TEST REPORT

SABS

MICROBIOLOGY DEPARTMENT 7218

Your ref: Ultra – S035

Our ref: 17/37/9

Enquiries: 428-6172

Date: 2005-03-24

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Page: 1 of 4

Health and Hygiene
Attention : Mr John Temperley
P O Box 347
SUNNINGHILL
2157

DISINFECTANT EFFICACY - NON POROUS SURFACE TEST - ASSIMILATION OF AUTOMATIC WASHING MACHINE

1 Description of samples

Disinfectant samples received for disinfectant efficacy testing to assimilate automatic washing machine, "OLYMPUS" used to wash and disinfect medical instruments. The samples were labeled – Health and Hygiene F10 Super Concentrate batch number 173 and batch number 174.

2 Test requested

Disinfectant efficacy tests to assimilate the automatic washing machine with ultrasonic cleaning & disinfecting process times as set in the tables below:

ULTRASONIC BATH

Washing	1 minute
Ultrasonic cleaning	5 minutes
Disinfect	15 minutes
Rinse	1 minute
Disinfectant solution temperature	22°C

Test organism used: *Bacillus subtilis* spores.

3. Test Method (European surface test method – based on BS / EN13697 2001)

3.1 Non Porous Surface test:

Two centimeter squared stainless steel discs – surfaces were seeded with the 0.1ml spore suspension containing 10^7 bacillus spore suspension / ml dried at 37°C for 1 hour . After completion of the recommended test cycle and contact times the stainless steel discs were placed in conical flasks containing 10 ml neutralizing medium and shaken to dislodge the bacterial spores. Then the neutralizer solution (1.0ml) and 10 fold dilutions of the solution were plated into sterile petri dishes to which cooled nutrient agar was added. The plates were incubated for 2 days at 37°C.
Colony forming units were counted.
Untreated stainless steel discs were used as controls and neutralization tests.

3.2 Test organism suspension:

Initial spore suspension containing $1,5 \times 10^8$ cfu /ml to 5×10^8 cfu/ml.
Bacillus subtilis SABS TCC Bac 35 NCTC 10073.

3.3 Disinfectant - F10SC Dilution : 1 / 100

This test was performed by Testing and Conformity Services (Pty) Ltd, an affiliate of the SABS.
This report relates only to the specific sample(s) tested as identified herein. It does not imply SABS approval of the quality and/or performance of the item(s) in question and the test results do not apply to any similar item that has not been tested.
(Refer also to the complete conditions printed on the back of the official test reports.)

4. Results – NON POROUS SURFACE TEST

4.1 DISINFECTANT EFFICACY TESTING - ASSIMILATION OF AUTOMATIC WASHING MACHINE – ULTRASONIC CLEANING & DISINFECTION

Sample : Health & Hygiene F10 Super Concentrate Batch no: 173 – dilution 1 / 100

Process Treatment	Dilution series	Duplicate analysis: Organism *B. subtilis*				Duplicate analysis: Organism*: B. subtilis*			
		Recovery	Percentage kill	Recovery	% kill	Recovery	% kill	Recovery	% kill
Ultrasonic Disinfection	Direct	54	99,999	45	99,999	14	99,999	5	99,999
5 min	10^{-1}	86	99,999	55	99,999	15	99,999	6	99,999
	10^{-2}	16	99,999	10	99,999	0	99,999	0	99,999
Disinfection Rinse 15 min	Direct	5	99,999	2	99,999	1	99,999	1	99,999
	10^{-1}	1	99,999	0	99,999	1	99,999	0	99,999
	10^{-2}	0		0		1		0	
Disc final in inactivator	Direct	> 300	99,990	>300	99,990	>300	99,990	> 300	99,990
	10^{-1}	21	99,999	5	99,999	3	99,999	0	99,999
	10^{-2}	3	99,999	0	99,999	0	99,999	0	99,999
	10^{-3}	1	99,999	0	99,999	0	99,999	0	99,999
B subtilis spore Control count			4.2×10^{6}						

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Results (Continued)

4.2 DISINFECTANT EFFICACY TESTING-ASSIMILATION OF AUTOMATIC WASHING MACHINE – ULTRASONIC CLEANING & DISINFECTION

Sample : Health & Hygiene F10 Super Concentrate Batch no: 174 – dilution 1 /100

Process Treatment	Dilution series	Duplicate analysis: Organism *B. subtilis*				Duplicate analysis: Organism*: B. subtilis*			
		Recovery	Percentage kill	Recovery	% kill	Recovery	% kill	Recovery	% kill
Ultrasonic Disinfection	Direct	4	99,999	2	99,999	13	99,999	10	99,999
5 min	10^{-1}	6	99,999	4	99,999	15	99,999	8	99,999
	10^{-2}	0	99,999	0	99,999	0	99,999	0	99,999
Disinfection Rinse 15 min	Direct	2	99,999	2	99,999	0	99,999	0	99,999
	10^{-1}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-2}	0	99,999	0	99,999	0	99,999	0	99,999
Disc final in inactivator	Direct	385	99,990	396	99,990	0	99,999	0	99,999
	10^{-1}	291	99,993	280	99,993	0	99,999	0	99,999
	10^{-2}	37	99,999	37	99,999	0	99,999	0	99,999
	10^{-3}	2	99,999	1	99,999	0	99,999	0	99,999
B subtilis spore Control count			4.2×10^{6}						

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Apparatus:

Ultrasonic Bath 50 Hz, 150W – Make and Model: P SELECTA Ultrasons 3000513.

Conclusion:

a) Disc final rinse inactivator – recoveries inconsistent , probably due to clumping or layers of spores on the disc surface not having contact with disinfectant.
b) Excellent disinfecting efficacy results were obtained using both ultrasonic cleaning process in combination with F10 Super Concentrate at a 1 /100 dilution.
c) Validation for neutralization was carried out at the same time as the test procedure, using the highest product concentration and the same conditions as used in the actual test. Recoveries > 3 x 10^5 cfu /ml from the neutralized disc rinse solution.
d) The sporocidal activity on the surfaces a 5 log reduction of viability was demonstrated under the required test conditions; 5 minute wash, 15 minute disinfecting between 22 °C ± 1°C and 25°C ±1°C.

Margot Kerr.

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2005 –03 - 24

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TEST REPORT

SABS

MICROBIOLOGY DEPARTMENT 7218

Your ref: Ultra /Mech

Our ref: 17/37/9

Enquiries: 428-6172

Date: 2005-03-24

1733791/ 04-6307/
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Page: 1 of 6

Health and Hygiene
Attention : Mr John Temperley
P O Box 347
SUNNINGHILL
2157

DISINFECTANT EFFICACY - NON POROUS SURFACE TEST - ASSIMILATION OF AUTOMATIC WASHING MACHINE

1 Description of samples

Disinfectant samples received for disinfectant efficacy testing to assimilate automatic washing machine, "OLYMPUS used to wash and disinfect medical instruments. The samples were labeled – Health and Hygiene F10 Super Concentrate batch number 172 and batch number 173.

2 Test requested

Disinfectant efficacy testing to assimilate the automatic washing machine with a) ultrasonic cleaning & disinfecting and b) mechanical cleaning & disinfecting processes with the recommended process times as set in the tables below:

ULTRASONIC BATH

Washing	1 minute
Ultrasonic cleaning	5 minutes
Disinfection	15 minutes
Rinse	1 minute
Disinfectant solution temperature	22°C

Test organism used: *Bacillus subtilis* spores.

MECHANICAL SHAKER

Washing	1 minute
Mechanical cleaning	5 minutes
Disinfection	15 minutes
Rinse	1 minute
Disinfectant solution temperature	22°C

Test organism used: *Bacillus subtilis* spores.

3. Test Method (European surface test method - based on BS / EN 13697 – 2001)

3.1 Non Porous Surface test:

Two centimeter squared stainless steel discs – surfaces were seeded with the 0.1ml spore suspension containing 10^7 bacillus spore suspension / ml dried at 37°C for 1 hour . After completion of the recommended test cycle and contact times the stainless steel discs were placed in conical flasks containing 10 ml neutralizing medium and shaken to dislodge the bacterial spores. Then the neutralizer solution (1.0ml) and 10 fold dilutions of the solution were plated into sterile petri dishes to which cooled nutrient agar was added. The plates were incubated for 2 days at 37°C. Colony forming units were counted.
Untreated stainless steel discs were used as controls and neutralization test

3.2 Test organism suspension:

Initial spore suspension containing $1,5 \times 10^8$ cfu /ml to 5×10^8 cfu/ml.
Bacillus subtilis SABS TCC Bac 35 NCTC 10073.

3.3 Dilution of the disinfectant – F10SC : 1 / 100

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4. RESULTS – NON POROUS SURFACE TEST

4.1 DISINFECTANT EFFICACY TESTING - ASSIMILATION OF AUTOMATIC WASHING MACHINE – ULTRASONIC CLEANING & DISINFECTION

Sample : Health & Hygiene F10 Super Concentrate Batch no: 172 – dilution 1 / 100

Process Treatment	Dilution series	Duplicate analysis: Organism *B. subtilis*				Duplicate analysis: Organism*: B. subtilis*			
		Recovery	Percentage kill	Recovery	% kill	Recovery	% kill	Recovery	% kill
Ultrasonic / Disinfection	10^{-1}	18	99,999	12	99,999	6	99,999	8	99,999
5 min	10^{-2}	14	99,999	8	99,999	10	99,999	13	99,999
	10^{-3}	1	99,999	1	99,999	0	99,999	2	99,999
	10^{-4}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-5}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-6}	0	99,999	0	99,999	0	99,999	0	99,999
Disinfectant Final Rinse	10^{-1}	4	99,999	2	99,999	0	99,999	0	99,999
15 min	10^{-2}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-3}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-4}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-5}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-6}	0	99,999	0	99,999	0	99,999	0	99,999
B subtilis spore Control count			$5{,}9 \times 10^{5}$						

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Results (Continued)

4.2 DISINFECTANT EFFICACY TESTING-ASSIMILATION OF AUTOMATIC WASHING MACHINE – ULTRASONIC CLEANING & DISINFECTION

Sample : Health & Hygiene F10 Super Concentrate Batch no: 173 – dilution 1 / 100

Process Treatment	Dilution / Replicates	Duplicate analysis: Organism *B. subtilis*				Duplicate analysis: Organism: *B. subtilis*			
		Recovery	Percentage kill	Recovery	% kill	Recovery	% kill	Recovery	% kill
Ultrasonic / Disinfection	10^{-1}	12	99,999	10	99,999	1	99,999	2	99,999
5 min	10^{-2}	13	99,999	13	99,999	0	99,999	3	99,999
	10^{-3}	5	99,999	1	99,999	0	99,999	0	99,999
	10^{-4}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-5}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-6}	0	99,999	0	99,999	0	99,999	0	99,999
Disinfectant Final Rinse	10^{-1}	0	99,999	0	99,999	4	99,999	4	99,999
15 min	10^{-2}	0	99,999	0	99,999	1	99,999	0	99,999
	10^{-3}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-4}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-5}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-6}	0	99,999	0	99,999	0	99,999	0	99,999
B subtilis spore Control count			5.9×10^5						

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Results (Continued)

4.3 DISINFECTANT EFFICACY TESTING - ASSIMILATION OF AUTOMATIC WASHING MACHINE – MECHANICAL CLEANING & DISINFECTION

Sample : Health & Hygiene F10 Super Concentrate Batch no: 172 – dilution 1 / 100

Process Treatment	Dilution/ Replicates	Duplicate analysis: Organism *B. subtilis*				Duplicate analysis: Organism*: B. subtilis*			
		Recovery	Percentage kill	Recovery	% kill	Recovery	% kill	Recovery	% kill
Mechanical / Disinfection	10^{-1}	1	99,999	1	99,999	0	99,999	0	99,999
5 min	10^{-2}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-3}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-4}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-5}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-6}	0	99,999	0	99,999	0	99,999	0	99,999
Disinfectant Final Rinse	10^{-1}	24	99,999	36	99,999	0	99,999	10	99,999
15 min	10^{-2}	1	99,999	2	99,999	0	99,999	0	99,999
	10^{-3}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-4}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-5}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-6}	0	99,999	0	99,999	0	99,999	0	99,999
B subtilis spore Control count			$5{,}9 \times 10^{5}$						

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Results (Continued)

4.4 DISINFECTANT EFFICACY TESTING - ASSIMILATION OF AUTOMATIC WASHING MACHINE – MECHANICAL CLEANING & DISINFECTION

Sample : Health & Hygiene F10 Super Concentrate Batch no: 173 – dilution 1 / 100

Process Treatment	Dilution / Replicates	Duplicate analysis: Organism *B. subtilis*				Duplicate analysis: Organism*: B. subtilis*			
		Recovery	Percentage kill	Recovery	% kill	Recovery	% kill	Recovery	% kill
Mechanical / Disinfection	10^{-1}	0	99,999	0	99,999	0	99,999	0	99,999
5 min	10^{-2}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-3}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-4}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-5}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-6}	0	99,999	0	99,999	0	99,999	0	99,999
Disinfectant Final Rinse	10^{-1}	0	99,999	0	99,999	4	99,999	1	99,999
15 min	10^{-2}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-3}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-4}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-5}	0	99,999	0	99,999	0	99,999	0	99,999
	10^{-6}	0	99,999	0	99,999	0	99,999	0	99,999
B subtilis spore Control count			5.9×10^5						

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Apparatus:

a) Ultrasonic Bath 50 Hz, 150W – Make and Model: P SELECTA Ultrasons 3000513.
b) Mechanical Shaker – LABOTEC – operating at 160 actions / min.

Conclusion:

a) Excellent disinfecting efficacy results were obtained using both ultrasonic / mechanical cleaning process in Combination with F10 Super Concentrate at 1 / 100 dilution.
b) Validation for neutralization was carried out at the same time as the test procedure, using the highest product concentration and the same conditions as used in the actual test. Recoveries > 3 x 10^5 cfu /ml from the neutralized disc rinse solution.
c) The sporocidal activity on the surfaces a 5 log reduction of viability was demonstrated under the required test conditions; 5 minute wash, 15 minute disinfecting between 22 °C ± 1°C and 25°C ±1°C.

M Kerr
Microbiology Department
2005-03-24

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Manager: Microbiology Department
2005-03-24

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