

DR. F. H. H. BRILL · C/O DR. BRILL + PARTNER GMBH · STIEGSTÜCK 34 · DE-22339 HAMBURG

Romdezimed Production SRL
Sos. Pandurilor Nr.29
RO - Bucuresti, Bl.P2a, ap.31, Sector 5

Hamburg, 08 May 2020

Expert opinion

Fungicidal Activity of **JACLOR** in the quantitative suspension test according to DIN EN 13624:2013 (Phase 2, Step 1)

The disinfectant **JACLOR** was tested and evaluated according to DIN EN 13624:2013 „Chemical Disinfectants and Antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test Method and Requirements (Phase 2, Step 1)“. The test was accomplished at $30^{\circ}\text{C} \pm 1^{\circ}\text{C}$ test temperature. Test stock solutions were prepared by dissolving 1 tab in 5 L WSH or 1 tab in 1.5 L WSH.

According to the test report no. L20/0183.2 dated 08/05/2020 of Dr. Brill + Partner GmbH the preparation showed fungicidal activity under clean conditions at $30^{\circ}\text{C} \pm 1^{\circ}\text{C}$ test temperature.

JACLOR complies with the requirements of DIN EN 13624:2013 (phase 2, step 1) with the following concentration-time relationship:

Claim	Organic load	Test temperature	Concentration	Contact time
Yeasticidal	clean conditions	$30^{\circ}\text{C} \pm 1^{\circ}\text{C}$	1 Tab in 15 l	30 minutes
Fungicidal	clean conditions	$30^{\circ}\text{C} \pm 1^{\circ}\text{C}$	1 Tab in 3 l	30 minutes
	clean conditions	$30^{\circ}\text{C} \pm 1^{\circ}\text{C}$	1 Tab in 10 l	60 minutes


Dr. Florian H. H. Brill



Test report no L20/0183.2

Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of **JACLOR** in the medical area according to DIN EN 13624:2013 (Phase 2, step 1)*

In accordance with your order, we tested the preparation **JACLOR** for its activity in the quantitative suspension test according to DIN EN 13624:2013* under clean conditions.

1 General Information and Material

1.1 Client

Client: Romdezimed Production SRL, Mrs Badescu, Sos. Pandurilor Nr.29, RO
- Bucuresti, Bl.P2a, ap.31, Sector 5

Date of order: 28/02/2020

Confirmation no.: 212270

1.2 Identification of Test Laboratory

Location: Dr. Brill + Partner GmbH · Institute for Hygiene and Microbiology,
Stiegstück 34, DE-22339 Hamburg, Germany

Study manager: Dipl.-Ing. Dr. rer. nat. Andreas Kampe

Scientific assistant: Dipl.-Biol. Henrik Gabriel

Laboratory technicians: Martina Müller

1.3 Table of Contents

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1.4 Identification of Sample

Name of product: **JACLOR**

Batch no.: -

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Germany, Telephone +49. 40. 557631-0, Telefax +49. 40. 557631-11, www.brillhygiene.com. No copying or transmission, in whole or in part, of this test report without the explicit prior written permission. The test results exclusively apply to the tested samples. Information on measurement uncertainty on request. © Dr. Brill + Partner GmbH 2020



Manufacturer: Romdezimed Production SRL, RO - Bucuresti, Bl.P2a, ap.31, Sector 5
Date of delivery: 02/03/2020
Storage conditions: room temperature and darkness
Appearance of product: white tabs
Odour: characteristic
Recommended diluent: Tap water
Diluent used: water of standardised hardness (WSH, pH 7.0)
pH value, concentrate: -
Active agents (Manufacturer's data): 78 % Dichloroisocyanurate sodium salt dihydrate

1.5 Test Conditions

Test period: 15/04/ - 04/05/2020
Lab task no.: L20/0183.2 + .6
Product test concentrations *C. albicans*: 5.0 + 15 + 50 % of stock solution 1
Product test concentrations *A. brasiliensis*:
30 min: 5.0 + 15 + 50 % of stock solution 2
60 min: 1.5 + 4.5 + 15 % of stock solution 2
Exposure time: 30 minutes (both) + 60 minutes (*A. brasiliensis*)
Test temperature: 30°C ± 1°C
Incubation temperature: 30°C ± 1°C
Organic load: clean conditions (0.3 g/L bovine albumin)
Neutraliser: 30 g/L polysorbate 80, 30 g/L saponine, 3 g/L lecithin, 1 g/L histidine,
5 g/L sodium thiosulphate (TLSH-Nt)
Test organisms: *Candida albicans* ATCC 10231
Aspergillus brasiliensis ATCC 16404

2 Methods

The tests were carried out according to DIN EN 13624:2013 „Chemical Disinfectants and Antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test Method and Requirements (Phase 2, Step 1)“.

The test was accomplished at 30°C ± 1°C test temperature. The test stock solution 1 for tests with *C. albicans* was prepared by dissolving 1 tab in 5 L WSH until no residue was visible. The test stock solution 2 for tests with *A. brasiliensis* was prepared by dissolving 1 tab in 1.5 L WSH until no residue was visible. Dilutions were prepared from these stock solutions.

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3 Results

The test results based on DIN EN 13624: 2013 are summarised in tables 1 to 2.

The test fungi were sufficiently (RF >4) inactivated with the following concentration-time relationship:

Yeasticidal:	clean conditions	15 % of stock solution 1	30 minutes
Fungicidal:	clean conditions	50 % of stock solution 2	30 minutes
	clean conditions	15 % of stock solution 2	60 minutes

Hamburg, 08/05/2020

Dipl.-Biol. Henrik Gabriel
Head of Laboratory

Dipl.-Ing. Dr. rer. nat. Andreas Kampe
Quality control



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Table 1: Validation, Controls and Evaluation (DIN EN 13624:2013*)

Product name: **JACLOR** Batch: -
Test organism: *Candida albicans* Temperature: 30°C ± 1°C
Organic load: clean conditions Neutraliser: TLSH-Nt
Contact time: **30 minutes** Lab task no.: L20/0183.2

Suspension for validation (N _{vo})			Control of test conditions (A)				Control of neutraliser (B)				Vali. of inactivation (C) Conc.: 50,00 %									
Microbial count			x̄		Microbial count		x̄		Microbial count		x̄		Microbial count		x̄					
V _{c1}	51		54,5		V _{c1}	31		33,5		V _{c1}	38		38,5		V _{c1}	48		53		
V _{c2}	58				V _{c2}	36				V _{c2}	39				V _{c2}	58				
30 ≤ x̄ of N _{vo} ≤ 160			Yes		x̄ of A(30') is ≥ 0,5 x x̄ of N _{vo} ?				Yes		x̄ of B is ≥ 0,5 x x̄ of N _{vo} ?				Yes		x̄ of C(30') is ≥ 0,5 x x̄ of N _{vo} ?		Yes	
Suspension for Validation (N _{vb})			V _{c1}		V _{c2}		x̄		30 ≤ x̄ of N _{vo} ≤ 160?											
			42		55		48,5		Yes											

Test suspension (N and N ₀)	N	Microbial count				V _{c1}	V _{c2}	x̄ _{wm} / lg N	N ₀ =N/10; lg N ₀	6,17 ≤ N ₀ ≤ 6,70?
	1,00E-05	>330		>330		>330	>330	2,40E+07	6,38	Yes
	1,00E-06	21		27		21	27	7,38		

Concentration of Stock solution 1 [%]	N	Microbial count				V _{c1}	V _{c2}	N _a = x̄ x 10	lg N _a	lg R (lg N ₀ = 6,38)
	5,00	1,00E+00	>330		>330		>330	>330	>3,30E+04	> 4,52
	1,00E-01	>330		>330		>330	>330			
15,00	1,00E+00	0		0		<14	<14	<1,40E+02	< 2,15	≥ 4,23
	1,00E-01	0		0		<14	<14			
50,00	1,00E+00	0		0		<14	<14	<1,40E+02	< 2,15	≥ 4,23
	1,00E-01	0		0		<14	<14			

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Table 2.1: Validation, Controls and Evaluation (DIN EN 13624:2013*)

Product name: **JACLOR** Batch: -
Test organism: *Aspergillus brasiliensis* Temperature: 30°C ± 1°C
Organic load: clean conditions Neutraliser: TLSH-Nt
Contact time: **30 minutes** Lab task no.: L20/0183.6

Suspension for validation (N _{vo})			Control of test conditions (A)			Control of neutraliser (B)			Vali. of inactivation (C)		
			Conc.: 50,00 %								
Microbial count	x̄		Microbial count	x̄		Microbial count	x̄		Microbial count	x̄	
V _{c1}	48	50	V _{c1}	40	49	V _{c1}	42	43	V _{c1}	46	48
V _{c2}	52		V _{c2}	58		V _{c2}	44		V _{c2}	50	
30 ≤ x̄ of N _{vo} ≤ 160			x̄ of A(30') is ≥ 0,5 x x̄ of N _{vo} ?			x̄ of B is ≥ 0,5 x x̄ of N _{vo} ?			x̄ of C(30') is ≥ 0,5 x x̄ of N _{vo} ?		
Yes			Yes			Yes			Yes		
Suspension for Validation (N _{VB})			V _{c1}	V _{c2}	x̄	30 ≤ x̄ of N _{vo} ≤ 160?					
			44	49	46,5	Yes					

Test suspension (N and N ₀)	N	Microbial count				V _{c1}	V _{c2}	x̄ _{wm} / lg N	N ₀ =N/10; lg N ₀	6,17 ≤ N ₀ ≤ 6,70 ?
	1,00E-05	>165		>165		>165	>165	2,80E+07	6,45	Yes
	1,00E-06	26		30		26	30	7,45		
Concentration of Stock solution 2 [%]	N	Microbial count				V _{c1}	V _{c2}	N _a = x̄ x 10	lg N _a	lg R
									(lg N ₀ = 6,45)	
5,00	1,00E-01	28		31		28	31	<2,95E+02	3,47	2,98
	1,00E-02	5		8		<14	<14			
15,00	1,00E-01	17		17		17	17	<1,70E+02	3,23	3,22
	1,00E-02	4		3		<14	<14			
50,00	1,00E+00	19		20		19	20	<1,95E+02	2,29	4,16
	1,00E-01	2		2		<14	<14			

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Table 2.2: Validation, Controls and Evaluation (DIN EN 13624:2013*)

Product name:	JACLOR	Batch:	-
Test organism:	<i>Aspergillus brasiliensis</i>	Temperature:	30°C ± 1°C
Organic load:	clean conditions	Neutraliser:	TLSH-Nt
Contact time:	60 minutes	Lab task no.:	L20/0183.3

Suspension for validation (N _{v0})			Control of test conditions (A)				Control of neutraliser (B)				Vali. of inactivation (C) Conc.: 15,00 %			
Microbial count			V _{c1}		V _{c2}		V _{c1}		V _{c2}		Microbial count			
V _{c1}	48	50	V _{c1}	46	49	V _{c1}	42	43	V _{c1}	47	47,5	V _{c2}	48	
V _{c2}	52		V _{c2}	52		V _{c2}	44		V _{c2}	48				
30 ≤ \bar{x} of N _{v0} ≤ 160			Yes		\bar{x} of A(60') is ≥ 0,5 x \bar{x} of N _{v0} ?		Yes		\bar{x} of B is ≥ 0,5 x \bar{x} of N _{v0} ?		Yes		\bar{x} of C(60') is ≥ 0,5 x \bar{x} of N _{v0} ?	
Suspension for Validation (N _{v0})			V _{c1}		V _{c2}		\bar{x}		30 ≤ \bar{x} of N _{v0} ≤ 160?					
			44		49		46,5		Yes					
Test suspension (N and N ₀)	N		Microbial count				V _{c1}	V _{c2}	$\bar{x}_{wm} / \lg N$	N ₀ =N/10; lg N ₀	6,17 ≤ N ₀ ≤ 6,70?			
	1,00E-05	>165	>165	>165	>330	>330	2,80E+07	6,45	Yes					
	1,00E-06	26	30	26	30	7,45								
Concentration of Stock solution 2 [%]	N		Microbial count				V _{c1}	V _{c2}	N _a = \bar{x} x 10	lg N _a	lg R (lg N ₀ = 6,45)			
	1,50	1,00E-01	>165	>165	>165	>165	>165	>165	>1,65E+04	> 4,22	≤ 2,23			
		1,00E-02	>165	>165	>165	>165	>165	>165						
4,50	1,00E+00	30	28	30	28	<2,90E+02	2,46	3,98						
	1,00E-01	4	2	<14	<14									
15,00	1,00E+00	0	0	<14	<14	<1,40E+02	< 2,15	≥ 4,30						
	1,00E-01	0	0	<14	<14									

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4 List of Abbreviations

A	=	control of test conditions
B	=	control of neutraliser
C	=	validation of method at highest product concentration
N	=	test suspension
N _{vo}	=	suspension for validation
n.t.	=	not tested
N ₀	=	microbial count of test suspension N / 10 (microbial count at time index 0)
R	=	germ reduction in log ₁₀ -steps
V _c	=	viable microbial count per ml
\bar{x}	=	weighted mean of N

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