

EFFICACY TESTS (EN 13697)

DIFFICIL-S DISINFECTANT

TESTS PERFORMED FOR CLINIMAX LTD

SCIENTIFIC SERVICES

WILLOW FARM

STEWTON

LOUTH

LN11 8SD

01507 328552

3/7/09

Manufacturer: Clinimax Ltd,
Shepherd Grove West,
Stanton,
Bury St. Edmunds,
Suffolk,
IP31 2AR

Test Products:

Difficil-S Part A: Ingredients - Sodium chlorite and excipients

Difficil-S Part B: Ingredients - Citric acid monohydrate and excipient

The test product is made up as a mixture of equal parts of Part A and Part B
BN 52016A, 52016B

Storage Conditions: Room temperature, in a dry place away from
direct sunlight

Test Organism Clostridium difficile NCTC 11209

Test Method and Validation EN13697 Chemical disinfectants and antiseptics - Quantitative Non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (phase 2, step 2).

Product test concentration (Manufacturers claimed Concentrations)	Difficil-S - 1:400 - 300ppm chlorine dioxide diluted further to 20%
Appearance of product dilution	Difficil-S - Clear yellow solution
Contact time	3, 5, 7 and 10 minutes
Test Temperature	20 C
Interfering substance	Bovine albumin, 3.0g/l (dirty conditions) (final concentration)
Inhibition method	Dilution neutralisation
Neutraliser	Tryptone Soya Broth containing Tween 80 10%, Lecithin 3%, Sodium thiosulphate 0.5% Cystine 0.1%, Histidine 0.1%

Tests were performed to establish the suitability of this neutraliser in neutralising the activity of the disinfectant without being toxic to the test organisms (method described in EN13697)

Summary of test method

The test method is described in EN13697 Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional area (Phase 2, step 2). Copies of EN 13697 are available from BSI, 389 Chiswick High Road, London W4 4AL.

The test method involves inoculating a suspension of the test organism in a solution of interfering substances onto a stainless steel surface and allowing to dry. A sample of the test product is applied to the film, and maintained at a specified temperature for a defined period of time. After the contact time, the surface is transferred to a recovery/neutraliser solution which is then plated out to detect surviving organisms.

In this test a suspension of spores was used in place of a vegetative suspension

Sporicidal activity of Difficil-S (20% of recommended strength)

Using Phase 2 step 2 Non-porous surface Test EN13697

(Test carried out in duplicate)

Log (10) reductions achieved dirty conditions			
Test Organism	Contact time	Log10 initial count (challenge) Mean	Log 10 reduction Mean
Clostridium difficile spores	3 min	6.41	2.52
	5 min	6.41	4.11
	7 min	6.41	5.41
	10 min	6.41	> 5.41

Conclusion

In the absence of an approved standard test for disinfectant activity against spores of *Clostridium difficile*, the results given here may be compared against two different standard tests:-

1. EN13697, a surface test for disinfectant activity against vegetative bacteria and fungi. The criteria of acceptance is a >4 log reduction in test bacteria within 5 minutes.
2. EN13704, a suspension test for disinfectant activity against spores, employing spores of *Bacillus subtilis* as test organism. The criteria of acceptance is a >3 log reduction in *Bacillus subtilis* spores within 60 minutes.

The 20% concentration of Difficil-S tested met the above criteria as follows:-

Sample	Log reduction achieved	Standard	Pass/Fail
20% Preparation	4.11 logs in 5 mins	EN13697	Pass
		EN13704	Pass



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Proprietor

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