



# Abbott Analytical



Consulting Scientists to the Disinfectant Industry

## Certificate of Analysis

**Sample(s):** One sample of Cleanitise Concentrate

**Received from:** Cleanitise Ltd. 14 Cherry Grove, Sketty, Swansea, SA2 8AS

**Date received:** 16 May 2011      **Date tested:** 18 May 2011

**Certificate no:** 11E.040S.CLE      **Certificate date:** 20 May 2011

**Sample ref:** 11E/040      **Page:** 1 of 2

**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:** 3.0g/l bovine albumin +  
3.0ml/l sheep erythrocytes

**Product test concentration:** 20% v/v

**Product diluent used during test:** Sterile hard water 300mg/l CaCO<sub>3</sub>

**Contact time:** 60 minutes

**Test temperature:** 20°C ± 0.5°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 strain(s) used:** *Bacillus subtilis* ATCC 51189  
(was *globigii*)  
*Bacillus cereus* ATCC 12826

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## Test results:

Test Organism	<i>Bacillus globigii</i>		<i>Bacillus cereus</i>	
Validation Suspension (N <sub>v</sub> )	Vc1 258	Vc2 300	Vc1 236	Vc2 268
	$\bar{x} = 279$		$\bar{x} = 252$	
Experimental Control (A)	Vc1 272	Vc2 260	Vc1 222	Vc2 204
	$\bar{x} = 266 \geq 0.5N_{v0}$		$\bar{x} = 213 \geq 0.5N_{v0}$	
Neutraliser Control (B)	Vc1 284	Vc2 246	Vc1 216	Vc2 235
	$\bar{x} = 265 \geq 0.5N_{v0}$		$\bar{x} = 226 \geq 0.5N_{v0}$	
Method Validation (C)	Vc1 270	Vc2 254	Vc1 206	Vc2 228
	$\bar{x} = 262 \geq 0.5N_{v0}$		$\bar{x} = 217 \geq 0.5N_{v0}$	
Test Suspension	10 <sup>-4</sup> Vc1 208	Vc2 234	Vc1 186	Vc2 244
	10 <sup>-5</sup> Vc1 35	Vc2 43	Vc1 24	Vc2 27
(N)	$\bar{w} = 2.36 \times 10^6$		$\bar{w} = 2.19 \times 10^6$	
(N <sub>0</sub> = 0.1N)	lg N = 6.37		lg N = 6.34	
	lg N <sub>0</sub> = 5.37		lg N <sub>0</sub> = 5.34	
Results 10 <sup>0</sup>	Vc1 <14	Vc2 <14	Vc1 <14	Vc2 <14
	10 $\bar{x}$ < 140		10 $\bar{x}$ < 140	
(Na)	lg Na < 2.15		lg Na < 2.15	
(R)	lg R > 3.23		lg R > 3.19	
Pass: lg R $\geq$ 3	PASS		PASS	

Vc = plate count per ml

$\bar{x}$  = average of Vc1 and Vc2

$\bar{w}$  = weighted mean of  $\bar{x}$

R = reduction (lg R = lg N<sub>0</sub> - lg Na)

## Conclusion:

This batch of Cleanitise Concentrate, when diluted to 20% v/v, passes the requirements of EN 13704 for sporicidal activity in 60 minutes at 20°C under dirty conditions against the reference organisms detailed.

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