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Test Report: EN 1650:2019

Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal 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/034

Name of the product:	Safe4 Alcohol-Free Hand Sanitiser
Batch number/reference and expiry date (if available):	L503, 22/07/21
Date of delivery:	09 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.

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 1650:2019 (5.5.2)

Experimental conditions:

Period of analysis:	17 September 2021 to 20 September 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:	30°C ± 1°C
Identification of the fungal 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 1650:2019 (5.4.2) or EN 1650:2019 (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 4 decimal log (lg) reduction against every test organism.

Conclusion:

According to EN 1650:2019, this sample of Safe4 Alcohol-Free Hand Sanitiser does not possess yeasticidal activity against the referenced strain of *Candida albicans*, 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: 24 September 2021

Results: EN 1650:2019

RST 005 (Issue 5)

Test organism:	*Candida albicans*		(DSM 1386)
Date of test:	17 September 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:	30°C ± 1°C

Validation and controls:

Validation suspension (Nv_o)			Experimental conditions control (*A*)			Neutraliser or filtration control (*B*)			Method validation (*C*) Product conc.: *Neat*		
*Vc*1	*35*	$\overline{n}$ =	*Vc*1	*90*	$\overline{n}$ =	*Vc*1	*112*	$\overline{n}$ =	*Vc*1	*77*	$\overline{n}$ =
*Vc*2	*36*	35.5	*Vc*2	*93*	91.5	*Vc*2	*76*	94	*Vc*2	*88*	82.5
$30 \le \overline{n}$ of $Nv_o \le 160$?			$\overline{n}$ of $A \ge 0.5 \times \overline{n}$ of Nv_o ?			$\overline{n}$ of $B \ge 0.5 \times \overline{n}$ of Nv_o ?			$\overline{n}$ of $C \ge 0.5 \times \overline{n}$ of Nv_o ?		
☒ yes ☐ no			☒ yes ☐ no			☒ yes ☐ no			☒ yes ☐ no		

Test suspension (*N* and N_o):

N	*Vc*1	*Vc*2			
10^{-5}	*296*	*296*	$\overline{n}$ wm = 3.01×10^7 ;	lg *N* =	7.48
10^{-6}	*32*	*38*	$N_o = N / 10$;	lg N_o =	6.48
			$6.17 \le \lg N_o \le 6.70$?	☒ yes	☐ no

Test:

Conc. of the product	Contact time	*Vc*1	*Vc*2	*Na* ($\overline{n} \times 10$)	lg *Na*	lg *R* (lg N_o - lg *Na*)
Neat	*30 s*	*320*	*296*	3080	3.49	2.99

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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
B	number of survivors per ml in the neutraliser or filtration control mixture
C	number of survivors per ml in the method validation mixture

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