

Abbott Analytical



Consulting Scientists to the Disinfectant Industry

Certificate of Analysis

Sample(s): One sample of Trionic D Concentrate

Expiry Date September 2014

Lot 02640

Received from: Ebiox Ltd. 822 Fountain Court, Birchwood Boulevard,

Birchwood, Warrington, WA3 7QZ

Date received: 11 January 2013 Date tested: 14 January 2013

Certificate no: 13A.031Cd.EBI Certificate date: 25 January 2013

Sample ref: 13A/031 Page: 1 of 3

Analysis required: EN 13704, Chemical disinfectants - Quantitative suspension

test for the evaluation of sporicidal activity of chemical disinfectants used in human medicine, veterinary field, and food, industrial, domestic and institutional areas - Test

method and requirements (phase 2, step 1)

Product stored at:
Room temperature

Active substance: Not declared

Test conditions: Dirty

Interfering substance: 3.0q/l bovine albumin

Product test concentration: 2% v/v

Product diluent used during test:
Sterile hard water 300mg/l CaCO3

Contact time: 1 minute & 3 minutes

Test temperature: $20^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$

Neutralising solution: 30g/l Polysorbate 80, 3g/l Lecithin,

1g/l Histidine, 1g/l Cysteine

Incubation temperature: 30°C ± 1°C

Identification of bacterial Clostridium difficile NCTC 11209

strain(s) used:

D C Watson



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<u>Test results: 1 minute</u>

Test		Clostridium						
Organism		di.	££.	ic	ile			
Validation		Vc	1	31	. 6	Vc2	272	
Suspension								
(Nv _o)		ÿ:	=	29	4			
Experimental		Vc	1	28	4	Vc2	302	
Control								
(A)		Χ̈́:	=	29	13	≥ 0.	.5Nv _o	
Neutraliser Control		Vc	1	32	:8	Vc2	274	
(B)		ÿ:	=	30	1	≥ 0.	.5Nv _o	
Method Validation		Vc	1	26	6	Vc2	292	
(C)		ÿ:	=	27	9	≥ 0.	.5Nvo	
Test 10 Suspension) ⁻⁴	Vc	1	32	2	Vc2	294	
10) - 5	Vc	1	35	i	Vc2	30	
(N = \(\vec{w}\))		lg	N		=	6.49)	
$(N_{\circ} = 0.1N)$		lg	N	0	=	5.49	9	
Results		Vc	1	27	'	Vc2	21	
(Na = 10x)		lg	Na	 а	=	2.38	3	
(R)		_				3.11		
Pass: lg R ≥ 3			PASS					

Vc = plate count per ml $\ddot{x} = \text{average of Vc1 and Vc2}$ $\ddot{w} = \text{weighted mean of } \ddot{x}$ $R = \text{reduction (lg } R = \text{lg } N_{\circ} - \text{lg Na)}$

Requirements & Conclusion:

This batch of Trionic D Concentrate, when diluted 1 part Trionic in 49 parts water , passes the requirements of EN 13704 for bactericidal activity in 1 minute at $20\,^{\circ}\text{C}$ under dirty conditions against all of the reference organisms detailed.



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Test results: 3 minutes

Test	Clostridium					
Organism	difficile					
Validation	Vc1 316 Vc2 272					
Suspension						
(Nv _o)	x = 294					
B	77 1 004 77 0 200					
Experimental Control	Vc1 284 Vc2 302					
(A)	$\ddot{x} = 293 \ge 0.5 \text{Ny}_{\circ}$					
(A)	X = 293 2 0.3NV6					
Neutraliser	Vc1 328 Vc2 274					
Control						
(B)	$\ddot{x} = 301 \ge 0.5 \text{Ny}_{\circ}$					
Method	Vc1 266 Vc2 292					
Method Validation	VC1 266 VC2 292					
(C)	$\ddot{x} = 279 \ge 0.5 \text{Ny}_{\odot}$					
(6)	273 = 0.0110					
Test 10 -4	Vc1 322 Vc2 294					
Suspension						
10 -5	Vc1 35 Vc2 30					
$(N = \ddot{w})$	lg N = 6.49					
$(N_{\circ} = 0.1N)$	$\log N_{\circ} = 5.49$					
(118 0.111)	19 10 0.13					
Results	Vc1 15 Vc2 11					
$(Na = 10\ddot{x})$	lg Na < 2.16					
(R)	lg R > 3.33					
Pass: lg R ≥ 3	PASS					

Vc = plate count per ml \ddot{x} = average of Vc1 and Vc2 \ddot{w} = weighted mean of \ddot{x} R = reduction (lg R = lg N_o - lg Na)

Requirements & Conclusion:

This batch of Trionic D Concentrate, when diluted 1 part Trionic in 49 parts water , passes the requirements of EN 13704 for bactericidal activity in 3 minute at $20\,^{\circ}\text{C}$ under dirty conditions against all of the reference organisms detailed.