



MINISTERUL SĂNĂTĂȚII AL REPUBLICII MOLDOVA
AGENȚIA NAȚIONALĂ PENTRU SĂNĂTATE PUBLICĂ



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**CERTIFICAT
DE ÎNREGISTRARE DE STAT**

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, țara)

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, țara)

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 Guștiuc Vasile
Date: 2025.09.24 15:46:37 EEST
Reason: MoldSign Signature
Location: Moldova

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Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:28:52 EEST
Reason: MoldSign Signature
Location: Moldova

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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(e) activă(e) a produsului

<i>Denumirea chimică (IUPAC, ISO sau alte)</i>	<i>Nr. CE</i>	<i>Nr. CAS</i>	<i>Cantitatea în produs</i>
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 până la 1000L.

IX. Domeniul și aria de utilizare

1. Domeniul de utilizare

2. Aria de aplicare

Dezinfecția igienică și chirurgicală a mâinilor.
Dezinfecția instrumentelor medicale și a suprafețelor.
Produse alimentare și hrana pentru animale.
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

<i>Activitatea</i>	<i>Metoda de testare/protocolul de testare</i>	<i>Specia/tulpina</i>	<i>Concentrații</i>	<i>Timp de acțiune</i>
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 în 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 în 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 în condiții de murdarie	EN 14348	Mycobactericidă terrae, Mycobacterium avium	80%	30 sec.
Testarea dermatologică	nr.167491/24/INT nr. 390311/25/INT			
Virucidă în condiții de murdarie	EN 14476	Polivirus type 1, Adenovirus type 5, Murine norovirus	80%; 50%;10%	30 sec

XI. Indicații de utilizare

<i>Metoda de aplicare</i>	<i>Concentrația soluției de lucru</i>	<i>Timpul de acțiune</i>
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.
dezinfecția 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, Populație, Industriali,

XIV. Recomandări/restricții privind protecția sănătății și a factorilor de mediu

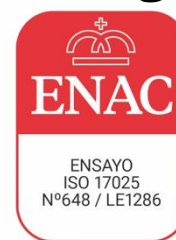
Utilizarea conform instrucțiunii de la producător.





Instituto Valenciano de Microbiología

Masía El Romeral
Ctra. Bétera – San Antonio de Benagéber, Km 0,3
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CIF B-96337217



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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Date: 2025.10.21 09:28:31 EEST
Reason: MoldSign Signature
Location: Moldova

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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 TCID₅₀
(Tissue Culture Infective Dose 50%).
- Incubation temperature 37°C ± 1°C.
- Product concentrations for the assay 80%, 50% and 0.1%.
- Contact time 30 seconds.
- Contact temperature 20°C ± 1°C.
- Procedure to stop product cytotoxicity . Molecular sieving (< 4 columns).
- Procedure to stop product activity Cooling with ice.
- Solvent of the product used in the assay Sterile distilled water.
- Aspect of the dilutions of the product ... Transparent.
- Stability of the mixture (interfering substance and product diluted in sterile 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 titre of the virus < 1 $\log_{10}$.

Control of the effectivity of the disinfectant suppression activity

- Viral quantification of Poliovirus type 1 after 30 minutes on bath ice without exposing the virus to the test sample $\log 10^{-7.16}$
- 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	$\geq 6.00 \pm 0.37$ TCID ₅₀ Shows	4.75 ± 0.45 TCID ₅₀ Shows	0.09 ± 0.46 TCID ₅₀ Does not show
Murine Norovirus	$\geq 7.33 \pm 0.28$ 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.

TCID₅₀: 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 20°C of temperature, **shows** activity against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus, when the activity is assayed according with the **EN 14476: 2013 + A2: 2019 Standard**.

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

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

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

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	Concentration	Interfering substance	Cytotoxicity 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	0340	0000	0000	0000	0000	0000	0000	NR	NR	NR
				4444	2040	0000	0000	0000	0000	0000	0000	0000	0000	
				4444	0332	0100	0000	0000	0000	0000	0000	0000	0000	
	50%		30 sec	4444	4444	4444	4444	0424	0000	0000	NR	NR	NR	
				4444	4444	4444	4444	3304	0000	0000	0000	0000	0000	
				4444	4444	4444	4444	0022	2010	0000	0000	0000	0000	
	0.1%		30 sec	4444	4444	4444	4444	4444	4434	0202	0000	0000	0000	0000
				4444	4444	4444	4444	4444	4340	0003	0000	0000	0000	0000
				4444	4444	4444	4444	4444	4334	2200	0010	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	2013	0000	0000	0000	
				4444	4444	4444	4444	4444	4444	0202	0000	0000	0000	
				4444	4444	4444	4444	4444	4444	0010	0000	0000	0000	
			30 sec	4444	4444	4444	4444	4444	4304	0230	0000	0000	0000	
				4444	4444	4444	4444	4444	0243	0200	0000	0000	0000	
				4444	4444	4444	4444	4444	0442	2302	0210	0000	0000	
Formaldehyde	0.7% (w:v)	NA	30 min	4444	4444	4444	4444	4444	0020	0000	NR	NR	NR	
				4444	4444	4444	4444	4444	1022	0000	0000	0000	0000	
				4444	4444	4444	4444	4444	0100	0000	0000	0000	0000	
			60 min	4444	4444	4444	3402	0000	0000	0000	NR	NR	NR	
				4444	4444	4444	0402	0010	0000	0000	0000	0000	0000	
				4444	4444	4444	2320	0201	0000	0000	0000	0000	0000	
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	3002	0000	0000	
				4444	4444	4444	4444	4444	4444	4444	0030	0000	0000	
				4444	4444	4444	4444	4444	4444	4444	2200	1000	0000	
			60 min	4444	4444	4444	4444	4444	4444	4430	0023	0020	0000	
				4444	4444	4444	4444	4444	4444	4243	0200	0000	0000	
				4444	4444	4444	4444	4444	4444	4424	0020	0000	0000	
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	C0C0	0000	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0C0C	0000	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0CC0	0000	0000	
			Cells treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCC0	C0CC	0000	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	C0CC	000C	0000	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0CC0	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	0C0C	0000	0000	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	00C0	0CC0	0000	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CC0C	0000	0000	0000	
			With sample	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	C00C	0000	0000	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	00C0	0000	0000	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	C000	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	Concentration	Interfering substance	Cytotoxicity 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	-	-	$\geq 6.00 \pm 0.37$
	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	Concentration	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}									
				1	2	3	4	5	6	7	8	9	10
Test sample	80%	3 g/L BSA + 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
			60 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
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
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
			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
Sensitivity control of cells to virus	NA	NA	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	Concentration	Interfering substance	Cytotoxicity 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	-	-	$\geq 7.33 \pm 0.28$
	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	Concentration	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}									
				1	2	3	4	5	6	7	8	9	10
Test sample	80%	3 g/L BSA + 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 CCCC0	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	CCCC CCCC CCCC	00C0 CCCC0 C0C0	0000 00C0 00CC
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	CCCC CCCC CCCC	0CC0 C0C0 C0C0	0000 0000 0000
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CC0C 000C 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).

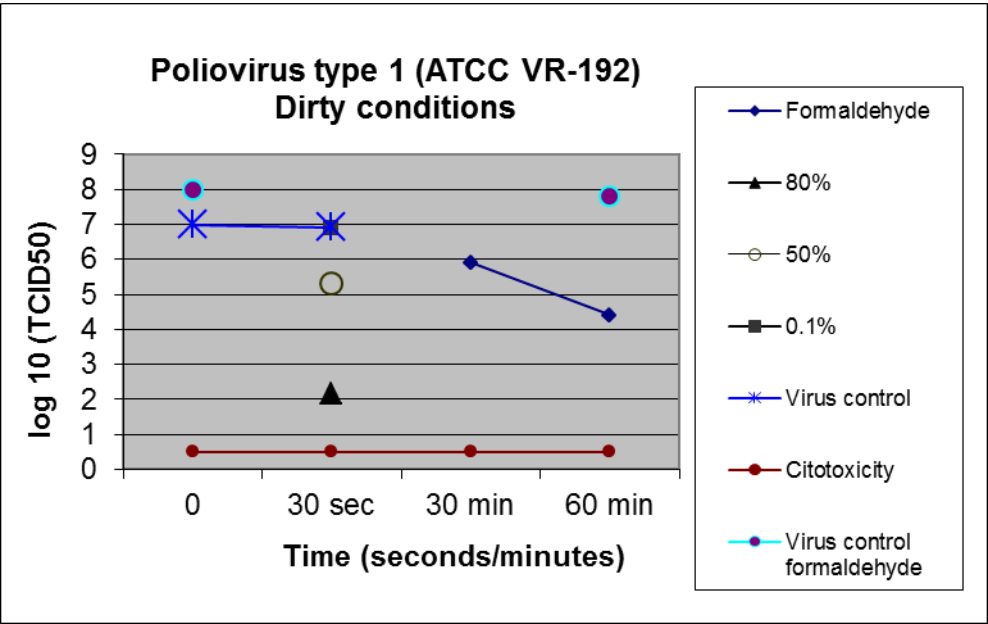


Figure 2. Results of the activity of the test sample under test conditions requested by the client with Adenovirus type 5 (ATCC VR-5).

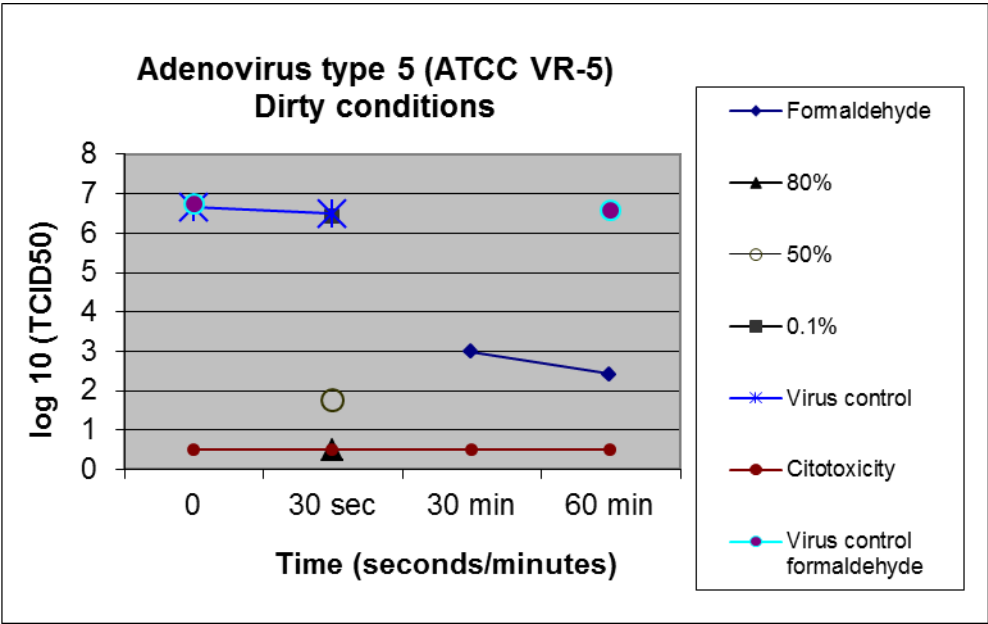
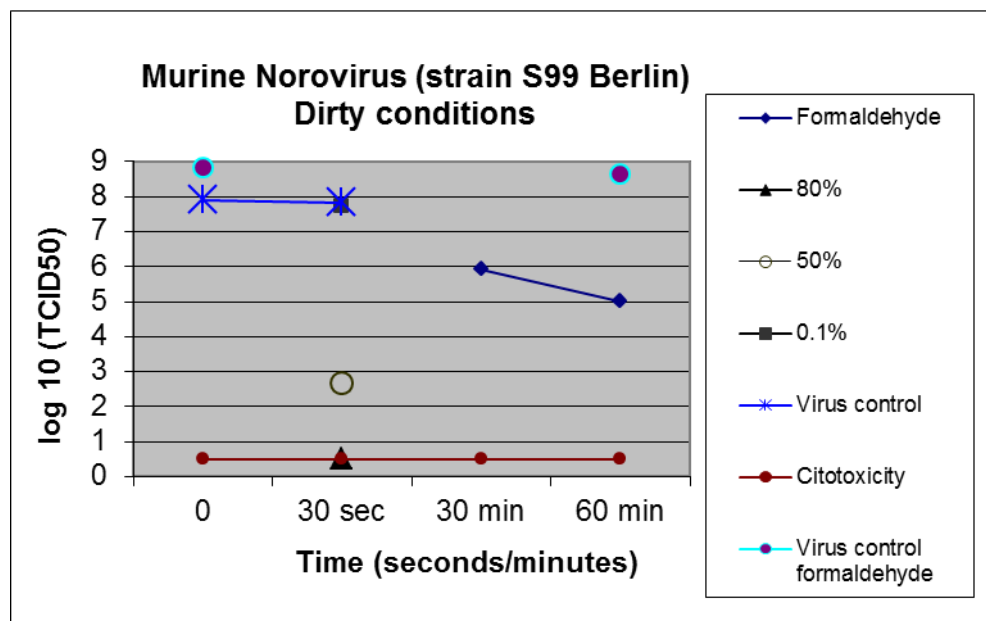


Figure 3. Results of the activity of the test sample under test conditions requested by the client with Murine Norovirus strain S99 Berlin.





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, Chişinău
MOLDOVA

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Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ



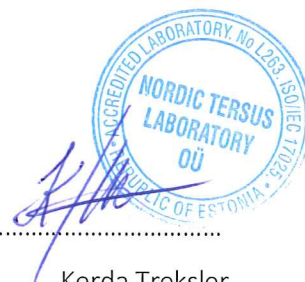
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Test report No. 125024hd

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, Chişinău, 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



Kerda Treksler
Microbiologist

Date of test report: 24.04.2024

* - Data provided by the customer

Appendix 1

TEST RESULTS (yeastidal 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 albumin 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
$30 \leq \bar{x} N_{vo} \leq 160?$ yes x; no ☐			$\bar{x} A \geq 0.5 \bar{x} N_{vo}?$ yes x; no ☐			$\bar{x} B \geq 0.5 \bar{x} N_{vo}?$ yes x; no ☐			$\bar{x} C \geq 0.5 \bar{x} N_{vo}?$ yes x; no ☐		

Test suspension and test

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

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	N_a ($=\bar{x} \cdot 10$)	$\log N_a$	$\log R$	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 ($t=0$)

N_a = surviving microbes after the test

R = reduction factor ($R = N_0 / N_a$; $\log R = \log N_0 - \log N_a$)

The test results apply to the tested sample only.

All the components of this test report are recognized as a portion of a complete report. The test report shall not be reproduced except in full, without approval of the laboratory.

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Appendix 2

TEST RESULTS (yeastidal 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 albumin 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
$30 \leq \bar{x} N_{vo} \leq 160?$ yes x; no □			$\bar{x} A \geq 0.5 \bar{x} N_{vo}?$ yes x; no □			$\bar{x} B \geq 0.5 \bar{x} N_{vo}?$ yes x; no □			$\bar{x} C \geq 0.5 \bar{x} N_{vo}?$ yes x; no □		

Test suspension and test

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

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	N_a ($=\bar{x} \cdot 10$)	$\log N_a$	$\log R$	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 ($t=0$)

N_a = surviving microbes after the test

R = reduction factor ($R = N_0 / N_a$; $\log R = \log N_0 - \log N_a$)

The test results apply to the tested sample only.

All the components of this test report are recognized as a portion of a complete report. The test report shall not be reproduced except in full, without approval of the laboratory.

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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 $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$, 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.



Kerda Treksler
Microbiologist

Date of test report: 24.04.2024



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, Chişinău
MOLDOVA

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L263

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, Chişinău, 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



Date of test report: 22.04.2024

* - Data provided by the customer

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 ☐			$\bar{x} A \text{ is } \geq 0.5 \bar{x} N_{vo}?$ yes x; no ☐			$\bar{x} B \text{ is } \geq 0.5 \bar{x} N_{vo}?$ yes x; no ☐			$\bar{x} C \text{ is } \geq 0.5 \bar{x} N_{vo}?$ yes x; no ☐		

Test suspension and test

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

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na ($=\bar{x} \cdot 10$)	$\log Na$	$\log R$	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 ($R = N_0 / Na$; $\log R = \log N_0 - \log Na$)

The test results apply to the tested sample only.

All the components of this test report are recognized as a portion of a complete report. The test report shall not be reproduced except in full, without approval of the laboratory.

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

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na ($=\bar{x} \cdot 10$)	$\log Na$	$\log R$	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 ($R = N_0 / Na$; $\log R = \log N_0 - \log Na$)

The test results apply to the tested sample only.

All the components of this test report are recognized as a portion of a complete report. The test report shall not be reproduced except in full, without approval of the laboratory.

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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 ☐			$\bar{x} A \text{ is } \geq 0.5 \bar{x} N_{vo}?$ yes x; no ☐			$\bar{x} B \text{ is } \geq 0.5 \bar{x} N_{vo}?$ yes x; no ☐			$\bar{x} C \text{ is } \geq 0.5 \bar{x} N_{vo}?$ yes x; no ☐		

Test suspension and test

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

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na ($=\bar{x} \cdot 10$)	$\log Na$	$\log R$	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 ($R = N_0 / Na$; $\log R = \log N_0 - \log Na$)

The test results apply to the tested sample only.

All the components of this test report are recognized as a portion of a complete report. The test report shall not be reproduced except in full, without approval of the laboratory.

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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
$30 \leq \bar{x} N_{vo} \leq 160$? 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 and N_0	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2.15 \times 10^8$; $\log N = 8.33$ $N_0 = N/10$; $\log N_0 = 7.33$ $7.17 \leq \log N_0 \leq 7.70$; yes x; no ☐
	10^{-6}	226	207	
	10^{-7}	22	17	

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	N_a ($=\bar{x} \cdot 10$)	$\log N_a$	$\log R$	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)

N_a = surviving microbes after the test

R = reduction factor ($R = N_0 / N_a$; $\log R = \log N_0 - \log N_a$)

The test results apply to the tested sample only.

All the components of this test report are recognized as a portion of a complete report. The test report shall not be reproduced except in full, without approval of the laboratory.

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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 ☐			$\bar{x} A \text{ is } \geq 0.5 \bar{x} N_{vo}?$ yes x; no ☐			$\bar{x} B \text{ is } \geq 0.5 \bar{x} N_{vo}?$ yes x; no ☐			$\bar{x} C \text{ is } \geq 0.5 \bar{x} N_{vo}?$ yes x; no ☐		

Test suspension and test

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

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na ($=\bar{x} \cdot 10$)	$\log Na$	$\log R$	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 ($R = N_0 / Na$; $\log R = \log N_0 - \log Na$)

The test results apply to the tested sample only.

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

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na ($=\bar{x} \cdot 10$)	$\log Na$	$\log R$	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 ($R = N_0 / Na$; $\log R = \log N_0 - \log Na$)

The test results apply to the tested sample only.

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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 $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ for all bacteria except *Enterococcus faecium* ATCC 6057, which was performed at $40\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$, 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.



Kerda Treksler
Microbiologist

Date of test report: 22.04.2024