



# Abbott Analytical



Consulting Scientists to the Disinfectant Industry

## Certificate of Analysis

Product name: Sanisafe Wipes

Batch or ref no:

Manufacturer or supplier: Allied Hygiene Systems Ltd  
5 Centurion Way, Erith, DA18 4AF

Sample ref: 16F/023 Date received: 13 June 2016

Date tested: 15 June 2016 Certificate date: 17 June 2016

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Analysis required: Adaptation of EN 13697:2015, 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 without mechanical action (phase 2, step 2) using medical dirty conditions

Storage conditions: Room temperature in darkness

Appearance of Clear colourless liquid product (solution):

Active substance(s) Not disclosed and their concentration(s):

### Notes

The test results in this report relate only to the sample(s) tested. 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.

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## Experimental conditions

Concentration(s) of product tested:	Neat solution squeezed from wipes
Product diluent:	N/A
Test organism(s):	Pseudomonas aeruginosa (NCTC 13359) Escherichia coli (NCTC 10418) Staphylococcus aureus (NCTC 10788) Enterococcus hirae (NCTC 13383)
Contact time(s):	5 min $\pm$ 10s
Test temperature:	20°C $\pm$ 1°C
Test conditions:	Medical dirty
Interfering substance:	3.0g/l bovine albumin + 3.0ml/l sheep erythrocytes
Method:	Dilution-neutralisation
Neutralising solution:	30g/l Polysorbate 80 + 3g/l Lecithin + 1g/l L-histidine + 1g/l L-cysteine
Incubation temperature:	37°C $\pm$ 1°C

## Conclusion

When tested neat the solution from this sample of Sanisafe Wipes meets the requirements of EN 13697:2015 for bactericidal activity in 5 minutes at 20°C, under medical dirty conditions, against the referenced strains of Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus and Enterococcus hirae.

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Results: Pseudomonas aeruginosa (NCTC 13359)

Validation and controls:

Bacterial test suspension (N)		Neutralizer toxicity control (NC)		Method validation (NT)	
Vc1	Vc2	Vc1	Vc2	Vc1	Vc2
>330	>330	10	10	-4949	810
-74539	10	-51111	110	-5101	210
$\bar{x}(wm) = 1.05 \times 10^7$		$\bar{x}(wm) = 9.90 \times 10^6$		$\bar{x}(wm) = 9.60 \times 10^6$	
$lg = 7.02$		$lg = 7.00$		$lg = 6.98$	
6.57 ≤ lg N ≤ 7.10 ?		x̄ (NC) ≥ 0.5 x x̄ (Nc) ?		x̄ (NT) ≥ 0.5 x x̄ (Nc) ?	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	
Control of weighted mean counts (N)		Quotient = N/A		-	
		Between 5 and 15 ?			
				<input type="checkbox"/> yes <input type="checkbox"/> no	

Water control:

Nc	Vc1	Vc2	
10 <sup>-4</sup>	165	169	$\bar{x}(wm) = 1.66 \times 10^7$
10 <sup>-5</sup>	11	15	lg Nc = 7.22
Nts	8		lg Nc ≥ 6.27 ?
			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

Product	Contact time	Diln. step	Vc1	Vc2	Nd = $\bar{x}(wm) \times 10^{lg R}$	Status
					lg Nd = (lg Nc - lg Nd)	
Neat	5 min	10 <sup>0</sup>	0	0	5.07	PASS < 2.15 >
		10 <sup>-1</sup>	0	0		
		10 <sup>-2</sup>	0	0		
		Nts	6			

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Results: Escherichia coli (NCTC 10418)

Validation and controls:

Bacterial test suspension (N)		Neutralizer toxicity control (NC)		Method validation (NT)	
Vc1Vc2		Vc1Vc2		Vc1Vc2	
-6330315	10	-410610810		-4989410	
-73929	10	-5141510		-5131110	
$\bar{x}(wm) = 8.10 \times 10^6$		$\bar{x}(wm) = 1.10 \times 10^7$		$\bar{x}(wm) = 9.60 \times 10^6$	
lg = 6.91		lg = 7.04		lg = 6.98	
6.57 ≤ lg N ≤ 7.10 ?		κ (NC) ≥ 0.5 x κ (Nc) ?		κ (NT) ≥ 0.5 x κ (Nc) ?	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	
Control of weighted mean counts (N)		Quotient = 9.49 - Between 5 and 15 ?		-	
				<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	

Water control:

Nc	Vc1	Vc2	$\bar{x}(wm) = 1.69 \times 10^7$ lg Nc = 7.23 lg Nc ≥ 6.27 ?
10 <sup>-4</sup>	164	169	
10 <sup>-5</sup>	22	17	
Nts	8		
			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

ProductContact test conc. time	Diln. step	Vc1	Vc2	Nd = $\bar{x}(wm) \times 10^{\lg R}$ lg Nd = (lg Nc - lg Nd)	Status
Neat 5 min	10 <sup>0</sup>				PASS < 2.15 >
	10 <sup>-1</sup>	0	0	5.08	
	10 <sup>-2</sup>	0	0		
	Nts	0	0		
		2			

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Results: Staphylococcus aureus (NCTC 10788)

Validation and controls:

Bacterial test suspension (N)		Neutralizer toxicity control (NC)		Method validation (NT)	
Vc1Vc2		Vc1Vc2		Vc1Vc2	
-6319321	10	-410410810		-4968810	
-74138	10	-5121510		-5101010	
$\bar{x}(wm) = 8.17 \times 10^6$		$\bar{x}(wm) = 1.08 \times 10^7$		$\bar{x}(wm) = 9.20 \times 10^6$	
lg = 6.91		lg = 7.03		lg = 6.96	
6.57 ≤ lg N ≤ 7.10 ?		κ (NC) ≥ 0.5 x κ (Nc) ?		κ (NT) ≥ 0.5 x κ (Nc) ?	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	
Control of weighted mean counts (N)		Quotient = 8.10 - Between 5 and 15 ?		-	
				<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	

Water control:

Nc	Vc1	Vc2	$\bar{x}(wm) = 1.34 \times 10^7$ lg Nc = 7.13 lg Nc ≥ 6.27 ?
10 <sup>-4</sup>	109	114	
	32	39	
Nts	9		
			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

Product Contact test conc. time	Diln. step	Vc1	Vc2	Nd = $\bar{x}(wm) \times 10^{lg R}$ lg Nd = (lg Nc - lg Nd)	Status	
Neat 5 min	10 <sup>0</sup>					PASS < 2.15 >
	10 <sup>-1</sup>	0	0	4.98		
	10 <sup>-2</sup>	0	0			
	Nts	0	0			
		1				

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Results: Enterococcus hirae (NCTC 13383)

Validation and controls:

Bacterial test suspension (N)		Neutralizer toxicity control (NC)		Method validation (NT)	
Vc1	Vc2	Vc1	Vc2	Vc1	Vc2
-6300321	10	-41029410		-41008610	
-74234	10	-5161110		-5141010	
$\bar{x}(wm) = 7.92 \times 10^6$		$\bar{x}(wm) = 1.01 \times 10^7$		$\bar{x}(wm) = 9.52 \times 10^6$	
lg = 6.90		lg = 7.00		lg = 6.98	
6.57 ≤ lg N ≤ 7.10 ?		x (NC) ≥ 0.5 x x (Nc) ?		x (NT) ≥ 0.5 x x (Nc) ?	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	
Control of weighted mean counts (N)		Quotient = 8.17 - Between 5 and 15 ?		-	
				<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	

Water control:

Nc	Vc1	Vc2	$\bar{x}(wm) = 8.45 \times 10^6$ lg Nc = 6.93 lg Nc ≥ 6.27 ?
10 <sup>-4</sup>	68	101	
-510	7	9	
Nts	7		
			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no

Test:

Product Contact test conc. time	Diln. step	Vc1	Vc2	Nd = $\bar{x}(wm) \times 10^{lg R}$ lg Nd = (lg Nc - lg Nd)	Status
Neat 5 min	10 <sup>0</sup>				PASS < 2.15 >
	10 <sup>-1</sup>	0	0	4.78	
	10 <sup>-2</sup>	0	0		
	Nts	0	0		
		8			

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