Report: ALH.20H042.SB **Issued:** 24 September 2020 **Page:** 1 of 8

Test Report: EN 13697:2015+A1:2019

Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 2)

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:	20H/042
Name of the product:	Sanisafe 3 Wipes
Batch number/reference and expiry date (if available):	N/A
Date of delivery:	06 August 2020
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 wipes from which was squeezed 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.

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 13697:2015+A1:2019 (5.5.2)

Experimental conditions:

Period of analysis:	18 September 2020 to 21 September 2020
Product test concentration(s):	Neat liquid squeezed from wipes
Diluent used for product test solution(s):	N/A
Contact time(s):	5 min ± 10 s
Test temperature(s):	20°C ± 1°C
Interfering substance:	3.0 g/l bovine albumin (dirty conditions)
Temperature of incubation:	36°C ± 1°C
Identification of the bacterial strain(s) used:	*Pseudomonas aeruginosa* (NCIMB 10421) *Escherichia coli* (NCTC 10418) *Staphylococcus aureus* (NCTC 10788) *Enterococcus hirae* (NCIMB 8192)

Deviations: None

Remarks:

1) All test conditions are as requested by the client, irrespective of whether these are in accordance with EN 13697:2015+A1:2019 (5.4.2) or EN 13697:2015+A1:2019 (5.5.1).

Requirements:

The product shall demonstrate at least a 4 decimal log (lg) reduction against every test organism.

Conclusion:

According to EN 13697:2015+A1:2019, the liquid squeezed from this sample of Sanisafe 3 Wipes possesses bactericidal activity against all of the referenced strains of *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus* and *Enterococcus hirae*, when tested neat with a contact time of 5 minutes at 20°C under dirty conditions.

Report prepared by:

Signed:

Name: Karl Cumings

Position: Microbiologist

Date: 24 September 2020

Approved by:

Signed:

Name: Tony Watson

Position: General Manager

Date: 24 September 2020

Results: EN 13697:2015+A1:2019

RST 012 (Issue 4)

Test organism:	*Pseudomonas aeruginosa*		(NCIMB 10421)
Date of test:	18 September 2020	Test temperature:	20°C ± 1°C
Interfering substance:	3.0 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:

Test and validation suspension (*N*)			Neutraliser toxicity control (*NC*)			Method validation (*NT*) Product conc.: *Neat**		
	*Vc*1	*Vc*2		*Vc*1	*Vc*2		*Vc*1	*Vc*2
10^{-6}	*264*	*248*	10^{-3}	*259*	*238*	10^{-3}	*232*	*241*
10^{-7}	*23*	*22*	10^{-4}	*27*	*29*	10^{-4}	*23*	*26*
			10^{-5}	*2*	*4*	10^{-5}	*2*	*2*
lg *N* = 6.80			lg *NC* = 6.40			lg *NT* = 6.38		
6.57 ≤ lg *N* ≤ 7.10 ? ☒ yes ☐ no			-0.3 ≤ lg *NC* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no			-0.3 ≤ lg *NT* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no		

Water control (*Nc*):

Nc	*Vc*1	*Vc*2	
10^{-3}	*240*	*240*	lg *Nc* = 6.38
10^{-4}	*28*	*22*	
10^{-5}	*4*	*3*	
Nts	*9*		

Test:

Conc. of the product	Contact time	Dilution step	*Vc*1	*Vc*2	lg *Nd*	lg *R* (lg *Nc* - lg *Nd*)
*Neat**	*5 min*	10^{0}	*0*	*0*	<0.10	>6.28
		10^{-1}	*0*	*0*		
		10^{-2}	*0*	*0*		
		Nts	*0*			

*Neat liquid squeezed from wipes

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A company registered in England and Wales
Company number: 10031406

Results: EN 13697:2015+A1:2019

RST 012 (Issue 4)

Test organism:	*Escherichia coli*		(NCTC 10418)
Date of test:	18 September 2020	Test temperature:	20°C ± 1°C
Interfering substance:	3.0 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:

Test and validation suspension (*N*)			Neutraliser toxicity control (*NC*)			Method validation (*NT*) Product conc.: *Neat**		
	*Vc*1	*Vc*2		*Vc*1	*Vc*2		*Vc*1	*Vc*2
10^{-6}	*224*	*232*	10^{-3}	*247*	*255*	10^{-3}	*239*	*245*
10^{-7}	*22*	*21*	10^{-4}	*25*	*29*	10^{-4}	*24*	*27*
			10^{-5}	*2*	*4*	10^{-5}	*2*	*3*
lg *N* = 6.75			lg *NC* = 6.40			lg *NT* = 6.39		
6.57 ≤ lg *N* ≤ 7.10 ? ☒ yes ☐ no			-0.3 ≤ lg *NC* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no			-0.3 ≤ lg *NT* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no		

Water control (*Nc*):

Nc	*Vc*1	*Vc*2	
10^{-3}	*256*	*250*	lg *Nc* = 6.41
10^{-4}	*30*	*28*	
10^{-5}	*3*	*3*	
Nts	*5*		

Test:

Conc. of the product	Contact time	Dilution step	*Vc*1	*Vc*2	lg *Nd*	lg *R* (lg *Nc* - lg *Nd*)
*Neat**	*5 min*	10^{0}	*0*	*0*	<0.10	>6.31
		10^{-1}	*0*	*0*		
		10^{-2}	*0*	*0*		
		Nts	*0*			

*Neat liquid squeezed from wipes

Results: EN 13697:2015+A1:2019

RST 012 (Issue 4)

Test organism:	*Staphylococcus aureus*		(NCTC 10788)
Date of test:	18 September 2020	Test temperature:	20°C ± 1°C
Interfering substance:	3.0 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:

Test and validation suspension (*N*)			Neutraliser toxicity control (*NC*)			Method validation (*NT*) Product conc.: *Neat**		
	*Vc*1	*Vc*2		*Vc*1	*Vc*2		*Vc*1	*Vc*2
10^{-6}	*288*	*288*	10^{-3}	*249*	*268*	10^{-3}	*264*	*259*
10^{-7}	*28*	*26*	10^{-4}	*28*	*30*	10^{-4}	*27*	*25*
			10^{-5}	*3*	*3*	10^{-5}	*2*	*2*
lg *N* = 6.85			lg *NC* = 6.42			lg *NT* = 6.42		
6.57 ≤ lg *N* ≤ 7.10 ? ☒ yes ☐ no			-0.3 ≤ lg *NC* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no			-0.3 ≤ lg *NT* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no		

Water control (*Nc*):

Nc	*Vc*1	*Vc*2	
10^{-3}	*256*	*288*	lg *Nc* = 6.44
10^{-4}	*32*	*28*	
10^{-5}	*2*	*4*	
Nts	*12*		

Test:

Conc. of the product	Contact time	Dilution step	*Vc*1	*Vc*2	lg *Nd*	lg *R* (lg *Nc* - lg *Nd*)
*Neat**	*5 min*	10^{0}	*0*	*0*	<0.10	>6.34
		10^{-1}	*0*	*0*		
		10^{-2}	*0*	*0*		
		Nts	*0*			

*Neat liquid squeezed from wipes

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Results: EN 13697:2015+A1:2019

RST 012 (Issue 4)

Test organism:	*Enterococcus hirae*		(NCIMB 8192)
Date of test:	18 September 2020	Test temperature:	20°C ± 1°C
Interfering substance:	3.0 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:

Test and validation suspension (*N*)			Neutraliser toxicity control (*NC*)			Method validation (*NT*) Product conc.: *Neat**		
	*Vc*1	*Vc*2		*Vc*1	*Vc*2		*Vc*1	*Vc*2
10^{-6}	*184*	*192*	10^{-3}	*242*	*249*	10^{-3}	*232*	*240*
10^{-7}	*15*	*17*	10^{-4}	*24*	*23*	10^{-4}	*28*	*26*
			10^{-5}	*2*	*2*	10^{-5}	*3*	*3*
lg *N* = 6.67			lg *NC* = 6.39			lg *NT* = 6.38		
6.57 ≤ lg *N* ≤ 7.10 ? ☒ yes ☐ no			-0.3 ≤ lg *NC* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no			-0.3 ≤ lg *NT* - lg *Nc* ≤ 0.3 ? ☒ yes ☐ no		

Water control (*Nc*):

Nc	*Vc*1	*Vc*2	
10^{-3}	*256*	*240*	lg *Nc* = 6.39
10^{-4}	*22*	*24*	
10^{-5}	*4*	*2*	
Nts	*5*		

Test:

Conc. of the product	Contact time	Dilution step	*Vc*1	*Vc*2	lg *Nd*	lg *R* (lg *Nc* - lg *Nd*)
*Neat**	*5 min*	10^{0}	*0*	*0*	<0.10	>6.29
		10^{-1}	*0*	*0*		
		10^{-2}	*0*	*0*		
		Nts	*0*			

*Neat liquid squeezed from wipes

Explanations:

Vc	count per ml (one plate or more)
N	number of cells per 0.025 ml in the test suspension
Nd	number of survivors per surface at the end of the contact time (before neutralisation)
Nc	number of survivors per water control surface
R	reduction (lg *R* = lg *Nc* - lg *Nd*)
NC	number of survivors per neutraliser toxicity control surface
NT	number of survivors per method validation control surface

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