

Report: SSL.19D033.MF2

Issued: 29 April 2019

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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.

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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 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): 30 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: *Aspergillus brasiliensis* (DSM 1988)
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).

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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 fungicidal activity when tested at a concentration of 1:20 with a contact time of 30 minutes at 20°C under clean conditions against both of the referenced strains of *Aspergillus brasiliensis* and *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

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Results: EN 13624:2013

Test organism:	<i>Aspergillus brasiliensis</i>	(DSM 1988)
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 (N_{V_0})			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: 1:20		
Vc1	39	\bar{x} =	Vc1	34	\bar{x} =	Vc1	39	\bar{x} =	Vc1	33	\bar{x} =
Vc2	36	37.5	Vc2	31	32.5	Vc2	40	39.5	Vc2	35	34
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	37	\bar{x} =	30 ≤ \bar{x} of $N_{V_B} / 1000$ ≤ 160 ?			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		
			Vc2	40	38.5						

Test suspension (N and N_0):

N	Vc1	Vc2	\bar{x} wm = 2.05 × 10 ⁷ ;	lg N = 7.31
10 ⁻⁵	>165	>165	$N_0 = N / 10$;	lg N_0 = 6.31
10 ⁻⁶	21	20	6.17 ≤ lg N_0 ≤ 6.70 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	

Test:

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	N_a (\bar{x} × 10 or \bar{x} wm × 10)	lg N_a	lg R (lg N_0 - lg N_a)
1:20	30 min	10 ⁰	10	8	<140	<2.15	>4.16
		10 ⁻¹	1	0			

Results: EN 13624:2013

Test organism:	<i>Candida albicans</i>	(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 (N_{V_0})			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: 1:20		
Vc1	40	\bar{x} =	Vc1	39	\bar{x} =	Vc1	39	\bar{x} =	Vc1	37	\bar{x} =
Vc2	43	41.5	Vc2	40	39.5	Vc2	45	42	Vc2	43	40
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	42	\bar{x} =	30 ≤ \bar{x} of $N_{V_B} / 1000$ ≤ 160 ?			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		
			Vc2	41	41.5						

Test suspension (N and N_0):

N	Vc1	Vc2	\bar{x} wm = 1.67 x 10 ⁷ ;	lg N = 7.22
10 ⁻⁵	165	167	$N_0 = N / 10$;	lg N_0 = 6.22
10 ⁻⁶	18	18	6.17 ≤ lg N_0 ≤ 6.70 ? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	

Test:

Conc. of the product	Contact time	Dilution step	Vc1	Vc2	N_a (\bar{x} x 10 or \bar{x} wm x 10)	lg N_a	lg R (lg N_0 - lg N_a)
1:20	30 min	10 ⁰	0	0	<140	<2.15	>4.07
		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 ($N_{v_o} = N_v / 10$)
- 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