Technical Service

Innovative Chemicals

Technical Service Report

No. 20/004

20th February 2020

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Objectives:

To examine the preservation efficacy in personal care products.

Test methods:

Sterility test	PCI Sterility test
Disinfectant test	BS EN 1040: 2005: Chemical disinfectant and antiseptics – Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics - Test Method and requirements (phase 1).

Test Samples:

Conclusions:

Sterility test (Table 1)

All tested samples were free from detectable bacteria and fungi.

Disinfection test (Table 2 & Table 3)

No.	Sample name	Contact time (Minute)	Pass/Fail
1	Hand Sanitizer	5	Pass

As for the detailed information, please refer to the Table 2 & Table 3.

Sterility test

Table 1

No.	Sample name	Microbial growth rating on sterility test		
		30°C TSA	25°C SDA	SFB
1	Hand Sanitizer	0	0	-

30ºC TSA: 30 ºC 2 days incubation on Trypticase Soya Agar for detection of bacteria.
25ºC SDA: 25 ºC 5 days incubation on Sabouraud Dextrose Agar for detection of fungi.
SFB: Spore forming bacteria check on TSA/SDA.

Key to growth rating:

Bacteria and Yeast	0 = no growth to 6 = highly contaminated
Mould	0 = no growth to XXXX = dense growth
SFB	++= dense growth + = light growth - = no detect

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Disinfection test –BS EN 1040: 2005

Inoculum: Standard inoculum
Pre-treatment: No

A. Test Organism: *Pseudomonas aeruginosa* ATCC 15442

Table 2

Test Organism	Contact time (Minute)	Bacterial Concentration (cfu/ml)	Log Reduction
Inoculum Control(N_0)	-	$4.54x10^7$	-
Hand Sanitizer (N_a)	5	<14	>5

B. Test Organism: *Staphylococcus aureus* ATCC 6538

Table 3

Test Organism	Contact time (Minute)	Bacterial Concentration (cfu/ml)	Log Reduction
Inoculum Control(N_0)	-	$5.10x10^7$	-
Hand Sanitizer (N_a)	5	<14	>5

N_0 = Number of cells per ml in the test mixture at the beginning of the contact time t = 0
Na = Number of surviving cells per ml in the test mixtures at the end of the contact time, t, i.e.

The brief introduction of test methods

1) PCI Sterility test:

Depending on the nature of the tested samples, different test protocols are used to determine the presence or absence of microorganisms. A small number of tested samples is transferred to appropriate nutrient media for micro-organisms. The inoculated agars are incubated at an appropriate temperature for 2-5 days and any microbiological growth is visually assessed using the rating scale.

2) BS EN 1040: 2005

A sample of the product as delivered (highest concentration) and/or diluted with water is added to a test suspension of containing bacteria. The mixture is maintained at 20°C±1°C for 5 minutes. At the end of the contact time, an aliquot is taken; the bactericidal and/or the bacteriostatic activity in this portion is immediately neutralized or suppressed by a validated method. The numbers of surviving bacteria in each sample are determined and the reduction is calculated as in log reduction. The product shall demonstrate at least 5 decimal log reduction.

Experimental Condition:
i) Experimental temperature: 20°C±1°C
ii) Contact time, t=5 minute
iii) Test culture used: Pseudomonas aeruginosa ATCC 15442
Staphylococcus aureus ATCC 6538

Products had passed validation tests on:
i) Validation of the selected experimental condition
ii) Verification of the absence of toxicity of the neutralizer
iii) Dilution-neutralizer validation (1/10 dilution or 1/100 dilution).

Calculation on Log Reduction: $\lg R = \lg N_0 - \lg Na$

No = Number of cells per ml in the test mixture at the beginning of the contact time t = 0
Na = Number of surviving cells per ml in the test mixtures at the end of the contact time, t, i.e. 5 minutes (1 minute for hand wash)

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Report review:

The work detailed in this report has been carried out according to BS EN 1040: 2005: Chemical disinfectant and antiseptics – Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics - Test Method and requirements (phase 1). All results have been checked by the responsible person and reviewed by laboratory supervisor/manager.

Prepared by: Alisha Li

Alisha Li
Technical Manager

Date: 20th February 2020

The data contained in this report are based on our current test method and our current knowledge and experience. In view of the many factors that may affect processing and application of products, the above data does not relieve manufacturers from carrying out their own tests; neither does the data imply or guarantee of certain properties, nor the suitability of the product for specific purposes nor agreed contractual quality of the product.

Please note that any conclusions and recommendations, either made or implied, are based on information drawn from examination of the samples identified in this report only. These results may be influenced by, for example, contamination level variations in raw materials, any stored component solutions and manufacturing equipment, or changes in formulation, manufacturing procedure or raw material suppliers.

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