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, 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.

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:	30°C ± 1°C
Identification of the bacterial 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 13624:2013 (5.4.2) or EN 13624:2013 (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 13624:2013, this sample of Safe4 Hand Sanitiser possesses yeasticidal activity against the referenced strain of *Candida albicans*, 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

Results: EN 13624:2013

RST 019 (Issue 3)

Test organism:	*Candida albicans*		(DSM 1386)
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:	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	*48*	$\overline{n}$ =	*Vc*1	*55*	$\overline{n}$ =	*Vc*1	*56*	$\overline{n}$ =	*Vc*1	*53*	$\overline{n}$ =
*Vc*2	*51*	49.5	*Vc*2	*52*	53.5	*Vc*2	*49*	52.5	*Vc*2	*51*	52
$30 \le \overline{n}$ of $Nv_o \le 160$? ☒ yes ☐ no			$\overline{n}$ of $A \ge 0.5 \times \overline{n}$ of Nv_o ? ☒ yes ☐ no			$\overline{n}$ of $B \ge 0.5 \times \overline{n}$ of Nv_o (or Nv_B / 1000) ? ☒ yes ☐ no			$\overline{n}$ of $C \ge 0.5 \times \overline{n}$ of Nv_o ? ☒ yes ☐ no		

Validation suspension (Nv_B)		
*Vc*1	*50*	$\overline{n}$ =
*Vc*2	*50*	50
$30 \le \overline{n}$ of $Nv_B / 1000 \le 160$? ☒ yes ☐ no		

Test suspension (*N* and N_o):

N	*Vc*1	*Vc*2		
10^{-5}	*248*	*252*	$\overline{n}$ wm = 2.47×10^7 ;	lg *N* = 7.39
10^{-6}	*22*	*21*	$N_o = N / 10$;	lg N_o = 6.39
			$6.17 \le \lg N_o \le 6.70$?	☒ yes ☐ no

Test:

Conc. of the product	Contact time	Dilution step	*Vc*1	*Vc*2	*Na* ($\overline{n}$ x 10 or $\overline{n}$ wm x 10)	lg *Na*	lg *R* (lg N_o - lg *Na*)
Neat	*60 s*	10^0	*20*	*22*	210	2.32	4.07
		10^{-1}	*1*	*2*			

Abbott Analytical Ltd
Unit 2, Hickmans Road,
Birkenhead, CH41 1JH, United Kingdom

T: +44 (0)151 345 6753
E: enqs@abbottanalytical.co.uk
W: www.abbottanalytical.co.uk

Registered address: Kemp House, 160 City Road,
London, EC1V 2NX, United Kingdom

A company registered in England and Wales
Company number: 10031406

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 ($Nv_o = Nv / 10$)
Nv_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