MINISTERUL SĂNĂTĂŢII AL REPUBLICII MOLDOVA

AGENŢIA NAŢIONALĂ PENTRU SĂNĂTATE PUBLICĂ

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CERTIFICAT
DE ÎNREGISTRARE DE STAT

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Nr.	B-0284/2025
din	10.09.2025

I. Denumirea comercială a produsului în Republica Moldova

Dezinfectant GamaDez

Alte denumiri comerciale

II. Date de identificare ale solicitantului (numele, adresa, ţara)

S.R.L. "ECOCHIM-GRUP", Republica Moldova, r-nul Ocnița, or. Otaci, str. Vasilii Voitovici, 21, 7106

III. Date de identificare a producătorului (numele, adresa, ţara)

S.R.L. ECOCHIM-GRUP S.R.L., str. Nationala 119, orasul Ungheni, Republica Moldova,

IV. Date de identificare a produsului

1. Categoria de produs	biocid
1.1. Grupa principală	1
1.2. Tip de produs	1,2,4

Certificatul de înregistrare este valabil până la data: 21.06.2029.

În conformitate cu Hotărârea Guvernului nr. 344 din 10.06.2020 s-a decis ca următorul produs biocid poate fi fabricat sau comercializat si utilizat în republica Moldova. Conform prevederilor legislației în vigoare.

Orice modificare a datelor de identificare a produsului biocid, duce în mod automat la anularea certificatului de înregistrare.

Director adjunct **Vasile Gustiuc**

Digitally signed by Guştiuc Vasile
Date: 2025.09.24 15:46:37 EEST
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Date: 2025.10.21 09:28:52 EEST
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Anexa 1
la certificatul nr. B-0284/2025 din 10.09.2025 pentru înregistrare de stat a produsului biocid

I. Denumirea comercială a produsului în Republica Moldova

Dezinfectant GamaDez

VI. Date privind substanța(ele) activă(e) a produsului

Denumirea chimică (IUPAC, ISO sau alte)	*Nr. CE*	*Nr. CAS*	*Cantitatea în produs*
Alcool etilic	200-578-6	64-17-5	72-76%
Alcool izopropilic	200-661-7	67-63-0	1-8%

VII. Forma de condiționare

lichid/gel

VIII. Modul de ambalare (tipul, capacitatea)

recipient din plastic de la 0,05L pănа la 1000L.

IX. Domeniul și aria de utilizare

1. Domeniul de utilizare	Dezinfecția igienică și chirurgicală a mâinilor. Dezinfecția instrumentelor medicale și a suprafețelor. Produse alimentare și hrana pentru animale.
2. Aria de aplicare	Dezinfecția igienică și chirurgicală a mâinilor, dezinfecția instrumentelor medicale și a suprafețelor, precum și dezinfectantul pentru industria alimentară și industria de preparare a furajelor, utilizat pentru dezinfecția echipamentului, recipientelor, ustensilelor de consum, suprafețelor sau conductelor în industria alimentară, transport, depozitare și consum.

X. Eficacitate

Activitatea	*Metoda de testare/protocolul de testare*	*Specia/tulpina*	*Concentrații*	*Timp de acțiune*
Bactericidă (Hygienic Handryb)	EN 1500	E.coli K12	100%	30 sec
Bactericidă (Hygienic Handwash)	EN 1499	E.coli K12	100%	30 sec.
Bactericidă (Surgical Handrub)	EN 12791:2016+A1:2017	Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae, Escherichia coli K12, Candida albicans	100%, 2x3ml	2x45 sec
Bactericidă in condiții de murdarie	EN 13727	Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae, Escherichia coli K12, Staphylococcus aureus MRSA,	80%; 50%;10%	30 sec.

		Enterococcus faecium		
Fungicidă în condiții de murdarie	EN 13624	Candida albicans, Aspergillus brasiliensis	80%, 50%, 10%	30 sec.
Levuricidă in condiții de murdarie	EN 1650	Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Escherichia coli K12, Enterococcus hirae, Enterococcus faecium, Candida albicans	50%; 80%	30 sec.
Levuricidă în condiții de murdarie	EN 1276	Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Escherichia coli K12, Enterococcus hirae, Enterococcus faecium, Candida albicans	50%; 80%	30 sec.
Micobactericidă in condiții de murdarie	EN 14348	Mycobactericidă terrae, Mycobacterium avium	80%	30 sec.
Testarea dermatologică	nr.167491/24/INT nr. 390311/25/INT			
Virucidă in condiții de murdarie	EN 14476	Polivirus type 1, Adenovirus type 5, Murine norovirus	80%; 50%;10%	30 sec

XI. Indicații de utilizare

Metoda de aplicare	*Concentrația soluției de lucru*	*Timpul de acțiune*
dezinfectarea mainilor prin frecare	nediluat/3 ml	30 sec
prin imersia, inmuiere, irigare sau stergere suprafețelor	nediluat	30 sec
dezinfecția prin spalare	nediluat/3ml	30 sec.
dezinfectia chirurgicală mainilor prin frecare	nediluat 100%, 2x3 ml	2x45 sec

XII. Etichetarea produsului biocid

Simboluri și indicarea pericolelor	PERICOL.
Fraze de risc (R) și/sau Pictograme de pericol (H)	R7:Poate provoca un incendiu. R10: Inflamabil. R22:Nociv în caz de înghitire.
Fraze de prudență (S) și/sau Fraze de precauție (P)	S2:A nu se lasa la îndemana copiilor. S15:A se pastra departe de caldura.

XIII.	**Categoria de utilizatori**
	Profesionali, Populatie, Industriali,
XIV.	**Recomandări/restricţii privind protecţia sănătăţii şi a factorilor de mediu**
	Utilizarea conform instrucțiunii de la producator.

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Instituto Valenciano de Microbiología

Masía El Romeral
Ctra. Bétera – San Antonio de Benagéber, Km 0,3
46117 Bétera (Valencia)
Tel. 96 169 17 02
e-mail: ivami@ivami.com
www.ivami.com
CIF B-96337217

ENAC
ENSAYO
ISO 17025
Nº648 / LE1286

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 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 "Disinfectant «GamaDez»" (EN 14476: 2013 + A2: 2019 Standard)

Report
Registration No.: D/24/V066.

1. **Laboratory identification** ……. Instituto Valenciano de Microbiología.

2. **Client identification** ……..……..… ECOCHIM – GRUP S.R.L.
   Address ……..……...…….. Republic of Moldova, Ungheni, str. Nationala 119. Ungheni, MD-3603.

3. **Sample identification** (information provided by the client)

- Product name ..……... **Disinfectant «GamaDez».**
- Batch number ……. Not indicated.
- Expiration date ..…….... 2027/02/15
- Manufacturer /supplier ..……. ECOCHIM – GRUP S.R.L.
- Store conditions ..……... Not indicated.
- Conditions of use ..……..……..... Hygienic handrub, instruments, surfaces.
- Diluent of the product recommended by the manufacturer ..... Not indicated.
- Active(s) Substance(s) and its concentration (s) ..……. Ethyl alcohol 72%, CAS 64-17-5 and CE 200-578-6 Alcohol Isopropyl 1%, CAS 67-63-0, CE 200-661-7.
- Concentrations ordered for the assay .... 80%.

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

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4. Information about sample reception

- Date of reception of the sample ..…….. 2024/03/13.
- Date of reception of order with test conditions ...…….….. 2024/03/18.
- Aspect of the received sample ..…….... Colourless liquid in plastic container with identification label.

5. Testing method

Procedure **DESIN-1078** (EN 14476: 2013 + A2: 2019 Standard).

6. Experimental conditions

- Assay period ..……... 2024/03/20 to 2024/04/05.
- Titration method ....……... $TCID_{50}$ (Tissue Culture Infective Dose 50%).
- Incubation temperature ……. 37ºC ± 1ºC.
- Product concentrations for the assay .... 80%, 50% and 0.1%.
- Contact time ..……..... 30 seconds.
- Contact temperature ..……... 20ºC ± 1ºC.
- 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 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 strains and number of passages ……. 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 passages) ……...…… Vero, ref: FTVE, working aliquot 11, passages 11, 13 and 16.

  Raw 264.7, Public Health England, working aliquot 11, passages 11, 13 and 16.

7. 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 ..... $\log 10^{-6.91}$

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 ..... $\log 10^{-6.41}$

Adenovirus type 5 (ATCC VR-5)

Titre of the viral suspension for the virus control (at the requested test time)
- Dirty conditions ..... $\log 10^{-6.50}$

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 ..... $\log 10^{-6.00}$

Murine Norovirus (strain S99 Berlin)

Titre of the viral suspension for the virus control (at the requested test time)
- Dirty conditions ..... $\log 10^{-7.83}$

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 ..... $\log 10^{-7.33}$

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 ..... $\log 10^{-4.41}$

Viral quantification in the reference test (formaldehyde) after 60 minutes and with Adenovirus type 5 ..... $\log 10^{-2.41}$

Viral quantification in the reference test (formaldehyde) after 60 minutes and with Murine Norovirus ..... $\log 10^{-5.00}$

Confidence interval

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

- Dirty conditions ..... $\log 10^{-6.91 \pm 0.46}$

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

- Dirty conditions ..... $\log 10^{-6.50 \pm 0.37}$

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

- Dirty conditions ..... $\log 10^{-7.83 \pm 0.28}$

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 ……...……..……..... $\log 10^{-8.00}$
- Viral quantification of Poliovirus type 1 with cells treated by the test solution with the test sample ……..... $\log 10^{-7.49}$

- Viral quantification of Adenovirus type 5 with cells not treated by the test solution with the test sample ……..... $\log 10^{-7.75}$
- Viral quantification of Adenovirus type 5 with cells treated by the test solution with the test sample ……. $\log 10^{-7.16}$

- Viral quantification of Murine Norovirus with cells not treated by the test solution with the test sample …… $\log 10^{-8.91}$

  Viral quantification of Murine Norovirus with cells treated by the test solution with the test sample ……...… $\log 10^{-8.25}$

  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 title 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 ……. $\log 10^{-7.16}$
- Viral quantification of Poliovirus type 1 exposing the virus to the test sample and incubated 30 minutes on ice bath ……... $\log 10^{-6.83}$

- Viral quantification of Adenovirus type 5 after 30 minutes on bath ice without exposing the virus to the test sample ……. $\log 10^{-7.00}$
- Viral quantification of Adenovirus type 5 exposing the virus to the test sample and incubated 30 minutes on ice bath ……... $\log 10^{-6.66}$

- Viral quantification of Murine Norovirus after 30 minutes on bath ice without exposing the virus to the test sample ……..... log $10^{-8.00}$
- Viral quantification of Murine Norovirus exposing the virus to the test sample and incubated 30 minutes on ice bath…….....……. log $10^{-7.66}$

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

8. 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	4.75 ± 0.57 $TCID_{50}$ Shows	1.59 ± 0.58 $TCID_{50}$ Does not show	0.01 ± 0.59 $TCID_{50}$ Does not show
Adenovirus type 5	≥ 6.00 ± 0.37 $TCID_{50}$ Shows	4.75 ± 0.45 $TCID_{50}$ Shows	0.09 ± 0.46 $TCID_{50}$ Does not show
Murine Norovirus	≥ 7.33 ± 0.28 $TCID_{50}$ Shows	5.17 ± 0.51 $TCID_{50}$ Shows	0.09 ± 0.51 $TCID_{50}$ Does not show

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

9.2 Tables of results and graphics

See tables 1 to 6 and figures 1 to 3.

10. Conclusion

The product **"Disinfectant «GamaDez»"**, batch **not indicated**, at **80%** concentration, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), requested by the client and during 30 seconds of contact time and 20ºC 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".

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), April 10, 2024.

FERNANDEZ FUENTES, MIGUEL ANGEL (FIRMA)
Signed. Miguel Ángel Fernández.
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 as well the Good Laboratory Practices (GLPs) and the final report contains the primary data obtained.

ROS ESTELLES, NOELIA (FIRMA)

Signed. Noelia Ros.
Responsible for the Laboratory Area
(Study Director)

ESTEBAN BERMUDEZ, ENCARNACION PILAR (FIRMA)

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

Reference

- **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).

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

Assay	Concen-tration	Interfering substance	Cytoto-xicity level	$\log_{10}$ $TCID_{50}$ after…				Reduction with the confidence interval of 95 %
				0 min	30 sec	30 min	60 min	
Test sample	80%	3 g/L BSA + erythrocytes 3 mL/L	0.50	-	2.16	-	-	4.75 ± 0.57
	50%		0.50	-	5.32	-	-	1.59 ± 0.58
	0.1%		0.50	-	6.90	-	-	0.01 ± 0.59
Virus control	NA	3 g/L BSA + erythrocytes 3 mL/L	NA	7.00	6.91	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.50	NR	NR	5.91	4.41	NA
Virus control formaldehyde	0.7% (w:v)	NA	NA	7.99	NR	NR	7.82	NA

Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) ……..... $\log 10^{-0.51}$

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)…….. $\log 10^{-0.33}$

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.

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	Concen-tration	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 + erythrocytes 3 mL/L	30 sec	4444 4444 4444	0340 2040 0332	0000 0000 0100	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	50%		30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0424 3304 0022	0000 0000 2010	0000 0000 0000	NR	NR	NR
	0.1%		30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4434 4340 4334	0202 0003 2200	0000 0000 0010	0000 0000 0000	0000 0000 0000
Cytotoxicity	80%	3 g/L BSA + erythrocytes 3 mL/L	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 + erythrocytes 3 mL/L	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2013 0202 0010	0000 0000 0000	0000 0000 0000	0000 0000 0000
			30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4304 0243 0442	0230 0200 2302	0000 0000 0210	0000 0000 0000	0000 0000 0000
Formaldehyde	0.7% (w:v)	NA	30 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0020 1022 0100	0000 0000 0000	NR	NR	NR
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	3402 0402 2320	0000 0010 0201	0000 0000 0000	0000 0000 0000	NR	NR	NR
Control of formaldehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + erythrocytes 3 mL/L	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 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	3002 0030 2200	0000 0000 1000	0000 0000 0000
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4430 4243 4424	0023 0200 0020	0020 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	C0C0 0C0C 0CC0	0000 0000 0000	0000 0000 0000
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCC0 C0CC 0CC0	C0CC 000C 0000	0000 0000 0000	0000 0000 0000
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + erythrocytes 3 mL/L	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0C0C 00C0 CC0C	0000 0CC0 0000	0000 0000 0000	0000 0000 0000
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	C00C 00C0 C000	0000 0000 0000	0000 0000 0000	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.

Table 3. Results of activity of the test sample with Adenovirus type 5 (ATCC VR-5), under test conditions requested by the client.

Assay	Concen-tration	Interfering substance	Cytoto-xicity level	$\log_{10}$ $TCID_{50}$ after…				Reduction with the confidence interval of 95 %
				0 min	30 sec	30 min	60 min	
Test sample	80%	3 g/L BSA + erythrocytes 3 mL/L	0.50	-	0.50	-	-	≥ 6.00 ± 0.37
	50%		0.50	-	1.75	-	-	4.75 ± 0.45
	0.1%		0.50	-	6.41	-	-	0.09 ± 0.46
Virus control	NA	3 g/L BSA + erythrocytes 3 mL/L	NA	6.66	6.50	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.50	NR	NR	2.99	2.41	NA
Virus control formaldehyde	0.7% (w:v)	NA	NA	6.75	NR	NR	6.57	NA

Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) ……..……..……. $\log10^{-0.31}$
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)…….……...……..... $\log10^{-0.34}$

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.

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	Concen-tration	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 + erythrocytes 3 mL/L	30 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%		30 sec	4444 4444 4444	0102 0020 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	0.1%		30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2430 4220 4333	0000 0000 2000	0000 0000 0000	0000 0000 0000	0000 0000 0000
Cytotoxicity	80%	3 g/L BSA + erythrocytes 3 mL/L	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 + erythrocytes 3 mL/L	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0001 0200 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000
			30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4240 2440 0223	0000 0020 2100	0000 0000 0000	0000 0000 0000	0000 0000 0000
Formaldehyde	0.7% (w:v)	NA	30 min	4444 4444 4444	4444 4444 4444	0030 2003 0402	0000 0001 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
			60 min	4444 4444 4444	3344 0204 4034	0100 0200 0000	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 + erythrocytes 3 mL/L	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 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	0020 0102 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3342 4220 3334	0002 1000 0000	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	000C 0000 0C0C	0000 0000 0000	0000 0000 0000
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	C00C 00C0 CCC0	0000 C0C0 0000	0000 0000 0000	0000 0000 0000
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + erythrocytes 3 mL/L	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	00CC 0CC0 0CC0	0000 0000 0000	0000 0000 0000	0000 0000 0000
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC 00CC CC0C	000C 0C00 0000	0000 0000 0000	0000 0000 0000	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.

Table 5. Results of activity of the test sample, with Murine Norovirus, strain S99 Berlin, under test conditions requested by the client.

Assay	Concen-tration	Interfering substance	Cytoto-xicity level	$\log_{10}$ $TCID_{50}$ after…				Reduction with the confidence interval of 95 %
				0 min	30 sec	30 min	60 min	
Test sample	80%	3 g/L BSA + erythrocytes 3 mL/L	0.50	-	0.50	-	-	≥ 7.33 ± 0.28
	50%		0.50	-	2.66	-	-	5.17 ± 0.51
	0.1%		0.50	-	7.74	-	-	0.09 ± 0.51
Virus control	NA	3 g/L BSA + erythrocytes 3 mL/L	NA	7.91	7.83	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.50	NR	NR	5.91	5.00	NA
Virus control formaldehyde	0.7% (w:v)	NA	NA	8.83	NR	NR	8.66	NA

Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) ……..……..... $\log10^{-0.66}$

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)…….……..... $\log10^{-0.34}$

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.

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	Concen-tration	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 + erythrocytes 3 mL/L	30 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%		30 sec	4444 4444 4444	4403 4424 0033	2030 0220 0000	0000 0001 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	0.1%		30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4243 0404 4044	0302 0020 0320	0010 0000 0000	0000 0000 0000
Cytotoxicity	80%	3 g/L BSA + erythrocytes 3 mL/L	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 + erythrocytes 3 mL/L	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0001 2100 2020	0000 0000 0000	0000 0000 0000
			30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	1020 0102 0000	0000 0000 0000	0000 0000 0000
Formaldehyde	0.7% (w:v)	NA	30 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3334 2434 2444	1220 0020 0100	0000 0000 0000	NR	NR	NR
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0300 1020 3011	0000 0000 0000	0000 0000 0000	NR	NR	NR
Control of formaldehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + erythrocytes 3 mL/L	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 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	4444 4444 4444	0000 2003 0120	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	3420 4340 2433	0000 2002 0210	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	00C0 0C00 CCC0	0000 0000 0000
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	00C0 CCC0 C0C0	0000 00C0 00CC	0000 0000 0000
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + erythrocytes 3 mL/L	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0CC0 C0C0 C0C0	0000 0000 0000	0000 0000 0000
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCC0 CCC0 CCCC	CC0C 000C 0000	0000 0000 0000	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.

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

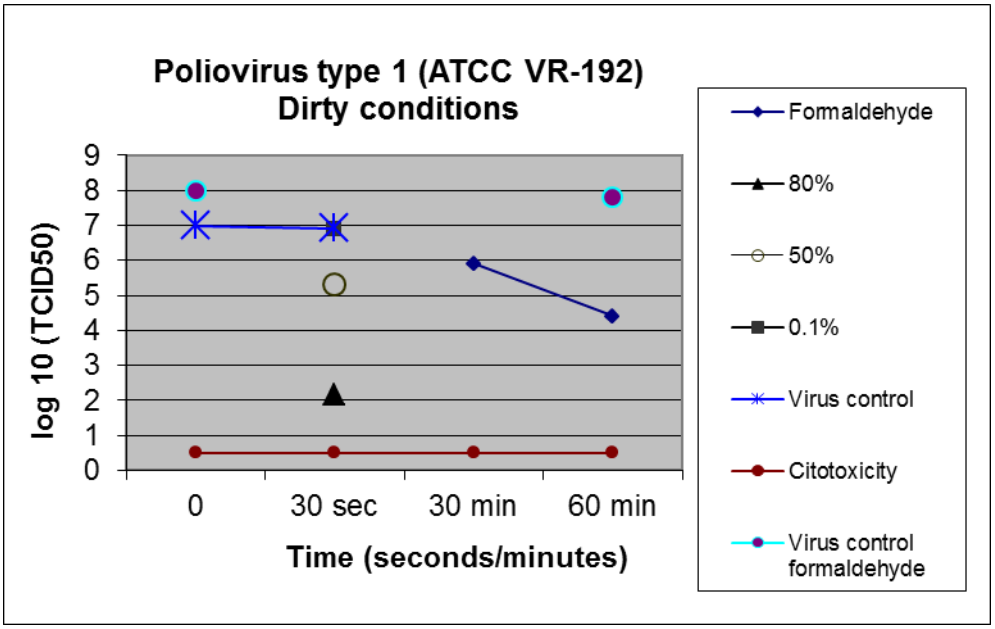


Figure 2. Results of the activity of the test sample under test conditions requested by the client with Adenovirus type 5 (ATCC VR-5).

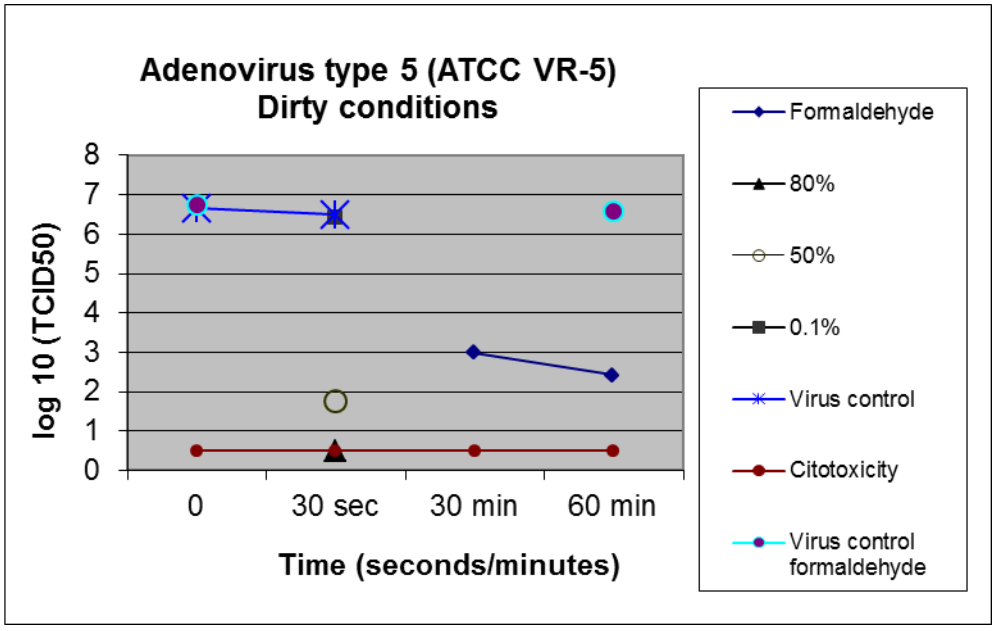
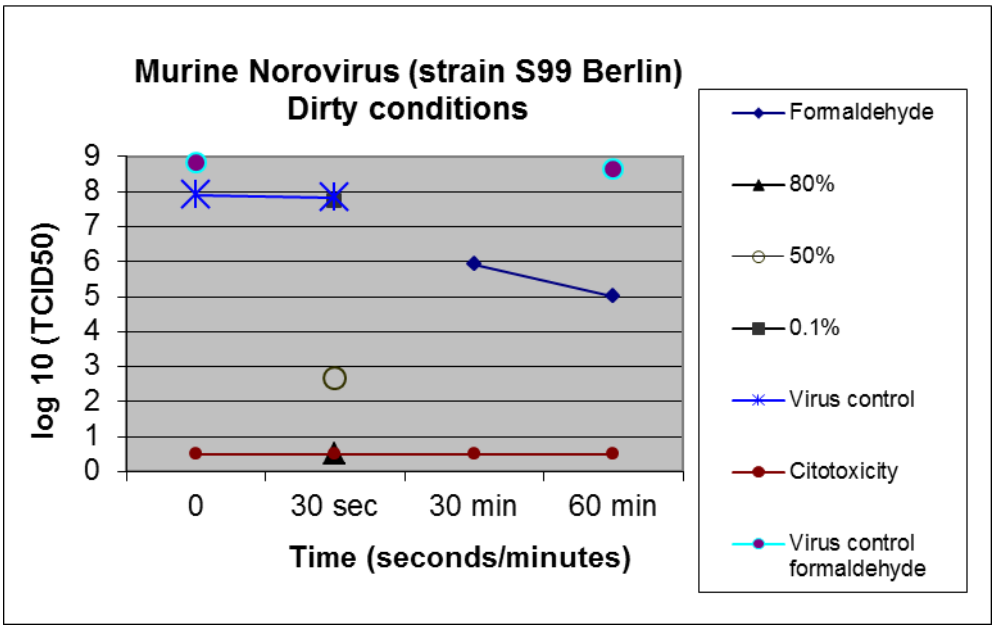


Figure 3. Results of the activity of the test sample under test conditions requested by the client with Murine Norovirus strain S99 Berlin.



Nordic Tersus
Laboratory

Test report no. 125024hd

EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY OF DISINFECTANTS AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13624)

Name of the product: DISINFECTANT "GAMADEZ"
Batch number: 15.02.2024
Date of test report: 24/04/2024

Client, representative:
Ecochim-Grup SRL
Academician Iachim Grosul 4
MD-2028, Chișinău
MOLDOVA

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Nordic Tersus
Laboratory

Test report No. 125024hd

EVALUATION OF FUNGICIDAL OR YEASTICIDAL ACTIVITY OF DISINFECTANTS AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13624)

Name of the product*:	DISINFECTANT "GAMADEZ"
Batch number*:	15.02.2024
Order number:	20272
Manufacturer*:	Ecochim-Grup SRL
Client, representative*:	Ecochim-Grup SRL; Academician Iachim Grosul 4, MD-2028, Chișinău, MOLDOVA; Mr. Evgeny, ecochim.marketing@gmail.com
Date of delivery:	12.03.2024
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.*:	Ethyl alcohol 72%, Isopropyl alcohol 1%
Appearance of the product:	Transparent, colourless liquid
Test concentration:	80%, 50%, 10%
Contact time:	30 seconds and 90 seconds
Interfering substance:	3 g/l bovine albumin solution + 3 ml/l sheep blood erythrocytes (dirty conditions)
Neutralizer:	-
Rinsing liquid:	Tryptone 1 g/l + NaCl, 9 g/l
Test organisms:	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis ATCC 16404*
Testing method:	**EVS-EN 13624:2021** **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)**
Testing period:	03.04.2024 – 24.04.2024
Results:	look appendix 1-2
Interpretation and conclusion:	look appendix 3

ACCREDITED LABORATORY No L263 ISO/IEC 17025 NORDIC TERSUS LABORATORY OÜ REPUBLIC OF ESTONIA

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Kerda Treksler
Microbiologist
Date of test report: 24.04.2024

** - Data provided by the customer*

Nordic Tersus Laboratory OÜ
Jälgimäe tee 17
76406, Tänassilma, Harjumaa, Estonia
Reg. no.: 12561442
Tel: +372 503 0197
info@ntl.ee

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Appendix 1

TEST RESULTS (yeasticidal suspension test)

EVS-EN 13624:2021; Phase 2, step 1
Membrane filtration method
Product diluent: Glass-Distilled water
Appearance of product solutions: Transparent, colourless liquid
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l
Test organism: *Candida albicans* ATCC 10231
Test temperature: +20° C; Incubation temperature: +30 °C
Interfering substance: 3 g/l bovine albmin solution + 3 ml/l sheep blood erythrocytes (dirty conditions);
Nordic Tersus Laboratory LLC.
Date of test: 03.04.2024
Responsible person: Kerda Treksler

Validation and controls

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$
51	47	49	31	41	36	41	48	44.5	43	32	37.5
30 ≤ $\bar{x}$ N_{vo} ≤160? yes x; no □			$\bar{x}$ A is ≥ 0.5 $\bar{x}$ N_{vo}? yes x; no □			$\bar{x}$ B is ≥ 0.5 $\bar{x}$ N_{vo}? yes x; no □			$\bar{x}$ C is ≥ 0.5 $\bar{x}$ N_{vo}? yes x; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ =1.55 x 10^7; log$N$ = 7.19
N and N_0	10^{-5}	149	161	$N_0 = N/10$; logN_0 =6.19
	10^{-6}	16	15	6.17≤ logN_0≤6.70; yes X; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.04	30 sec	Dirty
50.0%	-	>165	>165	>1650	>3.22	<2.97	30 sec	Dirty
10.0%	-	>165	>165	>1650	>3.22	<2.97	30 sec	Dirty
80.0%	-	<14	<14	<140	<2.15	>5.04	90 sec	Dirty
50.0%	-	>165	>165	>1650	>3.22	<2.97	90 sec	Dirty
10.0%	-	>165	>165	>1650	>3.22	<2.97	90 sec	Dirty

Explanations:
V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 2

TEST RESULTS (yeasticidal suspension test)

EVS-EN 13624:2021; Phase 2, step 1
Membrane filtration method
Product diluent: Glass-Distilled water
Appearance of product solutions: Transparent, colourless liquid
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l
Test organism: *Aspergillus brasiliensis* ATCC 16404
Test temperature: +20° C; Incubation temperature: +30 °C
Interfering substance: 3 g/l bovine albmin solution + 3 ml/l sheep blood erythrocytes (dirty conditions);
Nordic Tersus Laboratory LLC.
Date of test: 22.04.2024
Responsible person: Kerda Treksler

Validation and controls

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$
30	30	30	41	51	46	58	62	60	49	45	47
30 ≤ $\bar{x}$ N_{vo} ≤160? yes x; no □			$\bar{x}$ A is ≥ 0.5 $\bar{x}$ N_{vo}? yes x; no □			$\bar{x}$ B is ≥ 0.5 $\bar{x}$ N_{vo}? yes x; no □			$\bar{x}$ C is ≥ 0.5 $\bar{x}$ N_{vo}? yes x; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ =1.62 x 10^7; log$N$ = 7.21
N and N_0	10^{-5}	169	158	$N_0 = N/10$; logN_0 =6.21
	10^{-6}	12	18	6.17≤ logN_0≤6.70; yes X; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>4.06	30 sec	Dirty
50.0%	-	>165	>165	>1650	>3.22	<2.99	30 sec	Dirty
10.0%	-	>165	>165	>1650	>3.22	<2.99	30 sec	Dirty
80.0%	-	<14	<14	<140	<2.15	>4.06	90 sec	Dirty
50.0%	-	>165	>165	>1650	>3.22	<2.99	90 sec	Dirty
10.0%	-	>165	>165	>1650	>3.22	<2.99	90 sec	Dirty

Explanations:
V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 3

Interpretation:

The ready to use product **DISINFECTANT "GAMADEZ"** (batch no. 15.02.2024) was tested according to the test method EVS-EN 13624:2021. The test was performed at 20 °C ± 1 °C, under dirty conditions with the contact time of 30 seconds and 90 seconds. The membrane filtration method was used for testing the product's effectiveness against the reference strains *Candida albicans* ATCC 10231 and *Aspergillus brasiliensis* ATCC 16404. Under dirty conditions the sample of the ready to use product was effective against all the reference strains tested within 30 seconds.

Conclusion:

The surviving count of fungicidal reference strains showed at least 4lg reduction meaning that **according to EVS-EN 13624:2021 under dirty conditions the sample of the ready to use product DISINFECTANT "GAMADEZ" has a fungicidal effect against all the reference strains tested within 30 seconds.**

The results apply exclusively to the tested sample of the product with batch no. 15.02.2024.

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Kerda Treksler
Microbiologist
Date of test report: 24.04.2024

Nordic Tersus
Laboratory

Test report no. 124024hd

EVALUATION OF BACTERICIDAL ACTIVITY OF DISINFECTANTS AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13727)

Name of the product: DISINFECTANT "GAMADEZ"
Batch number: 15.02.2024
Date of test report: 22/04/2024

Client, representative:
Ecochim-Grup SRL
Academician Iachim Grosul 4
MD-2028, Chișinău
MOLDOVA

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Date: 2025.10.21 09:28:47 EEST
Reason: MoldSign Signature
Location: Moldova
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Nordic Tersus
Laboratory

Test report No. 124024hd

EVALUATION OF BACTERICIDAL ACTIVITY OF DISINFECTANTS AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13727)

Name of the product*:	**DISINFECTANT "GAMADEZ"**
Batch number*:	15.02.2024
Order number:	20272
Manufacturer*:	Ecochim-Grup SRL
Client, representative*:	Ecochim-Grup SRL; Academician Iachim Grosul 4, MD-2028, Chișinău, MOLDOVA; Mr. Evgeny, ecochim.marketing@gmail.com
Date of delivery:	12.03.2024
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.*:	Ethyl alcohol 72%, Isopropyl alcohol 1%
Appearance of the product:	Transparent, colourless liquid
Test concentration:	80%, 50%, 10%
Contact time:	30 seconds
Interfering substance:	3 g/l bovine albumin solution + 3 ml/l sheep blood erythrocytes (dirty conditions)
Neutralizer:	-
Rinsing liquid:	Tryptone 1 g/l + NaCl, 9 g/l
Test organisms:	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541 *Escherichia coli K12* NCTC 10538 *Staphylococcus aureus MRSA* ATCC 33592 *Enterococcus faecium* ATCC 6057
Testing method:	**EVS-EN 13727:2012+A2:2015** **Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)**
Testing period:	02.04.2024 – 18.04.2024
Results:	look appendix 1-6
Interpretation and conclusion:	look appendix 7

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NORDIC TERSUS LABORATORY OÜ

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Kerda Treksler
Microbiologist

Date of test report: 22.04.2024

** - Data provided by the customer*

Nordic Tersus Laboratory OÜ
Jälgimäe tee 17
76406, Tänassilma, Harjumaa, Estonia
Reg. no.: 12561442
Tel: +372 503 0197
info@ntl.ee

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Appendix 1

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Product diluent: Distilled water
Appearance of product solutions: Transparent, colourless liquid
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l
Test organism: *Staphylococcus aureus* ATCC 6538
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin solution + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 02.04.2024
Responsible person: Kerda Treksler

Validation and controls

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$
158	160	159	180	158	169	156	149	152.5	220	201	210.5
$30 \leq \bar{x}$ $N_{vo} \leq 160$? yes x; no □			$\bar{x}$ A is $\geq 0.5\ \bar{x}$ N_{vo}? yes x; no □			$\bar{x}$ B is $\geq 0.5\ \bar{x}$ N_{vo}? yes x; no □			$\bar{x}$ C is $\geq 0.5\ \bar{x}$ N_{vo}? yes x; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.95 \times 10^8$; $\log N = 8.47$
N and N_0	10^{-6}	>330	>330	$N_0 = N/10$; $\log N_0 = 7.47$
	10^{-7}	30	29	$7.17 \leq \log N_0 \leq 7.70$; yes x; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.32	30 sec	Dirty
50.0%	-	>165	>165	>1650	>3.22	<4.25	30 sec	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.25	30 sec	Dirty

Explanations:
V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 2

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Product diluent: Distilled water
Appearance of product solutions: Transparent, colourless liquid
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l
Test organism: *Enterococcus hirae* ATCC 10541
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin solution + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 17.04.2024
Responsible person: Kerda Treksler

Validation and controls

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$
44	50	47	36	53	44.5	74	45	59.5	42	39	40.5
$30 \leq \bar{x}\ N_{vo} \leq 160$? yes x; no □			$\bar{x}$ A is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □			$\bar{x}$ B is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □			$\bar{x}$ C is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1.75 \times 10^8$; $\log N = 8.24$
N and N_0	10^{-6}	149	191	$N_0 = N/10$; $\log N_0 = 7.24$
	10^{-7}	26	19	$7.17 \leq \log N_0 \leq 7.70$; yes x; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.09	30 sec	Dirty
50.0%	-	>165	>165	>1650	>3.22	<4.02	30 sec	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.02	30 sec	Dirty

Explanations:

V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 3

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Product diluent: Distilled water
Appearance of product solutions: Transparent, colourless liquid
Rinsing liquid: tryptone 1 g/l + NaCl 9 g/l
Test organism: *Pseudomonas aeruginosa* ATCC 15442
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin solution + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 02.04.2024
Responsible person: Kerda Treksler

Validation and controls

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$
78	92	85	122	126	124	115	117	116	94	78	86
$30 \leq \bar{x}\ N_{vo} \leq 160$? yes x; no □			$\bar{x}$ A is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □			$\bar{x}$ B is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □			$\bar{x}$ C is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 4.25 \times 10^8$; $\log N = 8.63$
N and N_0	10^{-6}	>330	>330	$N_0 = N/10$; $\log N_0 = 7.63$
	10^{-7}	39	46	$7.17 \leq \log N_0 \leq 7.70$; yes x; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.48	30 sec	Dirty
50.0%	-	<14	<14	<140	<2.15	>5.48	30 sec	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.41	30 sec	Dirty

Explanations:

V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 4

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Product diluent: Distilled water
Appearance of product solutions: Transparent, colourless liquid
Rinsing liquid: tryptone 1 g/l + NaCl 9 g/l
Test organism: *Escherichia coli* K12 NCTC 10538
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin solution + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 17.04.2024
Responsible person: Kerda Treksler

Validation and controls

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$
49	70	59.5	49	50	49.5	52	49	50.5	44	54	49
30 ≤ $\bar{x}$ N_{vo} ≤160? yes x; no □			$\bar{x}$ A is ≥ 0.5 $\bar{x}$ N_{vo}? yes x; no □			$\bar{x}$ B is ≥ 0.5 $\bar{x}$ N_{vo}? yes x; no □			$\bar{x}$ C is ≥ 0.5 $\bar{x}$ N_{vo}? yes x; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 2.15 x 10^8; log$N$ = 8.33
N and N_0	10^{-6}	226	207	N_0 = N/10; logN_0 =7.33
	10^{-7}	22	17	7.17≤ logN_0≤7.70; yes x; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.18	30 sec	Dirty
50.0%	-	<14	<14	<140	<2.15	>5.18	30 sec	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.11	30 sec	Dirty

Explanations:

V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 5

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Product diluent: Distilled water
Appearance of product solutions: Transparent, colourless liquid
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l
Test organism: *Staphylococcus aureus MRSA* ATCC 33592
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin solution + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 17.04.2024
Responsible person: Kerda Treksler

Validation and controls

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$
54	60	57	57	62	59.5	57	51	54	61	61	61
$30 \leq \bar{x}\ N_{vo} \leq 160$? yes x; no □			$\bar{x}$ A is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □			$\bar{x}$ B is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □			$\bar{x}$ C is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.02 \times 10^8$; $\log N = 8.30$
N and N_0	10^{-6}	222	185	$N_0 = N/10$; $\log N_0 = 7.30$
	10^{-7}	18	19	$7.17 \leq \log N_0 \leq 7.70$; yes x; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.15	30 sec	Dirty
50.0%	-	>165	>165	>1650	>3.22	<4.08	30 sec	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.08	30 sec	Dirty

Explanations:

V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 6

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1
Membrane filtration method
Product diluent: Distilled water
Appearance of product solutions: Transparent, colourless liquid
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l
Test organism: *Enterococcus faecium* ATCC 6057
Test temperature: +40° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin solution + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 17.04.2024
Responsible person: Kerda Treksler

Validation and controls

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$
123	131	127	74	75	74.5	80	66	73	74	79	76.5
$30 \leq \bar{x}\ N_{vo} \leq 160$? yes x; no □			$\bar{x}$ A is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □			$\bar{x}$ B is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □			$\bar{x}$ C is $\geq 0.5\ \bar{x}\ N_{vo}$? yes x; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 3.16 \times 10^8$; $\log N = 8.50$
N and N_0	10^{-6}	304	328	$N_0 = N/10$; $\log N_0 = 7.50$
	10^{-7}	33	30	$7.17 \leq \log N_0 \leq 7.70$; yes x; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	log Na	logR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>5.35	30 sec	Dirty
50.0%	-	>165	>165	>1650	>3.22	<4.28	30 sec	Dirty
10.0%	-	>165	>165	>1650	>3.22	<4.28	30 sec	Dirty

Explanations:

V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. Duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 7

Interpretation:

The ready to use product **DISINFECTANT "GAMADEZ"** (batch no. 15.02.2024) was tested according to the test method EVS-EN 13727:2012+A2:2015. The test was performed at 20 °C ± 1 °C for all bacteria except Enterococcus faecium ATCC 6057, which was performed at 40°C ± 1 °C, under dirty conditions with the contact time of 30 seconds. The membrane filtration method was used for testing the product's effectiveness against the reference strains: *Pseudomonas aeruginosa* ATCC 15442, *Enterococcus hirae* ATCC 10541, *Staphylococcus aureus* ATCC 6538, *Staphylococcus aureus MRSA* ATCC 33592, *Escherichia coli K12* NCTC 10538 and *Enterococcus faecium* ATCC 6057. Under dirty conditions the sample of the ready to use product was effective against all the reference strains tested within 30 seconds.

Conclusion:

The surviving count of bacterial reference strains showed at least 5lg reduction meaning that **according to EVS-EN 13727:2012+A2:2015 under dirty conditions the sample of the ready to use product DISINFECTANT "GAMADEZ" has a bactericidal effect against all the reference strains tested within 30 seconds.**

The results apply exclusively to the tested sample of the product with batch no. 15.02.2024.

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Kerda Treksler
Microbiologist
Date of test report: 22.04.2024