



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. 20/2021/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)

Customer:

SCHÜLKE CZ s r.o.

Lidická 445

735 81 Bohumín

IČ 24301779

Order nr.: 020-2021-10-22

Date of the order: 12.10.2021

Reference number: ZU/10564/2021

Sample identification:

Name of the product ⁱ:

chloramix® dt

Batch number ⁱ:

604555

Expiration date ⁱ:

01/2024

Expiration date ⁱ:

not mentioned

Manufacturer ⁱ:

Schülke CZ s r.o.

Storage conditions ⁱ:

room temperature, dark

Product diluent recommended by the manufacturer ⁱ:

hard water

Active substance(s) and concentration(s) ⁱ: 75 g sodium dichlorisokyanurate - dihydrate (1 tbl. approx. 1,5 g of active chlorine)

Supportive substance(s) and concentration(s) ⁱ:

Product type ⁱ:

Biocide

Appearance and composition:

White crystalline tablets (tbl.)

Date of delivery:

27.10.2021

Dates of testing:

31. 10. 2021, 14. 11. 2021

ⁱ - data provided by customer

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Results (see annexes for details):

For the reference strain *Mycobacterium terrae* DSM 43227, a reduction of > 4 log orders were achieved at a product concentration of 1 tbl. / 1 l at 15 and 30 minutes; 1 tbl. / 1.5 l at 15, 30 and 60 minutes and 1 tablet. / 3 l in 15 minutes.

For the reference strain *Mycobacterium avium* DSM 44157, a reduction of > 4 log orders of magnitude were achieved at a product concentration of 1 tbl. / 1 l at 15 and 30 minutes; 1 tbl. / 1.5 l at 15, 30 and 60 minutes and 1 tablet. / 3 l in 15 minutes.

Special notes regarding results: All controls and validations were within limits. No precipitates or turbidity were observed during the test procedure.

Conclusion:

According to EN 14348 product batch number 604555 chloramix® dt in a concentration of 1 tablet per 3l of water shows mycobactericidal activity within 15 minutes, at 20 ° C, under conditions of high organic load (bovine albumin 3 g / l + 3 ml erythrocytes) for reference strains *Mycobacterium avium* and *Mycobacterium terrae*. The mean reduction in six replicates with the *Mycobacterium avium* as a limit organism was 5.131 ± 0.04^a of logarithmic orders. The second test microorganism was tested once and showed a higher reduction compared to *Mycobacterium avium*.

Zdravotní ústav se sídlem v Ostravě
Centrum klinických laboratorí
Oddělení bakteriologie a mykologie
Laboratoř pro diagnostiku mykobakterií
Partyzánské náměstí 2633/7
Moravská Ostrava 702 00 Ostrava
Telefon: 596 200 220 2

In Ostrava: 15th December 2021

Authorized by: Mgr. Vít Ulmann
Head of the Laboratory

Protocol attachment Nr. 1: 20/2021/SMU

EN 14348 Product name: **chloramix® dt** Batch no.: **604555**, Manufacturer: Schülke CZ s.r.o.; Storage conditions (temperature and others): room temperature, darkness; Number of plates spread 2 ml; Neutralizing agent: Polysorbate 80–30 g / l, Sodium thiosulphate (Na₂S₂O₃) - 5 g / l, L-histidine - 1 g / l. Wash solution: Saline peptone solution Test temperature: 20 ° C. Interfering substances: High load - Bovine albumin 3 g / l + 3 ml (BA) erythrocytes (ERY); Test organism: *Mycobacterium terrae* DSM 43227, Incubation temperature 36 ° C Date of the test: **31st October 2021**

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}	100	X=100,5	V _{c1}	72	X=71	V _{c1}	90	X=90,5	V _{c1}	52	X=56,5
V _{c2}	101		V _{c2}	70		V _{c2}	91		V _{c2}	61	
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} = 317.72x 10 ⁷ = log = 9.50 N ₀ = N/10 = lg 8.50 8.17 ≤ N ₀ ≤ 8.70? YES <input checked="" type="checkbox"/> NO
	10 ⁻⁷	(128+132) 260	(141+112) 253	
	10 ⁻⁸	(35+58) 93	(52+41) 93	

Concentration of the product (dilution)	Dilution step	V _{c1}	V _{c2}	Lg N _a = lg (x x 10 or x _{wm} x 10)	Lg R (N ₀ = lg 8.50)	Exposure time
1 tbl. /1 l	10 ⁰	<14*	<14*	2.15	6.36	15 min
	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
1 tbl. /1 l	10 ⁰	<14*	<14*	2.15	6.36	30 min
	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
1 tbl. /1.5 l	10 ⁰	<14*	<14*	2.15	6.36	15 min
	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
1 tbl. /1.5 l	10 ⁰	<14*	<14*	2.15	6.36	30 min
	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
1 tbl. /1.5 l	10 ⁰	<14*	<14*	2.15	6.36	60 min
	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
1 tbl. /3 l	10 ⁰	171*(86+85)	186*(98+88)	3.25	5.25	15 min
	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			


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Protocol attachment Nr. 2: 20/2021/SMU

EN 14348 Product name: **chloramix® dt** Batch no.: **604555** Manufacturer: Schülke CZ s.r.o.; Storage conditions (temperature and others): room temperature. darkness; Number of plates spread 2 ml. Neutralizing agent: Polysorbate 80-30 g / l. Sodium thiosulphate (Na₂S₂O₃) - 5 g / l. L-histidine - 1 g / l; Wash solution: Saline peptone solution Test temperature: 20 ° C Interfering substances: High load - Bovine albumin 3 g / l + 3 ml (BA) erythrocytes (ERY); Test organism: **Mycobacterium avium** DSM 44157; Incubation temperature 36 ° C Date of the test: **31st October 2021**

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}	82	X=83	V _{c1}	65	X=64	V _{c1}	50	X=55	V _{c1}	46	X=42,5
V _{c2}	84		V _{c2}	63		V _{c2}	60		V _{c2}	39	
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} = 273.63x 10 ⁷ = log = 9.44 N ₀ = N/10 = lg 8.44 8.17 ≤ N ₀ ≤ 8.70? YES <input checked="" type="checkbox"/> NO
	10 ⁻⁷	(112+118) 230	(121+114) 235	
	10 ⁻⁸	(63+69) 132	(81+76) 157	

Concentration of the product (dilution)	Dilution step	V _{c1}	V _{c2}	Lg N _a = lg (x x 10 or x _{wm} x 10)	Lg R (N ₀ = lg 8.44)	Exposure time
1 tbl. /1 l	10 ⁰	<14*	<14*	2.15	6.29	15 min
	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
1 tbl. /1 l	10 ⁰	<14*	<14*	2.15	6.29	30 min
	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
1 tbl. /1.5 l	10 ⁰	<14*	<14*	2.15	6.29	15 min
	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
1 tbl. /1.5 l	10 ⁰	<14	<14	2.15	6.29	30 min
	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
1 tbl. /1.5 l	10 ⁰	<14	<14	2.15	6.29	60 min
	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
1 tbl. /3 l	10 ⁰	190*(89+101)	197*(92+105)	3.29	5.15**	15 min
	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			

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Protocol attachment Nr. 3: 20/2021/SMU

EN 14348 Product name: **chloramix® dt** Batch no.: **604555**; Manufacturer: Schülke CZ s r.o.; Storage conditions (temperature and others): room temperature. dark. Number of spread plates 2 ml; Neutralizing agent: Polysorbate 80-30 g / l. Sodium thiosulphate (Na₂S₂O₃) - 5 g / l. L-histidine - 1 g / l; Wash solution: Saline peptone solution; Test temperature: 20 ° C; Interfering substances: High load - Bovine albumin 3 g / l (BA) + 3 ml erythrocytes; Test organism: *Mycobacterium avium* DSM 44157; Incubation temperature 36 ° C
Date of the test: **14th November 2021**

Elaborated by: Vít Ulmann

Responsible person: Vít Ulmann

Signature: 

Repeated testing:

Concentration of the product (dilution)	Dilution step	V _{c1}	V _{c2}	Lg N _a = lg (x x 10 or x _{wm} x 10)	Lg R	Exposure time
14.11.2021	1				N ₀ = lg 8.44	15 min
1 tbl. /3 l	10 ⁰	235*(114+121)	229*(128+101)	3.32	5.12**	
BA 3 g/l+ERY	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
14.11.2021	2				N ₀ = lg 8.58	15 min
1 tbl. /3 l	10 ⁰	373*(191+182)	370*(172+198)	3.53	5.05**	
BA 3 g/l+ERY	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
14.11.2021	3				N ₀ = lg 8.48	15 min
1 tbl. /3 l	10 ⁰	235*(112+123)	219*(105+114)	3.31	5.16**	
BA 3 g/l+ERY	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
14.11.2021	4				N ₀ = lg 8.70	15 min
1 tbl. /3 l	10 ⁰	373*(181+192)	394*(205+189)	3.54	5.15**	
BA 3 g/l+ERY	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
14.11.2021	5				N ₀ = lg 8.54	15 min
1 tbl. /3 l	10 ⁰	255*(121+134)	280*(138+142)	3.39	5,15**	
BA 3 g/l+ERY	10 ⁻¹	<14	<14			
	10 ⁻²	<14	<14			
	10 ⁻³	<14	<14			
** The average LOG reduction within six repeats:					LOG 5,131	

a) the standard deviation of the LOG reduction within six repeats = **0.03LOG**

Notes: V_{c1} V_{c2}

1 N 10 ⁻⁷ : 231; 219	N= 2.75x10 ⁹ Lg N= 9.44	2 N 10 ⁻⁷ : 320; 311	N= 3.79x10 ⁹ Lg N= 9.58
10 ⁻⁸ : 76; 80	No= 2.8x10 ⁸ Lg No= 8.44	10 ⁻⁸ : 95; 109	No= 3.8x10 ⁸ Lg No= 8.58
3 N 10 ⁻⁷ : 271; 263	N= 3.01x10 ⁹ Lg N= 9.48	4 N 10 ⁻⁷ : 422; 429	N= 4.96x10 ⁹ Lg N= 9.70
10 ⁻⁸ : 64; 65	No= 3.0x10 ⁸ Lg No= 8.48	10 ⁻⁸ : 118; 123	No= 4.9x10 ⁸ Lg No= 8.70
5 N 10 ⁻⁷ : 298; 279	N= 3.45x10 ⁹ Lg N= 9.54		
10 ⁻⁸ : 92; 89	No= 3.5x10 ⁸ Lg No= 8.54		

Explanatory notes: *Encountered values

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)

End of the protocol

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