



Public Health Institute Ostrava
Center of Clinical Laboratories
Location nr. 1 - Ostrava
Laboratory for mycobacterial diagnostics
Partyzánské náměstí 2633/7, Moravská Ostrava, 702 00 Ostrava
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L 1554

Testing protocol n. 5/2019/SMU

EN 14 348 Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2. step 1)

Applicant:

SCHULKE CZ. s.r.o

Lidická 445
735 81 Bohumín

Order n.: 018-2019-08-02

Sample identification:

Product name:

desam® effect/desam® effekt+

LOT:

002A190620

Manufacturer:

SHULKE CZ. s.r.o.

Storage conditions:

room temperature. dark

Diluent (by manufacturer):

tap water

Active substances: 100g concentrate of product: Alkyl (C12-16) dimethylbenzyl ammonium chloride 19 g (CAS: 68424-85-1), 2-Phenoxyethanol 10 g (CAS: 122-99-6), N-(3-aminopropyl)-N-dodecylpropan-1,3-diamine 7,2 g (CAS: 2372-82-9), Didecylmethylammoniumchloride 3 g (CAS: 7173-51-5).

Appearance and composition:

Clear viscous liquid

Date of delivery:

1st July 2019

Dates of testing:

11th August 2019

Results: see attachments 1 – 2

Special notes according to test:

All controls and validations were within limits.

Coagulation of precipitate has occurred, nevertheless without any influence of plates reading.

Conclusion:

According to EN 14348. Product **desam® effect/desam® effekt+** LOT **002A190620** proved **tuberculocidal** activity within **30 minutes** on temperature **20°C** and **dirty conditions** (bovine albumin 3 g/l + sheep erythrocytes 3ml) in **0.5%** concentration for reference strain *Mycobacterium terrae*. Reduction with testing organism *Mycobacterium terrae* was **4.11 ± 0.035^{a)}** logarithmic orders.

Zdravotní ústav se sídlem v Ostravě
Centrum klinických laboratoří
Oddělení bakteriologie a mykologie
Laboratoř pro diagnostiku mykobakterií
Partyzánské náměstí 2633/7
Moravská Ostrava 702 00 Ostrava
Telefon: 596 200 220

In Ostrava: 2nd September 2019

Mgr. Vít Ulmann
Head of the Laboratory

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Protocol attachment n. 1: 5/2019/SMU

EN 14348 (phase 2/stage 1). Product name: **desam® effect/desam® effekt+**

LOT: 002A190620

Manufacturer: **Schulke CZ. s.r.o.** Storage conditions (temperature etc.): room temperature, dark

Number of seeded plates 2 ml. Neutralizer: Polysorbate 80 + 30 g/l, Sodium thiosulphate (Na₂S₂O₃) - 5g/l, L-histidine - 1g/l.

Test conditions: **20°C; High load (dirty condition):** Erythrocytes 3ml/l + Bovine albumin 3 g/l


Tested organism: **Mycobacterium terrae DSM 43227**. Temperature of incubation 36°C

Procedure: The product was diluted with hard water to a final concentration of **0.5%** during the test.

Date of the test: **11th August 2019**

Elaborated by: Vít Ulmann

Responsible person: Vít Ulmann

Signature: 

Controls and validations:

Validation suspension (N _{v0})			Experimental conditions control (A)			Neutralizer control (B)			Validation (product control) (C)		
V _{c1}	107	X=101.5	V _{c1}	114	X=109.5	V _{c1}	114	X=127.5	V _{c1}	53	X=63
V _{c2}	96		V _{c2}	105		V _{c2}	141		V _{c2}	73	
39 ≤ x from N _{v0} ≤ 160? YES <input checked="" type="checkbox"/> NO			X z A ≥ 0. 5 * x from N _{v0} ? YES <input checked="" type="checkbox"/> NO			X z B ≥ 0. 5 * x from N _{v0} ? YES <input checked="" type="checkbox"/> NO			X z C ≥ 0. 5 * x from N _{v0} ? YES <input checked="" type="checkbox"/> NO		

Test suspension and test:

Test suspension control (N a N ₀)	N	V _{c1}	V _{c2}	X _{wm} = 414.14x 107 = log = 9.62 N ₀ = N/10 = lg 8.65 8.17 ≤ N ₀ ≤ 8.70? YES <input checked="" type="checkbox"/> NO
	10 ⁻⁷	(196+118) 314	(199+1238) 437	
	10 ⁻⁸	(48+42) 90	(26+44) 70	

Concentration of the product %	Dilution step	V _{c1}	V _{c2}	Lg N _a = lg (x x 10 or x _{wm} x 10)	Lg R (N ₀ = lg 8.62)	Exposure time
0.5%	10 ⁰	>660	>660	4.51	4.11**	30 min
	10 ⁻¹	(180+161) 341*	(134+128) 262*			
	10 ⁻²	(32 + 23) 55*	(34+20) 54*			
	10 ⁻³	<14	<14			
0.5%	10 ⁰	(168+172) 340*	(194+205) 399*	3.65	4.97	30 min
	10 ⁻¹	(62 + 55) 118*	(63+58) 121*			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			

*Encountered values

Explanatory notes: V_c = count of colonies per ml, x = average V_{c1} a V_{c2} (1. + 2) duplicate determination, X_{wm} = weighted average x. R reduction (lg R = Lg N₀ - Lg N_a)

Protocol attachment n. 1: 5/2019/SMU

EN 14348 (phase 2/stage 1). Product name: **desam® effect/desam® effekt+**
002A190620

LOT:

Manufacturer: **Schulke CZ. s.r.o.**

Storage conditions (temperature etc.): room temperature, dark

Number of seeded plates 2 ml. Neutralizer: Polysorbate 80 + 30 g/l, Sodium thiosulphate (Na₂S₂O₃) - 5g/l,
L-histidine – 1g/l.

Washing solution: Physiological saline with peptone extract. Temperature within test: **20°C**

Test conditions: **High load (dirty condition)**: Erythrocytes 3ml/l + Bovine albumin 3 g/l

Tested organism: **Mycobacterium terrae DSM 43227**. Temperature of incubation **36°C**

Procedure: The product was diluted with hard water to a final concentration of **0.5%** during the test.

Date of the test: **11th August 2019, 12th August 2019**

elaborated by: **Vít Ulmann**

Responsible person: **Vít Ulmann**

Signature:

Repeated testing:

Concentration of the product %	Dilution step	V _{c1}	V _{c2}	Lg N_a = lg (x x 10 or x _{wm} x 10)	Lg R	Exposure time
11th August 2019	1			4.56	N ₀ = lg 8.58	30 min
0.5	10 ⁰	>660	>660		4.02**	
BA 3g/l + Eryt.	10 ⁻¹	320*	336*			
	10 ⁻²	81*	67*			
	10 ⁻³	<14	<14			
11th August 2019	2			4.53	N ₀ = lg 8.66	30 min
0.5	10 ⁰	>660	>660		4.13**	
BA 3g/l + Eryt.	10 ⁻¹	312*	261*			
	10 ⁻²	83*	82*			
	10 ⁻³	<14	<14			
12th August 2019	3			4.39	N ₀ = lg 8.49	30 min
0.5	10 ⁰	>660	>660		4.10**	
BA 3g/l + Eryt.	10 ⁻¹	222*	199*			
	10 ⁻²	63*	53*			
	10 ⁻³	<14	<14			
12th August 2019	4			4.45	N ₀ = lg 8.53	30 min
0.5	10 ⁰	>660	>660		4.08**	
BA 3g/l + Eryt.	10 ⁻¹	262*	234*			
	10 ⁻²	63*	58*			
	10 ⁻³	<14	<14			
12th August 2019	5			4.60	N ₀ = lg 8.69	30 min
0.5	10 ⁰	>660	>660		4.09**	
BA 3g/l + Eryt.	10 ⁻¹	386*	304*			
	10 ⁻²	99*	83*			
	10 ⁻³	<14	<14			
** The average reduction in six repetitions: 3.24 x 10⁴						

*Encountered values

a) the standard deviation of the reduction at six repetitions = 0.035 LOG

Notes: Vc1 Vc2

1 N 10 ⁻⁷ : 312; 413	N= 3.8x10 ⁹ Lg N= 9.58
10 ⁻⁸ : 67; 45	No= 3.8x10⁸ Lg No= 8.58
2 N 10 ⁻⁷ : 480; 328	N= 4.5x10 ⁹ Lg N= 9.66
10 ⁻⁸ : 89; 101	No= 4.5x10⁸ Lg No= 8.66
3 N 10 ⁻⁷ : 297; 305	N= 3.1x10 ⁹ Lg N= 9.49
10 ⁻⁸ : 64; 84	No= 3.1x10⁸ Lg No= 8.49
4 N 10 ⁻⁷ : 295; 354	N= 3.4x10 ⁹ Lg N= 9.53
10 ⁻⁸ : 53; 45	No= 3.4x10⁸ Lg No= 8.53
5 N 10 ⁻⁷ : 412; 435	N= 4.9x10 ⁹ Lg N= 9.69
10 ⁻⁸ : 101; 120	No= 4.6x10⁸ Lg No= 8.6

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