



REPORT OF ANALYSIS No. 60362/23/ROBCH

Client ECOCHIM-GRUP SRL OR. UNGHENI, STR. NAȚIONALĂ 119 - REPUBLICA MOLDOVA		Sample number: 60362/23/ROBCH Sample description (according to declaration of Client) Dezinfectant Universal "Bio-Dez" Lot: - Data fabricatiei: 05.08.2023 Data expirare: 05.08.2026 Data receptiei probei: 23.08.2023 Cantitate prelevata:500 ml Responsabil prelevare: Cristinov Alexandr Ora receptiei probei: 12:30 Temperatura receptie proba: 17°C Sample condition with no objections	
Sample received:	24.08.2023	Order of 24.08.2023 Sampling and delivery were carried out by client.	
Tests performed:	30.08.2023		
Tests completed:	30.10.2023		
Report dated:	30.10.2023		

Test	Method	Unit	Result
# * Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of virucidal activity in the medical area	UNE-EN 14476:2014 + A2:2019	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/23/V0259, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Test responsible: Mariana Ilinca, Manager of Microbiological Laboratory

Validated by: Mariana Ilinca, Manager of Microbiological Laboratory

Authorized by: Alina-Roxana Mihai, General Manager (Approved with qualified electronic signature)

Laboratory: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevarii probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercarii. Daca nu se specifica altfel, incertitudinea de masurare a fost estimata pentru coeficientul K= 2 si nivel de incredere 95%. Fara aprobarea scrisa a laboratorului acest raport de incercare nu poate fi reprodus decat integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se refera exclusiv la rezultatele si declaratiile prezentate in raportul original. Opiniile si interpretarile continute in prezentul raport de incercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare va rugam sa solicitati Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

* Test method accredited # Test performed by external provider

o Non accredited methods



ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

A) IDENTIFICATION OF THE SAMPLE	
Name of the product/Details about the product	DEZINFECTANT UNIVERSAL "BIO-DEZ" Manufacturer(supplier): Ecochim-Grup Condition of use: Instrument disinfection, surface disinfection, hygienic handrub.
Active(s) Substance(s) and its concentration(s)	Ethyl alcohol 72-76%, CAS 64-17-5 and CE 200-578-6, Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2, Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
Concentration ordered for the assay	80
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report D/23/V0259. Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1), against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus with the product "Dezinfectant Universal "Bio-Dez" (EN 14476: 2013 + A2: 2019 Standard)	EN 14476: 2013 + A2: 2019 Standard. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of virucidal activity in the medical area. Test method and requirements (phase 2/step1).
Testing method	Procedure DESIN-1078 (EN 14476: 2013 + A2: 2019 Standard).
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	2023/08/30
Date of reception of order with test conditions	2023/09/04.
Aspect of the received product	Blue transparent liquid in plastic container with identification label.
D) EXPERIMENTAL CONDITIONS	
Assay period	2023/09/06 to 2023/09/21.
Assay temperature	37°C ± 1°C
Titration method	TCID50 (Tissue Culture Infective Dose 50%).
Product concentrations for the assay	80%, 50% and 0.1%
Contact time	60 seconds
Contact temperature	20°C ± 1°C
Procedure to stop product cytotoxicity	Molecular sieving (< 4 columns).
Procedure to stop product activity	Cooling with ice
Solvent of the product used in the assay	Sterile distilled water
Aspect of the dilutions of the product	Transparent
Stability of the mixture (interfering substance and product diluted in sterile hard water/distilled water)	Stable
Interfering substance	Dirty conditions in the presence of bovine serum albumin 3 g/L and erythrocytes 3 mL/L.
Identification of the origin of viral stains and number of passes	Poliovirus type 1 (ATCC VR-192) aliquot: 2023/03/23 passage 2. Adenovirus type 5 (ATCC VR-5) aliquot: 2022/06/10 passage 2. Murine Norovirus (strain S99 Berlin) aliquot: 2022/06/22 passage 2.
Cell lines (name, origin, number of passes)	Vero, ref: FTVE, working aliquot 4, passages 18 21, 22 and 25. Raw 264.7, Public Health England, working aliquot 4, passages 18, 21 and 25

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Enclosure no. 1 subcontracted tests

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Date: 27.10.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

Validation of assay results

Poliovirus type 1 (ATCC VR-192)

Titre of the viral suspension for the virus control (at the requested test time)

- Dirty conditions log 10^{-7.50}
Cytotoxicity level (80%) log 10^{-0.50}

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):

- Dirty conditions log 10^{-7.00}

Adenovirus type 5 (ATCC VR-5)

Titre of the viral suspension for the virus control (at the requested test time)

- Dirty conditions log 10^{-6.82}
Cytotoxicity level (80%) log 10^{-0.50}

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):

- Dirty conditions log 10^{-6.32}

Murine Norovirus (strain S99 Berlin)

Titre of the viral suspension for the virus control (at the requested test time)

- Dirty conditions log 10^{-8.82}
Cytotoxicity level (80%) log 10^{-0.50}

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):

- Dirty conditions log 10^{-7.82}

Reference test (formaldehyde 1.4%)Cytotoxicity level of formaldehyde 0.7% log 10^{-0.50}Viral quantification in the reference test (formaldehyde) after 60 minutes and with Poliovirus type 1 log 10^{-3.08}Viral quantification in the reference test (formaldehyde) after 60 minutes and with Adenovirus type 5 log 10^{-2.75}Viral quantification in the reference test (formaldehyde) after 60 minutes and with Murine Norovirus log 10^{-4.99}

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH**Confidence interval**

Titre of virus with 95% confidence interval with Poliovirus type 1 (at the requested test time)

– Dirty conditions $\log 10^{-7.50 \pm 0.37}$

Titre of virus with 95% confidence interval with Adenovirus type 5 (at the requested test time)

– Dirty conditions $\log 10^{-6.82 \pm 0.41}$

Titre of virus with 95% confidence interval with Murine Norovirus (at the requested test time)

– Dirty conditions $\log 10^{-8.32 \pm 0.42}$

Reduction with the confidence interval of 95% See tables 1, 3 and 5.

Sensitivity of cells to virus

- Viral quantification of Poliovirus type 1 with cells not treated by the test solution with the test sample $\log 10^{-8.23}$
- Viral quantification of Poliovirus type 1 with cells treated by the test solution with the test sample $\log 10^{-7.65}$
- Viral quantification of Adenovirus type 5 with cells not treated by the test solution with the test sample $\log 10^{-7.41}$
- Viral quantification of Adenovirus type 5 with cells treated by the test solution with the test sample $\log 10^{-6.74}$
- Viral quantification of Murine Norovirus with cells not treated by the test solution with the test sample $\log 10^{-8.66}$
- Viral quantification of Murine Norovirus with cells treated by the test solution with the test sample $\log 10^{-7.99}$

Note: only can be used to determine the infectivity of cells, those dilutions which: a) show a low degree of cellular destruction (< 25% of cell monolayer) and b) produce a reduction of the titre of the virus < 1 \log_{10} .

Control of the effectivity of the disinfectant suppression activity

- Viral quantification of Poliovirus type 1 after 30 minutes on bath ice without exposing the virus to the test sample $\log 10^{-7.41}$
- Viral quantification of Poliovirus type 1 exposing the virus to the test sample and incubated 30 minutes on ice bath $\log 10^{-6.99}$
- Viral quantification of Adenovirus type 5 after 30 minutes on bath ice without exposing the virus to the test sample $\log 10^{-7.08}$
- Viral quantification of Adenovirus type 5 exposing the virus to the test sample and incubated 30 minutes on ice bath $\log 10^{-6.83}$

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- Viral quantification of Murine Norovirus after 30 minutes on bath ice without exposing the virus to the test sample $\log 10^{-8.25}$
- Viral quantification of Murine Norovirus exposing the virus to the test sample and incubated 30 minutes on ice bath $\log 10^{-7.74}$

Note: The difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension should be ≤ 0.5 .

Special remarks

- All controls and validation were between the basic limits.
- To be accepted the assay, at least one concentration of the product must show a log reduction equal or higher than 4 log, and at least one concentration must show a log reduction lower than 4 log.

9. Assay results
9.1 Description of the results under the requested test conditions

Virus of assay	Test concentrations, reduction obtained with the confidence interval of 95 % and virucidal activity		
	80%	50%	0.1%
Poliovirus type 1	$\geq 7.00 \pm 0.37$ TCID ₅₀ Shows	2.84 ± 0.56 TCID ₅₀ Does not show	0.01 ± 0.49 TCID ₅₀ Does not show
Adenovirus type 5	$\geq 6.32 \pm 0.41$ TCID ₅₀ Shows	5.07 ± 0.48 TCID ₅₀ Shows	0.07 ± 0.48 TCID ₅₀ Does not show
Murine Norovirus	$\geq 7.82 \pm 0.42$ TCID ₅₀ Shows	5.58 ± 0.56 TCID ₅₀ Shows	0.08 ± 0.54 TCID ₅₀ Does not show

Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.
TCID₅₀: Tissue Culture Infectious Dose 50%.

9.2 Tables of results and graphics

See tables 1 to 6 and figures 1 to 3.

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH**Conclusion**

The product "Dezinfectant Universal "Bio-Dez", batch 60362/23/ROBCH, at 80% concentration, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), requested by the client and during 60 seconds of contact time and 20°C of temperature, shows activity against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus, when the activity is assayed according with the EN 14476: 2013 + A2: 2019 Standard.

Therefore, the disinfectant tested shows general virucidal activity at 80% concentration, when the activity is assayed according with the EN 14476: 2013 + A2: 2019 Standard.

Note 1: The results obtained correspond to the sample received in this laboratory.

Note 2: The information that depend on the information received from the client and are not facilitated by the same one, shown as "not indicated".

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Table 1. Results of activity of the test sample with Poliovirus type 1 (ATCC VR-192) under test conditions requested by the client.

Assay	Concentration	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after...				Reduction with the confidence interval of 95 %
				0 min	60 sec	30 min	60 min	
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	0.50	-	0.50	-	-	≥ 7.00 ± 0.37
	50%		0.50	-	4.66	-	-	2.84 ± 0.56
	0.1%		0.50		7.49			0.01 ± 0.49
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	NA	7.58	7.50	-	-	NA
Formaldehyde	0.7% (w.v)	NA	0.50	NR	NR	4.99	3.08	NA
Virus control formaldehyde	0.7% (w.v)	NA	NA	7.58	NR	NR	7.32	NA
Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) log ₁₀ ^{-0.58}								
Control of the effectiveness of the disinfectant suppression activity (difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension)..... log ₁₀ ^{-0.42}								
NA: not applicable; NR: not realized. Times recommended by Standard for surfaces: maximum 5 or 60 minutes. Times recommended by Standard for instruments: maximum 60 minutes. Times recommended by Standard for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds. PBS: phosphate buffered saline; BSA: bovine serum albumin. Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.								

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**Table 2. Results of the activity of the test sample, with Poliovirus type 1 (ATCC VR-192)
(Assay of titration with 12 wells), under test conditions requested by the client.**

Assay	Concentration	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}											
				1	2	3	4	5	6	7	8	9	10		
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	60 sec	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR	
	50%		60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 0403 4432	3240 3010 0020	0002 0000 0000	0200 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	0.1%		60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3241 0344 3032	0000 0200 0001	0000 0000 0000	NR
Cytotoxicity	80%	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR	
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3244 3021 3044	0000 0220 0003	0000 0000 0000	NR	
			60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3204 4310 0233	0010 0000 2020	0000 0000 0000	NR
Formaldehyde	0.7% (w.v)	NA	30 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0030 2004 4030	0000 0020 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR	
			60 min	4444 4444 4444	4444 4444 4444	0302 2304 0002	0000 0000 0100	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR	
Control of formaldehyde cytotoxicity	0.7% (w.v)	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR	
Virus control formaldehyde	0.7% (w.v)	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0321 0044 4342	1000 2000 3020	0000 0000 0000	0000 0000 0000	
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0321 0404 4303	0000 2000 0020	0000 0000 0000	0000 0000 0000
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0000 0000 0000	NR
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0000 0000 0000
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + 3 mL/L erythrocytes	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0000 0000 0000	NR
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0000 0000 0000

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.

C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).

0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline.

sec: seconds; min: minutes;

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH
Table 3. Results of activity of the test sample with Adenovirus type 5 (ATCC VR-5), under test conditions requested by the client.

Assay	Concentration	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after...				Reduction with the confidence interval of 95 %
				0 min	60 sec	30 min	60 Min	
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	0.50	-	0.50	-	-	≥ 6.32 ± 0.41
	50%		0.50	-	1.75	-	-	5.07 ± 0.48
	0.1%		0.50	-	6.75	-	-	0.07 ± 0.48
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	NA	6.91	6.82	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.50	NR	NR	3.49	2.75	NA
Virus control formaldehyde	0.7% (w:v)	NA	NA	7.16	NR	NR	6.98	NA
Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) log ₁₀ ^{-0.67} Control of the effectiveness of the disinfectant suppression activity (difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension)..... log ₁₀ ^{-0.25}								
NA: not applicable; NR: not realized. Times recommended by Standard for surfaces: maximum 5 or 60 minutes. Times recommended by Standard for instruments: maximum 60 minutes. Times recommended by Standard for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds. PBS: phosphate buffered saline; BSA: bovine serum albumin. Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.								

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**Table 4. Results of the activity of the test sample, with Adenovirus type 5 (ATCC VR-5)
(Assay of titration with 12 wells), under test conditions requested by the client.**

Assay	Concentration	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}											
				1	2	3	4	5	6	7	8	9	10		
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	60 sec	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR	
	50%		60 sec	4433 2113 4443	0010 3002 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	0.1%		60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4433 1234 2000	0003 1000 0000	0000 0000 0000	0000 0000 0000	NR	NR
Cytotoxicity	80%	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR	
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3244 4302 3042	2004 0423 0001	0100 0000 0000	NR	NR	
			60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3201 4443 3440	0023 0102 0200	0000 0000 0001	0000 0000 0000	NR	NR
Formaldehyde	0.7% (w:v)	NA	30 min	4444 4444 4444	4444 4444 4444	3402 0303 2033	0001 2000 1000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
			60 min	4444 4444 4444	3334 2444 3442	0202 0010 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR
Control of formaldehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR	
Virus control formaldehyde	0.7% (w:v)	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0402 3030 4040	0000 0010 0020	0000 0000 0000	0000 0000 0000	
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4344 4340 2433	4020 0200 3200	0000 0010 0010	0000 0000 0000	0000 0000 0000	0000 0000 0000
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0000 0000 0000	NR	NR	
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0000 0000 0000	0000 0000 0000	NR	NR
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + 3 mL/L erythrocytes	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0000 0000 0000	NR	NR	
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0000 0000 0000	0000 0000 0000	NR	NR

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.

C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).

0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline.

sec: seconds; min: minutes.

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 27.10.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH
Table 5. Results of activity of the test sample, with Murine Norovirus, strain S99 Berlin, under test conditions requested by the client.

Assay	Concentration	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after...				Reduction with the confidence interval of 95 %
				0 min	60 sec	30 min	60 min	
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	0.50	-	0.50	-	-	≥ 7.82 ± 0.42
	50%		0.50	-	2.74	-	-	5.58 ± 0.56
	0.1%		0.50	-	8.24	-	-	0.08 ± 0.54
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	NA	8.41	8.32	-	-	NA
Formaldehyde	0.7% (w.v)	NA	0.50	NR	NR	5.74	4.99	NA
Virus control formaldehyde	0.7% (w.v)	NA	NA	8.50	NR	NR	8.32	NA
Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) log10 ^{-0.67}								
Control of the effectiveness of the disinfectant suppression activity (difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension)..... log10 ^{-0.43}								
NA: not applicable; NR: not realized. Times recommended by Standard for surfaces: maximum 5 or 60 minutes. Times recommended by Standard for instruments: maximum 60 minutes. Times recommended by Standard for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds. PBS: phosphate buffered saline; BSA: bovine serum albumin. Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.								

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH
Table 6. Results of the activity of the test sample, with Murine Norovirus strain S99 Berlin (Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concentration	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}										
				1	2	3	4	5	6	7	8	9	10	
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	60 sec	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR	
	50%		60 sec	4444 4444 4444	3244 3020 2244	0020 0122 0030	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR	
	0.1%		60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0302 2010 3212	0000 0000 0002	NR
Cytotoxicity	80%	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR	
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0323 0404 3302	0020 0000 0210	NR
			60 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3244 3321 2013	3213 0030 2203	0002 0200 0010
Formal-dehyde	0.7% (w:v)	NA	30 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3344 0334 4444	0200 0202 0100	0000 0000 0000	NR	NR	NR
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0030 4020 2200	0000 0100 0000	0000 0000 0000	NR	NR
Control of formal-dehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR	
Virus control formal-dehyde	0.7% (w:v)	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3042 4040 4433	0000 1000 0102	0000 0000 0000
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2002 0302 2434	0000 0000 0100	0000 0000 0000
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	NR
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + 3 mL/L erythrocytes	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	NR
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0000 CCCC CCCC	0000 0000 0000

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.

C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).

0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline.

Sec: seconds; min: minutes.

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Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Probat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

Figure 1. Results of the activity of the test sample under test conditions requested by the client with Poliovirus type 1 (ATCC VR-192).

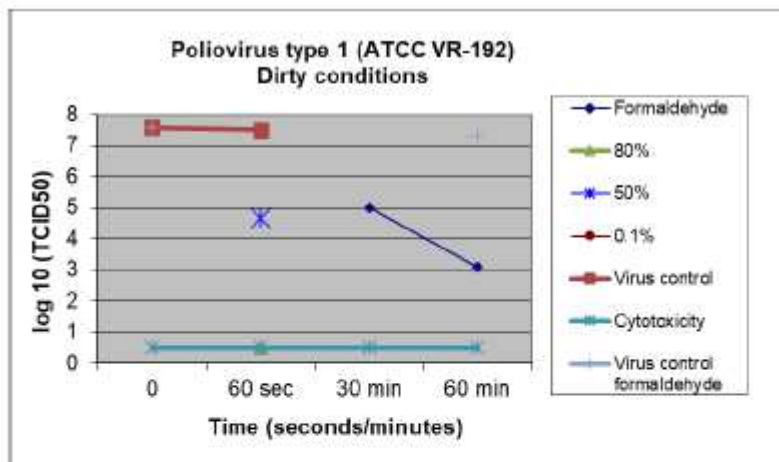
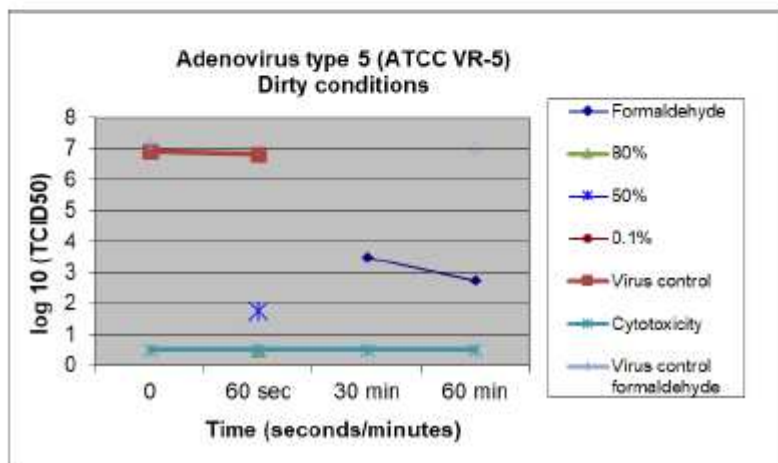


Figure 2. Results of the activity of the test sample under test conditions requested by the client with Adenovirus type 5 (ATCC VR-5).



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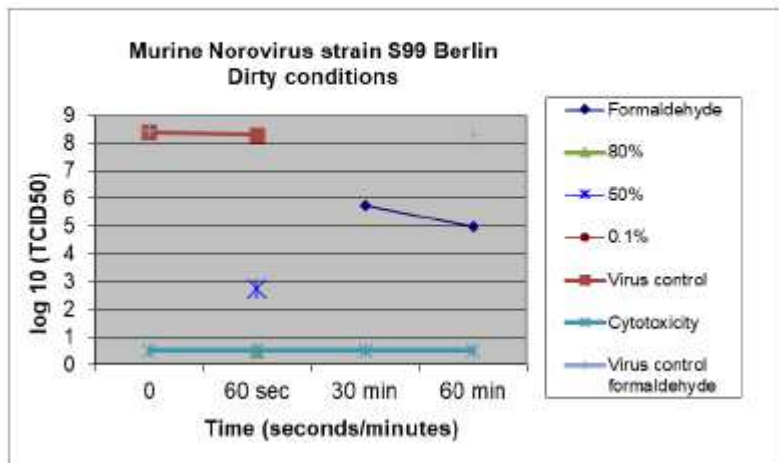
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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

Figure 3. Results of the activity of the test sample under test conditions requested by the client with Murine Norovirus strain S99 Berlin.



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RAPORT DE INCERCARE NR. 34692/23/ROBCH/Z1

Inlocuieste Raportul de Incercare Nr. 34692/23/ROBCH din 07.11.2023

Client ECOCHIM-GRUP SRL OR. UNGHENI, STR. NAȚIONALĂ 119 - REPUBLICA MOLDOVA	Numărul eșantionului: 34692/23/ROBCH Descriere obiect de incercat (conform cu declaratia Clientului) Dezinfectant Universal "Bio-Dez" Lot: - Cantitate prelevata:500 ml Responsabil prelevare: Cristinov Alexandr Ora receptiei probei: 08:00 Temperatura receptie proba: 15°C Sample condition with no objections
Data primirii obiectului de incercat:	17.05.2023
Data finalizarii incercarii:	07.11.2023
Data eliberarii raportului:	19.01.2024
Comanda numar 5331/23/ROBCH din 17.05.2023 Probele au fost prelevate si livrate de catre Client.	

Parametrii de testare	Metoda de testare	Unitate de masura	Rezultat
# * Quantitative suspension test for the evaluation of bactericidal activity in medical area ¹⁾	EN 13727:2012+A2:2015	-	Test efectuat de catre subcontractor.; rezultatele se regasesc integral in raportul Nr D/23/B0419, primit de la subcontractor. Rezultatele analizelor sunt incluse in anexa nr 1 la raportul de analiza.

¹⁾ Modificare efectuata: se ataseaza raportul de incercare Nr D23/B0840, primit de la subcontractor, raport care include rezultatele incercarii solicitate.

Preluare date de catre: Mariana Ilinca, Sef Laborator Microbiologie
Validat de: Mariana Ilinca, Sef Laborator Microbiologie
Autorizat de: Alina-Roxana Mihai, Manager General (Aprobat cu semnatura electronica)

Laborator: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevarii probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercarii. Daca nu se specifica altfel, incertitudinea de masurare a fost estimata pentru coeficientul K= 2 si nivel de incredere 95%. Fara aprobarea scrisa a laboratorului acest raport de incercare nu poate fi reprodus decat integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se refera exclusiv la rezultatele si declaratiile prezentate in raportul original. Opiniile si interpretarile continute in prezentul raport de incercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare va rugam sa solicitati Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

* Metoda de testare acreditata # Test efectuat de catre subcontractor

o Incercari neacreditate



ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

A) IDENTIFICATION OF THE SAMPLE	
Name of the product/Details about the product	Dezinfectant Universal "Bio-Dez". Manufacturer(supplier): Ecochim-Grup Condition of use: Instrument disinfection, surface disinfection, Hygienic handrub, surgical handrub.
Active(s) Substance(s) and its concentration(s)	Ethyl alcool 72-76%, CAS 64-17-5 and CE 200-578-6 Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2 Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
Concentration ordered for the assay	97%, 80%.
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report No.: D/23/B0419– Quantitative evaluation assay of the bactericidal activity in the medical area (phase 2, step 1), with the product "Dezinfectant Universal "Bio-Dez"". (EN 13727: 2012 + A2: 2015 Standard)	EN 13727: 2012 + A2: 2015. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in Medicine. Test method and requirements (phase 2, step 1).
Testing method	EN 13727: 2012 + A2: 2015 Standard
Methods of assay and its validation UNE-EN 13727: 2012 + A2: 2015 Standard	
Method	Dilution-neutralization.
Neutralizer	Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	2023/05/18.
Date of reception of order with test conditions	2023/08/30.
Aspect of the received product	Blue liquid in plastic container.
D) EXPERIMENTAL CONDITIONS	
Assay period	2023/10/11 to 2023/10/15.
Solvent of the product used in the assay	Sterile distilled water.
Product concentrations for the assay	97%, 80%, 50% and 0.1%.
Aspect of the dilutions of the product	97%, 80% and 50% blue liquid; 0.1% transparent liquid..
Contact time	60 seconds.
Assay temperature	20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L + erythrocytes 3 mL/L.
Stability of the mixture (interfering substance and product diluted in sterile distilled water)	97% flocs formation; 80%, 50% and 0.1% stable.
Incubation temperature	+36°C ± 1°C
Identification of the strains used:	– <i>Pseudomonas aeruginosa</i> CECT-116 (ATCC-15442). – <i>Staphylococcus aureus</i> CECT-239 (ATCC-6538). – <i>Enterococcus hirae</i> CECT-4081 (ATCC-10541). – <i>Escherichia coli</i> K12 (CECT 433 = NCTC 10538).

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

Results of the assay

- Assay of validation See tables 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 22 and 23.
- Evaluation of bactericidal activity See tables 3, 6, 9, 12, 15, 18, 21 and 24.
- Number of replicates per assay organism. 1.

Special remarks

- All controls and validation were between the basic limits.
- For a valid test, at least one concentration must show a log reduction lower than 5 log, and at least one concentration must show a log reduction equal or higher than 5 log.
- Flocc formation is observed during the test procedure at 97%.
- The client requests the complete test including the concentration of 80% as the maximum concentration. It also requests the modified method (97%) additionally.

Conclusion

The product **Dezinfectant Universal "Bio-Dez"**, batch 34692/23/ROBCH, when it is pure (97%) (modified method) and 80%, concentrations requested by the client, shows **bactericidal activity** after 60 seconds at 20°C ± 1°C, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), for the reference strains *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442), *Staphylococcus aureus* (CECT 239 = ATCC 6538), *Enterococcus hirae* (CECT 4081 = ATCC 10541) and *Escherichia coli* K12 (CECT 433 = NCTC 10538), when tested according to **EN 13727: 2012 + A2: 2015 Standard**.

Note: The results obtained correspond to the sample received in the laboratory.

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 1.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 80%		
V_{C1}	44	$X=42$	V_{C1}	36	$X=35$	V_{C1}	38	$X=$	V_{C1}	32	$X=33$
V_{C2}	40		V_{C2}	34		V_{C2}	37	37.5	V_{C2}	34	
$30 \leq X \text{ of } N_{V0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			$V_{C1}: 40 \quad V_{C2}: 39$			$X=39.5$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$			Yes		

Table 2.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.68 \times 10^8$, $\lg N = 8.22$ $N_0 = N/10$; $\lg N_0 = 7.22$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	164	171	
	10^{-7}	18	16	

Table 3.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.22$)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.07	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.07	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.70	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442) following the modified method (97%).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 4.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 97%		
V_{C1}	42	$\bar{X}=41$	V_{C1}	37	$\bar{X}=36$	V_{C1}	31	$\bar{X}=32$	V_{C1}	30	$\bar{X}=31$
V_{C2}	40		V_{C2}	35		V_{C2}	33		V_{C2}	32	
30 ≤ X of N_{V0} ≤ 160? Yes			X of A is ≥ 0.5 X of N_{V0} ? Yes			X of B is ≥ 0.5 X of N_{V0} ? Yes			X of C is ≥ 0.5 X of N_{V0} ? Yes		
Suspension of validation (N_{VB})			V_{C1} : 43 V_{C2} : 45			$\bar{X}=44$ 30 ≤ x of $N_{VB}/1000$ ≤ 160? Yes					

Table 5.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.86 \times 10^9$, $\lg N = 9.27$ $N_0 = N/100$; $\lg N_0 = 7.27$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-7}	189	183	
	10^{-8}	20	18	

Table 6.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10^0)$ $X_{wm} \times 10$	$\lg R$ ($\lg N_0 = 7.27$)	Time of contact (sec)
97%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 07.11.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Staphylococcus aureus* (CECT 239 = ATCC 6538).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 7.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 80%		
V_{C1}	48	$\bar{X}=49$	V_{C1}	47	$\bar{X}=46$	V_{C1}	48	$\bar{X}=46$	V_{C1}	40	$\bar{X}=42$
V_{C2}	50		V_{C2}	45		V_{C2}	44		V_{C2}	44	
$30 \leq X \text{ of } N_{V0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			$V_{C1}: 52 \quad V_{C2}: 56$			$\bar{X}=54$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$ Yes					

Table 8.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	
	10^{-6}	177	189	$\bar{X}_{wm} = 1.84 \times 10^8$, $\lg N = 8.27$ $N_0 = N/10$; $\lg N_0 = 7.27$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-7}	20	19	

Table 9.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } \bar{X}_{wm} \times 10)$	$\lg R$ ($\lg N_0=7.27$)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.75	60
	Na^{-1}	>330	>330			

Explanations:

V_C = number per mL (one or two plates); \bar{X}_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Staphylococcus aureus* (CECT 239 = ATCC 6538) following the modified method (97%).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 10.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 97%		
V_{C1}	51	$X=52$	V_{C1}	46	$X=48$	V_{C1}	50	$X=52$	V_{C1}	39	$X=40$
V_{C2}	53		V_{C2}	50		V_{C2}	54		V_{C2}	41	
$30 \leq X \text{ of } N_{V0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			$V_{C1}: 56 \quad V_{C2}: 58$			$X=57$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$ Yes					

Table 11.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.97 \times 10^9$, $\lg N = 9.29$ $N_0 = N/100$; $\lg N_0 = 7.29$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-7}	190	201	
	10^{-8}	22	20	

Table 12.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10^6 \text{ or } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.29$)	Time of contact (sec)
97%	Na^0	<14	<14	<2.15	>5.14	60
	Na^{-1}	<14	<14			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Enterococcus hirae* (CECT 4081 = ATCC 10541).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 13.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 80%		
V_{C1}	47	$\bar{X}=49$	V_{C1}	40	$\bar{X}=42$	V_{C1}	47	$\bar{X}=44.5$	V_{C1}	45	$\bar{X}=44$
V_{C2}	51		V_{C2}	44		V_{C2}	42		V_{C2}	43	
$30 \leq X \text{ of } N_{V0} \leq 160?$ Yes			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$ Yes			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$ Yes			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$ Yes		
Suspension of validation (N_{VB})			$V_{C1}: 50 \quad V_{C2}: 52$			$\bar{X}=51$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$ Yes					

Table 14.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	
	10^{-6}	181	192	$\bar{X}_{wm} = 1.88 \times 10^8$, $\lg N = 8.27$ $N_0 = N/10$; $\lg N_0 = 7.27$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-7}	20	21	

Table 15.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10^6 / \bar{X}_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.27$)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.75	60
	Na^{-1}	>330	>330			

Explanations:

V_C = number per mL (one or two plates); \bar{X}_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Enterococcus hirae* (CECT 4081 = ATCC 10541), following the modified method (97%).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 16.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 97%		
V_{C1}	46	$\bar{X}=47$	V_{C1}	40	$\bar{X}=42$	V_{C1}	42	$\bar{X}=44$	V_{C1}	37	$\bar{X}=36$
V_{C2}	48		V_{C2}	44		V_{C2}	46		V_{C2}	35	
$30 \leq X \text{ of } N_{V0} \leq 160?$ Yes			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$ Yes			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$ Yes			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$ Yes		
Suspension of validation (N_{VB})			$V_{C1}: 51 \quad V_{C2}: 53$			$X=52$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$ Yes					

Table 17.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	
	10^{-7}	179	188	$X_{wm} = 1.84 \times 10^9$, $\lg N = 9.27$ $N_0 = N/100$; $\lg N_0 = 7.27$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-8}	20	18	

Table 18.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10^0 \text{ or } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.27$)	Time of contact (sec)
97%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Escherichia coli* K12 (CECT 433 = NCTC 10538).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 19.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 80%		
V_{C1}	47	$X=46$	V_{C1}	40	$X=$	V_{C1}	39	$X=38$	V_{C1}	41	$X=42$
V_{C2}	45		V_{C2}	39	39.5	V_{C2}	37		V_{C2}	43	
$30 \leq X \text{ of } N_{V0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			$V_{C1}: 45 \quad V_{C2}: 41$			$X=43$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$			Yes		

Table 20.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.72 \times 10^8$, $\lg N = 8.24$ $N_0 = N/10$; $\lg N_0 = 7.24$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	168	175	
	10^{-7}	19	17	

Table 21.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0=7.24$)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.09	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.09	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.72	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Escherichia coli* K12 (CECT 433 = NCTC 10538), following the modified method (97%).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 22.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 97%		
V_{C1}	42	$X=43$	V_{C1}	36	$X=37.5$	V_{C1}	33	$X=34.5$	V_{C1}	37	$X=36$
V_{C2}	44		V_{C2}	39		V_{C2}	36		V_{C2}	35	
30 ≤ X of N_{V0} ≤ 160? Yes			X of A is ≥ 0.5 X of N_{V0} ? Yes			X of B is ≥ 0.5 X of N_{V0} ? Yes			X of C is ≥ 0.5 X of N_{V0} ? Yes		
Suspension of validation (N_{VB})			V_{C1} : 40 V_{C2} : 39			$X=39.5$ 30 ≤ x of $N_{VB}/1000$ ≤ 160? Yes					

Table 23.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.74 \times 10^9$, $\lg N = 9.24$ $N_0 = N/100$; $\lg N_0 = 7.24$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-7}	180	165	
	10^{-8}	19	18	

Table 24.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.24$)	Time of contact (sec)
97%	Na^0	<14	<14	<2.15	>5.09	60
	Na^{-1}	<14	<14			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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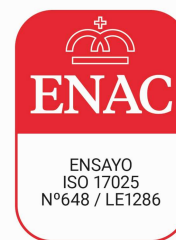
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)



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Test with the certificate of GLPs
(Good Laboratory Practices)
No. 2/23-C.VAL. General Directorate of
Pharmacy and Medical Devices of the Health
Department of the Valencian Region. Spain

**Quantitative evaluation assay of the bactericidal activity
in the medical area (phase 2, step 1),
with the product “Dezinfectant Universal “Bio-Dez”” with deviations from the standard.
(EN 13727: 2012 + A2: 2015 Standard)**

Report

Registration No.: D/23/B0840.

1. **Laboratory identification** Instituto Valenciano de Microbiología.
2. **Client identification** J.S. HAMILTON ROMANIA SRL.
Address Sos Berceni, Nr 8, sector 4, Bucuresti.
Romania.
3. **Sample identification** (information provided by the client)
 - Product name **Dezinfectant Universal “Bio-Dez”.**
 - Batch number 34692/23/ROBCH.
 - Expiration date Not indicated.
 - Manufacturer /supplier SRL “ Ecochim-Grup ”
 - Store conditions Not indicated.
 - Conditions of use Instrument disinfection, surface disinfection,
Hygienic handrub, surgical handrub.
 - Diluent of the product recommended by
the manufacturer Not indicated.
 - Active(s) Substance(s) and its
concentration (s) Ethyl alcool 72-76%, CAS 64-17-5 and CE
200-578-6, Benzalkonium chloride 0.024-
0.029%, CAS: 68424-85-1 and CE 270-325-2
Methylthonibium chloride 0.00024%, CAS
61-73-4 and 200-515-2.
 - Concentrations ordered for the assay Ready to use.

IVAMI is not responsible for client-supplied information. This information **is not covered**
by the ENAC accreditation.

DESIN-1031-b //EN 13727: 2012 + A2: 2015 Version 8 (2019-10-02)

DESIN-1031.5-b//EN 13727:2012+A2:2015- Additional bacteria Version 3 (2023-03-02)

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Registration No.: D/23/B0840

Instituto Valenciano de Microbiología

4. Information about sample reception

- Date of reception of the sample 2023/05/18.
- Date of reception of order with test conditions 2023/11/24.
- Aspect of the received sample..... Blue transparent liquid received in plastic container.

5. Method of assay and its validation (EN 13727: 2012 + A2: 2015 Standard)

- Method used Dilution-neutralization.
- Neutralizer Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.

6. Experimental conditions

- Assay period (including prior preparation of the strains)..... 2023/12/13 to 2023/12/17.
- Solvent of the product used in the assay ... Sterile distilled water.
- Product concentrations for the assay Pure (80%), 50% and 0.1%.
- Aspect of the dilutions of the product Pure (80%), and 50% bluish transparent liquid; 0.1% transparent liquid.
- Contact time 60 seconds.
- Assay temperature 20°C ± 1°C.
- Interfering substance Bovine serum albumin 3 g/L + erythrocytes 3mL/L.
- Stability of the mixture (interfering substance and product diluted in sterile distilled water) Stable.
- Incubation temperature +36°C ± 1°C.
- Identification of the strains used:
 - *Staphylococcus aureus* MRSA (ATCC 33592).
 - *Enterococcus faecium* (ATCC 6057 = CECT 8108).

7. Results of the assay

- Assay of validation See tables 1, 2, 4 and 5.
- Evaluation of bactericidal activity See tables 3 and 6.
- Number of replicates per assay organism. 1.

8. Special remarks

- All controls and validation were between the basic limits.
- For a valid test, at least one concentration must show a log reduction lower than 5 log, and at least one concentration must show a log reduction equal or higher than 5 log.
- No precipitation was observed during the assay procedure (the mixtures were homogenous).
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.

9. Conclusion

The product **Dezinfectant Universal “Bio-Dez”**, batch 34692/23/ROBCH, when it is pure (80%), concentration requested by the client, **shows bactericidal activity** after 60 seconds at $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3mL/L), for the reference strains *Staphylococcus aureus* MRSA (ATCC 33592) and *Enterococcus faecium* (ATCC 6057 = CECT 8108), when tested according to **EN 13727: 2012 + A2: 2015 Standard, with deviations from the standard due to not testing all mandatory microorganisms.**

With the results obtained with the product **Dezinfectant Universal “Bio-Dez”**, batch 34692/23/ROBCH, **it cannot be concluded** that the product has general bactericidal activity, but only that it has activity against *Staphylococcus aureus* MRSA and *Enterococcus faecium*.

Note: The results obtained correspond to the sample received in the laboratory.

Use of the ENAC mark: The ENAC “mark” can only be used by the holder of the accreditation. Its use in packaging, installations, shop windows, advertising or other documentation format other than that issued by the accredited entity (IVAMI) is not allowed.

Bétera (Valencia), January 4, 2024.

**GARCIA DE LOMAS
LATIN, JAIME (FIRMA)**

Signed. Jaime García de Lomas.
Responsible Technician
(Investigator)

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials, and reagents, following the Good Laboratory Practices (GLPs) as well and the final report contains the primary data obtained.

**MONTOYA VIECO,
ELENA (FIRMA)**

Signed. Elena Montoya.
Responsible for the Laboratory Area
(Study Director)

**TEMPRANO LOPEZ
ANA - 47374856P**

Signed. Encarnación Esteban.
Technical Director
(Quality Assurance Director)
Signed by delegation by Ana Temprano

Reference

- **EN 13727: 2012 + A2: 2015.** Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in Medicine. Test method and requirements (phase 2, step 1).

DESIN-1031-b //EN 13727: 2012 + A2: 2015 Version 8 (2019-10-02)

DESIN-1031.5-b//EN 13727:2012+A2:2015- Additional bacteria Version 3 (2023-03-02)

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Registration No.: D/23/B0840

Instituto Valenciano de Microbiología

Results of the assay (Bacterial suspension) with *Staphylococcus aureus* MRSA (ATCC 33592).

Method: Dilution-neutralization; Seeding: Pour plate; No. of plates: 1/mL.

Table 1.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: Pure (80%)		
V_{C1}	83	$X= 87$	V_{C1}	71	$X= 77$	V_{C1}	89	$X=$	V_{C1}	77	$X=$
V_{C2}	91		V_{C2}	83		V_{C2}	100	94.5	V_{C2}	80	78.5
$30 \leq X \text{ of } N_{V0} \leq 160?$ Yes			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$ Yes			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0} \text{ or } 0.0005 N_{VB}?$ Yes			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$ Yes		
Suspension of validation (N_{VB})			$V_{C1}: 100 \quad V_{C2}: 112$			$X = 106$ $30 \leq X \text{ of } N_{VB}/1000 \leq 160?$ Yes					

Table 2.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 2.70 \times 10^8,$ $\lg N = 8.43$ $N_0 = N/10;$ $\lg N_0 = 7.43$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	>330	>330	
	10^{-7}	24	30	

Table 3.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\text{Lg } N_a = \lg (X \times 10^6 \text{ o } X_{wm} \times 10)$	$\text{Lg } R$ ($\text{Lg } N_0=7.43$)	Time of contact (sec)
Pure (80%)	N_a^0	<14	<14	<2.15	>5.28	60
	N_a^{-1}	<14	<14			
50%	N_a^0	<14	<14	<2.15	>5.28	60
	N_a^{-1}	<14	<14			
0.1 %	N_a^0	>330	>330	>4.52	<2.91	60
	N_a^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg N_a$).

Results of the assay (Bacterial suspension) with *Enterococcus faecium* (ATCC 6057 = CECT 8108).

Method: Dilution-neutralization; Seeding: Pour plate; No. of plates: 1/mL.

Table 4.-Validation and controls

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: Pure (80%)		
V_{c1}	58	$X=60$	V_{c1}	57	$X=$	V_{c1}	54	$X=58$	V_{c1}	50	$X=$
V_{c2}	62		V_{c2}	56	56.5	V_{c2}	62		V_{c2}	57	53.5
30 ≤ X of N_{v0} ≤ 160?			X of A is ≥ 0.5 X of N_{v0} ?			X of B is ≥ 0.5 X of N_{v0} or 0.0005 N_{vB} ?			X of C is ≥ 0.5 X of N_{v0} ?		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{vB})			$V_{c1}: 68 \quad V_{c2}: 64$			$X=66$ 30 ≤ X of $N_{vB}/1000$ ≤ 160? Yes					

Table 5.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{c1}	V_{c2}	$X_{wm} = 2.45 \times 10^8$, $\lg N = 8.39$ $N_0 = N/10$; $\lg N_0 = 7.39$ $7.17 \leq \lg N_0 \leq 7.70$? Yes
	10^{-6}	>330	>330	
	10^{-7}	26	23	

Table 6.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{c1}	V_{c2}	$\lg Na = \lg (X \times 10^0 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0=7.39$)	Time of contact (sec)
Pure (80%)	Na^0	<14	<14	<2.15	>5.24	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.24	60
	Na^{-1}	<14	<14			
0.1 %	Na^0	>330	>330	>4.52	<2.87	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{c1} and V_{c2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$)

RAPORT DE INCERCARE NR. 1071/23/ROBCH/Z1

Inlocuieste Raportul de Incercare Nr. 1071/23/ROBCH din 02.03.2023

Client ECOCHIM-GRUP SRL STRADA PETRICANI 21/3 2059 CHIȘINĂU	Numărul eEantionului: 1071/23/ROBCH Descriere obiect de incercat (conform cu declaratia Clientului) Dezinfectant Universal "Bio-Dez" Lot: - Data fabricatie: 13.12.2022 Data expirarii: 13.12.2025 Data prelevarii: 13.12.2021 Cantitate prelevata:500 ml Responsabil prelevare: Cristinov Alexandr Ora receptiei probei: 08:00 Temperatura receptie proba: 15°C Sample condition with no objections
Data primirii obiectului de incercat:	11.01.2023
Data finalizarii incercarii:	02.03.2023
Data eliberarii raportului:	02.08.2023
Comanda din 11.01.2023 Probele au fost prelevate si livrate de catre Client.	

Parametrii de testare	Metoda de testare	Unitate de masura	Rezultat
# * Fungicidal activity in medical area. 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).	EN 13624:2014	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/23/B0019 , issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Responsabil incercare: Mariana Ilinca, Sef Laborator Microbiologie
Validat de: Mariana Ilinca, Sef Laborator Microbiologie
Autorizat de: Alina-Roxana Mihai, General Manager (Aprobat cu semnatura electronica)

Laborator: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevarii probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercarii. Daca nu se specifica altfel, incertitudinea de masurare a fost estimata pentru coeficientul K= 2 si nivel de incredere 95%. Fara aprobarea scrisa a laboratorului acest raport de incercare nu poate fi reprodus decat integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se refera exclusiv la rezultatele si declaratiile prezentate in raportul original. Opiniile si interpretarile continute in prezentul raport de incercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare va rugam sa solicitati Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

* Metoda de testare acreditata # Test efectuat de catre subcontractor
ø Incercari neacreditate



A) IDENTIFICATION OF THE SAMPLE	
Name of the product/Details about the product	Dezinfectant Universal "Bio-Dez" Manufacturer(supplier): Ecochim-Grup Condition of use: Instrument disinfection, surface disinfection without mechanical action textile disinfection
Solvent of the product recommended by the manufacturer	Not indicated
Active(S) substance (S) and its concentration(s)	Ethyl alcool 72-76%, CAS 64-17-5 and CE 200-578-6 Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2 Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
Concentrations requested for the assay	80% and 97%.
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report no.: D/23/B0019 and D/23/B0413- Quantitative evaluation assay of fungicidal activity in Medicine (phase 2, step1), with the product "Dezinfectant Universal "Bio-Dez"". (EN 13624 : 2022 Standard)	EN 13624: 2022. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of the fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1).
Testing method	EN 13624: 2022
Method	Dilution-neutralization
Neutralizer	Tryptone 5 g/L, yeast extract, 2.5 g/L, dextrose 10g/L, sodium thioglycolate 1g/L, sodium thiosulfate 1g/L, sodium bisulfide 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	2023/01/13
Date of reception of order with test conditions	2023/01/16.
Date of reception of order with test conditions (test at 97%)	2023/06/14
Aspect of the received product	Blue liquid in plastic package
D) EXPERIMENTAL CONDITIONS	
Assay period	2023/02/08 to 2023/02/17 (test at 80%). 2023/07/05 to 2023/07/15 (test at 97%).
Solvent of the product used in the assay	Sterile distilled water (test at 80%). Not applicable (test at 97%).
Product concentrations for the assay	First test: 80%, 50% and 0.1% Second test: 97%.
Aspect of the dilutions of the product	97%, 80% and 50% blue liquid; 0.1% transparent liquid.
Contact time	90 seconds
Assay temperature	+20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L plus erythrocytes 3 mL/L.
Stability of the mixture (interfering substance and product diluted in sterile distilled water)	Formation of flocs at 97% concentration and stable at 80%, 50% and 0,1%.
Temperature of incubation	+30°C ± 1°C
Identification of the origin of viral stains and number of passes	- <i>Aspergillus brasiliensis</i> (CECT 2574 = ATCC 16404). - <i>Candida albicans</i> (CECT 1394 = ATCC 10231).

Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosure cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosure.

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

JS. HAMILTON ROMANIA S.R.L.

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 02.08.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1

Results of the assay

- Assay of validation See tables 1, 2, 4 and 5.
- Evaluation of fungicidal activity See tables 3 and 6.
- Number of replicates per assay organism 1.

Special remarks

- All controls and validation were between the basic limits.
- For a valid test, at least one concentration must show a log reduction equal or higher than 4 log.
- Formation of flocs has been observed when mixed the product at 97% with the interference substance and the inoculum.
- No precipitate formed during the test procedure (test mixtures at 80%, 50 % and 0.1% were homogeneous).

Conclusion

The product **Dezinfectant Universal "Bio-Dez"**, batch 1071/23//ROBCH, at 80% **does not show fungicidal activity**, after 90 seconds at 20°C ±1°C, under **dirty conditions** (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), because it does not show activity against *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404) although it shows activity against *Candida albicans* (CECT 1394 = ATCC 10231), when tested as required by the **EN 13624: 2022 Standard**.

The product **Dezinfectant Universal "Bio-Dez"**, batch 1071/23//ROBCH, at 80% **shows yeasticidal activity**, after 90 seconds at 20°C ±1°C, under **dirty conditions** (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), for the strain *Candida albicans* (CECT 1394 = ATCC 10231), when tested as required by the **EN 13624: 2022 Standard**.

The product **Dezinfectant Universal "Bio-Dez"**, batch 1071/23//ROBCH, at 97% concentration requested by the client, **shows fungicidal activity**, after 90 seconds at 20°C ±1°C, under **dirty conditions** (bovine serum albumin 3 g/L plus erythrocytes 3ml/L), against the reference strains *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404) and *Candida albicans* (CECT 1394 = ATCC 10231), when tested as required by the **EN 13624: 2022 Standard**.

Note: The results obtained correspond to the sample received in the laboratory.

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1
Results of the assay with *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404).
First test at 80%.

Seeding: Pour plates. No. of plates: 4/mL.

Table 1.-Validation and controls.

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralizer (B)			Validation of the method (C) Sample concentration: 80%		
V_{C1}	72	$X=75$	V_{C1}	68	$X=67$	V_{C1}	61	$X=63$	V_{C1}	63	$X=66$
V_{C2}	78		V_{C2}	66		V_{C2}	65		V_{C2}	69	
30 ≤ X of N_{V0} ≤ 160? Yes			X of A is ≥ 0.5x X if N_{V0} ? Yes			X of B es ≥ 0.0005 N_{VB} ? Yes			X of C is ≥ 0.5x X of N_{V0} ? Yes		
Suspension of validation (N_{VB})			V_{C1} : 79 V_{C2} : 76			$X = 77.5$ 30 ≤ X de $N_{VB}/1000$ ≤ 160? Yes					

Table 2.-Suspension of the assay.

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 2.94 \times 10^7$ $\lg N = 7.47$ $N_0 = N/10$ $\lg N_0 = 6.47$ $6.17 \leq \lg N_0 \leq 6.70$?; Yes
	10^{-5}	291	297	
	10^{-6}	29	30	

Table 3.- Results of the activity test with the sample.

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 6.47$)	Time of contact (seconds)
Pure (80 %)	Na^0	>660	>660	4.05	2.42	90
	Na^{-1}	115	108			
50 %	Na^0	>660	>660	>4.82	<1.65	90
	Na^{-1}	>660	>660			
0.1 %	Na^0	>660	>660	>4.82	<1.65	90
	Na^{-1}	>660	>660			

Explanations:
 V_c = number per mL (one or two plates); X_{wm} = ponderated mean of X .

 X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2); R (reduction): ($\lg R = \lg N_0 - \lg Na$).

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PGL 09 F 04 Ed. 1 Rev. 0

Date: 02.08.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1**Counts per plate:** $(N) 10^{-5} = 70 + 73 + 74 + 74; 71 + 75 + 76 + 75;$ $10^{-6} = 6 + 7 + 8 + 8; 8 + 7 + 7 + 8;$ **Product:**Pure (80%) $\rightarrow Na^{-1} 28 + 27 + 31 + 30; 27 + 28 + 26 + 27;$ 50% $\rightarrow Na^{-1} = >165 + >165 + >165 + >165; >165 + >165 + >165 + >165;$ 0.1% $\rightarrow Na^{-1} = >165 + >165 + >165 + >165; >165 + >165 + >165 + >165;$ $A = 17+16+18+17; 17+16+16+17;$ $B = 15+16+15+15; 16+15+16+18;$ $C = 15+16+16+16; 17+18+16+18;$ $N_{V\theta} = 18+17+19+18; 19+20+20+19;$ $N_{VB} = 19+20+20+20; 19+19+19+19;$

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Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1
Results of the assay with *Aspergillus brasiliensis* (CECT 2574 = ATCC 16404).
Second test at 97%.

Seeding: plate pouring; No. of plates: 4/mL.

Table 1.-Validation and controls.

Suspension of validation (N_{V0})			Control of experimental (A)			Control of the neutralizer (B)			Validation of the method (C) Sample concentration: 97%		
V_{C1}	101	$X =$	V_{C1}	80	$X =$	V_{C1}	85	$X =$	V_{C1}	80	$X =$
V_{C2}	100	100.5	V_{C2}	82	81	V_{C2}	82	83.5	V_{C2}	82	81
30 ≤ X of N_{V0} ≤ 160? Yes			X of A is ≥ 0.5x X if N_{V0} ? Yes			X of B es ≥ 0.0005 N_{VB} ? Yes			X of C is ≥ 0.5x X of N_{V0} ? Yes		
Suspension of validation (N_{VB})			V_{C1} : 102 V_{C2} : 102			$X = 102$ 30 ≤ X de $N_{VB}/1000$ ≤ 160? Yes					

Table 2.-Suspension of the assay.

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.99 \times 10^8$ $\lg N = 8.30$ $N_0 = N/10$ $\lg N_0 = 7.30$ $7.17 \leq \lg N_0 \leq 7.70$?; Yes
10^{-6}	199	200		
10^{-7}	19	20		

Table 3.- Results of the activity test with the sample.

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.30$)	Time of contact (seconds)
97%	Na^0	<14	<14	<2.15	>5.15	90
	Na^{-1}	<14	<14			
	Na^{-2}	<14	<14			

Explanations:
 V_c = number per mL (one or two plates); X_{wm} = ponderated mean of X .

 X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2); R (reduction): ($\lg R = \lg N_0 - \lg Na$).

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PGL 09 F 04 Ed. 1 Rev. 0

Date: 02.08.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1

Counts per plate:

(N) $10^{-6} = 48 + 52 + 50 + 49; 49 + 50 + 51 + 50;$
 $10^{-7} = 4 + 5 + 5 + 5; 4 + 5 + 6 + 5.$

Sample:

97% = Na⁰ = 0 + 0 + 0 + 0; 0 + 0 + 0 + 0;

A = 19 + 20 + 22 + 19; 21 + 20 + 22 + 19;
B = 24 + 20 + 21 + 20; 19 + 21 + 22 + 20;
C = 20 + 21 + 20 + 19; 20 + 22 + 20 + 20;
N_{V0} = 28 + 26 + 24 + 23; 25 + 24 + 26 + 25;
N_{VB} = 27 + 24 + 26 + 25; 25 + 24 + 27 + 26.

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Page 6 of 8

Date: 02.08.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1
Results of the assay with *Candida albicans* (CECT 1394 = ATCC 10231).
First test at 80%.

Seeding: Pour plates. No. of plates: 1 /mL.

Table 4.-Validation and controls.

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralizer (B)			Validation of the method (C) Sample concentration: 80%		
V_{C1}	96	$X =$	V_{C1}	83	$X =$	V_{C1}	87	$X =$	V_{C1}	82	$X =$
V_{C2}	100	98	V_{C2}	89	86	V_{C2}	100	93.5	V_{C2}	85	83.5
$30 \leq X \text{ of } N_{V0} \leq 160?$ Yes			$X \text{ of } A \text{ is } \geq 0.5x$ $X \text{ if } N_{V0}?$ Yes			$X \text{ of } B \text{ es } \geq 0.0005$ $N_{VB}?$ Yes			$X \text{ of } C \text{ is } \geq 0.5x$ $X \text{ of } N_{V0}?$ Yes		
Suspension of validation (N_{VB})			$V_{C1}: 85 \quad V_{C2}: 87$			$X = 86$ $30 \leq X \text{ de } N_{VB}/1000 \leq 160?$ Yes					

Table 5. -Suspension of the assay.

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 3.65 \times 10^7$ $\lg N = 7.56$ $N_0 = N/10$ $\lg N_0 = 6.56$ $6.17 \leq \lg N_0 \leq 6.70?$ Yes
	10^{-5}	>330	>330	
	10^{-6}	38	35	

Table 6.-Results of the activity assays with the sample.

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10^0)$ $X_{wm} \times 10$	$\lg R$ ($\lg N_0 = 6.56$)	Time of contact (seconds)
Pure (80 %)	Na^0	<14	<14	<2.15	>4.41	90
	Na^{-1}	<14	<14			
50 %	Na^0	>330	>330	3.94	2.62	90
	Na^{-1}	88	87			
0.1 %	Na^0	>330	>330	>4.52	<2.04	90
	Na^{-1}	>330	>330			

Explanations:
 V_C = number per mL (one or two plates); X_{wm} = ponderated mean of X .

 X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2); R (reduction): ($\lg R = \lg N_0 - \lg Na$).

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*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 02.08.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 1071/23/ROBCH/Z1
Results of the assay with *Candida albicans* (CECT 1394 = ATCC 10231).
Second test at 97%.

Seeding: plate pouring; No. of plates: 1/mL.

Table 4.-Validation and controls.

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralizer (B)			Validation of the method (C) 97%		
V_{C1}	89	$X=87$	V_{C1}	80	$X=79.5$	V_{C1}	81	$X=82$	V_{C1}	80	$X=78$
V_{C2}	85		V_{C2}	79		V_{C2}	83		V_{C2}	76	
30 ≤ X of N_{V0} ≤ 160?			X of A is ≥ 0,5 x X of N_{V0} ?			X of B is ≥ 0,5 x X of N_{V0} , or 0.0005 N_{VB} ?			X of C is ≥ 0.5 x X of N_{V0} ?		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			V_{C1} : 87 V_{C2} : 89			$X=88$ 30 ≤ x de $N_{VB}/1000$ ≤ 160? Yes					

Table 5. -Suspension of the assay.

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 4.95 \times 10^8$ $\lg N = 8.69$ $N_0 = N/10$ $\lg N_0 = 7.69$ $7.17 \leq \lg N_0 \leq 7.70$? Yes
	10^{-6}	>330	>330	
	10^{-7}	51	48	

Table 6.-Results of the activity assays with the sample.

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0=7.69$)	Time of contact (seconds)
97%	Na^0	<14	<14	<2.15	>5.54	90
	Na^{-1}	<14	<14			
	Na^{-2}	<14	<14			

Explanations:
 V_C = number per mL (one or two plates); X_{wm} = ponderated mean of X .

 X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2); R (reduction): ($\lg R = \lg N_0 - \lg Na$).

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*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 02.08.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

RAPORT DE INCERCARE NR. 60363/23/ROBCH

Client ECOCHIM-GRUP SRL OR. UNGHENI, STR. NAȚIONALĂ 119 - REPUBLICA MOLDOVA	Numărul eșantionului: 60363/23/ROBCH Descriere obiect de incercat (conform cu declaratia Clientului) Dezinfectant Universal "Bio-Dez" Lot: - Data fabricatiei: 05.08.2023 Data expirare: 05.08.2026 Data receptiei probei: 23.08.2023 Cantitate prelevata:500 ml Responsabil prelevare: Cristinov Alexandr Ora receptiei probei: 12:30 Temperatura receptie proba: 17°C Sample condition with no objections Comanda din 24.08.2023 Probele au fost prelevate si livrate de catre Client.
Data primirii obiectului de incercat:	24.08.2023
Data inceperii incercarii:	30.08.2023
Data finalizarii incercarii:	22.11.2023
Data eliberarii raportului:	22.11.2023

Parametrii de testare	Metoda de testare	Unitate de masura	Rezultat
# * Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1) ¹⁾	EN 14348: 2005	-	Rezultatul incercarii se regaseste in raportul de incercare nr. D/23/B0672 primit de la subcontractor si anexat acestui raport.

¹⁾ Incercare efectuata de catre subcontractor cu Certificat de acreditare Nr. 648/LE1286.

Responsabil incercare: Mariana Iilca, Sef Laborator Microbiologie
 Validat de: Mariana Iilca, Sef Laborator Microbiologie
 Autorizat de: Manager general Mihai Alina-Roxana (Aprobat cu semnatura electronica)

Laborator: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevarii probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercarii. Daca nu se specifica altfel, incertitudinea de masurare a fost estimata pentru coeficientul K= 2 si nivel de incredere 95%. Fara aprobarea scrisa a laboratorului acest raport de incercare nu poate fi reprodus decat integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se refera exclusiv la rezultatele si declaratiile prezentate in raportul original. Opiniile si interpretarile continute in prezentul raport de incercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare va rugam sa solicitati Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

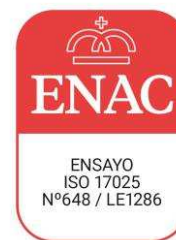
* Metoda de testare acreditata # Test efectuat de catre subcontractor
 ø Incercari neacreditate



Instituto Valenciano de Microbiología



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Test with the certificate of GLPs
(Good Laboratory Practices)
No. 2/21-C.VAL. General Directorate of
Pharmacy and Medical Devices of the Health
Department of the Valencian Region. Spain

Mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants (phase 2, step 1), with the product “Dezinfectant Universal “Bio-Dez””. (EN 14348: 2005 Standard)

Report

Registration No.: D/23/B0672.

1. **Laboratory identification** Instituto Valenciano de Microbiología.
2. **Client identification** J.S. HAMILTON ROMANIA SRL.
Address SOS BERCENI, NR 8, SECTOR 4
BUCURESTI, ROMANIA, 041914.
3. **Sample identification** (information provided by the client)
 - Product name **Dezinfectant Universal “Bio-Dez”.**
 - Batch number 60363/23/ROBCH.
 - Expiration date 05.08.2026.
 - Manufacturer/Supplier SRL “Ecochim-Grup”.
 - Keeping conditions Not indicated.
 - Condition for use Hygienic handrub, Instrument disinfection, surface disinfection.
 - Diluent recommended by the manufacturer ... Not indicated.
 - Active compound/s and its concentration/s ... Ethyl alcohol 72-76%, CAS 64-17-5 and CE 200-578-6 Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2 Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
 - Concentrations requested for the assay 80%

IVAMI is not responsible for client-supplied information. This information **is not covered** by the ENAC accreditation.

4. Information about sample reception

- Date of reception of the sample 2023/08/31.
- Date of reception of order with test conditions 2023/08/25.
- Aspect of the received samples..... Purple transparent liquid in plastic package.

5. Method of assay and its validation (EN 14348: 2005 Standard)

- Method used Dilution-neutralization.
- Neutralizer Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1g/L, sodium bisulphite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.

6. Experimental conditions

- Assay period (including prior preparation of the strains) 2023/09/28 to 2023/11/09.
- Solvent of the product used in the assay ... Sterile distilled water.
- Product concentrations for the assay 80%, 50% and 0.1%.
- Aspect of the dilutions of the product 80% purple transparent liquid;
50% blue transparent liquid;
0.1% transparent liquid.
- Contact time 60 seconds.
- Assay temperature 20°C ± 1°C.
- Interfering substance Bovine serum albumin 3 g/L and erythrocytes 3 mL/L.
- Stability of the mixture (interfering substance and product diluted in sterile distilled water) Stable.
- Temperature of incubation 36°C ± 1°C.
- Identification of the strains used

- *Mycobacterium avium* (ATCC 15769).
- *Mycobacterium terrae* (CECT 3028 = ATCC 15755).

7. Results of the assay

- Control and validation assays See tables 1, 2, 4 and 5.
- Evaluation of mycobactericidal activity See tables 3 and 6.
- Number of replicates for each assay microorganism 1.

8. Special remarks

- All controls and validation were between the basic limits.
- For a valid test, at least one concentration must show a reduction lower than 4 log and at least one concentration must show a reduction equal or higher than 4 log.
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.

9. Conclusion

The product **Dezinfectant Universal “Bio-Dez”**, batch 60363/23/ROBCH, when it is pure (80%), concentration requested by the client, **shows mycobactericidal activity** after 60 seconds, at $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), against the strains *Mycobacterium avium* (ATCC 15769) and *Mycobacterium terrae* (CECT 3028 = ATCC 15755), when tested as required by **EN 14348: 2005 Standard**.

Note: The results obtained correspond to the sample received in the laboratory.

Use of the ENAC mark: The ENAC “*mark*” can only be used by the holder of the accreditation. Its use in packaging, installations, shop windows, advertising or other documentation format other than that issued by the accredited entity (IVAMI) is not allowed.

Bétera (Valencia), November 9, 2023.

MIGUEL FRANCO,
CLAUDIA (FIRMA)

Signed: Claudia Miguel.
Responsible Technician

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials and reagents, following as well the Good Laboratory Practices (GLPs) and the final report contains the primary data obtained.

**MONTOYA VIECO,
ELENA (FIRMA)**

Signed. Elena Montoya.
Responsible for the Laboratory Area
(Study Director)

**ESTEBAN BERMUDEZ,
ENCARNACION PILAR
(FIRMA)**

Signed. Encarnación Esteban.
Technical Director
(Quality Assurance Director)

Reference

- **EN 14348: 2005.** Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1).

Table 1.-Assay with *Mycobacterium avium* (ATCC 15769): Validation and controls.

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Neutralizer (B)			Validation of the method (C) with sample concentration: 80%		
V_{c1}	97	$X = 100.5$	V_{c1}	98	$X = 96$	V_{c1}	92	$X = 95$	V_{c1}	93	$X = 91$
V_{c2}	104		V_{c2}	94		V_{c2}	98		V_{c2}	89	
$30 \leq X \text{ of } N_{v0} \leq 160?$ Yes			$X \text{ of } A \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ Yes			$X \text{ of } B \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ Yes			$X \text{ of } C \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ Yes		

Table 2.- Assay with *Mycobacterium avium* (ATCC 15769): Suspension of the assay.

Suspension of the assay (N_y N_0)	N	V_{c1}	V_{c2}	
	10^{-7}	391	405	$X_{wm} = 4.00 \times 10^9 = \lg = 9.60$ $N_0 = N/10 = \lg = 8.60$ $8.17 \leq N_0 \leq 8.70?$ Yes
	10^{-8}	44	41	

Table 3.- Assay with *Mycobacterium avium* (ATCC 15769).

Concentrations of the sample (%)	Dilutions	V_{c1}	V_{c2}	$\lg Na = \lg (X \times 10^0 / X_{wm} \times 10)$	$\lg R (\lg N_0 = 8.60)$	Time of contact (sec)
80 %	10^0	<14	<14	< 2.15	> 6.45	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
50 %	10^0	<14	<14	< 2.15	> 6.45	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
0.1 %	10^0	>660	>660	>6.82	<1.78	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			

Observations:

N 10^{-7} : 198 + 193; 202 + 203;

10^{-8} : 20 + 24; 19 + 22;

Na 80% 10^0 : 0 + 0; 0 + 0;

50% 10^0 : 0 + 0; 0 + 0;

0.1% 10^{-3} : >330 + >330; >330 + >330;

N_{v0} : 50 + 47; 55 + 49;

A: 46 + 52; 49 + 45;

B: 45 + 47; 49 + 49;

C: 48 + 45; 42 + 47;

Table 4.-Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755): Validation and controls.

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Neutralizer (B)			Validation of the method (C) with sample concentration: 80%		
V_{c1}	79	$X = 80.5$	V_{c1}	66	$X = 68$	V_{c1}	75	$X = 77$	V_{c1}	67	$X = 69.5$
V_{c2}	82		V_{c2}	70		V_{c2}	79		V_{c2}	72	
$30 \leq X \text{ of } N_{v0} \leq 160?$ Yes			$X \text{ of } A \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ Yes			$X \text{ of } B \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ Yes			$X \text{ of } C \text{ is } \geq 0.5 \times X \text{ of } N_{v0}?$ Yes		

Table 5.- Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755): Suspension of the assay.

Suspension of the assay (N_y N_0)	N	V_{c1}	V_{c2}	$X_{wm} = 2.86 \times 10^9 = \lg = 9.46$ $N_0 = N/10 = \lg = 8.46$ $8.17 \leq N_0 \leq 8.70?$ Yes
	10^{-7}	295	275	
	10^{-8}	32	29	

Table 6.- Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755).

Concentrations of the sample (%)	Dilutions	V_{c1}	V_{c2}	$Lg Na = \lg (X \times 10^0 / X_{wm} \times 10)$	$LgR (\lg N_0 = 8.46)$	Time of contact (sec)
80 %	10^0	<14	<14	<2.15	>6.31	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
50 %	10^0	<14	<14	<2.15	>6.31	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
0.1%	10^0	>660	>660	>6.82	<1.64	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			

Observations:

N 10^{-7} : 150 + 145; 130 + 145;

10^{-8} : 17 + 15; 14 + 15;

Na 80% 10^0 : 0 + 0; 0 + 0;

50% 10^0 : 0 + 0; 0 + 0;

0.1% 10^{-3} : >330 + >330; >330 + >330;

N_{v0} : 40 + 39; 40 + 42;

A : 32 + 34; 34 + 36;

B : 39 + 36; 40 + 39;

C : 36 + 31; 35 + 37;

Explanations:

V_c : Counts per mL.

X_{wm} : weighted mean of X .

X : Values of V_{c1} and V_{c2} (1. + 2. duplicates); R : reduction ($LgR = \lg N_0 - \lg Na$).