BluTest
GLOBAL MICROBIOLOGY EXPERTISE

Test Report: 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)

Test Laboratory

BluTest Laboratories Ltd
Robertson Incubator (Level 4)
Robertson Building
56 Dumbarton Road
Glasgow
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Identification of sample

Name of the product	**DUOMAX HAND SANITISER**
Batch number	N/A
Manufacturer	**Duotech Ltd,** 11-12 Queens Square, Bristol, BS1 4NT
Project Code	BT-DUO-17A-01
Date of Delivery	10 April 2012
Storage conditions	Ambient
Active substances	N/A

Test Method and its validation

Method	Chemical-neutralization
Neutralizer	Specialist neutraliser: Lecithin 11.7g/l, Polysorbate 80 100g/l, sodium thiosulphate 5.0g/l, sodium dodecyl sulphate 10.0g/l, sodium chloride 8.5g/l, tryptone 1.0g/l sterilized by autoclave.

Experimental Conditions

Period of analysis	23 May to 7 June 2012
Product diluent used	Sterile, distilled water
Product test concentrations	1.00% V/V; 50.00% V/V; 80.00% V/V
Appearance product dilutions	Clear
Contact time	t = 5 min $\pm$ 10 s
Test temperature	20°C $\pm$ 1°C
Interfering substance	0.3 g/l bovine serum albumin
Stability of mixture	Stable
Temperature of incubation	37°C + 1°C
Identification of strains	*Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* ATCC 10536 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae ATCC* 10541

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EN 1276 Results for the efficacy of DUOMAX HAND SANITISER from DUOTECH Ltd under CLEAN CONDITIONS

Test organisms	Validation test				Bacterial test suspension (N)	Exposure (mins)	Test procedure at concentration % (V/V)			
	Bacterial Suspension (Nv)	Experimental conditions (A)	Neutralizer toxicity Control or filtration control (B)	Dilution-neutralization control or filtration test control (C)				1.00%	50%	80.00%
Pseudomonas aeruginosa ATCC 15442	*V* c: 84 ; 81 *N* v: 8.25E+02	Vc: 53 ; 52 A: 5.25E+01	Vc: 76 ; 78 B: 7.70E+01	Vc: 53 ; 52 C: 5.25E+01	10^{-6}: 310 ; 269 10^{-7}: 25 ; 23 N: 2.90E+08	5 ☑ ☐	Vc Na R	0 ; 0 <1.40E+02 >10(5)	0 ; 0 <1.40E+02 >10(5)	0 ; 0 <1.40E+02 >10(5)
Validation	30 ≤ Nv_0 ≤ 160 ? yes	A ≥ 0.5 x Nv_0 ? yes	B ≥ 0.5 x Nv_0 ? yes	C ≥ 0.5 x Nv_0? yes	7.17≤ log N_0 ≤7.70? yes		Test is valid			
Escherichia coli ATCC 10536	*V* c: 46 ; 45 *N* v: 4.55E+02	Vc: 64 ; 54 A: 5.90E+01	Vc: 64 ; 58 B: 6.10E+01	Vc: 56 ; 57 C: 5.65E+01	10^{-6}: 241 ; 227 10^{-7}: 14 ; 15 N: 2.34E+08	5 ☑ ☐	Vc Na R	0 ; 0 <1.40E+02 >10(5)	0 ; 0 <1.40E+02 >10(5)	0 ; 0 <1.40E+02 >10(5)
Validation	30 ≤ Nv_0 ≤ 160 ? yes	A ≥ 0.5 x Nv_0 ? yes	B ≥ 0.5 x Nv_0 ? yes	C ≥ 0.5 x Nv_0? yes	7.17≤ log N_0 ≤7.70? yes		Test is valid			
Staphylococcus aureus ATCC 6538	*V* c: 101 ; 110 *N* v: 1.06E+03	Vc: 83 ; 99 A: 9.10E+01	Vc: 101 ; 117 B: 1.09E+02	Vc: 73 ; 102 C: 8.75E+01	10^{-6}: >330 ; >330 10^{-7}: 41 ; 45 N: 4.30E+08	5 ☑ ☐	Vc Na R	0 ; 0 <1.40E+02 >10(5)	0 ; 0 <1.40E+02 >10(5)	0 ; 0 <1.40E+02 >10(5)
Validation	30 ≤ Nv_0 ≤ 160 ? yes	A ≥ 0.5 x Nv_0 ? yes	B ≥ 0.5 x Nv_0 ? yes	C ≥ 0.5 x Nv_0? yes	7.17≤ log N_0 ≤7.70? yes		Test is valid			
Enterococcus hirae ATCC 10541	*V* c: 83 ; 111 *N* v: 9.70E+02	Vc: 108 ; 106 A: 1.07E+02	Vc: 104 ; 111 B: 1.08E+02	Vc: 103 ; 120 C: 1.12E+02	10^{-6}: >330 ; >330 10^{-7}: 41 ; 42 N: 4.15E+08	5 ☑ ☐	Vc Na R	0 ; 0 <1.40E+02 >10(5)	0 ; 1 <1.40E+02 >10(5)	0 ; 0 <1.40E+02 >10(5)
Validation	30 ≤ Nv_0 ≤ 160 ? yes	A ≥ 0.5 x Nv_0 ? yes	B ≥ 0.5 x Nv_0 ? yes	C ≥ 0.5 x Nv_0? yes	7.17≤ log N_0 ≤7.70? yes		Test is valid			

Please note: the upper limit for counting bacterial plates is 330 cfu. Enter as >330

Vc = viable count
N = number of cfu/ml of the bacterial test suspension
Nv = number of cfu/ml in the bacterial suspension
R = reduction in viability
Na = number of cfu/ml in the test mixture
A = number of cfu/ml of the experimental conditions validation
B = number of cfu/ml of the neutralizer toxicity validation or of the filtration validation
C = the number of cfu/ml of the dilution-neutralization validation or the membrane filtration test validation

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Conclusion

According to EN 1276, **DUOMAX HAND SANITISER**, is bactericidal at a concentration of 80.0% V/V under **CLEAN** conditions (0.3 g/l bovine serum albumin) for referenced strains *Pseudomonas aeruginosa ATCC* 15442, *Escherichia coli* ATCC 10536, *Staphylococcus aureus ATCC* 6538 *and Enterococcus hirae* ATCC 10541.

Signed



Dr Chris Woodall, Director
BluTest Laboratories Ltd
Glasgow, UK
27 June 2012

UKAS TESTING

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"A Statement of the Uncertainty of Measurement can be provided on request"

DISCLAIMER

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