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Test Report: EN 1276:2009

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, United Kingdom
Identification of the client:	Allied Hygiene Systems Ltd 5 Centurion Way, Erith, DA18 4AF, United Kingdom
Identification of the sample:	19F/024
Name of the product:	Sanisafe 3 No Alcohol
Batch number/reference and expiry date (if available):	N/A
Date of delivery:	7 June 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:	White ready-to-use wipes, containing a 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.
3) Re-issue of report ALH.19F024.IPaSa, dated 22 February 2021.

Test method and its validation:

Method:	Dilution-neutralisation
Neutraliser:	30.0 g/l Polysorbate 80 + 3.0 g/l Lecithin + 1.0 g/l L-histidine + 1.0 g/l L-cysteine (Neutraliser A)
Neutraliser validation:	Validated in accordance with EN 1276:2009 (5.5.2)

Experimental conditions:

Period of analysis:	18 June 2019 to 20 June 2019
Product test concentration(s):	Neat liquid squeezed from the wipes
Diluent used for product test solution(s):	N/A
Contact time(s):	2 min ± 10 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* (NCIMB 10421)

Deviations: None

Remarks:

1) All test conditions are as requested by the client, irrespective of whether these are in accordance with EN 1276:2009 (5.4.2) or EN 1276:2009 (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 1276:2009, the liquid squeezed from this sample of Sanisafe 3 No Alcohol wipes possesses bactericidal activity when tested neat with a contact time of 2 minutes at 20°C under clean conditions against the referenced strain of *Pseudomonas aeruginosa*.

Report re-issued by:		**Approved by:**	
Signed:		Signed:	
Name:	Tony Watson	Name:	Kirsty Murden
Position:	General Manager	Position:	Laboratory Manager
Date:	22 February 2021	Date:	22 February 2021

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A company registered in England and Wales
Company number: 10031406

Results: EN 1276:2009

Test organism:	*Pseudomonas aeruginosa*		(NCIMB 10421)
Date of test:	18 June 2019		
Test temperature:	20°C ± 1°C	Incubation temperature:	36°C ± 1°C
Dilution-neutralisation method:	Pour plate	Number of plates:	1 / ml
Neutraliser:	A	Test conditions:	Clean conditions

Validation and controls:

Validation suspension (Nv_o)			Experimental conditions control (*A*)			Neutraliser or filtration control (*B*)			Method validation (*C*) Product conc.: *Neat**		
*Vc*1	*43*	$\overline{\kappa}$ =	*Vc*1	*40*	$\overline{\kappa}$ =	*Vc*1	*40*	$\overline{\kappa}$ =	*Vc*1	*42*	$\overline{\kappa}$ =
*Vc*2	*45*	44	*Vc*2	*37*	38.5	*Vc*2	*39*	39.5	*Vc*2	*50*	46
$30 \le \overline{\kappa}$ of $Nv_o \le 160$?			$\overline{\kappa}$ of $A \ge 0.5 \times \overline{\kappa}$ of Nv_o ?			$\overline{\kappa}$ of $B \ge 0.5 \times \overline{\kappa}$ of Nv_o ?			$\overline{\kappa}$ of $C \ge 0.5 \times \overline{\kappa}$ of Nv_o ?		
☒ yes ☐ no			☒ yes ☐ no			☒ yes ☐ no			☒ yes ☐ no		

Test suspension (*N* and N_o):

N	*Vc*1	*Vc*2			
10^{-6}	*258*	*249*	$\overline{\kappa}$ wm = 2.55×10^{8} ;	lg *N* =	8.41
10^{-7}	*25*	*28*	$N_o = N / 10$;	lg N_o =	7.41
			$7.17 \le \lg N_o \le 7.70$?	☒ yes	☐ no

Test:

Conc. of the product	Contact time	*Vc*1	*Vc*2	*Na* ($\overline{\kappa} \times 10$)	lg *Na*	lg *R* (lg N_o - lg *Na*)
*Neat**	*2 min*	*0*	*0*	<140	<2.15	>5.26

*Neat liquid squeezed from wipes

Explanations:

Vc	count per ml (one plate or more)
$\overline{Vc}$	average of *Vc*1 and *Vc*2 (1 + 2 duplicate)
$\overline{Vc}$ wm	weighted mean of $\overline{Vc}$
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 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

All test results have an associated uncertainty of measurement, details of which are available on request.

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