

STERI-7 HALO[®]



COMPARISON

STERI-7 HALO vs CHLOR-CLEAN TABLETS

EN 13704:2002,
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)



Abbott Analytical



Consulting Scientists to the Disinfectant Industry

Certificate of Analysis

Product name: Chlor-Clean Tablets

Batch or ref no:

Manufacturer or supplier: Guest Medical

Sample ref: 16B/009 **Date received:** 2 February 2016

Date tested: 5 February 2016 **Certificate date:** 12 February 2016

Certificate no: 16B.009Mcd.STE **Page:** 1 of 3

Analysis required: EN 13704:2002, 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)

Storage conditions: Room temperature in darkness

Appearance of product (solution): Clear colourless liquid

Active substance(s) and their concentration(s): Not disclosed

Notes

The test results in this report relate only to the sample(s) tested. This test report may not be reproduced except in full, adapted, altered or used to create a derivative work, without written approval from Abbott Analytical.

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Certificate no: 16B.009Mcd.STE

Date: 12 February 2016

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Experimental conditions

Concentration(s) of product tested: One 6g tablet per 1000ml water
(0.6% w/v)

Product diluent: Sterile hard water (300mg/l CaCO₃)

Test organism(s): *Clostridium difficile* (NCTC 11209)

Contact time(s): 30s ± 5s & 60s ± 5s

Test temperature: 20°C ± 1°C

Test conditions: Medical dirty

Interfering substance: 3.0g/l bovine albumin +
3.0g/l sheep erythrocytes

Neutralising solution: 30g/l Polysorbate 80 + 3g/l Lecithin +
1g/l L-histidine + 1g/l L-cysteine

Incubation temperature: 37°C ± 1°C

Conclusion

When tested at a concentration of 0.6% this sample of Chlor-Clean Tablets solution does not pass the requirements of EN 13704:2002 for sporicidal activity in 60 seconds at 20°C, under medical dirty conditions, against *Clostridium difficile* (NCTC 11209).

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Results: Clostridium difficile (NCTC 11209)

Validation tests			
Spore suspension	Experimental conditions	Neutraliser toxicity	Dilution-neutralisation
Vc: 38 ; 40	Vc: 35 ; 38	Vc: 29 ; 36	Vc: 31 ; 35
Nv: 3.9×10^2	A: 3.7×10^1	B: 3.3×10^1	C: 3.3×10^1

Spore test suspension	Test procedure at	
	Contact time 30s Test conc. 0.6%	Contact time 60s Test conc. 0.6%
10^{-4} : 160 ; 172	Vc: 101 ; 98	Vc: 77 ; 85
10^{-5} : 15 ; 16	Na: 1.0×10^3 R: 1.7×10^2 lg R: 2.2 FAIL	Na: 8.1×10^2 R: 2.1×10^2 lg R: 2.3 FAIL
N: 1.7×10^6		

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Certificate of Analysis

Product name: Steri-7 Halo

Batch or ref no:

Manufacturer or supplier: Steri-7 Ltd
34 Baron Grove, Mitcham, CR4 4EH

Sample ref: 15M/031 **Date received:** 14 December 2015

Date tested: 5 February 2016 **Certificate date:** 12 February 2016

Certificate no: 15M.031McD.STE **Page:** 1 of 3

Analysis required: EN 13704:2002, 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)

Storage conditions: Room temperature in darkness

Appearance of product (solution): Clear colourless liquid

Active substance(s) and their concentration(s): Pure Hypochlorous Acid
1600ppm

Notes

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Certificate no: 15M.031MCd.STE

Date: 12 February 2016

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Experimental conditions

Concentration(s) of product tested: Neat as received

Product diluent: N/A

Test organism(s): *Clostridium difficile* (NCTC 11209)

Contact time(s): 30s ± 5s & 60s ± 5s

Test temperature: 20°C ± 1°C

Test conditions: Medical dirty

Interfering substance: 3.0g/l bovine albumin +
3.0g/l sheep erythrocytes

Neutralising solution: 30g/l Polysorbate 80 + 3g/l Lecithin +
1g/l L-histidine + 1g/l L-cysteine

Incubation temperature: 37°C ± 1°C

Conclusion

At a test concentration of 1600ppm this sample of Steri-7 Halo passes the requirements of EN 13704:2002 for sporicidal activity in 30 seconds at 20°C, under medical dirty conditions, against *Clostridium difficile* (NCTC 11209).

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Results: Clostridium difficile (NCTC 11209)

Validation tests			
Spore suspension	Experimental conditions	Neutraliser toxicity	Dilution-neutralisation
Vc: 38 ; 40	Vc: 35 ; 38	Vc: 29 ; 36	Vc: 31 ; 35
Nv: 3.9×10^2	A: 3.7×10^1	B: 3.3×10^1	C: 3.3×10^1

Spore test suspension	Test procedure at	
	Contact time 30s Test conc. 1600ppm	Contact time 60s Test conc. 1600ppm
10^{-4} : 160 ; 172	Vc: 3 ; 1	Vc: 1 ; 2
10^{-5} : 15 ; 16	Na: $< 1.5 \times 10^2$ R: $> 1.1 \times 10^3$ lg R: > 3.1 PASS	Na: $< 1.5 \times 10^2$ R: $> 1.1 \times 10^3$ lg R: > 3.1 PASS
N: 1.7×10^6		

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