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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.

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Test report No. S87-1/2020

DETERMINATION OF FUNGICIDAL (EN 13697:2015+A1:2019), SPORICIDAL (EN 13704:2018), BACTERICIDAL AND YEASTICIDAL (EN 16615:2015) ACTIVITY OF THE PRODUCT **JACLOR**[®] DETERMINATION OF VIRUCIDAL (EN 14476:2013 +A2:2019) 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

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From pages: 25

Incoming date:
2.3.2020

Delivery date:
22.7.2020

Hodonín, 22.7.2020



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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: 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: 15.4. – 7.5.2020
Delivered amount: 1 kg
Batch No: 07
Page: 2

Subject of testing:

Determination of bactericidal, fungicidal, sporicidal and virucidal 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 on carriers SOP-M-22-12

(EN 13697:2015+A1:2019)
Period of analysis: 27.4. – 30.4.2020
Test temperature: $18\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ až $25\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$
Test method: dilution neutralization method
Neutralization medium: Dey-Engley Neutralizing Broth M 1062
Product diluent: hard water
Appearance of the product: white tabs
Test concentration: 1 tab/10 l, 1 tab/5 l, 1 tab/3 l
Contact time: 15 min, 30 min, 60 min
Interfering substances: 0.3 g/l BSA (clean conditions)
Test organisms: *Candida albicans* ATCC 10231
Aspergillus brasiliensis (niger) ATCC 16404
Incubation conditions: $30\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$, 48 hours and additional period of 24 or 48 hours

Test procedure:

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

Note:

Presence of a high concentration (at least 75%) of *Aspergillus brasiliensis* spiny spores in the test suspension – yes.

Fungicidal activity – the capability of a product to produce a reduction in the number of viable fungi of relevant organisms on carriers under defined conditions by at least 3 orders (10^3).

Yeasticidal activity – the capability of a product to produce a reduction in the number of viable fungi belonging to reference strain *Candida albicans* on carriers under defined conditions by at least a 3 lg reduction (10^3).

The drying time: 25-40 min.

The standard:

EN 13697:2015+A1:2019 Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (phase 2, step 2) April 2015 + August 2019

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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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

1. Testing the efficacy of chemical disinfectant **JACLOR®** on carriers – fungicidal activity

Tab No. 1.1 Verification of methodology, clean conditions

Test organisms	Test suspension N	Validation test	
		NT (Product conc.: 1 tab/5 l) Neutralization test	NC Neutralization control
<i>Candida albicans</i> ATCC 10231	10 ⁻⁶ : >330, >330 10 ⁻⁷ : 39, 59 N : 7.09	10 ⁻³ : >330, >330 10 ⁻⁴ : 118, 131 NT : 7.10	10 ⁻³ : >330, >330 10 ⁻⁴ : 134, 102 NC : 7.07
Limit	6.57 ≤ lg N ≤ 7.10	NT - Nc ≤ ± 0.3 lg	NC - Nc ≤ ± 0.3 lg
Test organisms	Test suspension N	Validation test	
		NT (Product conc.: 1 tab/3 l) Neutralization test	NC Neutralization control
<i>Aspergillus brasiliensis (niger)</i> ATCC 16404	10 ⁻⁵ : >165, >165 10 ⁻⁶ : 36, 20 N : 5.85	10 ⁻² : >165, >165 10 ⁻³ : 44, 25 NT : 5.54	10 ⁻² : >165, >165 10 ⁻³ : 29, 42 NC : 5.55
Limit	5.57 ≤ lg N ≤ 6.10	NT - Nc ≤ ± 0.3 lg	NC - Nc ≤ ± 0.3 lg

$$N = \log_{10} [\{0.025 \cdot (x + x')\} / 2 \cdot d]$$

where x and x' are paired values for which the mean of the value falls between 14 and 330 colonies for yeast and 14 and 165 colonies for mould, d is the dilution factor for the dilution taken into account

$$NC \text{ or } NT = \log_{10} [\{10 \cdot (y + y')\} / 2 \cdot d]$$

where y and y' are paired values for which the mean of the value falls between 14 and 330 colonies for yeast and 14 and 165 colonies for mould, d is the dilution factor for the dilution taken into account

Tab No. 1.2 Testing the efficacy of chemical disinfectant **JACLOR®** on test strain, clean conditions

Test organisms	Water control Nc	Test procedure Nd at concentrations / contact time (min)	
		1 tab/5 l / 15	1 tab/10 l / 30
<i>Candida albicans</i> ATCC 10231	10 ⁻³ : >330, >330 10 ⁻⁴ : 156, 112 Nc : 7.13 Nts : >100	10 ⁰ : <14, <14 Nd : < 2.15 Nts : 0 R : ≥ 4.98	10 ⁻¹ : 58, 50 Nd : 3.73 Nts : 15 R : 3.40
Test organisms	Water control Nc	Test procedure Nd at concentrations / contact time (min)	
		1 tab/3 l / 60	-
<i>Aspergillus brasiliensis (niger)</i> ATCC 16404	10 ⁻² : >165, >165 10 ⁻³ : 34, 44 Nc : 5.59 Nts : >100	10 ⁰ : <14, <14 Nd : < 2.15 Nts : 0 R : ≥ 3.44	-
Limit	Nts : <100 CFU/ml for active concentration		

$$Nc \text{ or } Nd = \log_{10} [\{10 \cdot (a + a')\} / 2 \cdot d]$$

where a and a' are paired values for which the mean of the value falls between 14 and 330 colonies for yeast and 14 and 165 colonies for mould, d is the dilution factor for the dilution taken into account

$$\text{Reduction } R = Nc - Nd$$

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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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2. Evaluation of fungicidal activity of the product **JACLOR**[®] on carriers

Tab No. 2.1 The efficacy of chemical disinfectant **JACLOR**[®] on test strains – fungicidal activity on carriers

Fungicidal activity of the product on carriers (EN 13697:2015+A1:2019)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	R EN 13697:2015+A1:2019	R
<i>Candida albicans</i> ATCC 10231	20	15	1 tab/5 l	clean	≥ 3	> 3
<i>Candida albicans</i> ATCC 10231	20	30	1 tab/10 l	clean	≥ 3	> 3
<i>Aspergillus brasiliensis (niger)</i> ATCC 16404	20	60	1 tab/3 l	clean	≥ 3	> 3

Reduction R= Nc – Nd

Prepared by: Ing. Barbora Stoklásková, 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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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Experimental conditions:

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

SOP-M-19-00 (EN 13704:2018)

Period of analysis:

27.4. – 30.4.2020

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 tabs

Test concentration:

1 tab/3 l

Contact time:

30 min, 60 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Test organisms:

Bacillus subtilis ATCC 6633

Bacillus cereus ATCC 12826

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 strain of *Bacillus subtilis* under defined conditions by at least a 3 lg reduction (10³).

For specific applications additional strain may be chosen, for example *Bacillus cereus* (ATCC 12826), *Clostridium sporogenes* (ATCC 19404).

The standard:

EN 13704:2018 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) July 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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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

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/3 l		
V _{e1}	40	Φ _{Nv} = 36.5	V _{e1}	39	Φ _A = 33.5	V _{e1}	28	Φ _B = 33.5	V _{e1}	31	Φ _C = 33
V _{e2}	33		V _{e2}	28		V _{e2}	39		V _{e2}	35	
30 ≤ Φ _{Nv0} ≤ 160			Φ _A ≥ 0.5 Φ _{Nv0}			Φ _B ≥ 0.5 Φ _{Nv0}			Φ _C ≥ 0.5 Φ _{Nv0}		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Tab No. 3.2 Test suspension

Test suspension N Φ = 39.5 x 10 ⁵ = lg 6.60 6.17 ≤ lg N ≤ 6.70	N	V _{e1}	V _{e1}	Test suspension N ₀ lg N ₀ = lg N/10 = lg 5.60 5.17 ≤ lg N ₀ ≤ 5.70
	10 ⁻⁴	> 330	> 330	
	10 ⁻⁵	41	38	
				x yes No

Tab No. 3.3 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 = 5.60)
1 tab/3 l / 30 / clean	10 ⁰	49	45	2.67	2.93
1 tab/3 l / 60 / clean	10 ⁰	<14	<14	< 2.15	≥ 3.45

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

Tab No. 4.1 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/3 l		
V _{e1}	49	Φ _{Nv} = 46.5	V _{e1}	41	Φ _A = 43	V _{e1}	36	Φ _B = 41	V _{e1}	47	Φ _C = 46
V _{e2}	44		V _{e2}	45		V _{e2}	46		V _{e2}	45	
30 ≤ Φ _{Nv0} ≤ 160			Φ _A ≥ 0.5 Φ _{Nv0}			Φ _B ≥ 0.5 Φ _{Nv0}			Φ _C ≥ 0.5 Φ _{Nv0}		
x	yes	no	x	yes	no	x	yes	no	x	yes	no

Tab No. 4.2 Test suspension

Test suspension N Φ = 49 x 10 ⁵ = lg 6.69 6.17 ≤ lg N ≤ 6.70	N	V _{e1}	V _{e1}	Test suspension N ₀ lg N ₀ = lg N/10 = lg 5.69 5.17 ≤ lg N ₀ ≤ 5.70
	10 ⁻⁴	> 330	> 330	
	10 ⁻⁵	52	46	
				x yes No

Tab No. 4.3 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 = 5.69)
1 tab/3 l / 30 / clean	10 ⁰	264	306	3.46	2.23
	10 ⁻¹	39	25		
1 tab/3 l / 60 / clean	10 ⁰	<14	<14	< 2.15	≥ 3.54

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 bacterial test suspension at the beginning of the contact time = 0, N_a = the number of survivors per ml in the test mixture at the end of the contact time, N_{v0} = the number of cfu/ml of the spore validation test suspension, A,B,C = the number of surviving spores per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), 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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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

Tab No. 5.1 The efficacy of chemical disinfectant **JACLOR**[®] on test strains – sporicidal activity

Sporicidal activity of the product (EN 13704:2018)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 13704:2018	lg R
<i>Bacillus subtilis</i> ATCC 6633	20	30	1 tab/3 l	clean	≥ 3	< 3
<i>Bacillus cereus</i> ATCC 12826	20	30	1 tab/3 l	clean	≥ 3	< 3
<i>Bacillus subtilis</i> ATCC 6633	20	60	1 tab/3 l	clean	≥ 3	> 3
<i>Bacillus cereus</i> ATCC 12826	20	60	1 tab/3 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_0 = the number of cfu/ml of the bacterial test suspension at the beginning of the contact time = 0, N_a = the number of survivors per ml in the test mixture at the end of the contact time, N_{v0} = the number of cfu/ml of the spore validation test suspension, A,B,C = the number of surviving spores per ml in control tests (A – experimental conditions control, B – neutralizer toxicity validation, C – method validation), $lg R = lg N_0 - lg N_a$ = 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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method SOP-M-19-00

(EN 14476:2013 +A2:2019)

Period of analysis:

23.4. – 30.4.2020

Test temperature:

20 °C ± 1 °C

Method of titration:

virus titration on monolayers of cells on microtitre plates

Product diluent:

hard water

Appearance of the product:

white tabs

Test concentration:

1 tab/5 l

Contact time:

30 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Reference product:

Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No: K51622203930, expiry date: 31.7.2021

Test virus:

Adenovirus type 5, strain Adenoid 75, ATCC VR-5 (2nd passage)

Cell lines:

HeLa cells (11th passage)

Incubation:

36 °C ± 1 °C, 5 % CO₂, 96 h, and additional period of 72 hours. After

incubation, the titre infectivity is calculated according to Spearman-Kärber method.

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product
2. Preparation of cell culture
3. Preparation of the test virus suspension
4. Test of viral infectivity
5. Virus titration with interfering substance
6. Cytotoxicity of the product
7. Reference virus inactivation test
8. Test procedure for virucidal activity of product

Note:

Virucidal activity – the capability of a product to produce a reduction in the number of infectious virus particles under defined conditions by at least a 4 lg reduction.

The standard:

EN 14476:2013 +A2:2019 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (Phase 2/Step 1) August 2013 + July 2019

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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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6. Testing the efficacy of chemical disinfectant **JACLOR®** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Tab No. 6.1 Table of results of product **JACLOR®** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Product	Concentration	Interfering substances	Level of cytotoxicity	- log ₁₀ TCID ₅₀ after 30 min	- log ₁₀ TCID ₅₀ after 60 min
JACLOR®	1 tab/5 l	clean	2.50	2.50	-
Formaldehyde	0.7 % (w/v)	PBS	3.50	5.83	5.33
			Virus titration, time = 0		
Virus control	-	PBS	9.17	9.00	9.00
Virus control	-	clean	9.00	9.00	-

Tab No. 6.2 Testing the efficacy of chemical disinfectant **JACLOR®** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Test concentration	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
1 tab/5 l	9.00	clean	30 min	2.50	6.50

Tab No. 6.3 Testing the efficacy of reference item **Formaldehyde** on *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5

Test concentration	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
0.7 % (w/v)	9.17	PBS	30 min	5.83	3.34
0.7 % (w/v)	9.17	PBS	60 min	5.33	3.84

7. Evaluation of virucidal activity of the product **JACLOR®**

Tab No. 7.1 The efficacy of chemical disinfectant **JACLOR®** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013 +A2:2019)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013 +A2:2019	Δlog ₁₀ TCID ₅₀
<i>Adenovirus</i> type 5, strain Adenoid 75, ATCC VR-5	20	30	1 tab/5 l	clean	≥ 4	> 4

Tab No. 7.2 The efficacy of reference item **Formaldehyde** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013+A2:2019)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013+ A2:2019	Δlog ₁₀ TCID ₅₀
<i>Adenovirus</i> type 5, strain Adenoid 75, ATCC VR-5	20	30	0.7 % (w/v)	PBS	3.0 – 5.0	3.34
<i>Adenovirus</i> type 5, strain Adenoid 75, ATCC VR-5	20	60	0.7 % (w/v)	PBS	3.5 – 5.5	3.84

Note:

TCID₅₀- 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

Prepared by: Bc. Iva Čížová, 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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method SOP-M-19-00

(EN 14476:2013 +A2:2019)

Period of analysis:

30.4. – 7.5.2020

Test temperature:

20 °C ± 1 °C

Method of titration:

virus titration on monolayers of cells on microtitre plates

Product diluent:

hard water

Appearance of the product:

white tabs

Test concentration:

1 tab/5 l

Contact time:

30 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Reference product:

Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No:

K51622203930, expiry date: 31.7.2021

Test virus:

Murine norovirus (MNV) strain S99, RVB-651 (3rd passage)

Cell lines:

RAW 264.7 *Murine macrophage* cell line (3rd passage)

Incubation:

36 °C ± 1 °C, 5 % CO₂, 96 h, and additional period of 72 hours. After

incubation, the titre infectivity is calculated according to Spearman-Kärber method.

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product
2. Preparation of cell culture
3. Preparation of the test virus suspension
4. Test of viral infectivity
5. Virus titration with interfering substance
6. Cytotoxicity of the product
7. Reference virus inactivation test
8. Test procedure for virucidal activity of product

Note:

Virucidal activity – the capability of a product to produce a reduction in the number of infectious virus particles under defined conditions by at least a 4 lg reduction.

The standard:

EN 14476:2013 +A2:2019 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (Phase 2/Step 1) August 2013 + July 2019

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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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8. Testing the efficacy of chemical disinfectant **JACLOR®** on *Murine norovirus (MNV)* strain S99, RVB-651

Tab No. 8.1 Table of results of product **JACLOR®** on *Murine norovirus (MNV)* strain S99, RVB-651

Product	Concentration	Interfering substances	Level of cytotoxicity	- log ₁₀ TCID ₅₀ after 30 min	- log ₁₀ TCID ₅₀ after 60 min
JACLOR®	1 tab/5 l	clean	2.50	2.50	-
Formaldehyde	0.7 % (w/v)	PBS	3.50	7.67	6.83
			Virus titration, time = 0		
Virus control	-	PBS	9.33	9.33	9.50
Virus control	-	clean	9.50	9.50	-

Tab No. 8.2 Testing the efficacy of chemical disinfectant **JACLOR®** on *Murine norovirus (MNV)* strain S99, RVB-651

Test concentration	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
1 tab/5 l	9.50	clean	30 min	2.50	7.00

Tab No. 8.3 Testing the efficacy of reference item **Formaldehyde** on *Murine norovirus (MNV)* strain S99, RVB-651

Test concentration	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
0.7 % (w/v)	9.33	PBS	30 min	7.67	1.66
0.7 % (w/v)	9.33	PBS	60 min	6.83	2.50

9. Evaluation of virucidal activity of the product **JACLOR®**

Tab No. 9.1 The efficacy of chemical disinfectant **JACLOR®** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013 +A2:2019)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013 +A2:2019	Δlog ₁₀ TCID ₅₀
<i>Murine norovirus (MNV)</i> strain S99, RVB-651	20	30	1 tab/10 l	clean	≥ 4	> 4

Tab No. 9.2 The efficacy of reference item **Formaldehyde** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013 +A2:2019)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013 +A2:2019	Δlog ₁₀ TCID ₅₀
<i>Murine norovirus (MNV)</i> strain S99, RVB-651	20	30	0.7 % (w/v)	PBS	1.0 – 3.0	1.66
<i>Murine norovirus (MNV)</i> strain S99, RVB-651	20	60	0.7 % (w/v)	PBS	2.0 – 4.0	2.50

Note:

TCID₅₀- 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

Prepared by: Bc. Iva Čížová, 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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method SOP-M-19-00

(EN 14476:2013 +A2:2019)

Period of analysis:

16.4. – 24.4.2020

Test temperature:

20 °C ± 1 °C

Method of titration:

virus titration on monolayers of cells on microtitre plates

Product diluent:

hard water

Appearance of the product:

white tabs

Test concentration:

1 tab/5 l

Contact time:

30 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Reference product:

Formaldehyde 36 – 38% solution p.a., CAS: 50-00-0, Batch No: K51622203930, expiry date: 31.7.2021

Test virus:

Poliovirus type 1, LSc-2ab (2nd passage)

Cell lines:

HeLa cells (10th passage)

Incubation:

36 °C ± 1 °C, 5 % CO₂, 96 h, and additional period of 96 hours. After

incubation, the titre infectivity is calculated according to Spearman-Kärber method.

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product
2. Preparation of the cell culture
3. Preparation of the test virus suspension
4. Test of the viral infectivity
5. Virus titration with the interfering substance
6. Cytotoxicity of the product
7. Reference virus inactivation test
8. Test procedure for the virucidal activity of the product

Note:

Virucidal activity – the capability of a product to produce a reduction in the number of infectious virus particles under defined conditions by at least a 4 lg reduction (10⁴).

The standard:

EN 14476:2013 +A2:2019 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (Phase 2/Step 1) August 2013 + July 2019

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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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10. Testing the efficacy of chemical disinfectant **JACLOR®** on *Poliovirus* type 1, LSc-2ab

Tab No. 10.1 Table of results of product **JACLOR®** on *Poliovirus* type 1, LSc-2ab

Product	Concentration	Interfering substances	Level of cytotoxicity	- log ₁₀ TCID ₅₀ after 30 min	- log ₁₀ TCID ₅₀ after 60 min
JACLOR®	1 tab/5 l	clean	2.50	2.50	-
Formaldehyde	0.7 % (w/v)	PBS	3.50	7.17	6.17
			Virus titration, time = 0		
Virus control	-	PBS	9.00	9.00	9.17
Virus control	-	clean	8.83	8.83	-

Tab No. 10.2 Testing the efficacy of chemical disinfectant **JACLOR®** on *Poliovirus* type 1, LSc-2ab

Test concentration	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
1 tab/5 l	8.83	clean	30 min	2.50	6.33

Tab No. 10.3 Testing the efficacy of reference item **Formaldehyde** on *Poliovirus* type 1, LSc-2ab

Test concentration	Titre of the virus suspension - log ₁₀ TCID ₅₀	Interfering substances	Contact time	- log ₁₀ TCID ₅₀ after test procedure	Δlog ₁₀ TCID ₅₀
0.7 % (w/v)	9.00	PBS	30 min	7.17	1.83
0.7 % (w/v)	9.00	PBS	60 min	6.17	2.83

11. Evaluation of virucidal activity of the product **JACLOR®**

Tab No. 11.1 The efficacy of chemical disinfectant **JACLOR®** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013 +A2:2019)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013 +A2:2019	Δlog ₁₀ TCID ₅₀
<i>Poliovirus</i> type 1, LSc-2ab	20	30	1 tab/5 l	clean	≥ 4	> 4

Tab No. 11.2 The efficacy of reference item **Formaldehyde** on test viruses – virucidal activity

Virucidal activity of the product (EN 14476:2013+A2:2019)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	Δlog ₁₀ TCID ₅₀ EN 14476:2013+ A2:2019	Δlog ₁₀ TCID ₅₀
<i>Poliovirus</i> type 1, LSc-2ab	20	30	0.7 % (w/v)	PBS	0.5 – 2.5	1.83
<i>Poliovirus</i> type 1, LSc-2ab	20	60	0.7 % (w/v)	PBS	2.0 – 4.5	2.83

Note:

TCID₅₀- 50% infecting dose of a virus suspension or that dilution of the virus suspension that induce a CPE in 50% of cell culture units

Prepared by: Bc. Iva Čížová, 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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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Experimental conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents on carriers

SOP-M-19-00 (EN 16615:2015)

Period of analysis:

6.5. – 7.5.2020 (bacteria)

15.4. – 17.4.2020 (*Candida albicans*)

Lab temperature:

20 °C ± 2.5 °C

Temperature of media:

20 °C ± 1 °C

Test method:

dilution neutralization method

Neutralization medium:

Dey-Engley Neutralizing Broth M 1062

Appearance of the product:

white tabs

Water control:

hard water + polysorbate 80

Product diluent:

hard water

Test concentration:

1 tab/3 l, 1 tab/5 l

Contact time:

30 min, 60 min

Interfering substances:

0.3 g/l BSA (clean conditions)

Test organisms:

Pseudomonas aeruginosa

ATCC 15442

Staphylococcus aureus

ATCC 6538

Enterococcus hirae

ATCC 10541

Incubation conditions:

37 °C ± 1 °C, 24 hours

Test concentration:

1 tab/5 l, 1 tab/10 l

Contact time:

30 min, 60 min

Test organisms:

Candida albicans

ATCC 10231

Incubation conditions:

30 °C ± 1 °C, 48 hours and additional period of 24 or 48 hours

Test surface:

PVC with PUR coating, width 2.5 mm, 20 cm x 50 cm. The surface is cleaned by 70% n-propanol. After drying draw 4 squares 5 cm x 5 cm apart, mark them as test fields 1 to 4. The drying controls D_{Co} and D_{Ci} are performed on smaller surface (7 cm x 13 cm, 2 squares 5 cm x 5 cm).

Wipe:

17 cm x 29.5 cm, 55% cellulose, 45% polyethylenterephthalate (PET), the wipe is used only once. 30 minutes before testing put the wipe in PD with 16 ml of the product solution. The wet wipe is weighted before and after testing.

Test weight:

granite, length 11.9 cm, width 8.2 cm, height 8.4 cm, weight 2.4 kg

Tampons:

sterile, length 150 mm, disposable, tip made of pure cotton without compounds inhibiting or supporting the effect of product solution or growth of microorganisms, producer F.L. Medical

Parafilm:

Parafilm® M, 10.2 cm x 38 m, producer Brand

disposable, protecting the horizontal surface and vertical surfaces before contamination during wiping,

Test procedure:

1. Preparation of the test suspension
2. Determination of CFU in the test suspension
3. Quantitative test on carriers according to EN 16615
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 on nonporous surface in the field 1 by at least a 5 lg reduction (10^5).

$R = D_{Ci} / N_a$ or $\lg R = \lg D_{Ci} - \lg N_a$ the reduction in viability, the drying time: 20 – 35 min

Yeasticidal activity – the capability of a product to produce a reduction in the number of viable yeast cells of *Candida albicans* under defined conditions on nonporous surface in the field 1 by at least a 4 lg reduction (10^4).

$R = D_{Ci} / N_a$ or $\lg R = \lg D_{Ci} - \lg N_a$ the reduction in viability, the drying time: 15 – 20 min

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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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The standard:

EN 16615:2015 Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) – Test method and requirements (phase 2, step 2) April 2015

12. Testing the efficacy of chemical disinfectant **JACLOR®** on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces

Tab No. 12.1 Verification of methodology, temperature 20°C, clean conditions

Validation of suspension (N_{V0})				Neutralizer toxicity control (B)				Method validation (C), product conc. 1 tab/3 l			
V_{e1}	78	$\Phi_{N_{V0}} = 71$		V_{e1}	86	$\Phi_B = 68$		V_{e1}	68	$\Phi_C = 71.5$	
V_{e2}	64			V_{e2}	50			V_{e2}	75		
$30 < \Phi_{N_{V0}} \leq 160$				$\Phi_B \geq 0.5 \Phi_{N_{V0}}$				$\Phi_C \geq 0.5 \Phi_{N_{V0}}$			
x	yes		no	x	yes		no	x	yes		no

Tab No. 12.2 Test suspension

Test suspension N	Dilution	V_{e1}	V_{e1}	Test suspension N_0
$\Phi = 191 \times 10^7 = \lg 9.28$	10^{-7}	178	208	$N_0 = N/20, \lg N_0 = 7.98$
$9.17 \leq \lg N \leq 9.70$	10^{-8}	18	16	$7.88 \leq \lg N_0 \leq 8.40$
				x yes no

Tab No. 12.2.1 Drying in time 0

Drying control (D_{C0})	Dilution	V_{e1}	V_{e1}	$\lg D_{C0} = \lg (\Phi \times 5 \times 10^4) = 6.97$
	10^{-4}	208	162	$6.88 \leq \lg D_{C0} \leq 8.40$
	10^{-5}	21	17	
				x yes no

Tab No. 12.2.2.1 Drying in time 30 min

Drying control (D_{Ct})	Dilution	V_{e1}	V_{e1}	$\lg D_{Ct} = \lg (\Phi \times 5 \times 10^4) = 6.90$
	10^{-4}	130	182	$6.88 \leq \lg D_{Ct} \leq 8.40$
	10^{-5}	15	19	
				x yes no

Tab No. 12.2.2.2 Drying in time 60 min

Drying control (D_{Ct})	Dilution	V_{e1}	V_{e1}	$\lg D_{Ct} = \lg (\Phi \times 5 \times 10^4) = 6.90$
	10^{-4}	146	168	$6.88 \leq \lg D_{Ct} \leq 8.40$
	10^{-5}	17	16	
				x yes no

Tab No. 12.3.1.1 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions, 30 min

Field / contact time (min)	Dilution after test procedure	V_e	$N_w = (\Phi \times 5)$	N_w requirement >10 cfu/25 cm ²
2 / 30	10^0	14	70	yes
3 / 30	10^0	6	30	yes
4 / 30	10^0	9	45	yes

Tab No. 12.3.1.2 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions, 60 min

Field / contact time (min)	Dilution after test procedure	V_e	$N_w = (\Phi \times 5)$	N_w requirement >10 cfu/25 cm ²
2 / 60	10^0	11	55	yes
3 / 60	10^0	6	30	yes
4 / 60	10^0	5	25	yes

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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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Tab No. 12.3.2.1 Test – the effect of **JACLOR®** (Wipe with product) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions, field 2-4, 30 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement ≤ 50 cfu/25 cm ²
1 tab/3 l / 30 / clean /2	10 ⁰	0	<14	yes
1 tab/3 l / 30 / clean /3	10 ⁰	0	<14	yes
1 tab/3 l / 30 / clean /4	10 ⁰	0	<14	yes

Tab No. 12.3.2.2 Test – the effect of **JACLOR®** (Wipe with product) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions, field 2-4, 60 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement ≤ 50 cfu/25 cm ²
1 tab/3 l / 60 / clean /2	10 ⁰	0	<14	yes
1 tab/3 l / 60 / clean /3	10 ⁰	0	<14	yes
1 tab/3 l / 60 / clean /4	10 ⁰	0	<14	yes

Tab No. 12.3.2.3 Test – the effect of **JACLOR®** (Wipe with product) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions, field 2-4, 60 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement ≤ 50 cfu/25 cm ²
1 tab/5 l / 60 / clean /2	10 ⁰	0	<14	yes
1 tab/5 l / 60 / clean /3	10 ⁰	0	<14	yes
1 tab/5 l / 60 / clean /4	10 ⁰	0	<14	yes

Tab No. 12.3.3.1 Test – the effect of **JACLOR®** (Wipe with product) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions, field 1, 30 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a (\Phi \times 5)$	$\lg R$ ($\lg D_{Ct} = 6.90$)
1 tab/3 l / 30 / clean /1	10 ⁰	<14	<14	<1.85	≥ 5.05

Tab No. 12.3.3.2 Test – the effect of **JACLOR®** (Wipe with product) on *Pseudomonas aeruginosa* ATCC 15442 on non-porous surfaces, clean conditions, field 1, 60 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a (\Phi \times 5)$	$\lg R$ ($\lg D_{Ct} = 6.90$)
1 tab/3 l / 60 / clean /1	10 ⁰	<14	<14	<1.85	≥ 5.05
1 tab/5 l / 60 / clean /1	10 ⁰	<14	<14	<1.85	≥ 5.05

Tab No. 12.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
Wipe with product, 1 tab/3 l, 30 min	18.7	18.0	0.7
Wipe with product, 1 tab/3 l, 60 min	18.7	17.7	1.0
Wipe with product, 1 tab/5 l, 30 min	18.9	17.9	1.0
Wipe with hard water + polysorbate 80, 30 min	19.0	17.9	1.1
Wipe with hard water + polysorbate 80, 60 min	19.0	18.0	1.0

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 in the bacterial test suspension, N_{V0} = the number of cfu/ml in the bacterial test suspension for validation, 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 validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct}/N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ 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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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13. Testing the efficacy of chemical disinfectant **JACLOR®** on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces

Tab No. 13.1 Verification of methodology, temperature 20°C, clean conditions

Validation of suspension (N _{v0})				Neutralizer toxicity control (B)				Method validation (C), product conc. 1 tab/3 l			
V _{e1}	47	Φ _{Nv0} = 43	no	V _{e1}	37	Φ _B = 41.5	no	V _{e1}	48	Φ _C = 43	no
V _{e2}	39			V _{e2}	46			V _{e2}	38		
30 ≤ Φ _{Nv0} ≤ 160				Φ _B ≥ 0.5 Φ _{Nv0}				Φ _C ≥ 0.5 Φ _{Nv0}			
x	yes			x	yes			x	yes		

Tab No. 13.2 Test suspension

Test suspension N	Dilution	V _{e1}	V _{e1}	Test suspension N ₀ N ₀ = N/20, lg N ₀ = 8.27 7.88 ≤ lg N ₀ ≤ 8.40			
Φ = 37.5 x 10 ⁵ = lg 9.57	10 ⁻⁷	>330	>330				
9.17 ≤ lg N ≤ 9.70	10 ⁻⁸	36	39				
				x	yes		no

Tab No. 13.2.1 Drying in time 0

Drying control (D _{c0})	Dilution	V _{e1}	V _{e1}	lg D _{c0} = lg (Φ x 5 x 10 ⁵) = 7.60 6.88 ≤ lg D _{c0} ≤ 8.40			
	10 ⁻⁴	>330	>330				
	10 ⁻⁵	104	55				
				x	yes		no

Tab No. 13.2.2.1 Drying in time 30 min

Drying control (D _{c1})	Dilution	V _{e1}	V _{e1}	lg D _{c1} = lg (Φ x 5 x 10 ⁵) = 7.51 6.88 ≤ lg D _{c1} ≤ 8.40			
	10 ⁻⁴	>330	>330				
	10 ⁻⁵	78	52				
				x	yes		no

Tab No. 13.2.2.2 Drying in time 60 min

Drying control (D _{c1})	Dilution	V _{e1}	V _{e1}	lg D _{c1} = lg (Φ x 5 x 10 ⁵) = 7.45 6.88 ≤ lg D _{c1} ≤ 8.40			
	10 ⁻⁴	>330	>330				
	10 ⁻⁵	70	42				
				x	yes		no

Tab No. 13.3.1.1 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, 30 min

Field / contact time (min)	Dilution after test procedure	V _c	N _w = (Φ x 5)	N _w requirement >10 cfu/25 cm ²
2 / 30	10 ⁰	10	50	yes
3 / 30	10 ⁰	9	45	yes
4 / 30	10 ⁰	8	40	yes

Tab No. 13.3.1.2 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, 60 min

Field / contact time (min)	Dilution after test procedure	V _c	N _w = (Φ x 5)	N _w requirement >10 cfu/25 cm ²
2 / 60	10 ⁰	9	45	yes
3 / 60	10 ⁰	3	15	yes
4 / 60	10 ⁰	3	15	yes

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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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Tab No. 13.3.2.1 Test – the effect of **JACLOR®** (Wipe with product) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, field 2-4, 30 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement ≤ 50 cfu/25 cm ²
1 tab/3 l / 30 / clean /2	10 ⁰	2	<14	yes
1 tab/3 l / 30 / clean /3	10 ⁰	3	15	yes
1 tab/3 l / 30 / clean /4	10 ⁰	5	25	yes

Tab No. 13.3.2.2 Test – the effect of **JACLOR®** (Wipe with product) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, field 2-4, 60 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement ≤ 50 cfu/25 cm ²
1 tab/3 l / 60 / clean /2	10 ⁰	6	30	yes
1 tab/3 l / 60 / clean /3	10 ⁰	9	45	yes
1 tab/3 l / 60 / clean /4	10 ⁰	2	10	yes

Tab No. 13.3.2.3 Test – the effect of **JACLOR®** (Wipe with product) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, field 2-4, 60 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement ≤ 50 cfu/25 cm ²
1 tab/5 l / 60 / clean /2	10 ⁰	5	25	yes
1 tab/5 l / 60 / clean /3	10 ⁰	5	25	yes
1 tab/5 l / 60 / clean /4	10 ⁰	6	30	yes

Tab No. 13.3.3.1 Test – the effect of **JACLOR®** (Wipe with product) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, field 1, 30 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a (\Phi \times 5)$	$\lg R$ ($\lg D_{Ct} = 7.51$)
1 tab/3 l / 30 / clean /1	10 ⁰	17	19	1.95	5.56

Tab No. 13.3.3.2 Test – the effect of **JACLOR®** (Wipe with product) on *Staphylococcus aureus* ATCC 6538 on non-porous surfaces, clean conditions, field 1, 60 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a (\Phi \times 5)$	$\lg R$ ($\lg D_{Ct} = 7.45$)
1 tab/3 l / 60 / clean /1	10 ⁰	<14	<14	<1.85	≥ 5.60
1 tab/5 l / 60 / clean /1	10 ⁰	<14	<14	<1.85	≥ 5.60

Tab No. 13.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
Wipe with product, 1 tab/3 l, 30 min	19.0	18.0	1.0
Wipe with product, 1 tab/3 l, 60 min	18.9	18.0	0.9
Wipe with product, 1 tab/5 l, 30 min	19.2	18.1	1.1
Wipe with hard water + polysorbate 80, 30 min	19.1	18.0	1.1
Wipe with hard water + polysorbate 80, 60 min	19.0	18.3	0.7

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 in the bacterial test suspension, N_{V0} = the number of cfu/ml in the bacterial test suspension for validation, 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 validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct} / N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ 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: 15.4. – 7.5.2020
 Delivered amount: 1 kg
 Batch No: 07
 Page: 19

14. Testing the efficacy of chemical disinfectant JACLOR® on *Enterococcus hirae* ATCC 10541 on non-porous surfaces

Tab No. 14.1 Verification of methodology, temperature 20°C, clean conditions

Validation of suspension (N _{v0})			Neutralizer toxicity control (B)			Method validation (C), product conc. 1 tab/3 l		
V _{e1}	45	Φ _{Nv0} = 40	V _{e1}	29	Φ _B = 34	V _{e1}	27	Φ _C = 35.5
V _{e2}	35		V _{e2}	39		V _{e2}	44	
30 ≤ Φ _{Nv0} ≤ 160			Φ _B ≥ 0.5 Φ _{Nv0}			Φ _C > 0.5 Φ _{Nv0}		
x	yes	no	x	yes	no	x	yes	no

Tab No. 14.2 Test suspension

Test suspension N	Dilution	V _{e1}	V _{e1}	Test suspension N ₀ N ₀ = N/20, lg N ₀ = 7.96 7.88 ≤ lg N ₀ ≤ 8.40		
Φ = 183 x 10 ⁷ = lg 9.26	10 ⁻⁷	180	180			
9.17 ≤ lg N ≤ 9.70	10 ⁻⁸	25	18			
				x	yes	no

Tab No. 14.2.1 Drying in time 0

Drying control (D _{c0})	Dilution	V _{e1}	V _{e1}	lg D _{c0} = lg (Φ x 5 x 10 ⁵) = 7.36 6.88 ≤ lg D _{c0} ≤ 8.40		
	10 ⁻⁴	>330	>330			
	10 ⁻⁵	43	49			
				x	yes	no

Tab No. 14.2.2.1 Drying in time 30 min

Drying control (D _{c1})	Dilution	V _{e1}	V _{e1}	lg D _{c1} = lg (Φ x 5 x 10 ⁵) = 7.34 6.88 ≤ lg D _{c1} ≤ 8.40		
	10 ⁻⁴	>330	>330			
	10 ⁻⁵	42	45			
				x	yes	no

Tab No. 14.2.2.2 Drying in time 60 min

Drying control (D _{c1})	Dilution	V _{e1}	V _{e1}	lg D _{c1} = lg (Φ x 5 x 10 ⁵) = 7.34 6.88 ≤ lg D _{c1} ≤ 8.40		
	10 ⁻⁴	>330	>330			
	10 ⁻⁵	43	45			
				x	yes	no

Tab No. 14.3.1.1 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions, 30 min

Field / contact time (min)	Dilution after test procedure	V _c	N _w = (Φ x 5)	N _w requirement >10 cfu/25 cm ²
2 / 30	10 ⁰	3	15	yes
3 / 30	10 ⁰	3	15	yes
4 / 30	10 ⁰	22	110	yes

Tab No. 14.3.1.2 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions, 60 min

Field / contact time (min)	Dilution after test procedure	V _c	N _w = (Φ x 5)	N _w requirement >10 cfu/25 cm ²
2 / 60	10 ⁰	14	70	yes
3 / 60	10 ⁰	6	30	yes
4 / 60	10 ⁰	14	70	yes

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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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Tab No. 14.3.2.1 Test – the effect of **JACLOR®** (Wipe with product) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions, field 2-4, 30 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement ≤ 50 cfu/25 cm ²
1 tab/3 l / 30 / clean /2	10 ⁰	4	20	yes
1 tab/3 l / 30 / clean /3	10 ⁰	9	45	yes
1 tab/3 l / 30 / clean /4	10 ⁰	4	20	yes

Tab No. 14.3.2.2 Test – the effect of **JACLOR®** (Wipe with product) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions, field 2-4, 60 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement ≤ 50 cfu/25 cm ²
1 tab/3 l / 60 / clean /2	10 ⁰	3	15	yes
1 tab/3 l / 60 / clean /3	10 ⁰	5	25	yes
1 tab/3 l / 60 / clean /4	10 ⁰	4	20	yes

Tab No. 14.3.2.3 Test – the effect of **JACLOR®** (Wipe with product) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions, field 2-4, 60 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement ≤ 50 cfu/25 cm ²
1 tab/5 l / 60 / clean /2	10 ⁰	1	<14	yes
1 tab/5 l / 60 / clean /3	10 ⁰	7	35	yes
1 tab/5 l / 60 / clean /4	10 ⁰	3	15	yes

Tab No. 14.3.3.1 Test – the effect of **JACLOR®** (Wipe with product) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions, field 1, 30 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a (\Phi \times 5)$	$\lg R$ ($\lg D_{Ct} = 7.34$)
1 tab/3 l / 30 / clean /1	10 ⁰	<14	<14	<1.85	≥ 5.49

Tab No. 14.3.3.2 Test – the effect of **JACLOR®** (Wipe with product) on *Enterococcus hirae* ATCC 10541 on non-porous surfaces, clean conditions, field 1, 60 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a (\Phi \times 5)$	$\lg R$ ($\lg D_{Ct} = 7.34$)
1 tab/3 l / 60 / clean /1	10 ⁰	<14	<14	<1.85	≥ 5.49
1 tab/5 l / 60 / clean /1	10 ⁰	<14	<14	<1.85	≥ 5.49

Tab No. 14.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
Wipe with product, 1 tab/3 l, 30 min	19.1	18.1	1.0
Wipe with product, 1 tab/3 l, 60 min	19.2	18.0	1.2
Wipe with product, 1 tab/5 l, 30 min	19.2	18.1	1.1
Wipe with hard water + polysorbate 80, 30 min	19.2	18.4	0.8
Wipe with hard water + polysorbate 80, 60 min	19.4	18.4	1.0

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 in the bacterial test suspension, N_{v0} = the number of cfu/ml in the bacterial test suspension for validation, 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 validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct}/N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ 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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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15. Testing the efficacy of chemical disinfectant **JACLOR®** on *Candida albicans* ATCC 10231 on non-porous surfaces

Tab No. 15.1 Verification of methodology, temperature 20°C, clean conditions

Validation of suspension (N _{v0})			Neutralizer toxicity control (B)			Method validation (C), product conc. 1 tab/3 l		
V _{e1}	55	Φ _{Nv0} = 42.5	V _{e1}	45	Φ _B = 41	V _{e1}	31	Φ _C = 40
V _{e2}	30		V _{e2}	37		V _{e2}	49	
30 ≤ Φ _{Nv0} ≤ 160			Φ _B ≥ 0.5 Φ _{Nv0}			Φ _C ≥ 0.5 Φ _{Nv0}		
x	yes	no	x	yes	no	x	yes	no

Tab No. 15.2 Test suspension

Test suspension N	Dilution	V _{e1}	V _{e1}	Test suspension N ₀ N ₀ = N/20, lg N ₀ = 7.39 6.88 ≤ lg N ₀ ≤ 7.40
Φ = 49 x 10 ⁷ = lg 8.69 8.17 ≤ lg N ≤ 8.70	10 ⁻⁶	> 330	> 330	
	10 ⁻⁷	62	36	
				x yes no

Tab No. 15.2.1 Drying in time 0

Drying control (D _{c0})	Dilution	V _{e1}	V _{e1}	lg D _{c0} = lg (Φ x 5 x 10 ⁴) = 6.68 5.88 ≤ lg D _{c0} ≤ 7.40
	10 ⁻³	> 330	> 330	
	10 ⁻⁴	90	100	
				x yes no

Tab No. 15.2.2.1 Drying in time 30 min

Drying control (D _{c1})	Dilution	V _{e1}	V _{e1}	lg D _{c1} = lg (Φ x 5 x 10 ⁴) = 6.58 5.88 ≤ lg D _{c1} ≤ 7.40
	10 ⁻³	> 330	> 330	
	10 ⁻⁴	56	96	
				x yes no

Tab No. 15.2.2.2 Drying in time 60 min

Drying control (D _{c1})	Dilution	V _{e1}	V _{e1}	lg D _{c1} = lg (Φ x 5 x 10 ⁴) = 6.51 5.88 ≤ lg D _{c1} ≤ 7.40
	10 ⁻³	> 330	> 330	
	10 ⁻⁴	40	88	
				x yes no

Tab No. 15.3.1.1 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Candida albicans* ATCC 10231 on non-porous surfaces, clean conditions, 30 min

Field / contact time (min)	Dilution after test procedure	V _c	N _w = (Φ x 5)	N _w requirement >10 cfu/25 cm ²
2 / 30	10 ⁰	6	30	yes
3 / 30	10 ⁰	3	15	yes
4 / 30	10 ⁰	4	20	yes

Tab No. 15.3.1.2 Test with water N_w – the effect of water (Wipe with hard water + polysorbate 80) on *Candida albicans* ATCC 10231 on non-porous surfaces, clean conditions, 60 min

Field / contact time (min)	Dilution after test procedure	V _c	N _w = (Φ x 5)	N _w requirement >10 cfu/25 cm ²
2 / 60	10 ⁰	4	20	yes
3 / 60	10 ⁰	3	15	yes
4 / 60	10 ⁰	3	15	yes

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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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Tab No. 15.3.2.1 Test – the effect of **JACLOR®** (Wipe with product) on *Candida albicans* ATCC 10231 on non-porous surfaces, clean conditions, field 2-4, 30 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement ≤ 50 cfu/25 cm ²
1 tab/5 l / 30 / clean /2	10 ⁰	0	<14	yes
1 tab/5 l / 30 / clean /3	10 ⁰	0	<14	yes
1 tab/5 l / 30 / clean /4	10 ⁰	0	<14	yes

Tab No. 15.3.2.2 Test – the effect of **JACLOR®** (Wipe with product) on *Candida albicans* ATCC 10231 on non-porous surfaces, clean conditions, field 2-4, 30 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement ≤ 50 cfu/25 cm ²
1 tab/10 l / 30 / clean /2	10 ⁰	0	<14	yes
1 tab/10 l / 30 / clean /3	10 ⁰	0	<14	yes
1 tab/10 l / 30 / clean /4	10 ⁰	0	<14	yes

Tab No. 15.3.2.3 Test – the effect of **JACLOR®** (Wipe with product) on *Candida albicans* ATCC 10231 on non-porous surfaces, clean conditions, field 2-4, 60 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_c	$N_a = (\Phi \times 5)$	N_a requirement ≤ 50 cfu/25 cm ²
1 tab/10 l / 60 / clean /2	10 ⁰	0	<14	yes
1 tab/10 l / 60 / clean /3	10 ⁰	0	<14	yes
1 tab/10 l / 60 / clean /4	10 ⁰	0	<14	yes

Tab No. 15.3.3.1 Test – the effect of **JACLOR®** (Wipe with product) on *Candida albicans* ATCC 10231 on non-porous surfaces, clean conditions, field 1, 30 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a (\Phi \times 5)$	$\lg R$ ($\lg D_{Ct} = 6.58$)
1 tab/5 l / 30 / clean /1	10 ⁰	<14	<14	<1.85	≥ 4.73
1 tab/10 l / 30 / clean /1	10 ⁰	<14	<14	<1.85	≥ 4.73

Tab No. 15.3.3.2 Test – the effect of **JACLOR®** (Wipe with product) on *Candida albicans* ATCC 10231 on non-porous surfaces, clean conditions, field 1, 60 min

Test concentration /contact time (min) /conditions / field	Dilution after test procedure	V_{c1}	V_{c2}	$\lg N_a (\Phi \times 5)$	$\lg R$ ($\lg D_{Ct} = 6.51$)
1 tab/10 l / 60 / clean /1	10 ⁰	<14	<14	<1.85	≥ 4.66

Tab No. 15.4 Test – weight of wipes before and after testing

Weight of wipes	Weight before testing (g)	Weight after testing (g)	Difference (g)
Wipe with product, 1 tab/3 l, 30 min	19.0	18.1	0.9
Wipe with product, 1 tab/3 l, 60 min	19.1	18.2	0.9
Wipe with product, 1 tab/5 l, 30 min	19.1	18.0	1.1
Wipe with hard water + polysorbate 80, 30 min	19.1	18.1	1.0
Wipe with hard water + polysorbate 80, 60 min	19.2	18.3	1.1

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 in the bacterial test suspension, N_{V0} = the number of cfu/ml in the bacterial test suspension for validation, 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 validation, B – neutralizer toxicity validation, C – method validation $R = D_{Ct} / N_a$ or $\lg R = \lg D_{Ct} - \lg N_a$ 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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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16. Evaluation of bactericidal and yeasticidal activity of the product **JACLOR®**

Tab No. 16.1 The efficacy of chemical disinfectant **JACLOR®** on test strains – bactericidal and yeasticidal activity on non-porous surfaces, field 1

Bactericidal and yeasticidal activity of the product (EN 16615:2015)						
Strain	Test temperature [°C]	Contact time [min]	Product test concentrations	Interfering substances - conditions	lg R EN 16615:2015	lg R
<i>Pseudomonas aeruginosa</i> ATCC 15442	20	30	1 tab/3 l	clean	≥ 5	> 5
<i>Staphylococcus aureus</i> ATCC 6538	20	30	1 tab/3 l	clean	≥ 5	> 5
<i>Enterococcus hirae</i> ATCC 10541	20	30	1 tab/3 l	clean	≥ 5	> 5
<i>Candida albicans</i> ATCC 10231	20	30	1 tab/5 l	clean	≥ 4	> 4
<i>Candida albicans</i> ATCC 10231	20	30	1 tab/10 l	clean	≥ 4	> 4
<i>Pseudomonas aeruginosa</i> ATCC 15442	20	60	1 tab/3 l	clean	≥ 5	> 5
<i>Staphylococcus aureus</i> ATCC 6538	20	60	1 tab/3 l	clean	≥ 5	> 5
<i>Enterococcus hirae</i> ATCC 10541	20	60	1 tab/3 l	clean	≥ 5	> 5
<i>Pseudomonas aeruginosa</i> ATCC 15442	20	60	1 tab/5 l	clean	≥ 5	> 5
<i>Staphylococcus aureus</i> ATCC 6538	20	60	1 tab/5 l	clean	≥ 4	> 5
<i>Enterococcus hirae</i> ATCC 10541	20	60	1 tab/5 l	clean	≥ 5	> 5
<i>Candida albicans</i> ATCC 10231	20	60	1 tab/10 l	clean	≥ 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 bacterial test suspension, N_{v0} = the number of cfu/ml of the bacterial test suspension for validation, 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 validation, B – neutralizer toxicity validation, C – method validation) $R = N_0 / N_a$ = the reduction in viability, or $\lg R = \lg N_0 - \lg N_a$

Prepared by: Mgr. Karolína Světlíková, 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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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Interpretation:

Results of tests are in Tabs.

According to EN 13697:2015+A1:2019 the tested product **JACLOR**[®], batch No. 07, in the concentration 1 tab/5 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** on carriers (stainless steel discs) the number of viable yeast cells of *Candida albicans* ATCC 10231 by at least a 3 lg reduction.

According to EN 13697:2015+A1:2019 the tested product **JACLOR**[®], batch No. 07, in the concentration 1 tab/3 l, diluted in hard water, in the contact time 60 min under clean conditions at temperature 20 °C ± 1 °C by the dilution neutralization method **decreased** on carriers (stainless steel discs) the number of mould spores of *Aspergillus brasiliensis* (*niger*) ATCC 16404 by at least a 3 lg reduction.

According to EN 13704:2018 the tested product **JACLOR**[®], batch No. 07, in the concentration 1 tab/3 l, diluted in hard water, in the contact time 60 min under clean conditions at temperature 20 °C ± 1 °C by the dilution neutralization method **decreased** the number of viable bacterial spores of *Bacillus subtilis* ATCC 6633, *Bacillus cereus* ATCC 12826 by at least a 3 lg reduction (EN 13704:2018).

According to EN 14476:2013 +A2:2019 the tested product **JACLOR**[®], batch No. 07, in the concentration 1 tab/5 l, diluted in hard water, in the contact time 30 min under clean conditions at temperature 20 °C ± 1 °C **proved** by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious *Adenovirus* type 5, strain Adenoid 75, ATCC VR-5 particles under defined conditions by at least a 4 lg reduction.

According to EN 14476:2013 +A2:2019 the tested product **JACLOR**[®], batch No. 07, in the concentration 1 tab/5 l, diluted in hard water, in the contact time 30 min under clean conditions at temperature 20 °C ± 1 °C **proved** by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious *Murine norovirus* (*MNV*) strain S99, RVB-651 particles under defined conditions by at least a 4 lg reduction.

According to EN 14476:2013+A2:2019 the tested product **JACLOR**[®], batch No. 07, in the concentration 1 tab/5 l, diluted in hard water, in the contact time 30 min under clean conditions at temperature 20 °C ± 1 °C **proved** by the method of virus titration on monolayers of cells on microtitre plates to reduce the number of infectious *Poliovirus* type 1, LSc-2ab, particles under defined conditions by at least a 4 lg reduction.

According to EN 16615:2015 the tested product **JACLOR**[®], batch No. 07, in the concentration 1 tab/3 l, diluted in hard water (wet wipe), in the contact time 30 min and in the concentrations 1 tab/3 l and 1 tab/5 l, diluted in hard water (wet wipe), in the contact time 60 min under clean conditions at temperature 20 °C ± 2.5 °C by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of viable bacterial cells of *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 10541 by at least a 5 lg reduction.

According to EN 16615:2015 the tested product **JACLOR**[®], batch No. 07, in the concentration 1 tab/10 l, diluted in hard water (wet wipe), in the contact time 60 min and in the concentrations 1 tab/5 l and 1 tab/10 l, diluted in hard water (wet wipe), in the contact time 30 min under clean conditions at temperature 20 °C ± 2.5 °C by the dilution neutralization method **decreased** on non-porous surfaces on field 1 the number of viable yeast cells of *Candida albicans* ATCC 10231 by at least a 4 lg reduction.

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: 15.4. – 7.5.2020

Delivered amount: 1 kg

Batch No: 07

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Conclusion:

The product **JACLOR®** is capable of reducing the number vegetative yeast cells of the relevant organism under defined conditions (EN 13697:2015+A1:2019 – C.a., 1 tab/5 l, 15 min, 1 tab/10 l, 30 min, clean, 18 °C – 25 °C) to the declared values, and consequently, can be called yeasticidal.

The product **JACLOR®** is capable of reducing the number of mould spores of the relevant organism under defined conditions (EN 13697:2015+A1:2019 – A.b., 1 tab/3 l, 60 min, 18 °C – 25 °C) to the declared values, and consequently, can be called fungicidal.

The product **JACLOR®** is capable of reducing the number of viable bacterial spores of the relevant organisms under defined conditions (EN 13704:2018 – 1 tab/3 l, 60 min, clean, 20 °C) to the declared values, and consequently, can be called sporicidal.

The product **JACLOR®** is capable of reducing the number of infectious *Adenovirus*, *Murine norovirus (MNV)* and *Poliovirus* particles under defined conditions (EN 14476:2013 +A2:2019 – 1 tab/5 l, 30 min, clean, 20 °C) to the declared values, and consequently, can be called virucidal.

The product **JACLOR®** is capable of reducing the number of viable bacterial cells of the relevant organisms on non-porous surfaces under defined conditions (EN 16615:2015 – (used wipes with the product) 1 tab/3 l, 30 min and 60 min, 1 tab/5 l, 60 min, clean, 20 °C ± 2.5 °C) to the declared values and, consequently, can be called bactericidal on non-porous surfaces.

The product **JACLOR®** is capable of reducing the number of viable vegetative yeast cells of the relevant organism on non-porous surfaces under defined conditions (EN 16615:2015 – (used wipes with the product) 1 tab/5 l and 1 tab/10 l, 30 min, 1 tab/10 l, 60 min, clean, 20 °C ± 2.5 °C) to the declared values and, consequently, can be called yeasticidal on non-porous surfaces.

22.7.2020, Hodonín

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

