

Chemila
Chemila
Chemila



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 17025:2018.

Copy No.: 1
Issue No.: 1

Test report No. S87-2/2020

DETERMINATION OF SPORICIDAL (EN 17126:2018) ACTIVITY OF THE
PRODUCT **JACLOR®**

Sample ID: S87/2020
Sample name: **JACLOR®**
Client: Romdezimed Production SrL, Sos. Pandurilor nr.29, bl.P2a, sc.1, st.7, apod.31, cam.2, Sector 5, Bucuresti, Romania
Producer: Romdezimed Production SrL, Sos. Pandurilor nr.29, bl.P2a, sc.1, st.7, apod.31, cam.2, Sector 5, Bucuresti, Romania
Sampling point: Romdezimed Production SrL, Nb.6 Mioritei Str., Sacele, Brasov, Romania

Page: 1
From pages: 5

Incoming date:
2.3.2020

Delivery date:
22.7.2020

Hodonín, 22.7.2020



Ing. Jana Šlitrová, Head of Laboratory

The report may be reproduced only as a whole, in parts only upon written permission of the laboratory. The test results relate only to the samples stated in the Test Report. The Lab does not take any guarantee for the identity of samples not taken by the lab personnel.

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S87/2020
Rep No: 60
Sample name: **JACLOR®**
Sampled: by client
Sampling point: Romdezimed Production SrL, Sacele, Brasov, Romania
Client: Romdezimed Production SrL, Bucuresti, Romania

Sampling date: 13.2.2020
Sample delivered: 2.3.2020
Testing date: 27.4. – 19.6.2020
Delivered amount: 1 kg
Batch No: 07
Page: 2

Subject of testing:

Determination of sporicidal activity of the product.

Identification of the sample:

Name of the product: **JACLOR®**
Batch number: 1511
Date of manufacture: 10.2019
Expiry date: 09.2022
Manufacturer: Romdezimed Production SrL, Sos. Pandurilor nr.29, bl.P2a, sc.1, st.7, apod.31, cam.2, Sector 5, Bucuresti, Romania
Incoming date: 21.10.2019
Storage conditions: room temperature, dark area
Active compounds and concentrations:
Dichloroisocyanurate sodium salt dihydrate 78 % (CAS 51580-86-0, CE 220-767-7)

Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method

SOP-M-19-00 (EN 17126:2018)

Period of analysis: 27.4. – 4.5.2020, 15.6. – 19.6.2020 (B.s.)
Test temperature: 20 °C ± 1 °C
Test method: membrane filtration method
Filtration diluent: rinsing liquid
Product diluent: hard water
Appearance of the product: white tabs
Test concentration: 3 tabs/10 l, 1 tab/2 l, 1 tab/1 l
Contact time: 60 min
Interfering substances: 0.3 g/l BSA (clean conditions)
Test organisms: *Bacillus subtilis* ATCC 6633
Bacillus cereus ATCC 12826
Clostridium difficile ribotype 027 DSM 27147
Incubation conditions: 30 °C ± 1 °C, minimum 3 and maximum 7 days

Test procedure:

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

Note:

Sporicidal activity – the capability of a product to produce a reduction in the number of bacterial spores belonging to reference strains of *Bacillus subtilis* and *Bacillus cereus* under defined conditions by at least a 4 lg reduction (10^4).

Sporicidal activity against *Clostridium difficile* – the capability of a product to produce a reduction in the number of bacterial spores belonging to reference strain of *Clostridium difficile* under defined conditions by at least a 4 lg reduction (10^4).

The standard:

EN 17126:2018 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area – Test method and requirements (phase 2, step 1)
December 2018

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S87/2020

Rep No: 60

Sample name: **JACLOR®**

Sampled: by client

Sampling point: Romdezimed Production SrL, Sacele, Brasov, Romania

Client: Romdezimed Production SrL, Bucuresti, Romania

Sampling date: 13.2.2020

Sample delivered: 2.3.2020

Testing date: 27.4. – 19.6.2020

Delivered amount: 1 kg

Batch No: 07

Page: 3

The Number of CFU in the tested product: < 10¹ CFU/g

1. Testing the efficacy of chemical disinfectant **JACLOR®** on *Bacillus subtilis* ATCC 6633

Tab No. 1.1 Verification of methodology, clean conditions

Validation of suspension (N _{V0})			Validation of selected experimental conditions (A)			Membrane filtration control (B)			Method validation (C) Product conc. 1 tab/1 l		
V _{e1}	38	Φ _{N_{V0}} = 38	V _{e1}	35	Φ _A = 34	V _{e1}	40	Φ _B = 36.5	V _{e1}	37	Φ _C = 33.5
V _{e2}	38		V _{e2}	33		V _{e2}	33		V _{e2}	30	
30 ≤ Φ _{N_{V0}} ≤ 160			Φ _A ≥ 0.5 Φ _{N_{V0}}			Φ _B ≥ 0.5 Φ _{N_{V0}}			Φ _C ≥ 0.5 Φ _{N_{V0}}		
x	yes	no	x	yes	no	x	yes	no	x	yes	no
Validation of suspension (N _{VB})											
V _{e1}	46	V _{e2}	29	Φ _{N_{VB}}	37.5	30 < Φ _{N_{VB}} (N _{VB} /1000) ≤ 160					
									x	yes	no

Tab No. 1.2 Test suspension

Test suspension N	N	V _{e1}	V _{e1}	Test suspension N ₀
Φ = 41 x 10 ⁶ = lg 7.61	10 ⁻⁵	> 165	> 165	lg N ₀ = lg N/10 = lg 6.61
7.17 ≤ lg N ≤ 7.70	10 ⁻⁶	37	45	6.17 ≤ lg N ₀ ≤ 6.70
				x
				yes
				No

Tab No. 1.3 Testing the efficacy of chemical disinfectant **JACLOR®** on *Bacillus subtilis* ATCC 6633

Test concentration / contact time (min) / conditions	Dilution after test procedure	V _{e1}	V _{e2}	lg N _a = lg (Φ _a x 10)	lg R (lg N ₀ = 6.61)
1 tab/1 l / 60 / clean	10 ⁰	<14	<14	< 2.15	≥ 4.46

2. Testing the efficacy of chemical disinfectant **JACLOR®** on *Bacillus cereus* ATCC 12826

Tab No. 2.1 Verification of methodology, clean conditions

Validation of suspension (N _{V0})			Validation of selected experimental conditions (A)			Membrane filtration control (B)			Method validation (C) Product conc. 1 tab/2 l		
V _{e1}	33	Φ _{N_{V0}} = 31.5	V _{e1}	28	Φ _A = 29.5	V _{e1}	32	Φ _B = 31	V _{e1}	34	Φ _C = 44
V _{e2}	30		V _{e2}	31		V _{e2}	30		V _{e2}	54	
30 ≤ Φ _{N_{V0}} ≤ 160			Φ _A ≥ 0.5 Φ _{N_{V0}}			Φ _B ≥ 0.5 Φ _{N_{V0}}			Φ _C ≥ 0.5 Φ _{N_{V0}}		
x	yes	no	x	yes	no	x	yes	no	x	yes	no
Validation of suspension (N _{VB})											
V _{e1}	57	V _{e2}	25	Φ _{N_{VB}}	41	30 < Φ _{N_{VB}} (N _{VB} /1000) ≤ 160					
									x	yes	no

Tab No. 2.2 Test suspension

Test suspension N	N	V _{e1}	V _{e1}	Test suspension N ₀
Φ = 34.5 x 10 ⁶ = lg 7.54	10 ⁻⁵	> 165	> 165	lg N ₀ = lg N/10 = lg 6.54
7.17 ≤ lg N ≤ 7.70	10 ⁻⁶	38	31	6.17 ≤ lg N ₀ ≤ 6.70
				x
				yes
				No

Tab No. 2.3 Testing the efficacy of chemical disinfectant **JACLOR®** on *Bacillus cereus* ATCC 12826

Test concentration / contact time (min) / conditions	Dilution after test procedure	V _{e1}	V _{e2}	lg N _a = lg (Φ _a x 10)	lg R (lg N ₀ = 6.54)
3 tabs/10 l / 60 / clean	10 ⁻¹	63	45	3.73	2.81
1 tab/2 l / 60 / clean	10 ⁰	26	29	2.44	4.10

Note: V_e = value is the number of cfu per ml, Φ = average V_{e1} a V_{e2} (1. + 2. duplicate V_e values), N = the number of cfu/ml of the spore test suspension, N₀ = the number of cfu/ml of the test suspension at the beginning of the contact time (time „0“), N_a = the number of surviving spores 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 spores per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), R = N₀ / N_a or lg R = lg N₀ – lg N_a the reduction in viability

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S87/2020

Rep No: 60

Sample name: **JACLOR®**

Sampled: by client

Sampling point: Romdezimed Production SrL, Sacele, Brasov, Romania

Client: Romdezimed Production SrL, Bucuresti, Romania

Sampling date: 13.2.2020

Sample delivered: 2.3.2020

Testing date: 27.4. – 19.6.2020

Delivered amount: 1 kg

Batch No: 07

Page: 4

3. Testing the efficacy of chemical disinfectant **JACLOR®** on *Clostridium difficile* ribotype 027 DSM 27147

Tab No. 3.1 Verification of methodology, clean conditions

Validation of suspension (N _{V0})		Validation of selected experimental conditions (A)		Membrane filtration control (B)		Method validation (C) Product conc. 1 tab/2 l	
V _{e1}	60	V _{e1}	31	V _{e1}	61	V _{e1}	49
V _{e2}	33	V _{e2}	55	V _{e2}	32	V _{e2}	40
Φ _{NV0} = 46.5		Φ _A = 43		Φ _B = 46.5		Φ _C = 44.5	
30 ≤ Φ _{NV0} ≤ 160		Φ _A ≥ 0.5 Φ _{NV0}		Φ _B ≥ 0.5 Φ _{NV0}		Φ _C ≥ 0.5 Φ _{NV0}	
x	yes	x	yes	x	yes	x	yes
	no		no		no		no
Validation of suspension (N _{VB})		V _{e1}	54	V _{e2}	39	Φ _{NVB}	46.5
				30 ≤ Φ _{NVB} (N _{VB} /1000) ≤ 160			
				x		yes	
						no	

Tab No. 3.2 Test suspension

Test suspension N	N	V _{e1}	V _{e2}	Test suspension N ₀
Φ = 46 x 10 ⁶ = lg 7.66	10 ⁻⁵	> 165	> 165	lg N ₀ = lg N/10 = lg 6.66
7.17 ≤ lg N ≤ 7.70	10 ⁻⁶	31	61	6.17 ≤ lg N ₀ ≤ 6.70
				x
				yes
				No

Tab No. 3.3 Testing the efficacy of chemical disinfectant **JACLOR®** on *Clostridium difficile* ribotype 027 DSM 27147

Test concentration / contact time (min) / conditions	Dilution after test procedure	V _{e1}	V _{e2}	lg N _a = lg (Φ _a x 10)	lg R (lg N ₀ = 6.66)
3 tabs/10 l / 60 / clean	10 ⁰	19	21	2.30	4.36
1 tab/2 l / 60 / clean	10 ⁰	<14	<14	< 2.15	≥ 4.51

4. Evaluation of sporicidal activity of the product **JACLOR®**

Tab No. 4.1 The efficacy of chemical disinfectant **JACLOR®** on test strains – sporicidal activity

Sporicidal activity of the product (EN 17126:2018)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 17126:2018	lg R
<i>Bacillus cereus</i> ATCC 12826	20	60	3 tabs/10 l	clean	≥ 4	< 4
<i>Clostridium difficile</i> ribotype 027 DSM 27147	20	60	3 tabs/10 l	clean	≥ 4	> 4
<i>Bacillus subtilis</i> ATCC 6633	20	60	1 tab/1 l	clean	≥ 4	> 4
<i>Bacillus cereus</i> ATCC 12826	20	60	1 tab/2 l	clean	≥ 4	> 4
<i>Clostridium difficile</i> ribotype 027 DSM 27147	20	60	1 tab/2 l	clean	≥ 4	> 4

Note: V_c = value is the number of cfu per ml, Φ = average V_{e1} a V_{e2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the spore test suspension, N₀ = the number of cfu/ml of the test suspension at the beginning of the contact time (time „0“), N_a = the number of surviving spores 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 spores per ml in control tests (A – experimental conditions control, B – membrane filtration validation, C – method validation), R = N₀ / N_a or lg R = lg N₀ – lg N_a the reduction in viability

Prepared by: Ing. Eva Kremlová, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: S87/2020
Rep No: 60
Sample name: **JACLOR®**
Sampled: by client
Sampling point: Romdezimed Production SrL, Sacele, Brasov, Romania
Client: Romdezimed Production SrL, Bucuresti, Romania

Sampling date: 13.2.2020
Sample delivered: 2.3.2020
Testing date: 27.4. – 19.6.2020
Delivered amount: 1 kg
Batch No: 07
Page: 5

Interpretation:

Results of tests are in Tabs.

According to EN 17126:2018 the tested product **JACLOR®**, batch No. 07, in the concentration 1 tab/1 l, diluted in hard water, in the contact time 60 min under clean conditions at temperature $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the membrane filtration method **decreased** the number of viable bacterial spores of *Bacillus subtilis* ATCC 6633 by at least a 4 lg reduction.

According to EN 17126:2018 the tested product **JACLOR®**, batch No. 07, in the concentration 1 tab/2 l, diluted in hard water, in the contact time 60 min under clean conditions at temperature $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the membrane filtration method **decreased** the number of viable bacterial spores of *Bacillus cereus* ATCC 12826 by at least a 4 lg reduction.

According to EN 17126:2018 the tested product **JACLOR®**, batch No. 07, in the concentration 1 tab/2 l and 3 tabs/10 l, diluted in hard water, in the contact time 60 min under clean conditions at temperature $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the membrane filtration method **decreased** the number of viable bacterial spores of *Clostridium difficile* ribotype 027 DSM 27147 by at least a 4 lg reduction.

Conclusion:

The product **JACLOR®** is capable of reducing the number of viable bacterial spores of the relevant organism under defined conditions (EN 17126:2018, B.s. – 1 tab/1 l, 60 min, clean, $20\text{ }^{\circ}\text{C}$) to the declared values, and consequently, can be called sporicidal on *Bacillus subtilis* ATCC 6633.

The product **JACLOR®** is capable of reducing the number of viable bacterial spores of the relevant organism under defined conditions (EN 17126:2018, B.c. – 1 tab/2 l, 60 min, clean, $20\text{ }^{\circ}\text{C}$) to the declared values, and consequently, can be called sporicidal on *Bacillus cereus* ATCC 12826.

The product **JACLOR®** is capable of reducing the number of viable bacterial spores of the relevant organism under defined conditions (EN 17126:2018, Cl.d. – 1 tab/2 l and 3 tabs/10 l, 60 min, clean, $20\text{ }^{\circ}\text{C}$) to the declared values, and consequently, can be called sporicidal on *Clostridium difficile* ribotype 027 DSM 27147.

22.7.2020, Hodonín

Approved by: Mgr. Mirka Horáková, PhD., Leader of Study

