BACTERICIDAL EFICACY TEST

PrEN 12054

(PHASE 2 STEP 1)

NO-GERMS HANDRUB FORMULATION

ADVANCED FORMULATIONS (EUROPE) LTD

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MAY 2005

MANUFACTURER	Advanced Formulations (Europe) Ltd 191-193 Western Road LONDON SW19 2QD
TEST PRODUCT	**No-Germs Hand Sanitizer** (tested undiluted)
Lot number	PL 42A

TEST METHOD

PrEN 12054 Quantitative suspension test for the evaluation of bactericidal activity of products for hygienic and surgical handrub and handwash used in human medicine (phase 2/step 1).

This test has not yet been ratified by the European Commission and was in final draft form in July 1998.

TEST ORGANISMS

Staphylococcus aureus	NCTC 10788
Pseudomonas aeruginosa	NCTC 6749
Escherichia coli	NCTC 10418
Enterococcus hirae	NCTC 12367

At the request of the company an additional test orgnanism was tested

MRSA	NCTC12493

TEST REQUIREMENTS

Hygienic Handrub

The product shall demonstrate a 10^5 reduction in viable count at 1 minute. At the manufacturers request 30 seconds may also be tested. The product is tested undiluted.

Contact time	30 seconds and 1 minute.	
	(2 and 5 minutes were also tested)	
Test temperature	20°C	
Inhibition method	Dilution/neutralization	
Neutralizer	Lecithin	3g/l
	Tween 80	30g/l
	Sodium lauryl sulphate	4g/l

Tests were performed to establish the suitability of this neutralizer in neutralizing the activity of the disinfectant without being inhibitory to the test organisms.

SUMMARY OF TEST METHOD

The test method involves mixing 1 ml of the test bacteria with 9 ml of disinfectant. After the required contact time, 1 ml is removed to 9 ml of recovery/neutralizer, which is then diluted/plated to detect surviving test bacteria.

RESULTS

BACTERICIDAL ACTIVITY OF NO-GERMS HANDRUB FORMULATION USING SUSPENSION TEST prEN 12054

Log_{10} reductions achieved in 30 sec, 1, 2 and 5 minutes

(Tests carried out in duplicate)

Test organism	Log_{10} initial count (challenge)	Contact time			
		30 sec	1 minute	2 minutes	5 minutes
Ps. aeruginosa	6.47	>5.47	>5.47	>5.47	>5.47
Esch. coli	6.93	>5.93	>5.93	>5.93	>5.93
Staph. aureus	6.67	>5.67	>5.67	>5.67	>5.67
Ent. hirae	6.64	>5.64	>5.64	>5.64	>5.64
MRSA	6.57	>5.57	>5.57	>5.57	>5.57

CONCLUSION

When tested in accordance with PrEN 12054, No-Germs Handrub formulation possesses bactericidal activity at 20°C. A >5 $\log_{10}$ (99.999%) reduction was achieved with all test organisms i.e. *Ps. aeruginosa*, *Staph. aureus*, *Esch. coli*, *Ent. hirae* and MRSA in 1 min. To satisfy the requirements for the test, at least a 5 $\log_{10}$ reduction in specified test organisms is required within 1 minute for the hygienic handrub formulation. The product also passed the test at 30 seconds.

It is recommended that No-Germs Hand Rub is tested for complaince with the Phase 2 Step 2 test EN 1500. Compliance with this test is necessary before a label claim for a hygienic handrub can be made.

Testing by the Hospital Infection Research Laboratory does not imply approval or endorsement.

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Director

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