MINISTERUL SĂNĂTĂŢII AL REPUBLICII MOLDOVA

AGENŢIA NAŢIONALĂ PENTRU SĂNĂTATE PUBLICĂ

MD 2028, mun. Chişinău, str. Gh. Asachi 67A, Tel. +373 22 574 501, https://ansp.md e-mail: office@ansp.gov.md IDNO:1018601000021

CERTIFICAT
DE ÎNREGISTRARE DE STAT

Nr.	B-0283/2025
din	09.09.2025

I. Denumirea comercială a produsului în Republica Moldova

Săpun lichid 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. Națională 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, 4

Certificatul de înregistrare este valabil până la data: 16.09.2029.

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 15:45:41 EEST
Reason: MoldSign Signature
Location: Moldova
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Digitally signed by Poiata Cristian
Date: 2025.11.12 09:27:54 EET
Reason: MoldSign Signature
Location: Moldova
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Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:37:02 EEST
Reason: MoldSign Signature
Location: Moldova
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Anexa 1
la certificatul nr. B-0283/2025 din 09.09.2025 pentru înregistrare de stat a produsului biocid

I. Denumirea comercială a produsului în Republica Moldova

Săpun lichid 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 pana la 1000L.

IX. Domeniul și aria de utilizare

1. Domeniul de utilizare	TP1.Igiena umana. TP4.Dezinfectante pentru industria alimentara şi industria de preparare a furajelor.
2. Aria de aplicare	Detergent dezinfectant pentru spălarea, dezinfectarea igienica a măinilor in instituțiile medicale.Dezinfectante pentru industria alimentară şi industria de preparare a furajelor. Produsele utilizate pentru dezinfecţia echipamentului, recipientelor, ustensilelor de consum, suprafeţelor sau conductelor aferente producţiei, transportului, depozitării sau consumului de alimente, furaje sau băuturi (inclusiv apă potabilă) pentru oameni şi animale.

X. Eficacitate

Activitatea	*Metoda de testare/protocolul de testare*	*Specia/tulpina*	*Concentrații*	*Timp de acțiune*
Bactericidă (Hygienic Handrub)	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, Staphylococcus aureus MRSA,	80%	30 sec.

		Enterococcus faecium		
Bactericidă în condiții de murdarie	EN 16615:2015	Pseudomonas aeruginosa	100%	60 sec.
Fungicidă in condiții de murdarie	EN 13624	Aspergillus brasiliensis, Candida albicans	80%	30 sec.
Levuricidă in condiții de murdarie	EN 16615:2015	Candida albicans	100%	60 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	Mycobacterium terrae, Mycobacterium avium	80%	30 sec.
Testarea dermatologica	TEST Report No.390312/25/INT			
Virucidă in condiții de murdarie	EN 14476	Poliovirus type 1, Adenovirus type 5, Murine norovirus	80%	30 sec.

XI. Indicații de utilizare

Metoda de aplicare	*Concentrația soluției de lucru*	*Timpul de acțiune*
spalare si dezinfecția mainilor	3 ml/nediluat	30 sec.

XII. Etichetarea produsului biocid

Simboluri și indicarea pericolelor	Pericol.
Fraze de risc (R) și/sau Pictograme de pericol (H)	R7:Poate provaca un incendiu. R10: Inflamabil.
Fraze de prudență (S) și/sau	S2 A nu se lasa la îndemana copiilor. S15 A se pastra departe de caldura.

Fraze de precauție (P)	

XIII. Categoria de utilizatori

Profesionali, Populatie, Industriali,

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

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 10:40:46 EEST
Reason: MoldSign Signature
Location: Moldova

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AB 079

TEST REPORT NO 167490/24/INT

Client Ecochim - Grup SRL,. REPUBLIC OF MOLDOVA, OR. UNGHENI, STR. NATIONALA 119 ordered by: J.S. Hamilton Romania SRL BERCENI STREET 8 8041941 BUCHAREST	Sample (according to declaration of Client) Sample description: Dezinfectant "GamaDez" Production date: 15.02.2024 Expiration date: 15.02.2027 Sampling date: 18.03.2024 Sampling quantity: 3x 0.5l Sample temperature: 17°C Reception hour: 12:00 Responsible for sampling:Alexandr Sample condition with no objections
Sample reception date: 20.03.2024 Start of analysis 15.04.2024 End of analysis 17.04.2024 Test report date 17.04.2024	Sample status: no objections Sample received from the Client

Test Method	Unit	Result
* Hygienic handwash [1)] PN-EN 1499:2013-07	-	The product has bactericidal activity against transitional microorganism used in hygienic handwash procedure - 3ml of the product, washing hands for 30 seconds.

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

Authorized by:
Izabela Kobylecka, Senior Analyst Specialist, Cosmetics Microbiology Laboratory

Approved by: Marzena Bogdaniuk, Cosmetology Laboratory Director (Approved with electronic signature)

Laboratory address:
Goździków 1, 43-100 Tychy

* Test method accredited
\# Test performed by external provider

THE END OF THE REPORT

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:37:07 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

ANNEX NO 1 TO THE REPORT NO 167490/24/INT

A) IDENTYFICATION OF THE SAMPLE:	
Name of the product	**Dezinfectant "GamaDez"**
Active substance	Ethyl alcohol 72%, CAS: 64-17-5, CE 200-578-6; Isopropyl alcohol 1%, CAS: 67-63-0, CE 200-661-7.
B) TEST METHOD :	
Method	**EN 1499:2013 Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (*phase 2, step 2*)**
Neutralizer	Polysorbate 80- 30 g/l, Saponin- 30 g/l, Lecithin 3g/l
C) EXPERIMENTAL CONDITIONS:	
Product test concentrations (%V/V)	100%
Test temperature	20°C
Contact time	Single washing hands with 3 ml of product for 30 seconds
Incubation temperature	36±1°C
Test-organism	*E. coli* K12 NCTC 10538

Annex date: 17.04.2024

Authorized by: Izabela Kobylecka, Senior Analyst Specialist, Cosmetics Microbiology Laboratory

Approved by: Marzena Bogdaniuk, Cosmetology Laboratory Director *(Approved with electronic signature)*

J.S. HAMILTON POLAND Sp. z o.o.
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ANNEX NO 1 TO THE REPORT NO 167490/24/INT

Table 1. PROCEDURE FOR REFERENCE HYGIENIC HANDWASH

PRODUCT R: SOFT SOAP (linseed oil, potassium hydroxide, ethanol, hot distilled water)
TEST ORGANISM: *E. coli* K12 NCTC 10538
NUMBER IN CONTAMINATION FLUID: 3,1 x 10^8 cfu/ml

volunteer		number of cfu per plate from dilution 10x							Reduction
	Hand	prevalues			postvalues				
Nr	left/right	$x10^{-4}$	$x10^{-5}$	log x	$x10^{0}$	$x10^{-1}$	$x\ 10^{-2}$	log y	log z
	l	>330	66		>330	141	12		
1	p	>330	80	6,82	>330	170	17	3,19	3,63
	l	305	31		215	23	2		
2	p	269	27	6,46	199	21	2	2,32	4,14
	l	280	28		266	28	3		
3	p	199	21	6,37	>330	48	5	2,55	3,82
	l	>330	112		>330	91	10		
4	p	>330	77	6,93	>330	78	8	2,93	4,00
	l	299	32		312	33	3		
5	p	259	26	6,45	274	25	3	2,47	3,98
	l	>330	96		>330	69	7		
6	p	>330	71	6,88	>330	125	13	2,97	3,91
	l	>330	100		>330	151	15		
7	p	>330	105	6,97	>330	215	22	3,26	3,71
	l	>330	48		>330	148	15		
8	p	>330	66	6,71	>330	193	20	3,23	3,48
	l	>330	71		>330	69	7		
9	p	>330	60	6,77	>330	111	12	2,94	3,83
	l	257	27		291	30	3		
10	p	222	24	6,38	241	24	3	2,42	3,96
	l	>330	91		>330	112	12		
11	p	>330	102	6,94	>330	138	14	3,10	3,85
	l	243	25		311	32	3		
12	p	>330	55	6,54	>330	62	6	2,64	3,90
	l	>330	103		>330	144	14		
13	p	>330	74	6,90	>330	87	9	3,05	3,85
	l	>330	66		>330	203	20		
14	p	>330	80	6,82	>330	226	23	3,33	3,49
	l	>330	52		>330	115	12		
15	p	>330	42	6,63	>330	162	16	3,14	3,49
$x_{śr}$				6,70				2,90	3,80
s				0,22				0,33	0,20

log x-logarithm of the average value of the initial left and right hand
log y-logarithm of the average value of the final left and right hand
log z-logarithm reduction
x śr- overall average of log x, log y, log z

Annex date: 17.04.2024

Authorized by: Izabela Kobylecka, Senior Analyst Specialist, Cosmetics Microbiology Laboratory

Approved by: Marzena Bogdaniuk, Cosmetology Laboratory Director *(Approved with electronic signature)*

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ANNEX NO 1 TO THE REPORT NO 167490/24/INT

Table 2. HYGIENIC HANDWASH PROCEDURE WITH THE PRODUCT

PRODUCT P 167490/24/INT
TEST ORGANISM: *E. coli* K12 NCTC 10538
NUMBER IN CONTAMINATION FLUID: 3,1 x 10^8 cfu/ml

volunteer		number of cfu per plate from dilution 10x							Reduction
	Hand	prevalues			postvalues				
Nr	left /right	$x10^{-4}$	$x10^{-5}$	log x	$x10^{0}$	$x10^{-1}$	$x\ 10^{-2}$	log y	log z
	l	>330	60		>330	112	14		
1	p	>330	53	6,71	>330	34	3	2,79	3,92
	l	>330	40		214	21	2		
2	p	>330	43	6,58	271	30	30	2,38	4,19
	l	>330	53		>330	41	4		
3	p	316	35	6,59	>330	56	6	2,68	3,91
	l	>330	44		215	23	3		
4	p	>330	35	6,55	187	20	2	2,30	4,25
	l	264	27		>330	82	10		
5	p	319	31	6,46	>330	139	14	3,03	3,43
	l	292	32		>330	97	10		
6	p	261	26	6,44	>330	116	12	3,03	3,42
	l	>330	101		298	31	3		
7	p	>330	106	6,97	>330	79	8	2,69	4,29
	l	297	27		>330	91	9		
8	p	>330	47	6,55	292	61	6	2,73	3,82
	l	>330	89		>330	152	15		
9	p	>330	115	6,96	>330	188	20	3,23	3,73
	l	>330	125		>330	114	11		
10	p	>330	111	7,03	>330	93	9	3,01	4,02
	l	>330	52		114	12	1		
11	p	>330	42	6,63	169	17	2	2,14	4,48
	l	231	25		79	8	2		
12	p	240	26	6,38	62	6	1	1,84	4,53
	l	>330	39		>330	119	12		
13	p	>330	32	6,51	>330	92	10	3,02	3,49
	l	>330	108		94	9	1		
14	p	>330	64	6,88	86	9	2	1,95	4,92
	l	>330	34		169	18	2		
15	p	>330	50	6,57	201	20	2	2,27	4,31
$x_{śr}$				6,65				2,61	4,05
s				0,21				0,43	0,44

log x-logarithm of the average value of the initial left and right hand
log y-logarithm of the average value of the final left and right hand
log z-logarithm reduction
x śr- overall average of log x, log y, log z

Annex date: 17.04.2024

Authorized by: Izabela Kobylecka, Senior Analyst Specialist, Cosmetics Microbiology Laboratory

Approved by: Marzena Bogdaniuk, Cosmetology Laboratory Director *(Approved with electronic signature)*

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HAMILTON

ANNEX NO 1 TO THE REPORT NO 167490/24/INT

Table 3. LIST OF COMPUTED IG VALUES AND IG REDUCTIONS

volunteer		R			P		
Nr		log x	log y	log z	log x	log y	log z
1	R-P	6,82	3,19	3,63	6,71	2,79	3,92
2	R-P	6,46	2,32	4,14	6,58	2,38	4,19
3	R-P	6,37	2,55	3,82	6,59	2,68	3,91
4	R-P	6,93	2,93	4,00	6,55	2,30	4,25
5	R-P	6,45	2,47	3,98	6,46	3,03	3,43
6	R-P	6,88	2,97	3,91	6,44	3,03	3,42
7	R-P	6,97	3,26	3,71	6,97	2,69	4,29
8	R-P	6,71	3,23	3,48	6,55	2,73	3,82
9	P-R	6,77	2,94	3,83	6,96	3,23	3,73
10	P-R	6,38	2,42	3,96	7,03	3,01	4,02
11	P-R	6,94	3,10	3,85	6,63	2,14	4,48
12	P-R	6,54	2,64	3,90	6,38	1,84	4,53
13	P-R	6,90	3,05	3,85	6,51	3,02	3,49
14	P-R	6,82	3,33	3,49	6,88	1,95	4,92
15	P-R	6,63	3,14	3,49	6,57	2,27	4,31
X 15		**6,70**	2,90	3,80	**6,65**	2,61	4,05
X8(R-P)		6,70	2,86	**3,83**	6,61	2,71	**3,90**
X7(P-R)		6,71	2,95	**3,77**	6,71	2,50	**4,21**

Criteria:

Rs (R-P) = 3,83-3,90=-0,07
Rs (P-R) = 3,77-4,21=-0,44
Abs = -0,07-(-0,44)=0,37<2
logx(R) = 6,70> 5
logx(P) = 6,65> 5

Validation conditions of neutralizer and methods have been satisfied

Annex date: 17.04.2024

Authorized by: Izabela Kobylecka, Senior Analyst Specialist, Cosmetics Microbiology Laboratory

Approved by: Marzena Bogdaniuk, Cosmetology Laboratory Director *(Approved with electronic signature)*

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ANNEX NO 1 TO THE REPORT NO 167490/24/INT

Table 4. COMPUTATION OF INDIVIDUAL DIFFERENCES OF lg R-P

volunteer	log RF		difference	difference	
	R	P	R-P	high to low	range +/-
1	3,63	3,92	-0,28	0,55	1
2	4,14	4,19	-0,05	0,49	2
3	3,82	3,91	-0,09	0,37	3
4	4,00	4,25	-0,25	0,09	4
5	3,98	3,43	0,55	-0,05	-5
6	3,91	3,42	0,49	-0,06	-6
7	3,71	4,29	-0,57	-0,09	-7
8	3,48	3,82	-0,34	-0,25	-8
9	3,83	3,73	0,09	-0,28	-9
10	3,96	4,02	-0,06	-0,34	-10
11	3,85	4,48	-0,64	-0,57	-11
12	3,90	4,53	-0,63	-0,63	-12
13	3,85	3,49	0,37	-0,64	-13
14	3,49	4,92	-1,44	-0,81	-14
15	3,49	4,31	-0,81	-1,44	-15
sum of ranks (+): 10					
sum of ranks (-): 110					

Table 5. WILCOXON'S TMATCHED PAIRS SIGNED-RANKS TEST:
CRITICAL VALUES LESS WITH RANG SUM (+) OR (-) AT DIFFERENT LEVELS OF SIGNIFICANCE

n	one-sided level of significance		
	0,05	**0,01**	0,001
12	17	**9**	2
13	21	**12**	4
14	25	**15**	6
15	30	**19**	8

10 ≤ 19 The product P is more effective than standard R (soft soap).

Annex date: 17.04.2024

Authorized by: Izabela Kobylecka, Senior Analyst Specialist, Cosmetics Microbiology Laboratory

Approved by: Marzena Bogdaniuk, Cosmetology Laboratory Director *(Approved with electronic signature)*

J.S. HAMILTON POLAND Sp. z o.o.
TESTING LABORATORY
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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
Date of test report: 24/04/2024

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

Digitally signed by Crestinov Evghenii
Date: 2024.08.07 15:53:34 EEST
Reason: MoldSign Signature
Location: Moldova

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:37:13 EEST
Reason: MoldSign Signature
Location: Moldova

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EN ISO/IEC 17025
L263

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

.....

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

EAK
EN ISO/IEC 17025
L263

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.

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

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

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:37:20 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Digitally signed by Crestinov Evghenii
Date: 2024.08.07 15:54:22 EEST
Reason: MoldSign Signature
Location: Moldova

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EN ISO/IEC 17025
L263

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

ACCREDITED LABORATORY No L263. ISO/IEC 17025. REPUBLIC OF ESTONIA
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

EAK
EN ISO/IEC 17025
L263

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.

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: 22.04.2024

HAMILTON

AB 079

REPORT No. 390312/25/INT

Sponsor:		Investigational product (according to declaration of the Sponsor)
ECOCHIM-GRUP S.R.L., **UNGHENI CITY, NATIONALA 119 STREET**		**DISINFECTANT LIQUID SOAP ,,GAMADEZ,,** 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 3
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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REPORT No. 390312/25/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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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	Liquid soap
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 LIQUID SOAP ,,GAMADEZ,,** 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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