



**Nobactel**

**MGS: 10704 / SO No: 803**

**BS EN 1276 (1997)**

**Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics (Phase 2 / Step 1)**

**a) Identification of test laboratory:**

Test laboratory.....	MGS Laboratories Ltd Unit 9 Brunel Science Centre Coopers Hill Lane Egham Surrey TW20 0JZ United Kingdom
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**b) Identification of the sample:**

Name of product.....	Nobactel
Batch number .....	L260701
Manufacturer.....	Laboratoire Cellande
Date of delivery.....	05 July 2006
Storage conditions.....	Room temperature and darkness
Product diluent recommended by the manufacturer for use.....	Not stated
Active substance(s) and their concentration(s) (optional).....	Not stated

**c) Test method and its validation:**

Method.....	Dilution neutralisation
Neutraliser.....	Lecithin 3g/l, polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/l, saponin 30g/l, phosphate buffer powder 0.35g/l

**d) Experimental conditions:**

Period of analysis.....	12 July 2006 – 14 July 2006
Product diluent used during the test.....	Sterile distilled water



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**(Phase 2 / Step 1)**

Product test concentrations.....	1:100 (v/v)	
Appearance of product dilutions.....	Clear green solution	
Contact time.....	5 min ± 10s	
Test temperature.....	20°C ± 2°C	
Interfering substance.....	0.3 g/l of Bovine albumin 3.0 g/l of Bovine albumin	
Stability of the mixture.....	Precipitate absent throughout test	
Temperature of incubation.....	32°C ± 2°C	
Identification of the bacterial strain used:	<i>Escherichia coli</i>	NCTC 10418
	<i>Enterococcus hirae</i>	NCTC 12367
	<i>Staphylococcus aureus</i>	NCTC 10788
	<i>Pseudomonas aeruginosa</i>	NCTC 10332

**e) Results:**

Test results: See tables 1 – 4.

**f) Conclusion:**

According to BS EN 1276 (1997), the batch L260701 of the product Nobactel, when diluted at 1:100 (v/v) in distilled water, possesses a bactericidal activity in 5 minutes at 20 °C under clean and dirty conditions for the referenced strains *E. coli*, *E. hirae*, *S. aureus* and *P. aeruginosa*.

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**Position:** Laboratory Manager

**Position:** Technical Director

**Date:** 21 Nov 07

**Date:** 22 Nov 07

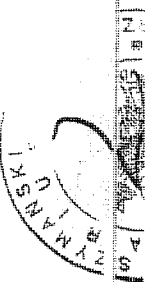


Table 1: Dilution neutralisation test results for *E. coli* at 1:100 (v/v) in 5 minutes at 20°C.

Interfering substance	Test organism	Validation tests					Bacterial test suspension	Test procedure
		Bacterial suspension	Experimental conditions control	Neutralisation toxicity control	Dilution-neutralisation control			
0.3g/l Bovine albumin (clean conditions)	<i>Escherichia coli</i>	Vc: 115; 116	Vc: 124; 115	Vc: 117; 91	Vc: 102; 97	10 <sup>-6</sup> ; 115; 116	Vc: <1; <1 Na: <1.0 x 10 <sup>2</sup> R: >10 <sup>5</sup>	
		NCTC 10418	Nv: 1.2 x 10 <sup>3</sup>	A: 1.2 x 10 <sup>2</sup>	B: 1.0 x 10 <sup>2</sup>	C: 1.0 x 10 <sup>2</sup>	10 <sup>-7</sup> ; 13; 20 N: 1.2 x 10 <sup>8</sup>	
3.0g/l Bovine albumin (dirty conditions)							Vc: <1; <1 Na: <1.0 x 10 <sup>2</sup> R: >10 <sup>5</sup>	

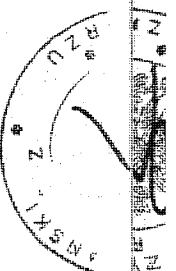


Table 2: Dilution neutralisation test results for *E. hirae* at 1:100 (v/v) in 5 minutes at 20°C.

Interfering substance	Test organism	Validation tests					Bacterial test suspension	Test procedure
		Bacterial suspension	Experimental conditions control	Neutralisation toxicity control	Dilution-neutralisation control			
0.3g/l Bovine albumin (clean conditions)	<i>Enterococcus hirae</i>	Vc: 142; 175	Vc: 154; 186	Vc: 161; 167	Vc: 147; 131	10 <sup>-6</sup> : 142; 175	Vc: <1; <1 Na: <1.0 x 10 <sup>2</sup> R: >10 <sup>5</sup>	
		Nv: 1.6 x 10 <sup>3</sup>	A: 1.7 x 10 <sup>2</sup>	B: 1.6 x 10 <sup>2</sup>	C: 1.4 x 10 <sup>2</sup>	10 <sup>-7</sup> : 20; 17		
3.0g/l Bovine albumin (dirty conditions)	NCTC 12367					N: 1.6 x 10 <sup>8</sup>	Vc: <1; <1 Na: <1.0 x 10 <sup>2</sup> R: >10 <sup>5</sup>	



Table 3: Dilution neutralisation test results for *S. aureus* at 1:100 (v/v) in 5 minutes at 20°C..

Interfering substance	Test organism	Validation tests					Bacterial test suspension	Test procedure
		Bacterial suspension	Experimental conditions control	Neutralisation toxicity control	Dilution-neutralisation control			
0.3g/l Bovine albumin (clean conditions)	<i>Staphylococcus aureus</i>	Vc: 30; 36	Vc: 272; 224	Vc: 258; 266	Vc: 31; 29	10 <sup>-6</sup> : >300, >300	Vc: <1; <1 Na: <1.0 x 10 <sup>2</sup> R: >10 <sup>5</sup>	
		Nv: 3.3 x 10 <sup>3</sup>	A: 2.5 x 10 <sup>2</sup>	B: 2.6 x 10 <sup>2</sup>	C: 3.0 x 10 <sup>2</sup>	10 <sup>-7</sup> : 30; 36 N: 3.3 x 10 <sup>8</sup>	Vc: <1; <1 Na: <1.0 x 10 <sup>2</sup> R: >10 <sup>5</sup>	
3.0g/l Bovine albumin (dirty conditions)	NCTC 10788							



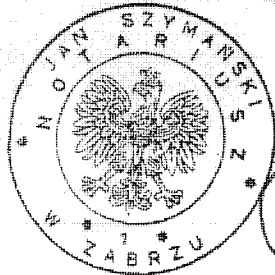
Table 4: Dilution neutralisation test results for *P. aeruginosa* at 1:100 (v/v) in 5 minutes at 20°C.

Interfering substance	Test organism	Validation tests				Bacterial test suspension	Test procedure
		Bacterial suspension	Experimental conditions control	Neutralisation toxicity control	Dilution-neutralisation control		
0.3g/l Bovine albumin (clean conditions)	<i>Pseudomonas aeruginosa</i>	Vc: 156; 150	Vc: 158; 150	Vc: 170; 158	Vc: 98; 95	10 <sup>6</sup> ; 156; 150	Vc: <1; <1 Na: <1.0 x 10 <sup>2</sup> R: >10 <sup>5</sup>
		Nv: 1.5 x 10 <sup>3</sup>	A: 1.5 x 10 <sup>2</sup>	B: 1.6 x 10 <sup>2</sup>	C: 9.7 x 10 <sup>1</sup>	10 <sup>7</sup> ; 15; 16	
3.0g/l Bovine albumin (dirty conditions)	NCTC 10332					N: 1.5 x 10 <sup>8</sup>	Vc: <1; <1 Na: <1.0 x 10 <sup>2</sup> R: >10 <sup>5</sup>

- Vc = Viable count  
 N = Number of cfu/ml of the bacterial test suspension  
 Nv = Number of cfu/ml of the bacterial suspension  
 R = Reduction of viability  
 Na = Number of cfu/ml in the test mixture  
 A = Number of cfu/ml of the experimental conditions validation  
 B = Number of cfu/ml of the neutraliser toxicity validation  
 C = Number of cfu/ml of the dilution-neutralisation validation

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Repertorium „A” numer 1417/2008  
Poświadczam zgodność odpisu z okazanym dokumentem.  
Pobrano wynagrodzenie za dokonanie czynności notarialnej  
z §13 pkt 2 rozp. Min. Sprawiedl. z dnia 28.06.2004 r.  
w sprawie maksym. stawek taksy notarialnej (Dz.U. nr 148  
poz. 1564) w kwocie 2,50 zł powiększone o podatek od  
towarów i usług zgodnie z art. 5, 8, 29 i 41 ustawy o podatku  
od towarów i usług z dnia 11.03.2004 r. (Dz. U. 54, poz. 535)  
według stawki 22% od kwoty 3,12 zł, czyli o kwotę 0,69 zł,  
a więc łącznie pobrano 3,19 zł.  
Zabrze dnia 23 STY. 2008



Jan Szymański  
*[Signature]*  
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