

**Investigation into the effectiveness of Cleanitise when tested in accordance with
BS EN 13704:2002 - 'Chemical disinfectants - Quantitative suspension test for the
evaluation of sporicidal activity of chemical disinfectants used in food, industrial,
domestic and institutional areas'**

CONFIDENTIAL TO:

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PROJECT: MB/REP/123672/1

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15th August 2011

Report Approved By:



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SUMMARY

Cleanitise was tested at 20% (1 in 5 dilution) possesses sporicidal activity against *Clostridium difficile* within 60 minutes at 20°C under clean conditions (0.03% bovine albumen final concentration in the test) when tested using the method BS EN 13704:2002.

1. INTRODUCTION

Mr Luxton requested that Campden Technology Limited (Campden BRI) assess the efficacy of Cleanitise for sporicidal activity against *C. difficile* using the method BS EN 13704:2002 - 'Chemical disinfectants - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas'.

2. METHOD

For the sporicidal test, the principles of BS EN 13704:2002 - 'Chemical disinfectants - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas' were followed.

NOTES

For the sporicidal test, *Clostridium difficile* was tested at the standard 60 minutes.

Sporicidal activity in general use conditions

- a) IDENTIFICATION OF THE TEST LABORATORY **Campden BRI**
- b) IDENTIFICATION OF THE SAMPLE **FH/123672/1**
Name of the product **Cleanitise**
Batch number **Not supplied**
Manufacturer **Cleanitise universal infection control**
Condition on receipt **OK**
Date of delivery **12.05.11**
Storage conditions **dark, ambient (Laboratory sample cupboard)**
Product diluent recommended by the manufacturer for use **N/A**
Active substance(s) and its (their) concentrations(optional) **N/A**
- c) EXPERIMENTAL CONDITIONS
Period of analysis **July 2011**
Product diluent used during the test **Water of Standard Hardness (WSH)**
Product test concentrations **20%, 10%, 1%**
Appearance of diluted product **Liquid, yellow, clear**
Contact time **Sporicidal test – 60 minutes**
Test temperature **Sporicidal test - 20°C**
Interfering substance **Bovine Serum Albumin @ 0.03% (“CLEAN”) in Sterile Distilled Water (SDW)**
Stability of mixture (interfering substance and product diluted in hard water) **Stable**
Temperature of incubation **30°C ± 1°C**
Identification of the spore strains used **Additional sporicidal test strain:
C. difficile NCIMB 10666
(Campden FH147)**
Preparation of the spore suspension **Spores cropped on 6.4.11
Heat treated on day of testing**
- d) OPERATING PROCEDURE
Methods used **Sporicidal test – BS EN 13704:2002
Clostridium difficile, anaerobic conditions,
Tryptone Soya agar + 5% defibrinated sheeps blood
incubated at 30°C ± 1°C for 5 days**
Deviations from methods **Dilution neutralisation**
Neutralisation method **Dilution neutralisation**
- e) TEST RESULTS **See attached table**

f) CONCLUSION

When tested *according* to the method BS EN 13704:2002, the supplied Cleanitise (FH/123672/1), at 20% possesses sporicidal activity against *Clostridium difficile* spores in 60 minutes at 20°C under clean conditions.

N.B. KEY TO CODES ON RESULT SHEET...

Vc:	viable count
R:	reduction in viability
Na:	the number of cfu/ml in the test mixture
Nv:	the number of cfu/ml of the spore suspension for validation controls
N:	the number of cfu/ml of the spore test suspension
A:	the number of cfu/ml of the experimental conditions control
B:	the number of cfu/ml of the neutraliser toxicity validation or of the filtration validation
C:	the number of cfu/ml of the dilution neutralisation test validation, or of the membrane filtration test validation

TABLE 1 - RESULTS AND VALIDATIONS
(Dilution Neutralisation)

Test criteria	Validation Test				Test suspension	Test procedure at concentration % (v/v)			Result
	Vc: 64, 52 Nv: 5.8 x 10 ²	Vc: 64, 62 A: 63	Vc: 58, 66 B: 62	Vc: 60, 56 C: 58		cfu/ml in test pot	1	10-	
<i>Clostridium difficile</i> NCIMB 10666 Clean 60 minutes					Vc: -4 230, 242 -5: 22, 20 N: 2.36 x 10 ⁶	2.3 x 10 ⁵	Vc : >300, >300 Na: >3.0 x 10 ³ R: <1.0 x 10 ³	Vc : 0, 0 Na: < 1.5 x 10 ² R: >1.0 x 10 ³	Pass/Fail/Invalid Pass at 20% Test Valid

