

Report: SSL.22B059.MB-HR

Issued: 28 February 2022

Page: 1 of 8

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, Great Britain

Identification of the client:

Safe Solutions (Safe4) Ltd
Wharton Green, Bostock Road, Winsford, CW7 3BD, Great Britain

Identification of the sample:

22B/059

Name of the product:

Safe4 Hand Sanitiser

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

516

Date of delivery:

08 February 2022

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.

Report: SSL.22B059.MB-HR

Issued: 28 February 2022

Page: 2 of 8

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: 22 February 2022 to 24 February 2022

Product test concentration(s): Neat

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

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)
Escherichia coli K12 (NCTC 10538)
Staphylococcus aureus (NCTC 10788)
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 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.

Report: SSL.22B059.MB-HR

Issued: 28 February 2022

Page: 3 of 8

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 Safe4 Hand Sanitiser possesses bactericidal activity against all of the referenced strains of *Pseudomonas aeruginosa*, *Escherichia K12*, *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: 28 February 2022

Report: SSL.22B059.MB-HR

Issued: 28 February 2022

Page: 4 of 8

Results: EN 13727:2012+A2:2015

RST 004 (Issue 4)

Test organism:	<i>Pseudomonas aeruginosa</i>	(DSM 939)
Date of test:	22 February 2022	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	42	$\bar{x} =$	Vc1	46	$\bar{x} =$	Vc1	52	$\bar{x} =$	Vc1	52	$\bar{x} =$
Vc2	50	46	Vc2	48	47	Vc2	46	49	Vc2	49	50.5
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	52	$\bar{x} =$									
Vc2	47	49.5									
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 = 3.08 x 10 ⁸ ; $N_0 = N / 10$; 7.17 ≤ lg N_0 ≤ 7.70 ?
10 ⁻⁶	304	296	lg N = 8.49 lg N_0 = 7.49
10 ⁻⁷	42	35	<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>	60 s	10 ⁰	0	0	<140	<2.15	>5.34
		10 ⁻¹	0	0			

Report: SSL.22B059.MB-HR

Issued: 28 February 2022

Page: 5 of 8

Results: EN 13727:2012+A2:2015

RST 004 (Issue 4)

Test organism:	<i>Escherichia coli</i> K12	(NCTC 10538)
Date of test:	22 February 2022	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	50	\bar{x} =	Vc1	44	\bar{x} =	Vc1	44	\bar{x} =	Vc1	50	\bar{x} =
Vc2	46	48	Vc2	49	46.5	Vc2	48	46	Vc2	45	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	56	\bar{x} =									
Vc2	46	51									
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 = 2.83 x 10 ⁸ ; $N_0 = N / 10$; 7.17 ≤ lg N_0 ≤ 7.70 ?
10 ⁻⁶	312	264	lg N = 8.45 lg N_0 = 7.45
10 ⁻⁷	24	23	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	Na (\bar{x} x 10 or \bar{x} wm x 10)	lg Na	lg R (lg N_0 - lg Na)
<i>Neat</i>	60 s	10 ⁰	0	0	<140	<2.15	>5.30
		10 ⁻¹	0	0			

Report: SSL.22B059.MB-HR

Issued: 28 February 2022

Page: 6 of 8

Results: EN 13727:2012+A2:2015

RST 004 (Issue 4)

Test organism:	<i>Staphylococcus aureus</i>	(NCTC 10788)
Date of test:	22 February 2022	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	58	$\bar{x} =$	Vc1	48	$\bar{x} =$	Vc1	56	$\bar{x} =$	Vc1	48	$\bar{x} =$
Vc2	52	55	Vc2	50	49	Vc2	52	54	Vc2	45	46.5
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	60	$\bar{x} =$									
Vc2	55	57.5									
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 = 2.38 × 10 ⁸ ; $N_0 = N / 10$; 7.17 ≤ lg N_0 ≤ 7.70 ?
10 ⁻⁶	240	240	lg N = 8.38 lg N_0 = 7.38
10 ⁻⁷	21	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 × 10)	lg Na	lg R (lg N_0 - lg Na)
<i>Neat</i>	60 s	10 ⁰	0	0	<140	<2.15	>5.23
		10 ⁻¹	0	0			

Report: SSL.22B059.MB-HR

Issued: 28 February 2022

Page: 7 of 8

Results: EN 13727:2012+A2:2015

RST 004 (Issue 4)

Test organism:	<i>Enterococcus hirae</i>	(DSM 3320)
Date of test:	22 February 2022	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	34	$\bar{x} =$	Vc1	44	$\bar{x} =$	Vc1	50	$\bar{x} =$	Vc1	40	$\bar{x} =$
Vc2	34	34	Vc2	40	42	Vc2	42	46	Vc2	42	41
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	38	$\bar{x} =$									
Vc2	33	35.5									
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 = 2.23 x 10 ⁸ ; $N_0 = N / 10$; 7.17 ≤ lg N_0 ≤ 7.70 ?
10 ⁻⁶	224	228	lg N = 8.35 lg N_0 = 7.35
10 ⁻⁷	19	20	<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>	60 s	10 ⁰	0	0	<140	<2.15	>5.20
		10 ⁻¹	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