



Abbott Analytical



Consulting Scientists to the Disinfectant Industry

Certificate of Analysis

Sample(s): One sample of Serenity Alcohol Free Hand Sanitiser

Received from: Serenity Group, Kemp House, London, EC1V 2NX

Date received: 16 November 2011 **Date tested:** 21 November 2011

Certificate no: 11L.037B.CLG **Certificate date:** 25 November 2011

Sample ref: 11L/037 **Page:** 1 of 3

Analysis required: EN 1276, 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)

Product stored at: Room temperature

Active substance: Not declared

Test conditions: Dirty

Interfering substance: 3.0g/l bovine albumin

Product test concentration: Neat as received
(80% in test suspension)

Product diluent used during test: N/A

Contact time: 1 minute & 5 minutes

Test temperature: 20°C ± 0.5°C

Neutralising solution: 30g/l polysorbate 80, 3g/l lecithin, 1g/l histidine, 1g/l cysteine

Incubation temperature: 37°C ± 1°C

Identification of bacterial strain(s) used:

<i>Pseudomonas aeruginosa</i>	NCIMB 10421
<i>Escherichia coli</i>	NCTC 10418
<i>Staphylococcus aureus</i>	NCTC 10788
<i>Enterococcus hirae</i>	NCIMB 8192

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Test results: Contact time 1 minute

Test Organism	<i>Pseudomonas aeruginosa</i>		<i>Escherichia coli</i>		<i>Staphylococcus aureus</i>		<i>Enterococcus hirae</i>	
Validation Suspension (N_v)	Vc1 144	Vc2 118	Vc1 126	Vc2 158	Vc1 118	Vc2 142	Vc1 164	Vc2 136
	$\bar{x} = 131$		$\bar{x} = 142$		$\bar{x} = 130$		$\bar{x} = 150$	
Experimental Control (A)	Vc1 138	Vc2 154	Vc1 116	Vc2 138	Vc1 124	Vc2 150	Vc1 174	Vc2 130
	$\bar{x} = 146 \geq 0.5N_{v0}$		$\bar{x} = 127 \geq 0.5N_{v0}$		$\bar{x} = 137 \geq 0.5N_{v0}$		$\bar{x} = 152 \geq 0.5N_{v0}$	
Neutraliser Control (B)	Vc1 126	Vc2 108	Vc1 152	Vc2 124	Vc1 126	Vc2 134	Vc1 162	Vc2 128
	$\bar{x} = 117 \geq 0.5N_{v0}$		$\bar{x} = 138 \geq 0.5N_{v0}$		$\bar{x} = 130 \geq 0.5N_{v0}$		$\bar{x} = 145 \geq 0.5N_{v0}$	
Method Validation (C)	Vc1 136	Vc2 124	Vc1 146	Vc2 138	Vc1 108	Vc2 146	Vc1 136	Vc2 152
	$\bar{x} = 130 \geq 0.5N_{v0}$		$\bar{x} = 142 \geq 0.5N_{v0}$		$\bar{x} = 127 \geq 0.5N_{v0}$		$\bar{x} = 144 \geq 0.5N_{v0}$	
Test Suspension	10^{-6} Vc1 268	10^{-6} Vc2 244	10^{-6} Vc1 252	10^{-6} Vc2 314	10^{-6} Vc1 234	10^{-6} Vc2 264	10^{-6} Vc1 318	10^{-6} Vc2 272
	10^{-7} Vc1 54	10^{-7} Vc2 31	10^{-7} Vc1 30	10^{-7} Vc2 44	10^{-7} Vc1 48	10^{-7} Vc2 31	10^{-7} Vc1 33	10^{-7} Vc2 35
(N)	$\bar{w} = 2.71 \times 10^8$		$\bar{w} = 2.91 \times 10^8$		$\bar{w} = 2.62 \times 10^8$		$\bar{w} = 2.99 \times 10^8$	
	lg N = 8.43		lg N = 8.46		lg N = 8.42		lg N = 8.48	
(N₀ = 0.1N)	lg N ₀ = 7.43		lg N ₀ = 7.46		lg N ₀ = 7.42		lg N ₀ = 7.48	
Results	Vc1 104	Vc2 86	Vc1 23	Vc2 13	Vc1 0	Vc2 0	Vc1 0	Vc2 0
(Na)	10 \bar{x} = 950		10 \bar{x} < 190		10 \bar{x} < 140		10 \bar{x} < 140	
	lg Na = 2.98		lg Na < 2.28		lg Na < 2.15		lg Na < 2.15	
(R)	lg R = 4.46		lg R > 5.19		lg R > 5.27		lg R > 5.33	
Pass: lg R \geq 5	FAIL		PASS		PASS		PASS	

Vc = plate count per ml

\bar{w} = weighted mean of \bar{x}

\bar{x} = average of Vc1 and Vc2

R = reduction (lg R = lg N₀ - lg Na)

Requirements & Conclusion:

This batch of Serenity Alcohol Free Hand Sanitiser, when used neat, passes the requirements of EN1276 for *E. coli*, *Staphylococcus aureus* and *Enterococcus hirae* and gives a 99.997% kill for *Pseudomonas* in 1 minute at 20°C under the test conditions detailed.

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Test results: Contact time 5 minutes

Test Organism	<i>Pseudomonas aeruginosa</i>		<i>Escherichia coli</i>		<i>Staphylococcus aureus</i>		<i>Enterococcus hirae</i>	
Validation Suspension (N_v)	Vc1 144	Vc2 118	Vc1 126	Vc2 158	Vc1 118	Vc2 142	Vc1 164	Vc2 136
	$\bar{x} = 131$		$\bar{x} = 142$		$\bar{x} = 130$		$\bar{x} = 150$	
Experimental Control (A)	Vc1 138	Vc2 154	Vc1 116	Vc2 138	Vc1 124	Vc2 150	Vc1 174	Vc2 130
	$\bar{x} = 146 \geq 0.5N_{v0}$		$\bar{x} = 127 \geq 0.5N_{v0}$		$\bar{x} = 137 \geq 0.5N_{v0}$		$\bar{x} = 152 \geq 0.5N_{v0}$	
Neutraliser Control (B)	Vc1 126	Vc2 108	Vc1 152	Vc2 124	Vc1 126	Vc2 134	Vc1 162	Vc2 128
	$\bar{x} = 117 \geq 0.5N_{v0}$		$\bar{x} = 138 \geq 0.5N_{v0}$		$\bar{x} = 130 \geq 0.5N_{v0}$		$\bar{x} = 145 \geq 0.5N_{v0}$	
Method Validation (C)	Vc1 136	Vc2 124	Vc1 146	Vc2 138	Vc1 108	Vc2 146	Vc1 136	Vc2 152
	$\bar{x} = 130 \geq 0.5N_{v0}$		$\bar{x} = 142 \geq 0.5N_{v0}$		$\bar{x} = 127 \geq 0.5N_{v0}$		$\bar{x} = 144 \geq 0.5N_{v0}$	
Test Suspension	10^{-6} Vc1 268	10^{-6} Vc2 244	10^{-6} Vc1 252	10^{-6} Vc2 314	10^{-6} Vc1 234	10^{-6} Vc2 264	10^{-6} Vc1 318	10^{-6} Vc2 272
	10^{-7} Vc1 54	10^{-7} Vc2 31	10^{-7} Vc1 30	10^{-7} Vc2 44	10^{-7} Vc1 48	10^{-7} Vc2 31	10^{-7} Vc1 33	10^{-7} Vc2 35
(N)	$\bar{w} = 2.71 \times 10^8$		$\bar{w} = 2.91 \times 10^8$		$\bar{w} = 2.62 \times 10^8$		$\bar{w} = 2.99 \times 10^8$	
	lg N = 8.43		lg N = 8.46		lg N = 8.42		lg N = 8.48	
(N₀ = 0.1N)	lg N ₀ = 7.43		lg N ₀ = 7.46		lg N ₀ = 7.42		lg N ₀ = 7.48	
Results	Vc1 0	Vc2 0	Vc1 0	Vc2 0	Vc1 0	Vc2 0	Vc1 0	Vc2 0
(Na)	10 \bar{x} < 140		10 \bar{x} < 140		10 \bar{x} < 140		10 \bar{x} < 140	
	lg Na < 2.15		lg Na < 2.15		lg Na < 2.15		lg Na < 2.15	
(R)	lg R > 5.29		lg R > 5.32		lg R > 5.27		lg R > 5.33	
Pass: lg R \geq 5	PASS		PASS		PASS		PASS	

Vc = plate count per ml

\bar{w} = weighted mean of \bar{x}

\bar{x} = average of Vc1 and Vc2

R = reduction (lg R = lg N₀ - lg Na)

Requirements & Conclusion:

This batch of Serenity Alcohol Free Hand Sanitiser, when used neat, **passes the requirements of EN 1276 for bactericidal activity** in 5 minutes at 20°C under dirty conditions against all of the reference organisms detailed.

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