

RAPORT DE INCERCARE NR. 17899/21/ROBCH/Z1

Inlocuieste Raportul de Incercare Nr. 17899/21/ROBCH din 26.04.2021

Client ECOCHIM-GRUP SRL STRADA PETRICANI 21/3 2059 CHIȘINĂU		Numă rul esantionului: Sample number Descriere obiect de incercat (conform cu declaratia Clientului) DEZINFECTANT UNIVERSAL "BIO-DEZ" Sample quantity: 1 pcs x 1 L Production date: 26.01.2021 Expiration date: 26.01.2024 Sampling date: 22.02.2021 Sample temperature: 15°C Reception hour: 15:00 Responsible for sampling: Crestinov Alexandr	
Data primirii obiectului de incercat:	15.03.2021	Sample condition with no objections	
Data finalizarii incercarii:	26.04.2021	Comanda din 15.03.2021	
Data eliberarii raportului:	14.09.2021	Probele au fost prelevate si livrate de catre Client.	

Parametrii de testare	Metoda de testare	Unitate de masura	Rezultat
# * 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/21/V0204, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborat de: Mariana Ilinca, Sef Laborator Microbiologie
 Autorizat de: Mariana Ilinca, Sef Laborator Microbiologie
 Aprobat de catre: 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

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17899/21/ROBCH/Z1

Conclusion

The disinfectant sample "DEZINFECTANT UNIVERSAL, BIO-DEZ", batch not indicated, under clean conditions (bovine serum albumin 0.3 g/L), at 3% concentration, requested by the client, and during 60 seconds of contact time and 20°C of temperature, does not show virucidal activity against the three mandatory viruses (Poliovirus type 1, Adenovirus type 5 and Murine Norovirus) when the activity is assayed according with the NF EN 14476: 2013 + A2: 2019 Standard. However, the disinfectant sample "DEZINFECTANT UNIVERSAL, BIO-DEZ", batch not indicated, under clean conditions (bovine serum albumin 0.3 g/L), at 80% concentration and during 60 seconds of contact time and 20°C of temperature, shows virucidal activity against the three mandatory viruses (Poliovirus type 1, Adenovirus type 5 and Murine Norovirus) when the activity is assayed according with the NF EN 14476: 2013 + A2: 2019 Standard.

Therefore, the disinfectant tested, **does not show general virucidal activity**, diluted at 3% and **it shows general virucidal activity**, diluted at 80% when the activity is evaluated according to the NF 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".

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.

Reference:

- NF EN 14476: 2013 + A2: 2019 Standard. Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (Phase 2/Step 1). AFNOR.

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.

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Enclosure no. 1 subcontracted tests

Date: 13.09.2021

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Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

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

REPORT OF ANALYSIS No. 80249/21/ROBCH

Client ECOCHIM-GRUP SRL STRADA PETRICANI 21/3 2059 CHIȘINĂU		Sample number: 80249/21/ROBCH Sample description (according to declaration of Client) DEZINFECTANT UNIVERSAL "BIO-DEZ" Lot: - Data fabricatie: 01.10.2021 Data expirarii: 01.10.2024 Data prelevării: - Cantitate prelevata: 1 x 500 ml Responsabil prelevare: CRESTINOV ALEXANDR Ora receptiei probei: 15:30 Temperatura receptie proba: 15°C Sample condition with no objections Order of 11.10.2021 Sampling and delivery were carried out by client.	
Sample received:	11.10.2021		
Tests performed:	21.10.2021		
Tests completed:	13.12.2021		
Report dated:	13.12.2021		

Test	Method	Unit	Result
# * Quantitative suspension test for the evaluation of bactericidal activity in medical area	EN 13727:2012+A2:2015	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/21/B0645, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborated by: Mariana Ilinca, Manager of Microbiological Laboratory

Authorized by: Mariana Ilinca, Manager of Microbiological Laboratory

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

Laboratory: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevării probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercării. 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

∅ Non accredited methods



ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

Results of the assay

- Assay of validation See tables 1, 2, 4, 5, 7, 8, 10 and 11.
- Evaluation of bactericidal activity See tables 3, 6, 9 and 12.
- Number of replicates per assay organism .. 1.

Special remarks

- All controls and validation were between the basic limits.
- At least one concentration of the sample showed a log reduction lower than 5 log.
- At least one concentration of the sample showed a log reduction higher than 5 log.
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.
- No precipitate formed during the test procedure (the test mixtures were homogeneous).

Conclusion

The product Desinfectant Universal "Bio-Dez", batch not indicated, when is pure (80%), 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 UNE-EN 13727: 2012 + A2: 2015 Standard.

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

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.

Reference

- UNE-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). AENOR.

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

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Enclosure no. 1 subcontracted tests

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Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

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

REPORT OF ANALYSIS No. 80248/21/ROBCH

Client ECOCHIM-GRUP SRL STRADA PETRICANI 21/3 2059 CHIȘINĂU		Sample number: 80248/21/ROBCH Sample description (according to declaration of Client) DEZINFECTANT UNIVERSAL "BIO-DEZ" Lot: - Data fabricatie: 01.10.2021 Data expirarii: 01.10.2024 Data prelevării: - Cantitate prelevata: 2 x 500 ml Responsabil prelevare: CRESTINOV ALEXANDR Ora receptiei probei: 15:30 Temperatura receptie proba: 15°C Sample condition with no objections	
Sample received:	11.10.2021	Order of 11.10.2021 Sampling and delivery were carried out by client.	
Tests performed:	21.10.2021		
Tests completed:	13.12.2021		
Report dated:	13.12.2021		

Test	Method	Unit	Result
# * 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/21/B0644 , issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Elaborated by: Mariana Ilinca, Manager of Microbiological Laboratory
 Authorized by: Mariana Ilinca, Manager of Microbiological Laboratory
 Approved by: Alina-Roxana Mihai, General Manager (Approved with qualified electronic signature)

Laboratory: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevării probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercării. Dacă 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

∅ Non accredited methods



Results of the assay

- Assay of validation See tables 1 and 2.
- Evaluation of yeasticidal activity See table 3.
- Number of replicates per assay organism 1.

Special remarks

- All controls and validation were between the basic limits.
- At least one concentration of the sample showed a log reduction lower than 4 log.
- At least one concentration of the sample showed a log reduction higher than 4 log.
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.
- No precipitate formed during the test procedure (the test mixtures were homogeneous).

Conclusion

The product Desinfectant Universal "Bio-Dez", batch not indicated, when is pure (80%), shows yeasticidal 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 strain *Candida albicans* (CECT 1394 = ATCC 10231), when tested as required by the UNE-EN 13624: 2014 Standard.

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

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.

Reference

- UNE-EN 13624 : 2014. 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). AENOR.

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

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Enclosure no. 1 subcontracted tests

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Date: 08.12.2021

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Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

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

REPORT OF ANALYSIS No. L21206/22/JSR

Client ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU	Sample description (according to declaration of Client) Dezinfectant Universal "Bio-Dez" Lot/Batch: - Production date: - Expiration date: 18.02.2025 Sampling date: 18.02.2022 Sampling quantity: 1x 500ml Sample temperature: 20°C Reception hour: 12:30 Responsible for sampling: Crestinov Alexandr Sample condition with no objections Sample No 1
Sample received: 2022-03-03	Order of 2022-03-02 The samples were delivered by Client
Analysis completed (the date of performance of the laboratory activity): 2022-04-13	
Report dated: 2022-04-13	

Test	Method	Unit	Result
* Bactericidal and/or fungicidal activity of disinfectants on non-porous surfaces - quantitative method ¹⁾	PN-EN 13697+A1:2019-08		Product undiluted and diluted to 50% shows bactericidal activity at 60 seconds, 20°C, in dirty conditions (3g/L bovine albumin) at reference strains: Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541, Pseudomonas aeruginosa ATCC 15442 and Escherichia coli ATCC 10536.

¹⁾ The results of the analysis in attachment No 1 to the report of analysis.

THE END OF THE REPORT

Authorized by: Daria Depa, Senior Analyst Specialist, Cosmetics Microbiology Laboratory
 Approved by: Hanna Wachowska, Laboratory Director (Approved with electronic signature)

Laboratory: Tychy 43-100, Goździków 1

The results relate to the analysed samples only. Unless otherwise specified given expanded measurement uncertainty was estimated for the coverage factor $k=2$ at 95% confidence level. Sampling uncertainty has not been taken into consideration. Unless otherwise specified when conformity is stated J.S. Hamilton Poland Sp. z o.o. applies the simple acceptance decision rule in accordance with ILAC-G8:09/2019. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on www.hamilton.com.pl

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