

# BluScientific Test Data

## Test Report. EN 14476:2005 Chemical disinfectants and antiseptics - Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2/step 1). BOVINE VIRAL DIARRHEA VIRUS (Hepatitis C virus surrogate)

### Test Laboratory

### BluScientific Test Data

School of Life Sciences  
Glasgow Caledonian University  
GLASGOW G4 0BA

### Identification of sample

Name of the product  
Manufacturer

**TEKNON BIOCLEANSE CONCENTRATE  
QUADRALENE LIMITED**

Date of Delivery  
Batch No  
Storage conditions  
Active substances

Bateman Street, Derby DE23 8JL, UK  
16 JUNE 2008  
TK200  
Room temperature and darkness  
Not Known

### Test Method and its validation

Method

1 part interfering substance + 1 part virus suspension + 8 parts biocide were mixed and incubated at the indicated contact temperature for the indicated contact times. Assays were validated by a cytotoxicity control, virotoxicity control and a formaldehyde internal standard.

Dilution-neutralization.  
Neutralizer

Dulbecco's modified Eagles medium + 5% v/v foetal bovine serum at 4°C

### Experimental Conditions

Period of analysis  
Product diluent used  
Product test concentrations  
Contact times  
Test temperature  
Interfering substances  
Stability of mixture  
Temperature of incubation  
Identification of virus

25 - 30 SEPTEMBER 2008  
Sterile Hard Water  
0.5%V/V; 1.0%V/V; 5.0% V/V  
**10 minutes ± 10s; 5 minutes ± 10s; 1 minute ± 10s**  
20°C ± 1°C  
0.6 g/l foetal bovine serum + 0.03% V/V BSA  
Precipitate absent throughout the test  
37°C ± 1°C + 5% CO<sub>2</sub>  
Bovine viral diarrhoea virus ATCC VR – 1422/BT-1 cells

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BluScientific Test Data is based in the School of Life Sciences at Glasgow Caledonian University  
Glasgow Caledonian University is a registered Scottish charity, number SC021474



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**BOVINE VIRAL DIARRHOEA VIRUS (HEPATITIS C VIRUS SURROGATE). EN 14476: 2005, QUADRALENE TEKNON BIOCLEANSE CONCENTRATE, BATCH TK200**

Exposure time	Virus recovery 0 min (TCID <sub>50</sub> /ml)		Cytotoxicity (1%) (TCID <sub>50</sub> /ml)		5% Disinfectant (TCID <sub>50</sub> /ml)		1% Disinfectant (TCID <sub>50</sub> /ml)		0.5% Disinfectant (TCID <sub>50</sub> /ml)	
	raw data		raw data		raw data		raw data		raw data	
<b>1 min</b>	5.83	2.14E+07	3.00	3.16E+04	3.00	3.16E+04	2.00	3.16E+03	2.00	3.16E+03
		2.14E+07		3.16E+04		3.16E+04		3.16E+03		3.16E+03
log		7.33		4.50		4.50		3.50		3.50
log difference						2.83		3.83		3.83
		5 min								
<b>5 min</b>	5.83	2.14E+07	3.00	3.16E+04	3.00	3.16E+04	2.00	3.16E+03	2.00	3.16E+03
		2.14E+07		3.16E+04		3.16E+04		3.16E+03		3.16E+03
log		7.33		4.50		4.50		3.50		3.50
log difference						2.83		3.83		3.83
		10 min								
<b>10 min</b>	5.83	2.14E+07	3.00	3.16E+04	3.00	3.16E+04	2.00	3.16E+03	2.00	3.16E+03
		2.14E+07		3.16E+04		3.16E+04		3.16E+03		3.16E+03
log		7.33		4.50		4.50		3.50		3.50
log difference						2.83		3.83		3.83
7.50	1.00E+09	VIRUS TITRE								



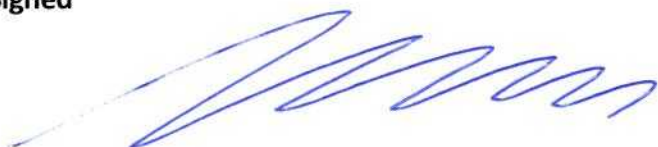
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## Conclusion

According to EN 14476: 2005, QUADRALENE TEKNON BIOCLEANSE CONCENTRATE, BATCH TK200 possesses virucidal activity at 0.5 % V/V against Bovine viral diarrhoea virus ATCC VR – 1422/BT-1 cells AT 1 MINUTE CONTACT UNDER CLEAN CONDITIONS.

This protocol employed dilution of the test mixture in order to achieve neutralization of the disinfectant. In this test, higher dilution of the disinfectant at higher disinfectant concentrations was required for effective neutralization, in comparison to lower disinfectant concentrations. The assay sensitivity was therefore reduced for higher disinfectant concentrations because residual cytotoxicity did not allow reading of the viral CPE at lower dilutions of the test mixture to demonstrate a 3 log reduction. Residual cytotoxicity did not obscure the reading of the CPE of lower dilutions of the test mixture to demonstrate a 3.0 log reduction. Logically, therefore a 3.0 log reduction in viral bioactivity was achieved at higher concentrations of the disinfectant, but these were obscured by residual cytotoxicity of the disinfectant at these concentrations.

Signed



**Dr Chris Woodall, Director**  
**BluScientific Test Data**  
**Glasgow, UK**  
**2 OCTOBER 2008**