

Test Report: EN 1276 2009 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 — Test method and requirements (phase 2, step 1)

Test Laboratory

BluTest Laboratories Ltd

Robertson Incubator (Level 4)
Robertson Building
56 Dumbarton Road
Glasgow
UK - G11 6NU

Identification of sample

Name of the product
Batch number
Client

CreBiSol X10

28.5.14

CREATIVE BIOCIDAL SOLUTIONS LIMITED

First Floor, Block C, Balbriggan Business Campus,
Balbriggan, CO Dublin

Project Code
Date of Delivery
Storage conditions
Active substances

BT-HIP-02A(1)

30 May 2014

Cool, well ventilated area. Keep container tightly closed
DDQ50

Test Method and its validation

Method
Neutralizer

Chemical-neutralization

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
Product diluent used
Product test concentrations
Appearance product dilutions

26-27 June 2014

Sterile, synthetic hard water

1.0 % V/V; 2.0 % V/V; 5.0 % V/V; 10.0 % V/V

Test mixture becomes cloudy at 10%, 5%, 2%, 1% and

Control C

$t = 30 \text{ s} \pm 10 \text{ s}$

$20^{\circ}\text{C} \pm 1^{\circ}\text{C}$

3.0g/l bovine serum albumin

Stable

$37^{\circ}\text{C} \pm 1^{\circ}\text{C}$

MRSA UK15

Contact time
Test temperature
Interfering substance
Stability of mixture
Temperature of incubation
Identification of strains

EN 1276 Results for the efficacy of CreBioSol X10 from Creative Biocidal Solutions Ltd under DIRTY CONDITIONS

Test organisms	Validation test			Bacterial test suspension (N)	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%	2.00%	5.00%	10.00%
MRSA UK15 <i>Neat</i>	Vc: 49 ; 52	Vc: 40 ; 48	Vc: 44 ; 48	Vc: 59 ; 64	10 ⁻⁸ : 215 ; 221 10 ⁻⁹ : 17 ; 27 N: 2.18E+10	N 32 ; 37 Na 3.45E+02 R <10(8)	0 ; 0 <1.40E+02 >10(8)	0 ; 1 <1.40E+02 >10(8)
ATCC 15442 <i>Validation</i>	Nv: 5.05E+02 30 ≤ N ₀ ≤ 160 ? yes	A: 4.40E+01 A ≥ 0.5 x N ₀ ? yes	B: 4.60E+01 B ≥ 0.5 x N ₀ ? yes	C: 6.15E+01 C ≥ 0.5 x N ₀ ? yes	Test is valid			
MRSA UK15 <i>10E-1 product</i>	Vc: 49 ; 52	Vc: 40 ; 48	Vc: 44 ; 48	Vc: 59 ; 64	10 ⁻⁸ : 215 ; 221 10 ⁻⁹ : 17 ; 27 N: 2.18E+10	-1 4 ; 6 Na <1.40E+02 R	0 ; 0 <1.40E+02 <1.40E+02	0 ; 0 <1.40E+02 <1.40E+02
ATCC 15442 <i>Validation</i>	Nv: 5.05E+02 30 ≤ N ₀ ≤ 160 ? yes	A: 4.40E+01 A ≥ 0.5 x N ₀ ? yes	B: 4.60E+01 B ≥ 0.5 x N ₀ ? yes	C: 6.15E+01 C ≥ 0.5 x N ₀ ? yes	Test is valid			
MRSA UK15 <i>10E-2 product</i>	Vc: 49 ; 52	Vc: 40 ; 48	Vc: 44 ; 48	Vc: 59 ; 64	10 ⁻⁸ : 215 ; 221 10 ⁻⁹ : 17 ; 27 N: 2.18E+10	-2 1 ; 3 Na <1.40E+02 R	0 ; 0 <1.40E+02 <1.40E+02	0 ; 0 <1.40E+02 <1.40E+02
ATCC 15442 <i>Validation</i>	Nv: 5.05E+02 30 ≤ N ₀ ≤ 160 ? yes	A: 4.40E+01 A ≥ 0.5 x N ₀ ? yes	B: 4.60E+01 B ≥ 0.5 x N ₀ ? yes	C: 6.15E+01 C ≥ 0.5 x N ₀ ? yes	Test is valid			

See comments below

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

COMMENTS

Test carried out using ~1.5-5.0 x 10¹⁰ cfu/ml as specified by the client. Additional dilutions to be carried out for test plates (10-1 and 10-2). Make ~50mls of N (at 1.5-5.0 x 10⁹ cfu/ml). Read 10-1 on the spec. to check the range. Centrifuge at 2000g

Conclusion

According to a modified EN 1276 2009 procedure, **CreBiSol X10 POSSESSES BACTERICIDAL** activity of > 8.0 \log_{10} reduction at a concentration of **2.0 % V/V** as tested after **30 SECONDS** at **20°C** under **DIRTY** conditions (3.0 g/l bovine serum albumin) against Meticillin resistant *Staphylococcus aureus* strain UK 15.

Signed



Dr Chris Woodall, Director
BluTest Laboratories Ltd
Glasgow, UK,
Date: 30 April 2015

Expanded Uncertainty of Measurement $U = \pm 0.49$ logs

DISCLAIMER

The results in this test report only pertain to the sample supplied.

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