

Test Report. *Mycobacterium avium*.

Test Laboratory

BluScientific Test Data

School of Life Sciences
Glasgow Caledonian University
GLASGOW
UK - G4 0BA

Identification of sample

Name of the product
Manufacturer

ANTIBAK POWDER.

BIOTECHNICS
Upper Mill, Inverberrie, Aberdeenshire
UK - DD10 0SP.

Date of Delivery
Storage conditions
Product diluent
Active substances

6TH JUNE.06
Room temperature and darkness.
Sterile Hard Water
Not Known.

Test Method and its validation

Method
Neutralizer

Method of EN 1276. 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

20TH MARCH – 25TH MAY 2006
Sterile Hard Water
0.5 % W/V; 1.0 % W/V; 1.8 % W/V.

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

15 minutes ± 10s; 5 minutes ± 10s
20 °C ± 1 °C
0.6 g/l foetal bovine serum
Precipitate absent throughout the test
37 °C ± 1 °C
Mycobacterium avium (ATCC 15769).

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RESULTS

BIOTECHNICS ANTIBAK POWDER. *Mycobacterium avium* (ATCC 15769).

Test Organism	Validation Tests					Contact time (min)	Test procedure at concentration % (v/v)		
	Bacterial suspension	Experimental conditions	Filtration test control	Filtration control	Bacterial test suspension		1.8	1	0.5
<i>Mycobacterium avium</i> (ATCC 15769).	Vc: 20, 40	Vc: 20, 20	Vc: 40, 30	Vc: 20, 20	10 ⁻⁴ : 42, 47	5	Vc: 0, 0	0, 0	0, 0
	Nv: 300	A: 20	C: 35	B: 20	N: 4.5 x 10 ⁵	15	R: >10 ³	>10 ³	>10 ³
Vc = viable count N = number of cfu/ml of the bacterial test suspension Nv = number of cfu/ml of 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 filtration validation C = number of cfu/ml of the membrane filtration test validation									
							Vc: 0, 0	0, 0	0, 0
							Na: <1.5 x 10 ¹	<1.5 x 10 ¹	<1.5 x 10 ¹
							R: >10 ³	>10 ³	>10 ³
							Vc: 0, 0	0, 0	0, 0
							Na: <1.5 x 10 ¹	<1.5 x 10 ¹	<1.5 x 10 ¹
							R: >10 ³	>10 ³	>10 ³

Conclusion. This test shows a greater than 3.0 log₁₀ reduction for *Mycobacterium avium* at both 5 minute and 15 contact times at a concentration of Antibak powder of 0.5% W/V. This is restricted by low counts of mycobacteria obtained for N and Nv (controls A, B & C are valid in relation to Nv).

Signed



Dr Chris Woodall
 Director, Bluscientific Test Data, 7th JUNE 2007, GLASGOW UK.

School of Life Sciences, Glasgow Caledonian University, Glasgow G4 0BA, Scotland, UK

T: +44 (0)141 331 8245 M: +44 (0)7989 96 48 11 F: +44 (0)141 331 3208 E: info@bluscientific.com W: www.bluscientific.com

Bluscientific Test Data is based in the School of Life Sciences at Glasgow Caledonian University.