

Chemical Disinfectants and Antiseptics - Quantitative Suspension Test for the Evaluation of Bactericidal Activity in the Medical Area - Test Method and Requirements (phase 2, step 1)

Company Name:	Modu Hygiene
Report Date:	05/07/2024
Melbec Ref Number:	75481
Name of Test Product:	Modu Hygiene Antibacterial Foam Soap
Batch Number:	F532

Sample Details:

Manufacture / Supplier:.....	Modu Hygiene
Product storage conditions:.....	Ambient
Appearance of the product (as supplied):.....	Clear colourless liquid
Appearance of the product (after dilution):.....	Clear colourless liquid
Appearance of product with interfering substance and test organism:	Cloudy brown liquid
Active substance and concentration:.....	BKC/DDAC/PE
Product dilution preparation.....	Volume/Volume
Product dilutions/concentrations:.....	50 %
Diluent used to dilute product:.....	Dilute product with hard water then use deionised water for the test
Incubation temperature:	35 °C to 38 °C

The test product was in satisfactory condition for testing when received.

Date product received: 18/06/24	Test date: 25/06/2024, 01/07/2024
---------------------------------	-----------------------------------

Experimental Conditions:

Interfering substance:	Bovine Albumin (dirty 3.0g/l) and 3ml/l erythrocytes
Test temperature:	19 to 21 °C
Contact time:	30 Seconds
Test organisms:	Pseudomonas aeruginosa ATCC 15442 Staphylococcus aureus ATCC 6538 Escherichia coli K12 NCTC 10538 Enterococcus hirae ATCC 10541

Deviations:

EN 13727 states incubation temperature of 36±1°C or 37±1°C. Melbec Microbiology Ltd method states 35°C - 38°C.
 The test product was tested at one concentration only at the clients request hence the testing is based on the test method of EN 13727.

Requirements of the Standard:

The test product shall demonstrate at least a 3 decimal logarithm (lg) reduction when tested in accordance with this standard under simulated dirty conditions.

Conclusion:

For the product Modu Hygiene Antibacterial Foam Soap, [Batch code: F532] the log reduction requirements as specified in EN 13727:2012 (3 lg within the relevant contact time) were met in dirty conditions with a contact time of 30 Seconds.

Report authorised by:



Name: Liam Stephens
Position: Technical Manager
Date: 05/07/2024

All samples are tested as received and the condition on receipt is deemed to be satisfactory for testing unless client is informed otherwise. If an unsatisfactory sample is received and tested on instruction from the client comments are included on the report detailing this information. Results given for this may be invalid. Results detailed above relate only to the samples tested. Sample description and batch references stated are as provided by the customer. This test report shall not be reproduced except in full without the approval of Melbec Microbiology Ltd.

Test Results:**Neutralisation Method Used:**

Membrane filtration

Rinsing Liquid Used: N7

***Pseudomonas aeruginosa* ATCC 15442**

Validation and controls												Melbec Ref No		75481	
Validation suspension (NvB) x 10^3			Validation suspension (Nv_0)			Experimental conditions control (A)			Neutralizer control (B)			Method validation (C)			
Vc 1	N/A	$\bar{X}$ =	Vc 1	100	$\bar{X}$ =	Vc 1	50	$\bar{X}$ =	Vc 1	45	$\bar{X}$ =	Vc 1	58	$\bar{X}$ =	
Vc 2	N/A	N/A	Vc 2	81	90.5	Vc 2	49	49.5	Vc 2	49	47	Vc 2	49	53.5	
$3.0 \times 10^4 \leq \bar{X} \text{ of } NvB \leq 1.6 \times 10^5$? N/A			$30 \leq \bar{X} \text{ of } Nv_0 \leq 160$? Yes			$\bar{X} \text{ of A is } \geq 0.5 \times \bar{X} \text{ of } Nv_0$? Yes			$\bar{X} \text{ of B is } \geq 0.5 \times \bar{X} \text{ of } Nv_0$? Yes			$\bar{X} \text{ of C is } \geq 0.5 \times \bar{X} \text{ of } Nv_0$? Yes			

Test suspension and test

Test suspension (N and N_0):	N	Vc 1	Vc 2	X_m 4.30E+08 ; $\lg N =$ 8.63
	10^{-6}	>330	>330	$N_0 = N/10$; $\lg N_0 =$ 7.63
	10^{-7}	51	35	$7.17 \leq \lg N_0 \leq 7.70$? Yes $\bar{X} \text{ quotient} = >5 \text{ and } <15$? N/A

Conc. of the active (%)	10^{-x}	Vc 1	Vc 2	$Na = \bar{X}$	$\lg Na$	$\lg R$ $N_0 =$ 7.63		Contact time	Result
50%	-1	<14	<14	1.40E+02	<2.15		>5.48	30 Seconds	Pass
	-2	-	-						

Staphylococcus aureus ATCC 6538

Validation and controls												Melbec Ref No		75481	
Validation suspension (NvB) x 10 ³			Validation suspension (Nv ₀)			Experimental conditions control (A)			Neutralizer control (B)			Method validation (C)			
Vc 1	N/A	$\bar{X}$ =	Vc 1	41	$\bar{X}$ =	Vc 1	55	$\bar{X}$ =	Vc 1	48	$\bar{X}$ =	Vc 1	63	$\bar{X}$ =	
Vc 2	N/A	N/A	Vc 2	40	40.5	Vc 2	55	55	Vc 2	42	45	Vc 2	56	59.5	
3.0x10 ⁴ ≤ $\bar{X}$ of NvB ≤ 1.6x10 ⁵ ? N/A			30 ≤ $\bar{X}$ of Nv ₀ ≤ 160 ? Yes			$\bar{X}$ of A is ≥ 0.5 x $\bar{X}$ of Nv ₀ ? Yes			$\bar{X}$ of B is ≥ 0.5 x $\bar{X}$ of Nv ₀ ? Yes			$\bar{X}$ of C is ≥ 0.5 x $\bar{X}$ of Nv ₀ ? Yes			

Test suspension and test

Test suspension (N and N_0):	N	Vc 1	Vc 2	$X_{wm} = 2.90E+08$; $\lg N = 8.46$
	10^{-6}	311	270	$N_0 = N/10$; $\lg N_0 = 7.46$
	10^{-7}	30	28	$7.17 \leq \lg N_0 \leq 7.70$? Yes $\bar{X} \text{ quotient} = >5 \text{ and } <15$? 10.02

Conc. of the active (%)	10^{-x}	Vc 1	Vc 2	$Na = \bar{X}$	$\lg Na$	$\lg R$ $N_0 =$	7.46	Contact time	Result
50%	-1	<14	<14	1.40E+02	<2.15		>5.31	30 Seconds	Pass
	-2	-	-						

Escherichia coli K12 NCTC 10538

Validation and controls											Melbec Ref No		75481	
Validation suspension (NvB) x 10^3			Validation suspension (Nv_o)			Experimental conditions control (A)			Neutralizer control (B)			Method validation (C)		
Vc 1	N/A	$\bar{X}$ =	Vc 1	93	$\bar{X}$ =	Vc 1	111	$\bar{X}$ =	Vc 1	80	$\bar{X}$ =	Vc 1	73	$\bar{X}$ =
Vc 2	N/A	N/A	Vc 2	68	80.5	Vc 2	97	104	Vc 2	61	70.5	Vc 2	70	71.5
$3.0 \times 10^4 \leq \bar{X} \text{ of } NvB \leq 1.6 \times 10^5$? N/A			$30 \leq \bar{X} \text{ of } Nv_o \leq 160$? Yes			$\bar{X} \text{ of A is } \geq 0.5 \times \bar{X} \text{ of } Nv_o$? Yes			$\bar{X} \text{ of B is } \geq 0.5 \times \bar{X} \text{ of } Nv_o$? Yes			$\bar{X} \text{ of C is } \geq 0.5 \times \bar{X} \text{ of } Nv_o$? Yes		

Test suspension and test

Test suspension (N and N_0):	N	Vc 1	Vc 2	X_m 3.80E+08 ; $\lg N =$ 8.58	
	10^{-6}	>330	>330	$N_0 = N/10$; $\lg N_0 =$ 7.58	
	10^{-7}	43	33	$7.17 \leq \lg N_0 \leq 7.70$? Yes	
				$\bar{X}$ quotient = >5 and <15? N/A	

Conc. of the active (%)	10^{-x}	Vc 1	Vc 2	$Na = \bar{X}$	$\lg Na$	$\lg R$ $N_0 =$	7.58	Contact time	Result
50%	-1	<14	<14	1.40E+02	<2.15		>5.43	30 Seconds	Pass
	-2	-	-						

***Enterococcus hirae* ATCC 10541**

Validation and controls												Melbec Ref No		75481	
Validation suspension (Nv_B) x 10^3			Validation suspension (Nv_o)			Experimental conditions control (A)			Neutralizer control (B)			Method validation (C)			
Vc 1	N/A	$\bar{X} =$	Vc 1	88	$\bar{X} =$	Vc 1	83	$\bar{X} =$	Vc 1	81	$\bar{X} =$	Vc 1	70	$\bar{X} =$	
Vc 2	N/A	N/A	Vc 2	85	86.5	Vc 2	68	75.5	Vc 2	69	75	Vc 2	67	68.5	
$3.0 \times 10^4 \leq \bar{X} \text{ of } Nv_B \leq 1.6 \times 10^5$? N/A			$30 \leq \bar{X} \text{ of } Nv_o \leq 160$? Yes			$\bar{X} \text{ of A is } \geq 0.5 \times \bar{X} \text{ of } Nv_o$? Yes			$\bar{X} \text{ of B is } \geq 0.5 \times \bar{X} \text{ of } Nv_o$? Yes			$\bar{X} \text{ of C is } \geq 0.5 \times \bar{X} \text{ of } Nv_o$? Yes			

Test suspension and test

Test suspension (N and N_0):	N	Vc 1	Vc 2	X_m 3.65E+08 ; $\lg N =$ 8.56
	10^{-6}	>330	>330	$N_0 = N/10$; $\lg N_0 =$ 7.56
	10^{-7}	38	35	$7.17 \leq \lg N_0 \leq 7.70$? Yes $\bar{X} \text{ quotient} = >5 \text{ and } <15$? N/A

Conc. of the active (%)	10^{-x}	Vc 1	Vc 2	$Na = \bar{X}$	$\lg Na$	$\lg R$ $N_0 =$ 7.56	Contact time	Result
50%	-1	<14	<14	1.40E+02	<2.15	>5.41	30 Seconds	Pass
	-2	-	-					