Abbott Analytical

Consulting Scientists to the Disinfectant Industry

Certificate of Analysis

Product name:	Sanigone Disinfectant Concentrate RM001		
Batch or ref no:			
Manufacturer or supplier:	Sanigone Ltd 86-90 Paul Street, London, United Kingdom, EC2A 4NE		
Sample ref:	15L/054	**Date received:**	23 November 2015
Date tested:	25 November 2015	**Certificate date:**	2 December 2015
Certificate no:	15L.054IB.NUV	**Page:**	1 of 4
Analysis required:	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)		
Storage conditions:	Room temperature in darkness		
Appearance of product (solution):	Clear colourless liquid		
Active substance(s) and their concentrations(s):	Not disclosed		

Notes

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

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Experimental conditions

Concentrations(s) of product tested:	1:100 v/v
Product diluent:	Sterile hard water (300mg/1 $CaCO_3$)
Test organism(s):	Pseudomonas aeruginosa (NCTC 13359) Escherichia coli (NCTC 10418) Staphylococcus aureus (NCTC 10788) Enterococcus hirae (NCTC 13383)
Contact time(s):	5 min ± 10s
Test temperature:	20°C ± 1°C
Test conditions:	Dirty
Interfering substance:	3.0g/1 bovine albumin
Method:	Dilution-neutralisation
Neutralising solution:	30g/1 Polysorbate 80 + 3g/1 Lecithin + 1g/1 L-histidine + 1g/1 L-cysteine
Incubation temperature:	37°C ± 1°C

Conclusion

When tested at a concentration of 1:100 this sample of Sanigone Disinfectant Concentrate RM001 passes the requirements of EN 1276:2009 for bactericidal activity in 5 minutes at 20°C, under dirty conditions, against Pseudomonas aeruginosa (NCTC 13359), Escherichia coli (NCTC 10418), Staphylococcus aureus (NCTC 10788) and Enterococcus hirae (NCTC 13383).

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Results: Pseudomonas aeruginosa (NCTC 13359)

Validation and controls:

Validation suspension (Nv_o)			Experimental conditions control (A)			Neutralizer or filtration control (B)			Method validation (C)		
$Vc1$	129	$\bar{x}$ =	$Vc1$	64	$\bar{x}$ =	$Vc1$	75	$\bar{x}$ =	$Vc1$	61	$\bar{x}$ =
$Vc2$	110	119.5	$Vc2$	71	67.5	$Vc2$	58	66.5	$Vc2$	79	70
$30 \leq \bar{x}\ (Nv_o) \leq 160$? ☒ yes ☐ no			$\bar{x}\ (A) \geq 0.5 \times \bar{x}\ (Nv_o)$? ☒ yes ☐ no			$\bar{x}\ (B) \geq 0.5 \times \bar{x}\ (Nv_o)$? ☒ yes ☐ no			$\bar{x}\ (C) \geq 0.5 \times \bar{x}\ (Nv_o)$? ☒ yes ☐ no		

Test suspension:
(N and N_o)

N	$Vc1$	$Vc2$	$\bar{x}$(wm) = 3.05 x10^{8} ; lg N = 8.48
10^{-6}	318	296	$N_o = N/10$; lg N_o = 7.48
10^{-7}	29	27	$7.17 \leq \lg N_o \leq 7.70$? ☒ yes ☐ no
Control of weighted mean counts (N)			Quotient = 10.96 Between 5 and 15 ? ☒ yes ☐ no

Test:

Product test conc.	Contact time	$Vc1$	$Vc2$	Na = ($\bar{x}$ x10)	lg Na =	lg R = (lg N_o − lg Na)	Status
1:100	5 min	0	0	< 140	< 2.15	> 5.33	PASS

Results: Escherichia coli (NCTC 10418)

Validation and controls:

Validation suspension (Nv_o)			Experimental conditions control (A)			Neutralizer or filtration control (B)			Method validation (C)		
$Vc1$	109	$\bar{x}$ =	$Vc1$	87	$\bar{x}$ =	$Vc1$	58	$\bar{x}$ =	$Vc1$	70	$\bar{x}$ =
$Vc2$	112	110.5	$Vc2$	70	78.5	$Vc2$	69	63.5	$Vc2$	62	66
$30 \leq \bar{x}\ (Nv_o) \leq 160$? ☒ yes ☐ no			$\bar{x}\ (A) \geq 0.5 \times \bar{x}\ (Nv_o)$? ☒ yes ☐ no			$\bar{x}\ (B) \geq 0.5 \times \bar{x}\ (Nv_o)$? ☒ yes ☐ no			$\bar{x}\ (C) \geq 0.5 \times \bar{x}\ (Nv_o)$? ☒ yes ☐ no		

Test suspension:
(N and N_o)

N	$Vc1$	$Vc2$	$\bar{x}$(wm) = 2.93 x10^{8} ; lg N = 8.47
10^{-6}	304	285	$N_o = N/10$; lg N_o = 7.47
10^{-7}	30	26	$7.17 \leq \lg N_o \leq 7.70$? ☒ yes ☐ no
Control of weighted mean counts (N)			Quotient = 10.52 Between 5 and 15 ? ☒ yes ☐ no

Test:

Product test conc.	Contact time	$Vc1$	$Vc2$	Na = ($\bar{x}$ x10)	lg Na =	lg R = (lg N_o − lg Na)	Status
1:100	5 min	0	0	< 140	< 2.15	> 5.32	PASS

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Results: Staphylococcus aureus (NCTC 10788)

Validation and controls:

Validation suspension (Nv_o)			Experimental conditions control (A)			Neutralizer or filtration control (B)			Method validation (C)		
$Vc1$	115	$\bar{x}$ =	$Vc1$	84	$\bar{x}$ =	$Vc1$	72	$\bar{x}$ =	$Vc1$	64	$\bar{x}$ =
$Vc2$	106	110.5	$Vc2$	77	80.5	$Vc2$	74	73	$Vc2$	79	71.5
$30 \leq \bar{x}\ (Nv_o) \leq 160$? ☒ yes ☐ no			$\bar{x}\ (A) \geq 0.5 \times \bar{x}\ (Nv_o)$? ☒ yes ☐ no			$\bar{x}\ (B) \geq 0.5 \times \bar{x}\ (Nv_o)$? ☒ yes ☐ no			$\bar{x}\ (C) \geq 0.5 \times \bar{x}\ (Nv_o)$? ☒ yes ☐ no		

Test suspension:
(N and N_o)

N	$Vc1$	$Vc2$	$\bar{x}$(wm) = 3.25 x10^{8} ; lg N = 8.51
10^{-6}	327	319	$N_o = N/10$; lg N_o = 7.51
10^{-7}	38	32	$7.17 \leq \lg N_o \leq 7.70$? ☒ yes ☐ no
Control of weighted mean counts (N)			Quotient = 9.23 Between 5 and 15 ? ☒ yes ☐ no

Test:

Product test conc.	Contact time	$Vc1$	$Vc2$	Na = ($\bar{x}$ x10)	lg Na =	lg R = (lg N_o − lg Na)	Status
1:100	5 min	0	0	< 140	< 2.15	> 5.36	PASS

Results: Enterococcus hirae (NCTC 13383)

Validation and controls:

Validation suspension (Nv_o)			Experimental conditions control (A)			Neutralizer or filtration control (B)			Method validation (C)		
$Vc1$	107	$\bar{x}$ =	$Vc1$	68	$\bar{x}$ =	$Vc1$	70	$\bar{x}$ =	$Vc1$	59	$\bar{x}$ =
$Vc2$	89	98	$Vc2$	74	71	$Vc2$	76	73	$Vc2$	71	65
$30 \leq \bar{x}\ (Nv_o) \leq 160$? ☒ yes ☐ no			$\bar{x}\ (A) \geq 0.5 \times \bar{x}\ (Nv_o)$? ☒ yes ☐ no			$\bar{x}\ (B) \geq 0.5 \times \bar{x}\ (Nv_o)$? ☒ yes ☐ no			$\bar{x}\ (C) \geq 0.5 \times \bar{x}\ (Nv_o)$? ☒ yes ☐ no		

Test suspension:
(N and N_o)

N	$Vc1$	$Vc2$	$\bar{x}$(wm) = 2.85 x10^{8} ; lg N = 8.45
10^{-6}	281	299	$N_o = N/10$; lg N_o = 7.45
10^{-7}	22	25	$7.17 \leq \lg N_o \leq 7.70$? ☒ yes ☐ no
Control of weighted mean counts (N)			Quotient = 12.34 Between 5 and 15 ? ☒ yes ☐ no

Test:

Product test conc.	Contact time	$Vc1$	$Vc2$	Na = ($\bar{x}$ x10)	lg Na =	lg R = (lg N_o − lg Na)	Status
1:100	5 min	0	0	< 140	< 2.15	> 5.30	PASS

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