ ; 7.17 ≤ lg $N_0$ ≤ 7.70 ?
10 <sup>-6</sup>	288	288	lg $N$ = 8.46 lg $N_0$ = 7.46
10 <sup>-7</sup>	28	26	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

**Test:**

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	$Na$ ( $\bar{x} \times 10$ or $\bar{x}$ wm × 10)	lg $Na$	lg $R$ (lg $N_0$ - lg $Na$ )
<i>Neat</i>	30 s	10 <sup>0</sup>	0	0	<140	<2.15	>5.31
		10 <sup>-1</sup>	0	0			

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Results: EN 13727:2012+A2:2015

RST 004 (Issue 4)

Test organism:	<i>Enterococcus hirae</i>	(NCIMB 8192)
Date of test:	18 September 2020	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 ( $N_{V_0}$ )			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: <i>Neat</i>		
Vc1	35	$\bar{x} =$	Vc1	33	$\bar{x} =$	Vc1	37	$\bar{x} =$	Vc1	32	$\bar{x} =$
Vc2	36	35.5	Vc2	39	36	Vc2	35	36	Vc2	40	36
30 ≤ $\bar{x}$ of $N_{V_0}$ ≤ 160 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x}$ of A ≥ 0.5 x $\bar{x}$ of $N_{V_0}$ ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x}$ of B ≥ 0.5 x $\bar{x}$ of $N_{V_0}$ ? (or $N_{V_B} / 1000$ ) ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			$\bar{x}$ of C ≥ 0.5 x $\bar{x}$ of $N_{V_0}$ ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no		
Validation suspension ( $N_{V_B}$ )											
Vc1	33	$\bar{x} =$									
Vc2	37	35									
30 ≤ $\bar{x}$ of $N_{V_B} / 1000$ ≤ 160 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no											

**Test suspension ( $N$  and  $N_0$ ):**

$N$	Vc1	Vc2	$\bar{x}$ wm = 1.85 x 10 <sup>8</sup> ; $N_0 = N / 10$ ; 7.17 ≤ lg $N_0$ ≤ 7.70 ?
10 <sup>-6</sup>	184	192	lg $N$ = 8.27 lg $N_0$ = 7.27
10 <sup>-7</sup>	15	17	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

**Test:**

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	$Na$ ( $\bar{x} \times 10$ or $\bar{x}$ wm x 10)	lg $Na$	lg $R$ (lg $N_0$ - lg $Na$ )
<i>Neat</i>	30 s	10 <sup>0</sup>	0	0	<140	<2.15	>5.12
		10 <sup>-1</sup>	0	0			

**Explanations:**

$V_c$	count per ml (one plate or more)
$\bar{x}$	average of $V_{c1}$ and $V_{c2}$ (1 + 2 duplicate)
$\bar{x}_{wm}$	weighted mean of $\bar{x}$
$N$	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 ( $N_o = N / 10$ )
$N_a$	number of survivors per ml in the test mixture at the end of the contact time (before neutralisation or filtration)
$R$	reduction ( $\lg R = \lg N_o - \lg N_a$ )
$N_v$	number of cells per ml in the validation suspension
$N_{v_o}$	number of cells in the validation mixtures at the beginning of the contact time ( $N_{v_o} = N_v / 10$ )
$N_{v_b}$	number of cells per ml in the neutraliser control validation suspension
$A$	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