University Hospital Birmingham NHS
NHS Foundation Trust

ASSESSMENT OF BACTERICIDAL EFFICACY TESTS (EN 1276 - PHASE 2, STEP 1)

DUO MAX

for

DUO TECH LTD

HOSPITAL INFECTION RESEARCH LABORATORY
UNIVERSITY HOSPITAL NHS FOUNDATION TRUST
QUEEN ELIZABETH HOSPITAL
BIRMINGHAM B15 2TH

AUGUST 2009

MANUFACTURER	Duo Tech Ltd 11-12 Queen's Square Bristol BS1 4NT
TEST PRODUCT	Duo Max A, B, C and D
Batch number:	Not Stated
Lot number:	Not Stated

STORAGE CONDITIONS

At room temperature in a dry place out of direct sunlight.

TEST ORGANISMS

Staphylococcus aureus	NCTC 10788
Pseudomonas aeruginosa	NCTC 6749
Escherichia coli	NCTC 10418
Enterococcus hirae	NCTC 12367
Methicillin resistant *Staph. aureus* (MRSA)	NCTC 12493

(This test strain is not listed in the EN but was requested by the manufacturer)

TEST METHOD AND VALIDATION

EN 1276 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (Phase 2, step 1). Tests for disinfectants for medical establishments not yet ratified. Copies of EN 1276 are available from BSI, 389 Chiswick High Road, London W4 4AL.

PRODUCT TEST CONCENTRATION

1:20 for all 4 products

CONTACT TIMES

1 and 5 minutes

TEST TEMPERATURE

20^{o}C

INTERFERING SUBSTANCE

Clean Conditions: 0.03% w/v albumin (final concentration)

Dirty Conditions: 0.3% w/v albumin (final concentration)

INHIBITION METHOD

Dilution/neutralization

NEUTRALIZER

Tween 80, 30g/l; saponin, 30g/l; lecithin, 3g/l; sodium thiosulphate, 5g/l; sodium lauryl sulphate, 5g/l; L-histidine, 1g/l; L-cysteine, 1g/l; sodium chloride, 8.5g/l; tryptone, 1g/l.

Tests were performed to establish the suitability of the neutralizer in neutralizing the activity of the disinfectant without being inhibitory to the test organisms (method described in EN 1276). The above neutralizer was found to be suitable with an additional dilution step.

SUMMARY OF TEST METHOD

The test method involves mixing 1ml of the test bacteria with 1ml of interfering substance (0.3 or 3g/L albumin) and then adding 8ml of test product. After the required contact time, 0.1ml is removed and added to 8.9ml of the neutralizer and 1ml of sterile distilled water. Following a 5 minute neutralization period, 1 ml is plated onto Tryptone Soya Agar to detect surviving test bacteria.

RESULTS

BACTERICIDAL ACTIVITY OF DUO MAX
EN 1276 PHASE 2 STEP 1

(All tests carried out in duplicate)

PRODUCT A

Test Organism	**Log_{10} Initial Count (mean)**	**Contact Time**	**Log_{10} Reduction Achieved**					
			Clean Conditions (0.3% w/v albumin)			**Dirty Conditions** (3% w/v albumin)		
			Test 1	**Test 2**	**Mean**	**Test 1**	**Test 2**	**Mean**
Staphylococcus aureus	7.58	1 min	>6.58	>6.58	**>6.58**	>6.58	>6.58	**>6.58**
		5 mins	>6.58	>6.58	**>6.58**	>6.58	>6.58	**>6.58**
Pseudomonas aeruginosa	7.58	1 min	>6.58	>6.58	**>6.58**	>6.58	>6.58	**>6.58**
		5 mins	>6.58	>6.58	**>6.58**	>6.58	>6.58	**>6.58**
Escherichia coli	7.59	1 min	>5.99	6.96	**>6.48**	>5.99	>7.19	**>6.59**
		5 mins	>5.99	>7.19	**>6.59**	>5.99	>7.19	**>6.59**
Enterococcus hirae	7.46	1 min	>6.06	>6.85	**>6.46**	>6.06	>6.85	**>6.46**
		5 mins	>6.06	>6.85	**>6.46**	>6.06	>6.85	**>6.46**
MRSA	7.68	1 min	>6.07	>7.29	**>6.68**	>6.07	>7.29	**>6.68**
		5 mins	>6.07	>7.29	**>6.68**	>6.07	>7.29	**>6.68**

PRODUCT B

Test Organism	Log_{10} Initial Count (mean)	Contact Time	Log_{10} Reduction Achieved					
			Clean Conditions (0.3% w/v albumin)			Dirty Conditions (3% w/v albumin)		
			Test 1	Test 2	Mean	Test 1	Test 2	Mean
Staphylococcus aureus	7.58	1 min	6.25	>7.06	**>6.66**	6.50	>7.06	**>6.78**
		5 mins	6.50	>7.06	**>6.78**	6.80	>7.06	**>6.93**
Pseudomonas aeruginosa	7.58	1 min	5.15	>7.04	**>6.10**	5.14	>7.04	**>6.09**
		5 mins	>6.11	>7.04	**>6.58**	>6.11	>7.04	**>6.58**
Escherichia coli	7.59	1 min	>5.99	>7.19	**>6.59**	>5.99	>7.19	**>6.59**
		5 mins	>5.99	>7.19	**>6.59**	>5.99	>7.19	**>6.59**
Enterococcus hirae	7.46	1 min	>6.06	>6.85	**>6.46**	>6.06	>6.85	**>6.46**
		5 mins	>6.06	>6.85	**>6.46**	>6.06	>6.85	**>6.46**
MRSA	7.68	1 min	>6.07	>7.29	**>6.68**	>6.07	>7.29	**>6.68**
		5 mins	>6.07	>7.29	**>6.68**	>6.07	>7.29	**>6.68**

PRODUCT C

Test Organism	Log_{10} Initial Count (mean)	Contact Time	Log_{10} Reduction Achieved					
			Clean Conditions (0.3% w/v albumin)			Dirty Conditions (3% w/v albumin)		
			Test 1	Test 2	Mean	Test 1	Test 2	Mean
Staphylococcus aureus	7.58	1 min	6.80	>7.06	**>6.93**	6.50	>7.06	**>6.78**
		5 mins	>6.10	>7.06	**>6.58**	6.80	>7.06	**>6.93**
Pseudomonas aeruginosa	7.58	1 min	5.14	>7.04	**>6.09**	5.03	>7.04	**>6.04**
		5 mins	6.16	>7.04	**>6.60**	5.81	>7.04	**>6.43**
Escherichia coli	7.59	1 min	>5.99	>7.19	**>6.59**	>5.99	>7.19	**>6.59**
		5 mins	>5.99	>7.19	**>6.59**	>5.99	>7.19	**>6.59**
Enterococcus hirae	7.46	1 min	>6.06	>6.85	**>6.46**	>6.06	>6.85	**>6.46**
		5 mins	>6.06	>6.85	**>6.46**	>6.06	>6.85	**>6.46**
MRSA	7.68	1 min	>6.07	>7.29	**>6.68**	>6.07	>7.29	**>6.68**
		5 mins	>6.07	>7.29	**>6.68**	>6.07	>7.29	**>6.68**

PRODUCT D

Test Organism	Log_{10} Initial Count (mean)	Contact Time	Log_{10} Reduction Achieved					
			Clean Conditions (0.3% w/v albumin)			Dirty Conditions (3% w/v albumin)		
			Test 1	Test 2	Mean	Test 1	Test 2	Mean
Staphylococcus aureus	7.58	1 min	>6.10	>7.06	**>6.58**	>6.10	>7.06	**>6.58**
		5 mins	>6.10	>7.06	**>6.58**	>6.10	>7.06	**>6.58**
Pseudomonas aeruginosa	7.58	1 min	5.03	>7.04	**>6.04**	5.08	>7.04	**>6.06**
		5 mins	6.03	>7.04	**>6.54**	6.03	>7.04	**>6.54**
Escherichia coli	7.59	1 min	>5.99	>7.19	**>6.59**	>5.99	>7.19	**>6.59**
		5 mins	>5.99	>7.19	**>6.59**	>5.99	>7.19	**>6.59**
Enterococcus hirae	7.46	1 min	>6.06	>6.85	**>6.46**	>6.06	>6.85	**>6.46**
		5 mins	>6.06	>6.85	**>6.46**	>6.06	>6.85	**>6.46**
MRSA	7.68	1 min	>6.07	>7.29	**>6.68**	>6.07	>7.29	**>6.68**
		5 mins	>6.07	>7.29	**>6.68**	>6.07	>7.29	**>6.68**

To meet the requirements of EN 1276 at least a 5 Log_{10} reduction in all test bacteria within 5 minutes is required.

The results show that the 4 Duo Max products demonstrate high activity against the 5 test bacteria ie *Staph. aureus*, MRSA, *Ent. hirae, Ps. aeruginosa* and *Esch. coli* and fulfil the requirements of EN 1276 following the test method as described in EN 1276.

CONCLUSION

When tested in accordance with EN 1276, the 4 Duo Max products achieve a >5 $\log_{10}$ reduction at 1 and 5 minutes at 20^{o}C under both clean and dirty conditions for all the test bacteria.

To satisfy the requirements of EN 1276, at least a 5 $\log_{10}$ reduction in specified test organisms is required within 5 minutes when the disinfectant is tested at its intended use dilution. This was achieved and, therefore, the Duo Max products meet the requirements of EN 1276.

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

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Biomedical Statistician

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