

TEST REPORT N. 20/000332738

date of issue 28/08/2020

Customer ID 0052504

Messrs
ICF DET SRL
31 VIA M. BELLISARIO
26020 PALAZZO PIGNANO (CR)
IT**Sample information**

Acceptance number 20.515825.0001

Delivered by TNT Traco on 23/05/2020

Receiving Date 23/05/2020

Place of origin ICF DET SRL 31 VIA M. BELLISARIO 26020 PALAZZO PIGNANO (CR) IT

Sample Description DIDECID (PMC REG N°19186)

Sampling information

Sampled by Customer

ANALYTICAL RESULTS

	Value/ Uncertainty	Unit of measure	LoQ	LoD	Start/end date of analysis	Op. units	Line
ON SAMPLE AS IT IS							1
BACTERICIDAL ACTIVITY IN PRESENCE OF INTERFERING SUBSTANCES Met.: UNI EN 13623:2010	view attached report				28/05/2020- -28/08/2020	09	2

Operative units

Unit 09 : Via Fratta Resana PHARMA (TV)

Information provided by the clientSampled by: Customer
Pick Address: ICF DET SRL 31 VIA M. BELLISARIO 26020 PALAZZO PIGNANO (CR) IT
Description: DIDECID (PMC REG N°19186)

Biologist responsible
Dott.ssa Federica Cattapan Ordine nazionale dei biologi Albo professionale n.045961 sez.A
Num. certificato 18128093 emesso dall'ente certificatore ArubaPEC S.p.A. NG CA 3, ArubaPEC S.p.A., IT

- If not otherwise specified, the uncertainty is extended and has been calculated with a coverage factor $k=2$ corresponding to a probability interval of about 95%. - LoD is the detection limit and identifies a confidence interval of zero with a probability interval of about 99%. - LoQ is the limit of quantification. "n.d" is not detected and indicates a value inferior to the LoD. "traces (X)" means a value between LoD and LoQ, this value is indicative. "<x" or ">x" indicate inferior or superior to the measurement field of the test. - If not differently specified, the sums are calculated by lower bound criteria (L.B.). - In case of alteration of the sample the laboratory declines any responsibility on the results that can be influenced by the deviation in case the customer asks for the execution of the test anyway. - If the sampling is not carried out by the laboratory staff, the results obtained are considered referring to the sample as received and the laboratory declines its responsibility for the results calculated considering the sampling data provided by the Customer. The name and contact information of the Customer are always provided by the Customer. - If not differently specified the quantitative microbiological tests (excluded MPN) are performed on single repetition and two consecutive dilutions in accordance to ISO 7218:2007/Amd1:2013.

Laboratory

CHELAB SRL MÉRIEUX NUTRISCIENCES
25, VIA FRATTA
31023 RESANA
ITALY

Client

ICF DET SRL
VIA BELLISARIO, 31
26020 PALAZZO PIGNANO (CR)
IT

DIDECID

Evaluation of bactericidal activity against *Legionella* according to UNI EN 13623:2010

Prepared by: Lelia Vecchio

Date: 04/08/2020

1. Reference Standard:

UNI EN 13623:2010

Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal against Legionella of chemical disinfectants for aqueous systems – Test method and requirements (phase 2, step 1)

2. Sample Identification:

Product name	DIDECID
Reference number	PMC REG N°19186
Batch number	B200162B
Manufacturing date	n.a.
Expiry date	02/2022
Laboratory number	20.515825.0001
Receiving date	27/05/2020
Storage conditions	RT, darkness
Product appearance	liquid, clear, red
Active substances	DIDECYLDIMETHYLAMMONIUM CHLORIDE (CAS N° 7173-51-5)

3. Evaluation of bactericidal activity for general purposes according to UNI EN 13623:2010

3.1 Test Method: Membrane Filtration

3.2 Product test concentrations

dilution	preparation	appearance
5%	solution 50% (v/v) in HWGP	liquid, clear, red
3%	solution 30% (v/v) in HWGP	liquid, clear, red
1%	solution 10% (v/v) in HWGP	liquid, clear, light red

3.3 Test conditions

Test strain (standard)	<i>Legionella pneumophila</i> ATCC 33152
Contact time	10 min ± 10 sec
Test temperature	20 °C ± 1 °C (standard for general purposes)
Interfering substance	Yeast extract 0.005 g/l (standard)
Dilution water	Hard water for general purposes (standard)
Incubation conditions	36 °C ± 1 °C for 7 days

3.4 Materials and reagents

Diluent	Page's Saline	
Incubation medium	Buffered Charcoal Yeast Extract Agar	
Rinsing liquid	Polysorbate 80 Diluent	0.5 g/l

3.5 Remarks

Test mixture appearance	homogeneous, no precipitate
All controls and validations were within the basic limits	
At least one concentration of the product demonstrated a log $R < 4$	

3.6 Results: see tables 1-2

3.7 Testing period: 27/07/2020 – 03/08/2020

4. Conclusions

According to UNI EN 13623:2010, the test product DIDECID has bactericidal activity against *Legionella* ($\log R \geq 4$) for general purposes when used at concentrations

- 5% (v/v)
- 3% (v/v)
- 1% (v/v)

under the following obligatory test conditions

- Contact time: 10 min \pm 10 sec
- Temperature: 20 °C \pm 1 °C (standard)
- Interfering substance: Yeast extract 0.005 g/l (standard)
- Dilution water: HWGP (standard)
- Test strain: *Legionella pneumophila* ATCC 33152

Table 1: Validation procedure UNI EN 13623:2010

Test Organisms	Validation Suspension N_V	Validation Suspension N_{VB}	Validation Test		
			Experimental Conditions Control A	Neutralizer Control B	Method Validation C
<i>Legionella pneumophila</i> ATCC 33152	10^{-1}: 39 - 28 N_V: $3,35 \times 10^2$ N_{V0}: 33,5	10^{-3}: 110 - 112 N_{VB}: $1,11 \times 10^5$	V_c: 18 - 21 A: 19,5 PASS	V_c: 23 - 20 B: 21,5 PASS	V_c: 16 - 21 C: 18,5 PASS

V_c = viable count
 N_V = number of cfu/ml in the validation suspension
 N_{V0} = number of cfu/ml in the validation/control mixtures at the beginning of the contact time
A = number of cfu/ml in the experimental conditions control at the end of the contact time
B = number of cfu/ml in the filtration control at the end of the contact time
C = number of cfu/ml in the method validation at the end of the contact time
 Requirements: $30 \leq N_{V0} \leq 160$; $A, B, C \geq 0.5 N_{V0}$

Table 2: Test procedure UNI EN UNI EN 13623:2010

Test Organisms	Test Suspension	Test Procedure		
		5%	3%	1%
<i>Legionella pneumophila</i> ATCC 33152	10^{-6}: 155 - 154 10^{-7}: 15 - <14 N: $1,54 \times 10^8$ N_0: $1,54 \times 10^7$ log N_0: 14 - <14	10^0: <14 - <14 N_a < $1,4 \times 10^2$ log N_a < 2,15 log R > 5,04 ACTIVE	10^0: <14 - <14 N_a < $1,4 \times 10^2$ log N_a < 2,15 log R > 5,04 ACTIVE	10^0: <14 - <14 N_a < $1,4 \times 10^2$ log N_a < 2,15 log R > 5,04 ACTIVE

V_c = viable count
N = number of cfu/ml in the test suspension
 N_0 = number of cfu/ml in the test mixture at the beginning of the contact time
 N_a = number of cfu/ml in the test mixture at the end of the contact time
R = reduction in viability ($\log R = \log N_0 - \log N_a$)
 Requirement: $7.17 \leq \log N_0 \leq 7.70$
 ACTIVE if $\log R \geq 4$

The test results contained in this Test Report refer only to the analyzed sample. This test report can not be copied, even partially, without Chelab's written permission.