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Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025.

Copy No.: 1
Issue No.: 1

Test report No. D283-1/2016

DETERMINATION OF BACTERICIDAL (EN 13727+A2) AND SPORICIDAL (EN 13704) ACTIVITY OF THE PRODUCT **JACLOR®**

Sample ID: D283/2016

Sample name: **JACLOR®**

Client: Romdezimed Production SRL, Str. Sg. Maj. Vasile Topliceanu Nr. 16, Sector 5, Bucuresti

Producer: Romdezimed Production SRL, Str. Sg. Maj. Vasile Topliceanu Nr. 16, Sector 5, Bucuresti

Sampling point: Romdezimed Production SRL, Nb. 6 Mioritei Street, Sacele, Brasov

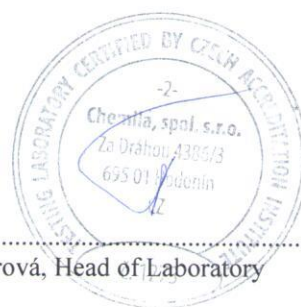
Page: 1

From pages: 10

Incoming date:
24.10.2016

Delivery date:
23.12.2016

Hodonín, 23.12.2016



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Ing. Jana Šlitrová, Head of Laboratory

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

Sample ID: D283/2016
Rep No: 262
Sample name: **JACLOR®**
Sampled: by client
Sampling point: Romdezimed Production SRL, Sector 5, Bucuresti
Client: Romdezimed Production SRL, Sector 5, Bucuresti

Sampling date: 18.10.2016
Sample delivered: 24.10.2016
Testing date: 16.11. – 21.12.2016
Delivered amount: 2 x 250 tabs
Batch No: 10
Page: 2

Subject of testing:

Determination of bactericidal and sporicidal activity of the product.

Identification of the sample:

Name of the product:	JACLOR®
Batch number:	10
Date of manufacture:	6.10.2016
Expiry date:	6.10.2019
Manufacturer:	Romdezimed Production SRL, Str. Sg. Maj. Vasile Topliceanu Nr. 16, Sector 5, Bucuresti
Incoming date:	24.10.2016
Storage conditions:	stated by the manufacturer
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 13727:2012+A2:2015)

Period of analysis:	20.12. – 21.12.2016
Test temperature:	20 °C ± 1 °C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Product diluent:	hard water
Appearance of the product:	white tab
Test concentration:	1 tab/8 l, 1 tab/10 l
Contact time:	15 min and 30 min
Interfering substances:	0.3 g/l BSA (clean conditions)
Test organisms:	<i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541
Incubation conditions:	37 °C ± 1 °C, 24 hours

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:

Bactericidal activity – the capability of a product to produce a reduction in the number of viable bacterial cells of relevant organisms under defined conditions by at least 5 orders (10^5).

The standard:

EN 13727:2012+A2:2015 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1) October 2015

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D283/2016

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The Number of CFU in the tested products **JACLOR®**: $<10^1$ CFU/g

1. Testing the efficacy of chemical disinfectant **JACLOR®** on *Pseudomonas aeruginosa* ATCC 15442

Tab No. 1.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc. 1 tab/8 l		
V_{c1}	58	$\Phi_{N_{V0}} = 49$	V_{c1}	49	$\Phi_A = 47.5$	V_{c1}	55	$\Phi_B = 48.5$	V_{c1}	42	$\Phi_C = 49.5$
V_{c2}	40		V_{c2}	46		V_{c2}	42		V_{c2}	57	
$30 \leq \Phi_{N_{V0}} \leq 160$			$\Phi_A \geq 0.5 \Phi_{N_{V0}}$			$\Phi_B \geq 0.5 \Phi_{N_{V0}}$			$\Phi_C \geq 0.5 \Phi_{N_{V0}}$		
x	yes	no	x	Yes	no	x	yes	no	x	yes	no
Validation of suspension (N_{VB})			V_{c1}	46	V_{c2}	53	$\Phi_{N_{VB}}$	49.5	$30 \leq \Phi_{N_{VB}} (N_{VB}/1000) \leq 160$		
									x	yes	no

Tab No. 1.2 Test suspension

Test suspension N $\Phi = 49 \times 10^7 = \lg 8.69$ $8.17 \leq \lg N \leq 8.70$	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 7.69$ $7.17 \leq \lg N_0 \leq 7.70$
	10^{-6}	> 330	> 330	
	10^{-7}	47	51	
				x
				yes
				no

Tab No. 1.3 Testing the efficacy of chemical disinfectant **JACLOR®** on *Pseudomonas aeruginosa* ATCC 15442

Test concentration (%) / contact time (min) / conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	lg R ($\lg N_0 = \lg 7.69$)
1 tab/8 l/15/clean	10^0	<14	<14	< 2.15	≥ 5.54
1 tab/10 l/30/clean	10^0	<14	<14	< 2.15	≥ 5.54

2. Testing the efficacy of chemical disinfectant **JACLOR®** on *Staphylococcus aureus* ATCC 6538

Tab No. 2.1 Verification of methodology, clean conditions

Validation of suspension (N_{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc. 1 tab/8 l		
V_{c1}	50	$\Phi_{N_{V0}} = 51.5$	V_{c1}	44	$\Phi_A = 47.5$	V_{c1}	46	$\Phi_B = 49$	V_{c1}	57	$\Phi_C = 48.5$
V_{c2}	53		V_{c2}	51		V_{c2}	52		V_{c2}	40	
$30 \leq \Phi_{N_{V0}} \leq 160$			$\Phi_A \geq 0.5 \Phi_{N_{V0}}$			$\Phi_B \geq 0.5 \Phi_{N_{V0}}$			$\Phi_C \geq 0.5 \Phi_{N_{V0}}$		
x	yes	no	x	yes	no	x	yes	no	x	yes	no
Validation of suspension (N_{VB})			V_{c1}	54	V_{c2}	50	$\Phi_{N_{VB}}$	52	$30 \leq \Phi_{N_{VB}} (N_{VB}/1000) \leq 160$		
									x	yes	no

Tab No. 2.2 Test suspension

Test suspension N $\Phi = 49.5 \times 10^7 = \lg 8.69$ $8.17 \leq \lg N \leq 8.70$	N	V_{c1}	V_{c1}	Test suspension N_0 (time = 0) $\lg N_0 = \lg N/10 = \lg 7.69$ $7.17 \leq \lg N_0 \leq 7.70$
	10^{-6}	> 330	> 330	
	10^{-7}	52	47	
				x
				yes
				no

Tab No. 2.3 Testing the efficacy of chemical disinfectant **JACLOR®** on *Staphylococcus aureus* ATCC 6538

Test concentration (%) / contact time (min) / conditions	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a = \lg (\Phi_a \times 10)$	lg R ($\lg N_0 = \lg 7.69$)
1 tab/8 l/15/clean	10^0	<14	<14	< 2.15	≥ 5.54
1 tab/10 l/30/clean	10^0	<14	<14	< 2.15	≥ 5.54

Note: V_c = value is the number of cfu per ml, Φ = average V_{c1} + V_{c2} (1. + 2. duplicate V_c values), N = the number of cfu/ml of the bacterial test suspension, N_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_V = the number of cfu/ml of the bacterial test suspension for validation, N_{V0} (A,C), N_{VB} (B) = the number of cfu/ml of the bacterial test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of survivors per ml in the test mixture, A, B, C = the number of survivors per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), R = N_0 / N_a = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D283/2016
 Rep No: 262
 Sample name: **JACLOR®**
 Sampled: by client
 Sampling point: Romdezimed Production SRL, Sector 5, Bucuresti
 Client: Romdezimed Production SRL, Sector 5, Bucuresti

Sampling date: 18.10.2016
 Sample delivered: 24.10.2016
 Testing date: 16.11. – 21.12.2016
 Delivered amount: 2 x 250 tabs
 Batch No: 10
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3. Testing the efficacy of chemical disinfectant **JACLOR®** on *Enterococcus hirae* ATCC 10541

Tab No. 3.1 Verification of methodology, clean conditions

Validation of suspension (N _{V0})			Validation of selected experimental conditions (A)			Neutralizer toxicity control (B)			Method validation (C) Product conc. 1 tab/8 l		
V _{e1}	52	Φ _{N_{V0}} = 49	V _{e1}	44	Φ _A = 47.5	V _{e1}	53	Φ _B = 48	V _{e1}	56	Φ _C = 47.5
V _{e2}	46		V _{e2}	51		V _{e2}	43		V _{e2}	39	
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}	51	V _{e2}	47	Φ _{N_{VB}}	49	30 ≤ Φ _{N_{VB}} (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 = 48 x 10 ⁷ = lg 8.68 8.17 ≤ lg N ≤ 8.70	10 ⁻⁶	> 330	> 330	lg N ₀ = lg N/10 = lg 7.68 7.17 ≤ lg N ₀ ≤ 7.70	
	10 ⁻⁷	48	48		
					x

Tab No. 3.3 Testing the efficacy of chemical disinfectant **JACLOR®** on *Enterococcus hirae* ATCC 10541

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 = lg 7.68)
1 tab/8 l / 15/clean	10 ⁰	<14	<14	< 2.15	≥ 5.53
1 tab/10 l / 30/clean	10 ⁰	<14	<14	< 2.15	≥ 5.53

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

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

Bactericidal activity of the product (EN 13727:2012+A2:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 13727:2012 +A2:2015	lg R
<i>Pseudomonas aeruginosa</i> ATCC 15442	20	15	1 tab/8 l	clean	≥ 5	> 5
<i>Staphylococcus aureus</i> ATCC 6538	20	15	1 tab/8 l	clean	≥ 5	> 5
<i>Enterococcus hirae</i> ATCC 10541	20	15	1 tab/8 l	clean	≥ 5	> 5
<i>Pseudomonas aeruginosa</i> ATCC 15442	20	30	1 tab/10 l	clean	≥ 5	> 5
<i>Staphylococcus aureus</i> ATCC 6538	20	30	1 tab/10 l	clean	≥ 5	> 5
<i>Enterococcus hirae</i> ATCC 10541	20	30	1 tab/10 l	clean	≥ 5	> 5

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 bacterial test suspension, N₀ = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_v = the number of cfu/ml of the bacterial test suspension for validation, N_{v0} (A,C), N_{VB} (B) = the number of cfu/ml of the bacterial test suspensions for validation in the test mixture A, B, C at the beginning of the contact time = 0, N_a = the number of survivors per ml in the test mixture, A, B, C = the number of survivors per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), R = N₀/ N_a = the reduction in viability, or lg R = lg N₀ – lg N_a

Prepared by: Hana Konevalíková, Lab Technician

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

Sample ID: D283/2016

Rep No: 262

Sample name: **JACLOR®**

Sampled: by client

Sampling point: Romdezimed Production SRL, Sector 5, Bucuresti

Client: Romdezimed Production SRL, Sector 5, Bucuresti

Sampling date: 18.10.2016

Sample delivered: 24.10.2016

Testing date: 16.11. – 21.12.2016

Delivered amount: 2 x 250 tabs

Batch No: 10

Page: 5

Experimental conditions:

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

SOP-M-19-00 (EN 13704:2002)

Period of analysis:

16.11. – 21.11.2016

Test temperature:

20 °C ± 1 °C

Test method:

dilution neutralization method

Neutralization medium:

Dey-Engley Neutralizing Broth M 1062

Product diluent:

hard water

Appearance of the product:

white tab

Test concentration:

3 tab/10 l

Contact time:

30 min and 60 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Test organisms:

Bacillus subtilis ATCC 6633

Incubation conditions:

30 °C ± 1 °C, minimum 3 and maximum 7 days

Test procedure:

1. Preparation of the test suspension
2. Preparation of the 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 strain of *Bacillus subtilis* under defined conditions by at least 3 orders (10^3).

$$\lg R = \lg [(N \times 10^{-1})/N_a]$$

The standard:

EN 13704:2002 Chemical disinfectants – Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1) February 2002

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D283/2016

Rep No: 262

Sample name: **JACLOR**[®]

Sampled: by client

Sampling point: Romdezimed Production SRL, Sector 5, Bucuresti

Client: Romdezimed Production SRL, Sector 5, Bucuresti

Sampling date: 18.10.2016

Sample delivered: 24.10.2016

Testing date: 16.11. – 21.12.2016

Delivered amount: 2 x 250 tabs

Batch No: 10

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5. Testing the efficacy of chemical disinfectant **JACLOR**[®] on *Bacillus subtilis* ATCC 6633

Tab No. 5.1 Verification of methodology, clean conditions

Validation of suspension (N_v) x 10^1		Validation of selected experimental conditions (A)		Neutralizer toxicity control (B)		Method validation (C) Product conc.: 3 tab/10 l						
V_{c1}	65	$\Phi_{Nv} = 62.5$	V_{c1}	55	$\Phi_A = 59$	V_{c1}	57	$\Phi_B = 55$	V_{c1}	58	$\Phi_C = 60$	
V_{c2}	60		V_{c2}	63		V_{c2}	53		V_{c2}	62		
$60 \leq \Phi_{Nv} \leq 300$		$\Phi_A \geq 0.05 \Phi_{Nv}$		$\Phi_B \geq 0.05 \Phi_{Nv}$		$\Phi_C \geq 0.5 \Phi_B$						
x	yes		x	yes		x	yes		x	yes		no

Tab No. 5.2 Test suspension

Test suspension (N)	N	V_{c1}	V_{c1}	$\Phi = 151 \times 10^4 = \lg 6.18$ $6.17 \leq \lg N \leq 6.70$			
	10^{-4}	151	148				
	10^{-5}	18	16				
				x	yes		no

Tab No. 5.3 Testing the efficacy of chemical disinfectant **JACLOR**[®] on *Bacillus subtilis* ATCC 6633

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 = lg 6.18)
3 tab/ 10 l/30/clean	10^0	<14	<14	< 2.15	≥ 3.03
3 tab/ 10 l/60/clean	10^0	<14	<14	< 2.15	≥ 3.03

6. Evaluation of sporicidal activity of the product **JACLOR**[®]

Tab No. 6.1 The efficacy of chemical disinfectant **JACLOR**[®] on test strains – sporicidal activity

Sporicidal activity of the product (EN 13704:2002)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 13704:2002	lg R
<i>Bacillus subtilis</i> ATCC 6633	20	30	3 tab/10 l	clean	≥ 3	> 3
<i>Bacillus subtilis</i> ATCC 6633	20	60	3 tab/10 l	clean	≥ 3	> 3

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 spore test suspension, N_a = the number of survivors per ml in the test mixture at the end of the contact time, N_v = the number of cfu/ml of the spore validation test suspension, A,B,C = the number of cfu/ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation), $\lg R = \lg [(N \times 10^{-1})/N_a]$ = the reduction in viability

Prepared by: Hana Konevalíková, Lab Technician

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

Sample ID: D283/2016

Rep No: 262

Sample name: **JACLOR®**

Sampled: by client

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Sample delivered: 24.10.2016

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Delivered amount: 2 x 250 tabs

Batch No: 10

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Experimental conditions:

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

SOP-M-19-00 (EN 13704:2002)

Period of analysis:

26.11. – 2.12.2016

Test temperature:

20 °C ± 1 °C

Test method:

dilution neutralization method

Neutralization medium:

Dey-Engley Neutralizing Broth M 1062

Product diluent:

hard water

Appearance of the product:

white tab

Test concentration:

1 tab/5 l, 3 tab/10 l

Contact time:

30 min and 60 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Test organisms:

Bacillus cereus ATCC 12826

Clostridium sporogenes ATCC 19404*

Incubation conditions:

30 °C ± 1 °C, minimum 3 and maximum 7 days

Test procedure:

1. Preparation of the test suspension
2. Preparation of the 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 strain of *Bacillus subtilis* under defined conditions by at least 3 orders (10^3).

$$\lg R = \lg [(N \times 10^{-1})/N_a]$$

* The test strain was used according to the client's request.

The standard:

EN 13704:2002 Chemical disinfectants – Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1) February 2002

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D283/2016

Rep No: 262

Sample name: **JACLOR®**

Sampled: by client

Sampling point: Romdezimed Production SRL, Sector 5, Bucuresti

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

Tab No. 7.1 Verification of methodology, clean conditions

Validation of suspension (N_v) x 10^1		Validation of selected experimental conditions (A)		Neutralizer toxicity control (B)		Method validation (C) Product conc.: 3 tab/10 l	
V_{c1}	83	V_{c1}	88	V_{c1}	82	V_{c1}	86
V_{c2}	90	V_{c2}	80	V_{c2}	87	V_{c2}	76
$\Phi_{Nv} = 86.5$		$\Phi_A = 84$		$\Phi_B = 84.5$		$\Phi_C = 81$	
$60 \leq \Phi_{Nv} \leq 300$		$\Phi_A \geq 0.05 \Phi_{Nv}$		$\Phi_B \geq 0.05 \Phi_{Nv}$		$\Phi_C \geq 0.5 \Phi_B$	
x	yes	x	yes	x	yes	x	yes
	no		no		no		no

Tab No. 7.2 Test suspension

Test suspension (N)	N	V_{c1}	V_{c1}	$\Phi = 34 \times 10^5 = \lg 6.53$ $6.17 \leq \lg N \leq 6.70$			
	10^{-4}	>330	>330				
	10^{-5}	34	34				
				x	yes		no

Tab No. 7.3 Testing the efficacy of chemical disinfectant **JACLOR®** on *Bacillus cereus* ATCC 12826

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 = lg 6.53)
1 tab/ 5 l/30/clean	10^0	<14	<14	< 2.15	≥ 3.38
3 tab/ 10 l/30/clean	10^0	<14	<14	< 2.15	≥ 3.38
3 tab/ 10 l/60/clean	10^0	<14	<14	< 2.15	≥ 3.38

8. Testing the efficacy of chemical disinfectant **JACLOR®** on *Clostridium sporogenes* ATCC 19404*

Tab No. 8.1 Verification of methodology, clean conditions

Validation of suspension (N_v) x 10^1		Validation of selected experimental conditions (A)		Neutralizer toxicity control (B)		Method validation (C) Product conc.: 3 tab/10 l	
V_{c1}	68	V_{c1}	74	V_{c1}	73	V_{c1}	68
V_{c2}	79	V_{c2}	60	V_{c2}	62	V_{c2}	70
$\Phi_{Nv} = 73.5$		$\Phi_A = 67$		$\Phi_B = 67.5$		$\Phi_C = 69$	
$60 \leq \Phi_{Nv} \leq 300$		$\Phi_A \geq 0.05 \Phi_{Nv}$		$\Phi_B \geq 0.05 \Phi_{Nv}$		$\Phi_C \geq 0.5 \Phi_B$	
x	yes	x	yes	x	yes	x	yes
	no		no		no		no

Tab No. 8.2 Test suspension

Test suspension (N)	N	V_{c1}	V_{c1}	$\Phi = 310 \times 10^4 = \lg 6.49$ $6.17 \leq \lg N \leq 6.70$			
	10^{-4}	327	288				
	10^{-5}	31	35				
				x	yes		no

Tab No. 8.3 Testing the efficacy of chemical disinfectant **JACLOR®** on *Clostridium sporogenes* ATCC 19404*

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 = lg 6.49)
1 tab/ 5 l/30/clean	10^0	<14	<14	< 2.15	≥ 3.34
3 tab/ 10 l/30/clean	10^0	<14	<14	< 2.15	≥ 3.34
3 tab/ 10 l/60/clean	10^0	<14	<14	< 2.15	≥ 3.34

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 spore test suspension, N_a = the number of survivors per ml in the test mixture at the end of the contact time, N_v = the number of cfu/ml of the spore validation test suspension, A,B,C = the number of cfu/ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation), $\lg R = \lg [(N \times 10^{-1})/N_a]$ = the reduction in viability

* The test strain was used according to the client's request.

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

Sample ID: D283/2016

Rep No: 262

Sample name: **JACLOR**[®]

Sampled: by client

Sampling point: Romdezimed Production SRL, Sector 5, Bucuresti

Client: Romdezimed Production SRL, Sector 5, Bucuresti

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9. Evaluation of sporicidal activity of the product **JACLOR**[®]

Tab No. 9.1 The efficacy of chemical disinfectant **JACLOR**[®] on test strains – sporicidal activity

Sporicidal activity of the product (EN 13704:2002)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 13704:2002	lg R
<i>Bacillus cereus</i> ATCC 12826	20	30	1 tab/5 l	clean	≥ 3	> 3
<i>Clostridium sporogenes</i> ATCC 19404*	20	30	1 tab/5 l	clean	≥ 3	> 3
<i>Bacillus cereus</i> ATCC 12826	20	30	3 tab/10 l	clean	≥ 3	> 3
<i>Clostridium sporogenes</i> ATCC 19404*	20	30	3 tab/10 l	clean	≥ 3	> 3
<i>Bacillus cereus</i> ATCC 12826	20	60	3 tab/10 l	clean	≥ 3	> 3
<i>Clostridium sporogenes</i> ATCC 19404*	20	60	3 tab/10 l	clean	≥ 3	> 3

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 spore test suspension, N_a = the number of survivors per ml in the test mixture at the end of the contact time, N_v = the number of cfu/ml of the spore validation test suspension, A,B,C = the number of cfu/ml in control tests (A – experimental conditions validation, B – neutralizer toxicity validation, C – method validation), $\lg R = \lg [(N \times 10^{-1})/N_a]$ = the reduction in viability

* The test strain was used according to the client's request.

Prepared by: Hana Konevalíková, Lab Technician

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D283/2016
Rep No: 262
Sample name: **JACLOR**[®]
Sampled: by client
Sampling point: Romdezimed Production SRL, Sacele, Brasov
Client: Romdezimed Production SRL, Sector 5, Bucuresti

Sampling date: 18.10.2016
Sample delivered: 24.10.2016
Testing date: 16.11. – 21.12.2016
Delivered amount: 2 x 250 tabs
Batch No: 10
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Interpretation:

Results of tests are in Tabs.

According to EN 13727:2012+A2:2015 the tested product **JACLOR**[®], batch No. 10, in the concentration 1 tab/8 l, diluted in hard water, in the contact time 15 min and in the concentration 1 tab/10 l, diluted in hard water, in the contact time 30 min under clean conditions at temperature 20 °C ± 1 °C by the dilution neutralization method **decreased** the number of alive microbes *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 by at least 5 (lg) orders.

According to EN 13704:2002 the tested product **JACLOR**[®], batch No. 10, in the concentration 3 tab/10 l, diluted in hard water, in the contact times 30 min and 60 min under clean conditions at temperature 20 °C ± 1 °C by the dilution neutralization method **decreased** the number of bacterial spores *Bacillus subtilis* ATCC 6633 by at least 3 (lg) orders (EN 13704).

According to EN 13704:2002 the tested product **JACLOR**[®], batch No. 10, in the concentration 1 tab/5 l, diluted in hard water, in the contact time 30 min and in the concentration 3 tab/10 l, diluted in hard water, in the contact times 30 min and 60 min under clean conditions at temperature 20 °C ± 1 °C by the dilution neutralization method **decreased** the number of bacterial spores *Bacillus cereus* ATCC 12826 and *Clostridium sporogenes* ATCC 19404 by at least 3 (lg) orders (EN 13704).

Conclusion:

The product **JACLOR**[®] is capable of reducing the number of viable bacterial cells of the relevant organisms under defined conditions to the declared values, and consequently, may be called bactericidal.

The product **JACLOR**[®] is capable of reducing the number of bacterial spores of the relevant organisms under defined conditions to the declared values, and consequently, may be called sporicidal.

23.12.2016, Hodonín

Eva Kremlová

Ing. Eva Kremlová, Leader of Study

