

Test Report: EN 14476; Standard Test Method for Efficacy of Antimicrobial Agents against Viruses in Suspension modified for Feline Calicivirus (Human Norovirus surrogate)

Test Laboratory

BluTest Laboratories Ltd

Robertson Incubator (Level 4)
Robertson Building
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Identification of sample

Name of the product
Supplier

STERIZAR

CSS LTD, Malvern Suite South Wing, Earl Mill, Dowry Street,
Oldham, OL8 2PF
BT-CSS-01
16 December 2010
Room Temperature
Not known

Project Code
Sample Delivery Date
Storage conditions
Active substances

Test Method and its validation

Method

A virus suspension of 0.1 ml was challenged with 0.8 ml of disinfectant agent in the presence of 0.1 ml of interfering substance. Column chromatography

Neutralization

Experimental Conditions

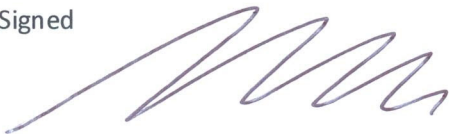
Period of analysis
Product diluent used
Product test concentrations
Appearance product dilutions
Contact time (minutes)
Test temperature
Interfering substance
Stability of mixture
Temperature of incubation
Identification of virus

18 to 24 January 2011
Sterile, hard water
80.0 % V/V
Clear product solution
 $t = 5 \pm 10$ s; $t = 15 \pm 10$ s; $t = 30 \pm 10$ s; $t = 60 \pm 10$ s
 $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$
0.6 g/L foetal bovine serum + 0.3g/L bovine serum albumin
Precipitate absent throughout the test
 $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$
Feline calicivirus/CRFK cells (Human norovirus surrogate)

Conclusion

According to EN 14476, **SteriZar** from CSS Ltd is virucidal ($> 4.0 \log_{10}$ reduction) in 5 minutes at 20°C under CLEAN conditions (0.6 g/L protein as foetal bovine serum + 0.3 g/L bovine serum albumin) for feline calicivirus (human norovirus surrogate).

Signed



Dr Chris Woodall
Director, BluTest Laboratories Ltd
Glasgow, UK, 25 January 2011

Suspension test results for the efficacy of SteriZar from CSS Ltd against FELINE CALICIVIRUS under CLEAN CONDITIONS

Exposure Time	Virus Recovery 0 min		Virus Recovery 60 min		Cytotoxicity		Disinfectant Suppression		80% (v/v)	
	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml
t = 60	5.00	3.16E+06	5.00	3.16E+06	1.00	3.16E+02	2.33	6.76E+03	1.00	3.16E+02
		3.16E+06		3.16E+06		3.16E+02		6.76E+03		3.16E+02
	log	6.50		6.50		2.50		3.83		2.50
	log difference							2.67		4.00
t = 30	5.00	3.16E+06	5.00	3.16E+06					1.00	3.16E+02
		3.16E+06		3.16E+06						3.16E+02
	log	6.50		6.50						2.50
	log difference									4.00
t = 15	5.00	3.16E+06	5.00	3.16E+06					1.00	3.16E+02
		3.16E+06		3.16E+06						3.16E+02
	log	6.50		6.50						2.50
	log difference									4.00
t = 5	5.00	3.16E+06	5.00	3.16E+06					1.00	3.16E+02
		3.16E+06		3.16E+06						3.16E+02
	log	6.50		6.50						2.50
	log difference									4.00

Table of results of virucidal activity against FELINE CALICIVIRUS under clean conditions for SteriZar from CSS Ltd under CLEAN CONDITIONS

Product:	Interfering substance	Concentration	Level of cytotoxicity	lg TCID50					>4 lg reduction after .. Min
				0 min	5 min	15 min	30min	60 min	
STERIZAR	0.3g/l BSA	80% (v/v)	2.50	6.50	2.50	2.50	2.50	2.50	5
Formaldehyde		0.7% (w/v)	1.50	6.50	5.83	3.00	2.50	2.50	30
Virus Control		n.a.	n.a.	6.50	n.a.	n.a.	n.a.	6.50	n.a.

CONTROL DATA

Stock Virus (TCID ₅₀)	6.33	6.76E+07
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Formaldehyde reference inactivation control

Exposure time	Virus recovery 0 min		Virus recovery 60 min		Cytotoxicity		0.7% Formaldehyde							
							5		15		30		60	
	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml	raw data	TCID ₅₀ /ml
60 min	5.00	3.16E+06	5.00	3.16E+06	0.00	3.16E+01	4.33	6.76E+05	1.50	1.00E+03	1.00	3.16E+02	1.00	3.16E+02
log		3.16E+06		3.16E+06		3.16E+01		6.76E+05		1.00E+03		3.16E+02		3.16E+02
log difference		6.50		6.50		1.50		5.83		3.00		2.50		2.50
								0.67		3.50		4.00		4.00

No Column Control

Virus Recovery t min	
raw data	TCID ₅₀ /ml
6.17	4.68E+07
	4.68E+07
	7.67

PASS

Interference control

Virus dilution

		Cytotoxicity dilution		
		-1	-2	-3
-5	+++	+++	+++	+++
-6	+++	+++	+++	++-
-7	-+-	-+-	-+-	-+-

PASS

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