BluTest
GLOBAL MICROBIOLOGY EXPERTISE

Test Report: Standard Test Method for Efficacy of Antimicrobial Agents against Viruses in Suspension using Feline Leukaemia Virus

Test Laboratory

BluTest Laboratories Ltd
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Identification of sample

Name of the product	**SAFE 4**
Manufacturer	Safe Solutions Ltd, Wharton Green House, Bostock, Winsford, Cheshire, CW7 3BD
Date of Delivery	10 February 2006
Storage conditions	Room temperature and darkness
Active substances	Not Known

Test Method and its validation

Method	SAFE4 was diluted and 0.8 ml mixed with 0.2 ml virus suspension (DMEM + 5% FBS) and 0.1 ml sterile distilled water
Dilution-neutralization	Virus CPE detected by antibody staining
Neutralizer	Dulbecco's modified Eagles medium + 5% v/v foetal bovine serum at 4°C

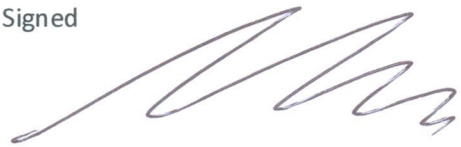
Experimental Conditions

Period of analysis	7 – 12 August 2006
Product diluent used	Sterile Hard Water
Product test concentrations	1.0 % V/V; 2.0 % V/V; 5.0% V/V
Contact times	5 minutes ± 10s;
Test temperature	20°C ± 1°C
Interfering substance	0.6 g/l foetal bovine serum
Stability of mixture	Precipitate absent throughout the test
Temperature of incubation	37°C ± 1°C + 5% CO_2
Identification of virus	Feline Leukaemia virus ATCC VR - 717 (FEA cells)

Conclusion

SAFE 4 retains virucidal activity at 5 minutes contact, at 1 % V/V, (reduction in viral viability, 3.50 Log_{10}) contact at 20°C under clean conditions (0,6 g/L protein as foetal bovine serum) for suspensions of Feline Leukaemia Virus (ATCC VR – 717).

Signed



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24 June 2010

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FELINE LEUKAEMIA VIRUS

SAFE 4 CONCENTRATION	Contact time.	Log_{10} reduction in virus viability (mean of 2 samples, 2 replicates/sample)
1.0 % V/V	5 minutes	3.50 = **PASS***
2.0 % V/V	5 minutes	3.50 = **PASS***
5.0 % V/V	5 minutes	3.50 = **PASS***

* This is the maximum achievable log_{10} reduction for this virus when detection is limited by a residual cytoxicity of log_{10} 3.5 and is therefore recorded as a PASS.

Controls	
CELL CULTURE	Cell death was not observed. Antibody staining was not observed (2 replicates/sample controlled for each sample).
CYTOTOXICITY	Cytotoxicity was not observed at a greater dilution than 10^{-2}. This restricts the sensitivity of the assay to <3.5 Log_{10} $TCID_{50}$ units/ml (2 samples, 2 replicates/sample)

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