

### Test report no. L 06/001

#### Efficacy testing of the surgical skin disinfectant *CHEMISEPT G* according to EN 14348: 2005

In accordance with your request, we tested the preparation *CHEMISEPT G*, referred to in the following as the test preparation, for its efficacy against *Mycobacterium terrae* under low organic load according to EN 14348: 2005.

#### 1. General information and material

##### a) Client

- Client: Chemi-Pharm AS, Mr Andres Paling, Pollu 132  
EST - 10917 Tallinn
- Date of request: 25.11.2005

##### b) Identification of the testing laboratory

- Dr. Brill + Partner GmbH · Labor für Hygiene und Mikrobiologie, Papenreye 61, 22453 Hamburg; Dr. Holger Brill, Florian Brill, Carmela Jänicke

##### c) Identification of the sample

- Name of product: *CHEMISEPT G*
- Batch number: 25.11.2005
- Manufacturer: Chemi-Pharm AS, Tallinn, Estonia
- Date of supply: 28.11.2005
- Lagerbedingungen: Raumtemperatur und Dunkelheit

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- Appearance of concentrate: crystal clear solution
  - Odour: aromatic, alcoholic
  - Recommended diluent: potable drinking water
  - Diluent used: water of standardised hardness (WSH)
  - pH-value, 100 %: 9.15
  - Active agents in 100 g test preparation: 75.0 g ethanol  
0.1 g blend of N-alkylbenzyltrimethyl ammonium chloride  
and N-alkyldimethyl ammonium chloride

#### d) Test conditions

- Period of testing: 23.02. to 16.03.2006
- Product test concentrations: 100 volume-%
- Test temperature: 20°C ± 2°C
- Exposure times: 0.5; 3 and 5 minutes
- Incubation temperature: 36°C ± 1°C
- Organic load: low (0.03 % bovine albumin)
- Neutraliser mycobacteria: 30 g/L polysorbate 80, 30 g/L saponine, 1 g/L histidine, 5 g/L sodium thiosulphate (TSH-NT) in phosphate buffer
- Test germs: Mycobacterium terrae ATCC 15755

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2. Results: Determination of the mycobactericidal effect within the quantitative suspension test according to EN 14348: 2005

The results are summarised in table no. 1.1 and 1.2. The sufficiently effective concentration-time relationship ( $\geq$  RF 4) for the test organism *Mycobacterium terrae* was at low organic load:

100 % in 30 seconds

Hamburg, 12 April 2006



Dr. Holger Brill

**DR. BRILL + PARTNER GMBH**  
LABOR FÜR HYGIENE UND MIKROBIOLOGIE

Test report no. L 06/001 Table 1.1: Validation (EN 14348: 2005)

Test preparation: Chemisept G  
Organic load: low (0.03 % albumin)

Test germ: Mycobacterium terrae  
Inactivation: TSH-NT in phosphate buffer

Validation and controls

NVO: Suspension validation		A: Control of test conditions at an exposure time of (in minutes)						B: Control of neutralisation		C: Validation of procedure at 100 %	
		0,5			3			5			
VC1	103	VC1	98	VC1	110	VC1	114	VC1	95	VC1	102
	50	Median	50	Median	61	Median	58	Median	45	Median	60
VC2	115	VC2	107	VC2	105	VC2	97	VC2	100	VC2	102
	55	Median	56	Median	52	Median	45	Median	50	Median	58
	60		51		53		52		50		44

Evaluation validation and controls

<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	30 ≤ median of NVO ≤ 160 ?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	Median of A (0.5') is ≥ 0.5 x median of NVO ?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	Median of A (3') is ≥ 0.5 x median of NVO ?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	Median of A (5') is ≥ 0.5 x median of NVO ?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	Median of B is ≥ 0.5 x median of NVO ?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	Median of C is ≥ 0.5 x median of NVO ?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
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Legend: VC = number of viable cells per ml  
 Median = average of VC1 and VC2 (1<sup>st</sup> and 2<sup>nd</sup> repeated determination)      R = Median 1  
 germ reduction (lg R = N0 - lg Na) weighted average

**DR. BRILL + PARTNER GMBH**  
LABOR FÜR HYGIENE UND MIKROBIOLOGIE

Test report no. L 06/001 Table 1.2: Test results (EN 14348: 2005)

Test preparation: Chemisept G  
Organic load: low (0.03 % albumin)

Test germ: Mycobacterium terrae  
Inactivation: TSH-NT in phosphate buffer

Test suspension and test results

N and N0	Median 1		Factor	Ig
1E-07	VC1	258	1,57E+09	9,20
		131		
	VC2	243		
		128		
1E-08	VC1	58	N0 = N/10 = 8,20	
		22		
	VC2	68		
		35		

Exposure time in minutes	0,5	3	5
Use concentration in %	100	100	100
VC1	12	1	0
VC2	15	2	0
Na = Median x 10	270	30	0
Ig Na	2,43	1,48	0,00
Ig R (N0)	5,76	6,72	8,20

Evaluation of the test suspension:  $8.17 \leq N0 \leq 8.70$ :  Yes  No

Legend: VC = number of viable cells per ml  
Median = average of VC1 and VC2 (1<sup>st</sup> and 2<sup>nd</sup> repeated determination)

R = germ reduction (Ig R = N0 - Ig Na)  
Median 1 weighted average