Chemila, spol. s r.o., Za Dráhou 4386/3, Hodonín 69501, Phone +420518340919, chemila@chemila.cz
Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025:2005.

Copy No.: 1
Issue No.: 1

Test report No. S129-2/2018

DETERMINATION OF MYCOBACTERICIDAL AND TUBERCULOCIDAL (EN 14348:2005) ACTIVITY OF THE PRODUCT **Sterisept Wipes**

Sample ID: S129/2018
Sample name: **Sterisept Wipes**
Client: AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia
Producer: AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia
Sampling point: AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia

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Incoming date:
11.6.2018

Delivery date:
13.2.2019

Hodonín, 13.2.2019

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Ing. Jana Šlitrová, Head of Laboratory

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: S129/2018
Rep No: 83
Sample name: **Sterisept Wipes**
Sampled: by client
Sampling point: AS CHEMI-PHARM, Pöllu 132, Tallinn, Estonia
Client: AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia

Sampling date: 8.6.2018
Sample delivered: 11.6.2018
Testing date: 25.9. – 17.10.2018
Delivered amount: 100 ml
Batch No: 14310518

Subject of testing:
Determination of mycobactericidal and tuberculocidal activity of the product.

Identification of the sample:

Name of the product:	**Sterisept Wipes**
Batch number:	14310518
Date of manufacture:	31.05.2018
Expiry date:	31.05.2021
Manufacturer:	AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia
Incoming date:	11.6.2018
Storage conditions:	room temperature, dark area

Active ingredients:
Didecyl-Dimethyl-Ammonium Chloride (DDAC) 0,45 %
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 0,45 %

Experimental conditions:	**Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method** SOP-M-19-00 (EN 14348:2005)
Period of analysis:	26.9. – 17.10.2018 (*M.a.*), 25.9. – 16.10.2018 (*M.t.*)
Test temperature:	20 °C ± 1 °C
Test method:	membrane filtration method
Filtration diluent:	rinsing liquid
Appearance of the product:	colourless liquid
Test concentration:	100% (concentrated)*
Contact time:	5 min, 10 min, 15 min
Interfering substances:	3 g/l BSA and 3 ml/l sheep erythrocytes (dirty conditions)
Test organisms:	*Mycobacterium avium* ATCC 15769 *Mycobacterium terrae* ATCC 15755
Incubation conditions:	37 °C ± 1 °C, 21 days

Test procedure:
1. Preparation of test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:
Mycobactericidal activity – the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* and *Mycobacterium avium* under defined conditions by at least a 4 lg reduction (10^4).
Tuberculocidal activity - the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* under defined conditions by at least a 4 lg reduction (10^4).
$R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability
* Product can only be tested at a concentration of 97% (RTU – modified method according to EN 13727) or less, as some dilution is always produced by adding the test organisms and interfering substance.

The standard:
EN 14348:2005 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test method and requirements (phase 2, step 1) January 2005

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Delivered amount: 100 ml
Batch No: 14310518

The Number of CFU in the tested product: 0 CFU/ml

1. Testing the efficacy of chemical disinfectant **Sterisept Wipes** on *Mycobacterium avium* ATCC 15769

Tab No. 1.1 Verification of methodology, dirty conditions

Validation of suspension (N_{vo})			Validation of selected experimental conditions (A)			Membrane filtration control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	40	$\Phi_{Nvo} = 47.5$	V_{c1}	43	$\Phi_A = 31.5$	V_{c1}	28	$\Phi_B = 44.5$	V_{c1}	39	$\Phi_C = 36$
V_{c2}	55		V_{c2}	20		V_{c2}	61		V_{c2}	33	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Tab No. 1.2 Test suspensions

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)
$\Phi = 46.5 \times 10^8 = \lg 9.67$	10^{-7}	>165	>165	$\lg N_0 = \lg N/100 = \lg 7.67$*
$9.17 \leq \lg N \leq 9.70$	10^{-8}	62	31	$7.17 \leq \lg N_0 \leq 7.70$
				x yes no

Tab No. 1.3 Testing the efficacy of chemical disinfectant **Sterisept Wipes** on *Mycobacterium avium* ATCC 15769

Test concentration (%)*/contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 7.67$*)**
100 / 5 / dirty	10^{-1}	21	61	3.61	**4.06**
100 / 10 / dirty	10^{-1}	16	18	3.23	**4.44**
100 / 15 / dirty	10^{-1}	<14	<14	< 3.15	**≥ 4.52**

2. Testing the efficacy of chemical disinfectant **Sterisept Wipes** on *Mycobacterium terrae* ATCC 15755

Tab No. 2.1 Verification of methodology, dirty conditions

Validation of suspension (N_{vo})			Validation of selected experimental conditions (A)			Membrane filtration control (B)			Method validation (C) Product conc.: 100%*		
V_{c1}	46	$\Phi_{Nvo} = 47$	V_{c1}	53	$\Phi_A = 47.5$	V_{c1}	19	$\Phi_B = 39.5$	V_{c1}	44	$\Phi_C = 34.5$
V_{c2}	48		V_{c2}	42		V_{c2}	60		V_{c2}	25	
$30 \leq \Phi_{Nvo} \leq 160$			$\Phi_A \geq 0.5\ \Phi_{Nvo}$			$\Phi_B \geq 0.5\ \Phi_{Nvo}$			$\Phi_C \geq 0.5\ \Phi_{Nvo}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Tab No. 2.2 Test suspensions

Test suspension N	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0)
$\Phi = 48 \times 10^8 = \lg 9.68$	10^{-7}	>165	>165	$\lg N_0 = \lg N/100 = \lg 7.68$*
$9.17 \leq \lg N \leq 9.70$	10^{-8}	41	55	$7.17 \leq \lg N_0 \leq 7.70$
				x yes no

Tab No. 2.3 Testing the efficacy of chemical disinfectant **Sterisept Wipes** on *Mycobacterium terrae* ATCC 15755

Test concentration (%)*/contact time (min)/conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	**lg R ($\lg N_0 = \lg 7.68$*)**
100 / 5 / dirty	10^{-1}	36	37	3.56	**4.12**
100 / 10 / dirty	10^{-1}	<14	<14	< 3.15	**≥ 4.53**
100 / 15 / dirty	10^{-1}	<14	<14	< 3.15	**≥ 4.53**

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time (time „0"), N_a = the number of surviving bacteria per ml in the test mixture at the end of the contact time and before the membrane filtration, N_v = the number of cfu/ml of the test suspension for validation, N_{v0}= the number of cfu/ml of the test suspension in the mixture A,B,C at the beginning of the contact time (time „0"), A,B,C = the number of surviving bacteria per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), $R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability

* Product can only be tested at a concentration of 97% (RTU – modified method according to EN 13727) or less, as some dilution is always produced by adding the test organisms and interfering substance.

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

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Client: AS CHEMI-PHARM, Pöllu 132, 109 17 Tallinn, Estonia

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Delivered amount: 100 ml
Batch No: 14310518

3. Evaluation of mycobactericidal and tuberculocidal activity of the product **Sterisept Wipes**

Tab No. 3.1 The efficacy of chemical disinfectant **Sterisept Wipes** on test strain – mycobactericidal and tuberculocidal activity

Mycobactericidal and tuberculocidal activity of the product (EN 14348:2005)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations [%]*	Interfering substances - conditions	lg R EN 14348:2005	**lg R**
Mycobacterium avium ATCC 15769	20	5	100	dirty	≥ 4	**> 4**
Mycobacterium terrae ATCC 15755	20	5	100	dirty	≥ 4	**> 4**
Mycobacterium avium ATCC 15769	20	10	100	dirty	≥ 4	**> 4**
Mycobacterium terrae ATCC 15755	20	10	100	dirty	≥ 4	**> 4**
Mycobacterium avium ATCC 15769	20	15	100	dirty	≥ 4	**> 4**
Mycobacterium terrae ATCC 15755	20	15	100	dirty	≥ 4	**> 4**

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} a V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the test suspension, N_0 = the number of cfu/ml of the test suspension at the beginning of the contact time (time „0"), N_a = the number of surviving bacteria per ml in the test mixture at the end of the contact time and before the membrane filtration, N_v = the number of cfu/ml of the test suspension for validation, N_{v0}= the number of cfu/ml of the test suspension in the mixture A,B,C at the beginning of the contact time (time „0"), A,B,C = the number of surviving bacteria per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), $R = N_0 / N_a$ or $\lg R = \lg N_0 - \lg N_a$ the reduction in viability
* Product can only be tested at a concentration of 97% (RTU – modified method according to EN 13727) or less, as some dilution is always produced by adding the test organisms and interfering substance.

Prepared by: Ing. Eva Kremlová, Lab Technician

Description: *Testing the efficacy of chemical disinfectants and antiseptics*

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Delivered amount: 100 ml
Batch No: 14310518
Page: 5

Interpretation:
Results of tests are in Tabs.
According to EN 14348:2005 the tested concentrated* product **Sterisept Wipes**, batch No. 14310518, in the contact times 5 min and 10 min, 15 min under dirty conditions at temperature 20 °C ± 1 °C by the membrane filtration method **decreased** the number of viable cells of *Mycobacterium avium* ATCC 15769 and *Mycobacterium terrae* ATCC 15755 by at least a 4 lg reduction.

* Product can only be tested at a concentration of 97% (RTU – modified method according to EN 13727) or less, as some dilution is always produced by adding the test organisms and interfering substance.

Conclusion:
The product **Sterisept Wipes** is capable of reducing the number of viable mycobacterial cells of the relevant test organisms under defined conditions to the declared values, and consequently, may be called mycobactericidal and tuberculocidal.

13.2.2019, Hodonín

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-2-
Chejnila, spol. s r.o.
Za Bránou 4, 695 01 Hodonín
CZ
č. 1273

Ing. Barbora Stoklásková, Leader of Study


TESTING LABORATORY CERTIFICATE
Chemlia, spol. s.r.o.
Za Dráhou 428/3
695 01 Hodonín
CZ
č. 1273