New Zealand Laboratory Services Limited
Part of the Bureau Veritas Group
35 O'Rorke Road
P.O. Box 12-545
Penrose, Auckland
New Zealand
Phone 64 9 579-2669
Fax 64 9 579-9044

BACTERICIDAL ACTIVITY REPORT FOR HAND SANITISER

Client	Brookfield Healthcare(NZ)	Testing Facility	New Zealand Laboratory Services Limited
Address:	PO Box 38 314 Howick Auckland NEW ZEALAND	Address:	35 O'Rorke Road PO Box 12545 Penrose Auckland New Zealand
Contact:	Lindsay Brook		

Identification of the sample

Project number:	11NZAK0055551
Sample number:	2569651
Name of the product:	Dermasoft Instant Hand Sanitiser
Batch number:	22-7-11
Date of delivery:	27/07/2011
Storage conditions:	Room Temperature
Contact time recommended by the manufacturer:	1 minute
Active substance :	Benzalkonium Chloride

Experimental conditions

Date of analysis:	01/09/2011
Test temperature:	19.9 – 20.1°C
Product test concentration:	Product diluted to 55% (V/V) in hard water
Contact time:	1 minute
Counting procedure:	Pour plate
Temperature of incubation:	37 +/- 1°C
Product diluent used during test:	Hard water

New Zealand Laboratory Services Limited
Part of the Bureau Veritas Group
35 O'Rorke Road
P.O. Box 12-545
Penrose, Auckland
New Zealand
Phone 64 9 579-2669
Fax 64 9 579-9044

Procedure for validation of test conditions

Neutralisation medium: Sodium Thioglycolate (1g/l) + Sodium Thiosulfate (6g/l) + Sodium Bisulfite (2.5g/l) + Polysorbate 80 (5g/g) + Lecithin (7g/l)

Identification of the test

Test methodology used: PrEN12054 – Chemical disinfectants and antiseptics – (Modified)

Test methodology modification The reference strain of *Escherichia coli* [CIP 54.117, NCTC 10538, NCIMB 10083] was not available.

Escherichia coli ATCC 11229 was used – this is recommended for use in the testing of bacterial resistance of latex paints, disinfectants, **sanitisers**, membrane filters.

Identification of the test organisms

Escherichia coli	ATCC 11229
Enterococcus hirae	ATCC 10541
Staphylococcus aureus	ATCC 6538
Pseudomonas aeruginosa	ATCC 15442

The strains used in the test proper were purchased from the Institute of Environmental Science & Research Limited – New Zealand Reference Culture Collection Medical Section.

Cultures are maintained in accordance with the recommendations of the Curator of the Culture Collections Centre NZ Communicable Disease Centre and New Zealand Laboratory Services Limited quality control systems.

New Zealand Laboratory Services Limited
Part of the Bureau Veritas Group
35 O'Rorke Road
P.O. Box 12-545
Penrose, Auckland
New Zealand
Phone 64 9 579-2669
Fax 64 9 579-9044

Verification of Methodology

Interpretation

- N is the average plate count of the test suspension control (in cfu
- A is the average plate count of the test suspension control for validation of the experimental (hard water) conditions
- N^1 is the average plate count of the neutralisation medium control
- n^1 is the average plate count of the dilution neutralisation test control

To verify validation the following conditions must be met

no individual plate count used for calculation of N, A and N^1 is to be greater than 300cfu

the average plate counts of N, A and N^1 must be between 100 and 300 cfu

the average plate counts of N^1 and A must be equal to or greater than 0.5 times the average plate count of N

the average plate counts of n^1 must be equal to or greater than 0.5 times the average plate count of N^1

Table 1 – Validation of dilution-neutralisation method

Test Organism	ATCC Number	Recovery Level (average number of cfu)		
		Bacterial test suspension	Validation of neutralization	
			Control	Test
		N	N^1	n^1
Escherichia coli	11229	299	287	292
Enterococcus hirae	10541	142	124	133
Staphylococcus aureus	6538	266	204	205
Pseudomonas aeruginosa	15442	162	176	174

Conclusion – The conditions have been met, therefore neutralization is validation with the neutralisation medium used is validated.

New Zealand Laboratory Services Limited
Part of the Bureau Veritas Group
35 O'Rorke Road
P.O. Box 12-545
Penrose, Auckland
New Zealand
Phone 64 9 579-2669
Fax 64 9 579-9044

Table 2 – Validation of experimental (hard water) conditions

Test Organism	ATCC Number	Recovery Level (average number of cfu)	
		Bacterial test suspension N	Experimental test with hard water A
Escherichia coli	11229	299	300
Enterococcus hirae	10541	142	131
Staphylococcus aureus	6538	266	206
Pseudomonas aeruginosa	15442	162	160

Conclusion – The conditions have been met, therefore the method has been validated for the experimental (hard water) conditions

Table 3 – Test results for the Dermasoft Instant Hand Sanitiser diluted to 55% (V/V) in hard water conditions

Test Organism	ATCC Number	Bacterial test suspension (N)	Recovery Level (cfu/ml) After 1 minute contact time	Reported result after 1 minute contact time
Escherichia coli	11229	3.0×10^8	NR	$<3 \times 10^2$
Enterococcus hirae	10541	1.4×10^8	NR	$<3 \times 10^2$
Staphylococcus aureus	6538	2.7×10^8	NR	$<3 \times 10^2$
Pseudomonas aeruginosa	15442	1.6×10^8	NR	$<3 \times 10^2$

Interpretation

NR – no recovery (cfu/ml) of the test organisms.

Where the calculated viable count is less than 3×10^2 cfu it will be reported as $<3 \times 10^2$ cfu

Requirements for a hygienic handwash product

For each organism tested, the product must demonstrate a reduction in viable counts from 1×10^7 to 3×10^7 cfu/ml to no more than 1×10^4 to 3×10^4 cfu/ml with 1 minute at 20 +/- 1°C under the conditions described in prEN 12054:1995.

New Zealand Laboratory Services Limited
Part of the Bureau Veritas Group
35 O'Rorke Road
P.O. Box 12-545
Penrose, Auckland
New Zealand
Phone 64 9 579-2669
Fax 64 9 579-9044

Conclusion

a) The Dermasoft Instant Hand Sanitiser possesses bactericidal activity under the conditions described in prEN 12054:1995.

b) The Dermasoft Instand Hand Sanitiser is bactericidal at 1 minute contact time according to the requirements for a hygienic handwash product, for each organism tested.

Date of issue: 16 September, 2011

Authorised By: Wendy Wakefield

Team Leader – Pharmaceutical Microbiological Services

Authorising Signature:

Authorised By: Meghana Desai

Laboratory Technician – Pharmaceutical Microbiological Services

Authorising Signature: