MINISTERUL SĂNĂTĂŢII AL REPUBLICII MOLDOVA

AGENŢIA NAŢIONALĂ 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, 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**

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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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HAMILTON

AB 079

REPORT No. 390313/25/INT

Sponsor:		Investigational product (according to declaration of the Sponsor)
ECOCHIM-GRUP S.R.L., **UNGHENI CITY, NATIONALA 119 STREET**		**DISINFECTANT ,,GAMADEZ,, IN GEL FORM WITH A FLUORESCENT COMPONENT** Ora receptiei probei: 15:00 Data receptiei probei in Laboratorul din Romania: 02.06.2025 Temperatura probei la receptie: 15°C Responsabil prelevare: Alexandr Crestinov Sample No 4
Sample reception date:	06.06.2025	
Start of study:	10.06.2025	
End of study:	13.06.2025	
Report date:	16.06.2025	Sample status: no objections Sample received from the Sponsor

DERMATOLOGICAL TEST - PRESENCE OF AN ALLERGIC REACTION/CONTACT ECZEMA. IN VIVO SKIN IRRITATION METHOD - OPEN TEST (25 SUBJECTS WITH ALLERGOLOGICAL HISTORY, 25 SUBJECTS WITHOUT ALLERGOLOGICAL HISTORY)

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J.S. HAMILTON POLAND Sp. z. o.o.
TESTING LABORATORY
ul. Chwaszczyńska 180, 81-571 Gdynia, Poland, tel. +48 58 766 99 00

REPORT No. 390313/25/INT

THE STUDY IS COMPLIANT WITH:

- Regulation of the European Parliament and of the Council (EC) No. 1223/2009 of 30 November 2009 on Cosmetic Products.
- Cosmetics Europe – The Personal Care Association (formerly COLIPA) Guidelines Product Test Guidelines for the Assessment of Human Skin Compatibility 1997.
- Cosmetics Europe – The Personal Care Association (formerly COLIPA) Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008.

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REPORT No. 390313/25/INT

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J.S. HAMILTON POLAND Sp. z. o.o.
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1. BASIS OF THE STUDY

The test sample was delivered by the Client.
The qualitative composition of the product was delivered by the Client.
The results of microbiological purity of the product provided by the Client (or the Client's declaration concerning microbiological purity) do not apply to low microbiological risk products.

The Client is responsible for compliance with the declared qualitative composition and microbiological purity of the product sample sent for testing.

2. OBJECT OF THE STUDY

Parameter	Description
Intended use	Disinfectant
Packaging	Replacement packaging containing the name and sample number for testing

3. QUALITATIVE COMPOSITION OF THE PRODUCT

The qualitative composition was delivered to the Laboratory by the Client before the start of the study.

4. PURPOSE OF THE STUDY

The purpose of the study was to assess irritating properties (skin tolerance) of the product on a healthy adult skin, with applied patch test.

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5. DESCRIPTION OF VOLUNTEERS

The volunteers (50 people) were healthy, 25 people with negative and 25 people with positive history of allergies. The selection of the group included the criteria of inclusion and exclusion. General inclusion criteria: healthy men and women over 18 years old, phototype: I-IV on Fitzpatrick scale, Caucasians, skin without irritations or changes requiring pharmacological treatment. General exclusion criteria: volunteers who use any treatment on the skin area subject to the study, volunteers exhibiting or having a known history of acute or chronic dermatological, medical and/or physical conditions that could influence the outcome of the study, pregnant or breastfeeding women or women planning a pregnancy during the study. None of the volunteers reported documented oversensitivity or history of adverse reactions to individual ingredients of the product tested. All the volunteers fulfilled the requirements of inclusion for tests and signed the Informed Consent Form (ICF). Additionally, they were informed on the purpose, methodology of the study and possible adverse effects. The skin at the application spot (arms or interscapular area) was healthy, without lesions. The volunteers were advised to exercise caution in handling the applied contact tests.

6. TESTING METHODOLOGY

The preparation in the appropriate concentration is applied onto to the skin on the forearm in the area of 3x3 cm. Reading the response of the skin was performed 15 minutes, 30 minutes, 1 hour, and 24 hours after the test application. Simultaneously, to objectify the results of the study and in order to exclude possible reading errors connected with dermal irritations one control samples (control sample with water) are carried out. The purpose of this study is to the results of the study are presented in section 10 of this report. If irritations appear or persist 24h after the application, an additional examination takes place after 48 hours. Determining the response of the skin, the dermatologist assesses the irritating and sensitising effects of the tested product. The study results may be influenced by factors such as lifestyle, stress, diet and environmental conditions, etc.

* Dermatological test - Presence of an allergic reaction/contact eczema. In vivo skin irritation method - semi-open and closed test PB-561 ed. 3 of 15.01.2024

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7. EVALUATION PARAMETERS

EVALUATION PARAMETERS OF SKIN REACTION	
Erythema	**Classification point**
No erythema	0
Light erythema	0.5
Erythema and/or papules	1
Erythema and/or papules and/or vesicles	2
Erythema and/or papules and/or vesicles and/or blisters	3
Erythema Bullous and/or ulcerative reaction and/or papules and/or vesicles and/or blisters	4
Edema	**Classification point**
No edema	0
Very light edema (hardly visible)	1
Light edema	2
Moderate edema (about 1mm raised skin)	3
Strong edema (extended swelling even beyond the application area)	4

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8. RESULTS

8.1. CHARACTERISTICS OF VOLUNTEERS

Table 1

No. of subject	Identification of subject	Begining of the study	Age	Sex	Phototype
1	WOJ.JU	10.06.2025	26	F	II
2	DAW.NA	10.06.2025	26	F	II
3	GAN.AG	10.06.2025	28	F	II
4	KRZ.EW	10.06.2025	38	F	II
5	ZAM.PA	10.06.2025	34	F	II
6	ROS.WI	10.06.2025	48	F	II
7	JAN.AG	10.06.2025	38	F	II
8	ADA.AN	10.06.2025	41	F	II
9	JUR.ED	10.06.2025	41	F	II
10	CYB.MA	10.06.2025	64	F	II
11	GOL.DA	10.06.2025	22	M	II
12	DIE.TO	10.06.2025	54	M	II
13	WRO.AL	10.06.2025	49	F	II
14	DOB.MI	10.06.2025	65	F	II
15	WOD.KA	10.06.2025	36	F	II
16	WEN.MO	10.06.2025	27	F	II
17	BOC.AL	10.06.2025	46	F	II
18	ZIE.RO	10.06.2025	26	F	II
19	LIP.KL	10.06.2025	27	F	II
20	WOZ.MA	10.06.2025	26	F	II
21	DUR.MI	10.06.2025	66	F	II
22	TRE.MI	10.06.2025	58	F	II
23	LUG.GR	10.06.2025	56	F	II
24	SZY.BR	10.06.2025	46	F	II
25	MIK.PA	10.06.2025	41	F	II
		Min	22	**No. F**	**phototype I**
		Max	66	23	0
		Average	41	**No. M**	**phototype II**
				2	25
					phototype III
					0
					phototype IV
					0

Table 1. Characteristics of volunteers with negative history of allergies

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Table 2

No. of subject	Identification of subject	Begining of the study	Age	Sex	Phototype
1	PIO.AN	10.06.2025	52	F	II
2	SZR.MA	10.06.2025	46	F	II
3	PIA.DA	10.06.2025	60	F	II
4	OKU.AG	10.06.2025	53	F	II
5	SZY.MA	10.06.2025	53	F	II
6	DUD.IR	10.06.2025	67	F	II
7	BAR.KA	10.06.2025	46	F	II
8	WYS.BE	10.06.2025	37	F	II
9	SZT.EL	10.06.2025	21	F	II
10	PLO.BO	10.06.2025	61	F	II
11	WAN.SY	10.06.2025	26	F	II
12	KOV.OL	10.06.2025	43	F	II
13	NEC.OL	10.06.2025	39	F	II
14	RAD.MA	10.06.2025	59	F	II
15	HAN.AN	10.06.2025	25	F	II
16	STA.KA	10.06.2025	24	F	II
17	SRE.DO	10.06.2025	53	F	II
18	PIS.MA	10.06.2025	66	F	II
19	DRO.KR	10.06.2025	61	F	II
20	ROZ.AG	10.06.2025	42	F	II
21	SKU.CA	10.06.2025	20	F	II
22	SKU.IW	10.06.2025	47	F	II
23	MAN.MA	10.06.2025	50	F	II
24	PLE.EW	10.06.2025	32	F	II
25	MAR.AN	10.06.2025	53	F	II
		Min	20	**No. F**	**phototype I**
		Max	67	25	0
		Average	45	**No. M**	**phototype II**
				0	25
					phototype III
					0
					phototype IV
					0

Table 2. Characteristics of volunteers with positive history of allergies

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8.2. TABLE OF SKIN RESPONSE

Table 3

No.	Evaluation after 15 minutes of product application		Evaluation after 30 minutes of product application		Evaluation after 1 hour of product application		Evaluation after 24 hours of product application		Evaluation after 48 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
2	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
3	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
4	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
5	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
6	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
7	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
8	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
9	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
10	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
11	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
12	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
13	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
14	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
15	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
16	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
17	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
18	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
19	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
20	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
21	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
22	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
23	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
24	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	
25	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	Examination skipped	

Table 3. Results for volunteers with negative history of allergies

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Table 4

No.	Evaluation after 15 minutes of product application		Evaluation after 30 minutes of product application		Evaluation after 1 hour of product application		Evaluation after 24 hours of product application		Evaluation after 48 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	0	0	0	0	Examination skipped	
2	0	0	0	0	0	0	0	0	Examination skipped	
3	0	0	0	0	0	0	0	0	Examination skipped	
4	0	0	0	0	0	0	0	0	Examination skipped	
5	0	0	0	0	0	0	0	0	Examination skipped	
6	0	0	0	0	0	0	0	0	Examination skipped	
7	0	0	0	0	0	0	0	0	Examination skipped	
8	0	0	0	0	0	0	0	0	Examination skipped	
9	0	0	0	0	0	0	0	0	Examination skipped	
10	0	0	0	0	0	0	0	0	Examination skipped	
11	0	0	0	0	0	0	0	0	Examination skipped	
12	0	0	0	0	0	0	0	0	Examination skipped	
13	0	0	0	0	0	0	0	0	Examination skipped	
14	0	0	0	0	0	0	0	0	Examination skipped	
15	0	0	0	0	0	0	0	0	Examination skipped	
16	0	0	0	0	0	0	0	0	Examination skipped	
17	0	0	0	0	0	0	0	0	Examination skipped	
18	0	0	0	0	0	0	0	0	Examination skipped	
19	0	0	0	0	0	0	0	0	Examination skipped	
20	0	0	0	0	0	0	0	0	Examination skipped	
21	0	0	0	0	0	0	0	0	Examination skipped	
22	0	0	0	0	0	0	0	0	Examination skipped	
23	0	0	0	0	0	0	0	0	Examination skipped	
24	0	0	0	0	0	0	0	0	Examination skipped	
25	0	0	0	0	0	0	0	0	Examination skipped	

Table 4. Results for volunteers with positive history of allergies

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9. CALCULATED VALUES

The following calculated values present the sum of negative reaction (erythema and edema) defined as Average Irritation Index (X_{av}).

	Evaluation after 15 minutes of product application	Evaluation after 30 minutes of product application	Evaluation after 1 hour of product application	Evaluation after 24 hours of product application	Evaluation after 48 hours of product application
The sum of negative reaction (the sume of classification points)	0,00	0,00	0,00	0,00	Examination skipped
X_{av}	0,00				

10. INTERPRETATION

The average irritation index (X_{av}) was calculated. The product was then classified according to the following table:

Average irritation index (xav)	Class
$\mathbf{X_{av}} < 0.50$	Non irritating
$0.50 \leq \mathbf{X_{av}} < 2.00$	Slightly irritating
$2.00 \leq \mathbf{X_{av}} < 5.00$	Moderately irritating
$5.00 \leq \mathbf{X_{av}}$	Highly irritating

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11. CONCLUSION

The open test study was performed under dermatological control on a group of 50 volunteers, including 25 volunteers with positive history of allergies/atopy (sensitive skin). The study allows to conclude that product **DISINFECTANT ,,GAMADEZ,, IN GEL FORM WITH A FLUORESCENT COMPONENT** used by volunteers, who didn't report documented oversensitivity or a history of adverse reactions to individual ingredients of the tested product, is well tolerated by the skin. In the tested group of volunteers there were no irritations or allergic reactions. The product meets the requirements of compatibility test with the skin (Skin Compatibility Test) and can be classified as **NON IRRITATING**.

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12. SIGNATURES

DERMATOLOGY AND APPLICATIONS SECTION MANAGER	Sign and date:  16.06.2025
SENIOR TECHNICIAN	Sign and date:  16.06.2025
QUALITY ASSURANCE AUDITOR	Sign and date:  16.06.2025
DERMATOLOGIST	Sign and date:  16.06.2025 Registered N° **2880077**

Attention: The released opinion of dermatological compatibility does not apply to people who are allergic to any ingredient of the tested product.

Authorized by: Anna Adamska, Senior Specialist for Cosmetic Products Research

The test report bears the certified electronic seal of J.S. Hamilton Poland Sp. z o.o.

Laboratory: ul. Bajana 3D, 80-463 Gdańsk, Poland

The results relate to the analysed samples only.

*Accredited study

THE END OF THE REPORT

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