

Test Report EN 1657 *MICROSPORUM CANIS* and *TRICHOPHYTON MENTAGROPHYTES* Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in veterinary field - Test method and requirements (phase 2/step 1)

Test Laboratory

BluTest Laboratories Ltd

Robertson Incubator (Level 4)
Robertson Building
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Identification of sample

Name of the product
Project Code
Manufacturer

DUOMAX

BT-DUO-08
DUOTECH LTD, 11-12 QUEENS SQUARE, BRISTOL,
BS1 4NT
29 October 2010
Room temperature
Unknown

Date of Delivery
Storage Conditions
Active substances

Test Method and its validation

Method
Neutralizer

Filtration-neutralization
Lecithin 3g/l, Polysorbate 80 30g/l, sodium thiosulphate
5g/l, L-histidine 1g/l, phosphate buffer 0.0025mol/l,
sterilized by autoclave

Experimental Conditions

Period of analysis
Product diluent used
Product test concentrations
Appearance product dilutions
Contact time
Test temperature
Interfering substance
Stability of mixture
Temperature of incubation
Identification of strains

15 to 21 June 2011
Sterile, synthetic hard water
10.0 % V/V; 20.0 % V/V; 80.0% V/V
Clear
 $t = 30 \text{ min} \pm 10 \text{ s}$
 $10^{\circ}\text{C} \pm 1^{\circ}\text{C}$
3.0 g/l bovine albumin
No precipitation
 $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$
Microsporium canis CBS 132.88
Trichophyton mentagrophytes CBS 120356

Conclusion

According to the EN 1657 procedure, **DUOMAX** possesses fungicidal activity after 30 minutes at 10°C under CLEAN conditions (3.0 g/l bovine serum albumin) for the referenced strains *Microsporium canis* CBS 132.88 and *Trichophyton mentagrophytes* CBS 120356 at a concentration of 10.0% V/V.

Signed



Dr Chris Woodall, Director
BluTest Laboratories Ltd
Glasgow, UK
24 June 2011

EN 1657: *Microsporum canis* and *Trichophyton mentagrophytes* for DUOMAX from DUOTECH LTD under CLEAN conditions

Test organisms	Validation test				Fungal test suspension (N)	Test procedure at concentration % (V/V)			
	Fungal Suspension (Nv)	Experimental conditions (A)	Neutralizer toxicity Control or filtration control (B)	Dilution-neutralization control or filtration test control (C)			10	50	80
<i>Microsporum canis</i> CBS 132.88	Vc: 66 ; 77	Vc: 117 ; 100	Vc: 98 ; 111	Vc: 103 ; 103	10 ⁻⁵ : >55 ; >55	Vc	6 ; 6	0 ; 0	0 ; 0
					10 ⁻⁶ : 36 ; 40	Na	<1.40E+02	<1.40E+02	<1.40E+02
	Nv: 7.15E+02	A: 1.09E+02	B: 1.05E+02	C: 1.03E+02	N: 3.80E+07	R	>10(4)	>10(4)	>10(4)
Validation	30 ≤ Nv ₀ ≤ 160 ?	A ≥ 0.5 x Nv ₀ ?	B ≥ 0.5 x Nv ₀ ?	C ≥ 0.5 x Nv ₀ ?	6.17≤ log N ₀ ≤6.70?	Test is valid			
	yes	yes	yes	yes	yes				
Please note: the upper limit for <i>C. albicans</i> on membranes is 165 and should be entered as >165 . The upper limit for <i>M. canis</i> on membranes is 55 and should be entered as >55.									
Vc = viable count.									
N = number of cfu/ml of the fungal test suspension:									
Nv = number of cfu/ml in the fungal 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									

Test organisms	Validation test				Fungal test suspension (N)	Test procedure at concentration % (V/V)		
	Fungal Suspension (Nv)	Experimental conditions (A)	Neutralizer toxicity Control or filtration control (B)	Dilution-neutralization control or filtration test control (C)		10	50	80
<i>Trichophyton mentagrophytes</i> CBS 120356	Vc: 74 ; 80 Nv: 7.70E+02	Vc: 84 ; 91 A: 8.75E+01	Vc: 71 ; 89 B: 8.00E+01	Vc: 72 ; 69 C: 7.05E+01	10 ⁵ : >55 ; >55 10 ⁶ : 35 ; 39 N: 3.70E+07	Vc: 0 ; 1 Na: <1.40E+02 R: >10(4)	0 ; 0 0 ; 0 >10(4)	0 ; 0 <1.40E+02 >10(4)
Validation	30 ≤ Nv ₀ ≤ 160 ? yes	A ≥ 0.5 × Nv ₀ ? yes	B ≥ 0.5 × Nv ₀ ? yes	C ≥ 0.5 × Nv ₀ ? yes	6.17 ≤ log N ₀ ≤ 6.70 ? yes	Test is valid		

Please note: the upper limit for *C. albicans* on membranes is 165 and should be entered as >165 . The upper limit for *T. mentagrophytes* on membranes is 55 and should be entered as >55.

Vc = viable count.
N = number of cfu/ml of the fungal test suspension:
Nv = number of cfu/ml in the fungal 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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