

Report: SSL.21J129.IB-HR

Issued: 01 November 2021

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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:

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

Identification of the sample:

21J/129

Name of the product:	Safe4 Alcohol-Free Hand Sanitiser
Batch number/reference and expiry date (if available):	5547
Date of delivery:	28 September 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:	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 1276:2019 (5.5.2)

Experimental conditions:

Period of analysis: 26 October 2021 to 28 October 2021

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* (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 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, this sample of Safe4 Alcohol-Free Hand Sanitiser 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.

Approved by:

Signed:



Name: Tony Watson

Position: General Manager

Date: 01 November 2021

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Results: EN 1276:2019

RST 002 (Issue 5)

Test organism:	<i>Pseudomonas aeruginosa</i>	(DSM 939)
Date of test:	26 October 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 (N_{V_0})			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: <i>Neat</i>		
Vc1	65	$\bar{x} =$	Vc1	66	$\bar{x} =$	Vc1	84	$\bar{x} =$	Vc1	61	$\bar{x} =$
Vc2	75	70	Vc2	83	74.5	Vc2	70	77	Vc2	66	63.5
30 ≤ \bar{x} of N_{V_0} ≤ 160 ?			\bar{x} of A ≥ 0.5 x \bar{x} of N_{V_0} ?			\bar{x} of B ≥ 0.5 x \bar{x} of N_{V_0} ?			\bar{x} of C ≥ 0.5 x \bar{x} of N_{V_0} ?		
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		

Test suspension (N and N_0):

N	Vc1	Vc2	\bar{x} wm = 2.49 x 10 ⁸ ; lg N = 8.40	
10 ⁻⁶	268	228	$N_0 = N / 10$; lg N_0 = 7.40	
10 ⁻⁷	28	23	7.17 ≤ lg N_0 ≤ 7.70 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	

Test:

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

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Results: EN 1276:2019

RST 002 (Issue 5)

Test organism:	<i>Escherichia coli</i> K12	(NCTC 10538)
Date of test:	26 October 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 (N_{V_0})			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: <i>Neat</i>		
Vc1	40	$\bar{x} =$	Vc1	47	$\bar{x} =$	Vc1	42	$\bar{x} =$	Vc1	45	$\bar{x} =$
Vc2	43	41.5	Vc2	36	41.5	Vc2	38	40	Vc2	36	40.5
30 ≤ \bar{x} of N_{V_0} ≤ 160 ?			\bar{x} of A ≥ 0.5 × \bar{x} of N_{V_0} ?			\bar{x} of B ≥ 0.5 × \bar{x} of N_{V_0} ?			\bar{x} of C ≥ 0.5 × \bar{x} of N_{V_0} ?		
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		

Test suspension (N and N_0):

N	Vc1	Vc2	\bar{x} wm = 2.10 × 10 ⁸ ;	lg N = 8.32
10 ⁻⁶	212	184	$N_0 = N / 10$;	lg N_0 = 7.32
10 ⁻⁷	41	24	7.17 ≤ lg N_0 ≤ 7.70 ?	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

Conc. of the product	Contact time	Vc1	Vc2	N_a ($\bar{x} \times 10$)	lg N_a	lg R (lg N_0 - lg N_a)
<i>Neat</i>	30 s	0	0	<140	<2.15	>5.17

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Results: EN 1276:2019

RST 002 (Issue 5)

Test organism:	<i>Staphylococcus aureus</i>	(NCTC 10788)
Date of test:	26 October 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 (N_{v0})			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: <i>Neat</i>		
Vc1	88	$\bar{x} =$	Vc1	60	$\bar{x} =$	Vc1	95	$\bar{x} =$	Vc1	76	$\bar{x} =$
Vc2	80	84	Vc2	42	51	Vc2	96	95.5	Vc2	38	57
30 ≤ \bar{x} of N_{v0} ≤ 160 ?			\bar{x} of A ≥ 0.5 x \bar{x} of N_{v0} ?			\bar{x} of B ≥ 0.5 x \bar{x} of N_{v0} ?			\bar{x} of C ≥ 0.5 x \bar{x} of N_{v0} ?		
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		

Test suspension (N and N_0):

N	Vc1	Vc2	\bar{x} wm = 1.71 x 10 ⁸ ;	lg N = 8.23
10 ⁻⁶	176	166	$N_0 = N / 10$;	lg N_0 = 7.23
10 ⁻⁷	18	16	7.17 ≤ lg N_0 ≤ 7.70 ?	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

Conc. of the product	Contact time	Vc1	Vc2	N_a ($\bar{x} \times 10$)	lg N_a	lg R (lg N_0 - lg N_a)
<i>Neat</i>	30 s	0	0	<140	<2.15	>5.08

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RST 002 (Issue 5)

Test organism:	<i>Enterococcus hirae</i>	(DSM 3320)
Date of test:	26 October 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 (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	68	$\bar{x} =$	Vc1	90	$\bar{x} =$	Vc1	110	$\bar{x} =$
Vc2	45	48.5	Vc2	52	60	Vc2	97	93.5	Vc2	116	113
30 ≤ \bar{x} of N_{V_0} ≤ 160 ?			\bar{x} of A ≥ 0.5 × \bar{x} of N_{V_0} ?			\bar{x} of B ≥ 0.5 × \bar{x} of N_{V_0} ?			\bar{x} of C ≥ 0.5 × \bar{x} of N_{V_0} ?		
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		

Test suspension (N and N_0):

N	Vc1	Vc2	\bar{x} wm = 2.64 × 10 ⁸ ;	lg N = 8.42
10 ⁻⁶	228	280	$N_0 = N / 10$;	lg N_0 = 7.42
10 ⁻⁷	29	43	7.17 ≤ lg N_0 ≤ 7.70 ?	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

Conc. of the product	Contact time	Vc1	Vc2	N_a ($\bar{x} \times 10$)	lg N_a	lg R (lg N_0 - lg N_a)
<i>Neat</i>	30 s	0	0	<140	<2.15	>5.27

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_0	number of cells in the test mixture at the beginning of the contact time ($N_0 = N / 10$)
N_a	number of survivors per ml in the test mixture at the end of the contact time (before neutralisation or filtration)
R	reduction ($\lg R = \lg N_0 - \lg N_a$)
N_v	number of cells per ml in the validation suspension
N_{v_0}	number of cells in the validation mixtures at the beginning of the contact time ($N_{v_0} = N_v / 10$)
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.