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Laboratory for mycobacterial diagnostics

L 1554

Testing protocol n. 3/2016/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:
SCHÜLKE CZ s.r.o.
Lidická 326
735 81 Bohumín
Czech Republic
Order n.:
Sample identification:

Digitally signed by Grițaenco Andrei
Date: 2022.12.26 16:29:05 EET
Reason: MoldSign Signature
Location: Moldova

Product name:	**Desam EFFEKT+**
LOT n.:	**019A160407**
Manufacturer:	SCHÜLKE CZ s.r.o
Storage conditions:	room temperature, dark
Dilution agent:	drinking water
Active compounds:	Quaternary Ammonium salts, bis (3-aminoprophyl) dodecylamine, 2-fenoxyethanol
Product delivered:	3rd May 2016
Dates of testing:	10th, 11th May 2016

Results: see attachments 1 - 2
Conclusion:
According to EN 14348, Product **Desam EFFEKT+** LOT **019A160407** after dilution by hard water to 1 **% (m/v), proved tuberculocidal activity** within 15 **minutes** on temperature 20° C, dirty conditions (bovine albumin 3 g/l + sheep erythrocytes 3ml) for reference strains *Mycobacterium terrae*. Average reduction by six repetitions with *Mycobacterium terrae* in dirty conditions was **8,24 x 10^4**.

In Ostrava: 31st May 2016

Vít Ulmann, MSc.
Specialist supervisor for laboratory
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Zdravotní ústav se sídlem v Ostravě
Centrum klinických laboratoří
Oddělení bakteriologie a mykologie
Laboratoř pro diagnostiku mykobakterií
Partyzánské náměstí 7, 702 00 Ostrava
Tel.: 596 200 220

Protocol attachment n. 1: 3/2016/SMU

EN **14348 (phase** 2/stage 1), Product name: **Desam EFFEKT+** LOT: **019A160407**

Manufacturer: **SCHÜLKE CZ s.r.o.**

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

Number of seeded plates 2 ml, Neutralizer: Polysorbate 80 30.0 g/l + natrium thiosulphate ($Na_2S_2O_3$) 5 g/l, L-histidine 1 g/l.

Test conditions: 20°C Load: High - Erytrocytes 3ml/l + Bovine albumin 3 g/l,

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

Procedure: Product was diluted by hard water to final concentrations **1 %** (m/V).

Date of the test: 10th May 2016

Elaborated by: Vít Ulmann

Controlled by: Vít Ulmann Signature:

Controls and validations:

Validation suspension (N_{V0})			Experimental conditions control (A)			Neutralizer control (B)			Validation (product control) (C)		
V_{c1}	156	X=141	V_{c1}	55	X=56,5	V_{c1}	59	X=66,5	V_{c1}	60	X=60,5
V_{c2}	126		V_{c2}	58		V_{c2}	74		V_{c2}	61	
39 ≤ x from N_{V0} ≤ 160 ? YES ☒ NO			X z A ≥ 0,5 * x from N_{V0} ? YES ☒ NO			X z B ≥ 0,5 * x from N_{V0} ? YES ☒ NO			X z C ≥ 0,5 * x from N_{V0} ? YES ☒ NO		

Test suspension and test:

Test suspension control (N a N_0)	**N**	V_{c1}	V_{c2}	X_{wm} = 500,00x 10^7 = log = 9,42 N_0 = N/10 = lg 8,42 8,17 ≤ N_o ≤ 8,70? YES ☒ NO
	10^{-7}	**245**	**235**	
	10^{-8}	**51**	**43**	

Products concentration %	Dilution step	V_{c1}	V_{c2}	**Lg N_a =** lg (x x 10 nebo x_{wm} x 10)	**Lg *R*** (N_w = lg 8,42)	Exposure time (min)
1	10^0	236*	221*	3,26	5,16	15 min
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			

Test conditions: 20°C Load: Low - Bovine albumin 0.3 g/l,

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

Procedure: Product was diluted by hard water to final concentration **1 %** (m/V).

Date of the test: 10th May 2016

Products concentration %	Dilution step	V_{c1}	V_{c2}	**Lg N_a =** lg (x x 10 nebo x_{wm} x 10)	**Lg *R*** (N_w = lg 8,42)	Exposure time (min)
1	10^0	119	120	3,11	5,31	15 min
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			

*Encountered values

Comments: N 10^{-7} : 121 + 124; 120 + 115 Nvo: 79 + 77; 68 + 58

10^{-8} : 16 + 35; 18 + 25

Explanatory notes: V_c = count per ml, x = average V_{c1} a V_{c2} (1. + 2) duplicate determination, Xwm = weighted average x, R reduction (lg R = Lg N_0 - Lg N_0)

Protocol attachment n. 2: 3/2016/SMU

EN **14348 (phase** 2/stage 1), Product name: **Desam EFFEKT+** LOT: **019A160407**

Manufacturer: **SCHÜLKE CZ s.r.o**

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

Number of seeded plates 2 ml, Neutralizer: Polysorbate 80 30, 0 g/l + natrium thiosulphate ($Na_2S_2O_3$) 5 g/l, L-histidine 1 g/l.

Test conditions: 20°C Load: High: Erytrocytes 3ml/l + Bovine albumin 3 g/l

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

Procedure: Product was diluted by hard water to final concentration **1 %** (m/V). Each test was provided with newly prepared culture suspension and product dilution.

Dates of the test: 11th May 2016

Elaborated by: Vít Ulmann

Controlled by: Vít Ulmann Signature:

Repetitions with organism:

Products concentration %	Dilution step	V_{c1}	V_{c2}	**Lg N_a =** lg (x x 10 or x $_{wm}$ x 10)	Lg *R*	Exposure time (min)
1	**1**			3,46	N_0 = lg 8,36	15 min
	10^0	291	280		**4,90****	
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
1	**2**			3,31	N_0 = lg 8,51	15 min
	10^0	194	210		**5,20****	
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
1	**3**			3,28	N_0 = lg 8,45	15 min
	10^0	198	185		5,16**	
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
1	**4**			3,23	N_0 = lg 8,30	15 min
	10^0	168	172		**5,07****	
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
1	**5**			3,26	N_0 = lg 8,19	15 min
	10^0	184	176		**4,94****	
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
****Average reduction by the six repetitions:**					**8,24 x 10^4**	

*Encountered values

Comments: Vc1 Vc2

1 N 10^{-7}: 218; 190 N= 2,9x10^9 Lg N= 9,36
10^{-8}: 45; 49 **No= 2,9x10^8 Lg No= 8,36**

2 N 10^{-7}: 292; 258 N= 4,9x10^9 Lg N= 9,51
10^{-8}: 81; 78 **No= 4,9x10^8 Lg No= 8,51**

3 N 10^{-7}: 220; 249 N= 3,7x10^9 Lg N= 9,45
10^{-8}: 67; 79 **No= 3,7x10^8 Lg No= 8,45**

4 N 10^{-7}: 151;201 N= 5,0x10^9 Lg N= 9,30
10^{-8}: 35; 48 **No= 5,0x10^8 Lg No= 8,30**

5 N 10^{-7}: 125; 134 N= 2,7x10^9 Lg N= 9,19
10^{-8}: 48; 36 **No= 2,7x10^8 Lg No= 8,19**