ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 8024/21/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**DEZINFECTANT UNIVERSAL "BIO-DEZ"** Expiration date: 01.10.2024. Manufacturer (supplier): Ecochim-Grup SRL. Storing conditions: Dry, without sun, 5-25 Celsius degree. Conditions of use: Hygienic handrub, surface disinfection, medical instruments disinfection, surgical handrub
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	Pure (80%).
B) TEST METHOD	
Performed in accredited contracted partner laboratory, Scope of Accreditation Nr. 648/LE1286 Report Registration No. D/21/B0644 Quantitative evaluation assay of yeasticidal activity under dirty conditions, in the medical area (phase 2, step 1), with product Desinfectant Universal"Bio-Dez", (UNE-EN 13624: 2014 Standard).	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.
Testing method	Procedure DESIN-1058-b // EN 13624:2014
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of order with test conditions	21.10.2021
Date of reception of the sample	25.10.2021
Aspect of the received product	Blue liquid in plastic package
D) METHOD OF ASSAY AND ITS VALIDATION (UNE-EN 13624: 2014 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, soy lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and Saponin 30 g/L.
E) EXPERIMENTAL CONDITIONS	
Assay period	2021/11/08 to 2021/11/14.
Solvent of the product used in the assay	Sterile distilled water.
Product concentrations for the assay	Pure (80%), 50%, 0.1%
Aspect of the dilutions of the product	Pure (80%) and 50% blue liquid; 0.1% transparent.
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	+30°C± 1°C
Identification of the strain used	*Candida albicans* CECT-1394 (ATCC 10231)

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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)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80248/21/ROBCH

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 20ºC ± 1ºC, 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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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80249/21/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**DEZINFECTANT UNIVERSAL "BIO-DEZ"** Expiration date: 01.10.2024. Manufacturer (supplier): Ecochim-Grup SRL. Storing conditions: Dry, without sun, 5-25 Celsius degree. Conditions of use: Hygienic handrub, surface disinfection, medical instruments disinfection, surgical handrub
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	Pure (80%).
B) TEST METHOD	
Performed in accredited contracted partner laboratory, Scope of Accreditation Nr. 648/LE1286 Report Registration No. D/21/B0645 Quantitative evaluation assay of the bactericidal activity under dirty conditions, in the medical area (phase 2, step 1) with product Desinfectant Universal"Bio-Dez", (UNE-EN 13727: 2012 + A2: 2015 Standard).	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.
Testing method	DESIN-1031-b //EN 13727: 2012 + A2: 2015
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of order with test conditions	21.10.2021
Date of reception of the sample	25.10.2021
Aspect of the received product	Blue liquid in plastic package
D) METHOD OF ASSAY AND ITS VALIDATION (UNE-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.
E) EXPERIMENTAL CONDITIONS	
Assay period	2021/11/10 to 2021/11/14.
Solvent of the product used in the assay	Sterile distilled water.
Product concentrations for the assay	Pure (80%), 50%, 0.1%
Aspect of the dilutions of the product	Pure (80%) and 50% blue liquid; 0.1% transparent.
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 strain used	– *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442). – *Staphylococcus aureus* (CECT 239 = ATCC 6538). – *Enterococcus hirae* (CECT 4081 = ATCC 10541). – *Escherichia coli K12* (CECT 433 = NCTC 10538).

Date: 08.12.2021
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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE 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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ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17898/21/ROBCH

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**DEZINFECTANT UNIVERSAL "BIO-DEZ"** Expiration date: 26.01.2024 Manufacturer (supplier): ECOCHIM-GRUP Storing conditions: Dry, without sun, 5-25 Celsius degree. Conditions of use: 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; Methylthioninium chloride 0.00024%, CAS 61-73-4 and 200
Concentrations requested for the assay	3%/ on May 5 the client requested to perform the test at 80% concentration (Pure).
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report D/21/B0152 Mycobactericidal and tuberculocidal activity of chemical disinfectants in the medical area including instrument disinfectants under clean conditions with the product **DEZINFECTANT UNIVERSAL "BIO-DEZ"** with deviations from the standard **(UNE-EN 14348: 2005 Standard)**	UNE-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). AFNOR
C) METHOD OF ASSAY AND ITS VALIDATION (UNE-EN 14348: 2005 Standard)	
Testing method	DESIN-1052-b // EN 14348: 2005
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 saponim 30 g/L.
D) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	24.03.2021
Date of reception of order with test conditions	14.04.2021: 3% concentration 05.05.2021: 80% concentration
Aspect of the received product	Blue liquid in plastic package.
E) EXPERIMENTAL CONDITIONS	
Assay period	2021/04/12 to 2021/05/24 (including prior preparation of the strains)
Solvent of the product used in the assay	Sterile hard water
Product concentrations for the assay	Pure (80%), 3% and 0.1%
Aspect of the dilutions of the product	Pure (80%) Blue liquid; 3% and 0.1% transparent
Contact time	60 seconds
Assay temperature	20°C ± 1°C
Interfering substance	Bovine albumin 0.3 g/L
Stability of the mixture (interfering substance and product diluted in sterile hard water)	stable
Temperature of incubation	36°C ± 1°C
Identification of the origin of viral stains and number of passes	*Mycobacterium avium* (ATCC 15769) *Mycobacterium terrae* (CECT 3028 = ATCC 15755)

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Date: 09.06.2021
Authorized by: Mariana Ilinca, Manager of Microbiological laboratory
Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 17898/21/ROBCH

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.

Special remarks

- All controls and validation were between the basic limits.
- One concentration of the sample at least showed a log reduction less than 4 log.
- One concentration of the sample at least 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.
- When the client requested to perform the test at 80% concentration, the test had been started, using hard water.

Conclusion

The product **DEZINFECTANT UNIVERSAL „BIO-DEZ"**, batch not indicated, when tested pure (80%), **shows mycobactericidal activity** after 60 seconds at 20°C under clean conditions (bovine albumin 0.3 g/L), against *Mycobacterium avium* (ATCC 15769) and *Mycobacterium terrae* (CECT 3028 = ATCC 15755), when tested as required by **UNE-EN 14348: 2005 Standard** with deviations from the standard since the dilutions of the product, ready to use, have been prepared in sterile hard water instead of in sterile distilled water. The client informed us that the product was ready to use once the test have been started.

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 as well the Good Laboratory Practices (GLPs) and the final report contains the primary data obtained.

Reference:

- **UNE-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). AENOR.

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

A) IDENTYFICATION OF THE SAMPLE	
Name of the product/Details about the product	**DEZINFECTANT UNIVERSAL "BIO-DEZ"** Sample quantity: 1 pcs x 1 L Production date: 26.01.2021 Expiration date: 26.01.2024 Manufacturer(supplier): ECOCHIM-GRUP Dry, without sun, 5-25^{0}C
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; Methylthioninium chloride 0,00024%, CAS 61-73-4 and 200.
Concentration ordered for the assay	3%
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report D/21/V0204- Modified report Virucidal test with the sample **DEZINFECTANT UNIVERSAL "BIO-DEZ"** against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus (NF EN 14476:2013+A2:2019 Standard)	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/Step1).AFNOR
Testing method	Procedure DESIN-1078 (NF EN 14476:2013+ A2:2019 Standard)
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	22.03.2021
Date of reception of order with test conditions	22.03.2021
Aspect of the received product	Blue transparent liquid in a plastic container
D) EXPERIMENTAL CONDITIONS	
Assay period	From 22.03.2021 to 01.04.2021
Assay temperature	37°C ± 1°C
Titration method	TCID50 (Tissue Culture Infective Dose 50%)
Product concentrations for the assay	80%, 3% and 0.03%
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	Hard 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	Clean conditions in the presence of bovine serum albumin 0.3 g/L.
Identification of the origin of viral stains and number of passes	Poliovirus type 1 aliquot: 2021/01/07 passage 2; Adenovirus type 5 aliquot: 2021/01/14 passage 2; Murine Norovirus aliquot: 2021/02/11 passage 2;
Cell lines (name, origin, number of passes)	Vero ref: FTVE, working aliquot 12 passages 13 and 17; Raw 264.7, Public Health England, working aliquot 12, passages 12, 16 and 18;

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Date: 13.09.2021
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ENCLOSORE 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.

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HAMILTON

AB 079

REPORT OF ANALYSIS No. 136987/21/JSHR/Z2

Replaces Report of Analysis No. 136987/21/JSHR of 2021-04-14

Client **ECOCHIM-GRUP SRL** STRADA PETRICANI 21/3 2059 CHIȘINĂU		Sample description *(according to declaration of Client)* **DEZINFECTANT UNIVERSAL "BIO-DEZ"** **Sample quantity: 2 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**
Sample received:	**2021-03-18**	**Sample condition with no objections**
Analysis completed (the date of performance of the laboratory activity):	**2021-04-14**	**Order of 2021-03-09**
Report dated:	**2021-07-27**	The samples were delivered by Client

Test	Method	Unit	Result
* Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2)[1)]	PN-EN 1500:2013-07		The preparation has bactericidal effect against transient microorganisms used in the hygienic procedure of hand disinfection - a single rubbing of 3ml of the preparation for 60 seconds.

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

Identification of the change: test result

THE END OF THE REPORT

Authorized by:
Approved by: Hanna Wachowska, Laboratory Director *(Approved with electronic signature)*

Laboratory: Tychy 43-100, Goździków 1

* Test method accredited; # Test performed by external provider

Form PO-10/02a of 20.01.2020

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