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

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Date: 2025.11.11 15:07:22 EET
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Nr.	B-0284/2025
din	10.09.2025

I. Denumirea comercială a produsului în Republica Moldova

Dezinfectant GamaDez

Alte denumiri comerciale

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

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

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

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

IV. Date de identificare a produsului

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

Certificatul de înregistrare este valabil până la data: 21.06.2029.

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

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

Director adjunct **Vasile Gustiuc**

Digitally signed by Guştiuc Vasile
Date: 2025.09.24 15:46:37 EEST
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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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AB 079

TEST REPORT NO 167489/24/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 hand disinfection [1] PN-EN 1500:2013-07	-	The preparation has bactericidal effect against transient microorganisms used in the hygienic procedure of hand disinfection - a single rubbing of 3ml of the preparation for 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

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J.S. HAMILTON POLAND Sp. z o.o.
TESTING LABORATORY
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HAMILTON

ANNEX NO. 1 TO THE TEST REPORT NO 167489/24/INT

A) IDENTYFICATION OF THE SAMPLE:	
Name of the product	**Dezinfectant "GamaDez"**
The 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 1500:2013 Chemical disinfectants and antiseptics - Hygienic handrub - 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	Rubbing 3ml of the preparation 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 (the qualified electronic signature)

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ANNEX NO. 1 TO THE TEST REPORT NO 167489/24/INT

PRODUCT: Standard 2-propanol 60% (V/V)
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							
	Hand	prevalues			postvalues				Reduction
Nr	left/right	$x10^{-4}$	$x10^{-5}$	log x	$x10^{0}$	$x10^{-1}$	$x\ 10^{-2}$	log y	log z
	l	>330	47		188	19	2		
1	r	>330	96	6,79	215	22	2	2,30	4,48
	l	>330	58		69	7	1		
2	r	>330	35	6,61	40	4	1	1,72	4,89
	l	>330	105		89	10	1		
3	r	>330	114	7,00	147	15	2	2,06	4,94
	l	311	32		69	8	1		
4	r	302	29	6,49	51	5	1	1,78	4,71
	l	251	25		74	8	2		
5	r	217	22	6,37	66	8	1	1,85	4,52
	l	>330	74		115	12	2		
6	r	299	33	6,65	101	10	2	2,03	4,62
	l	258	26		43	4	1		
7	r	230	23	6,39	38	4	1	1,61	4,78
	l	174	18		33	5	2		
8	r	216	23	6,29	49	5	1	1,61	4,67
	l	>330	101		118	12	2		
9	r	>330	147	7,04	137	14	3	2,11	4,94
	l	>330	87		99	11	1		
10	r	>330	69	6,85	74	7	1	1,93	4,91
	l	315	32		59	6	1		
11	r	282	28	6,47	47	5	1	1,72	4,75
	l	162	16		35	4	1		
12	r	269	28	6,32	68	7	1	1,69	4,63
	l	271	27		42	4	1		
13	r	253	25	6,42	38	4	0	1,60	4,82
	l	>330	115		139	14	2		
14	r	>330	91	6,97	114	12	1	2,10	4,87
	l	>330	61		115	13	1		
15	r	>330	47	6,69	84	10	1	2,00	4,69
	l	214	22		69	8	1		
16	r	261	26	6,37	81	8	0	1,88	4,50
	l	>330	91		111	15	2		
17	r	>330	116	6,97	158	16	3	2,13	4,84
	l	>330	91		74	8	1		
18	r	>330	60	6,83	53	5	0	1,80	5,03
	l	>330	39		40	4	1		
19	r	>330	44	6,58	62	6	1	1,70	4,88
	l	>330	51		101	10	1		
20	r	>330	59	6,70	116	13	2	2,04	4,66
$x_{śr}$				6,64				1,88	4,76
s				0,25				0,21	0,16

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 (the qualified electronic signature)

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ANNEX NO. 1 TO THE TEST REPORT NO 167489/24/INT

Table 2. PROCEDURE FOR HYGIENIC HANDRUB WITH THE PRODUCT

PRODUCT P: 167489/24/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							
	Hand	prevalues			postvalues				Reduction
Nr	left/right	$x10^{-4}$	$x10^{-5}$	log x	$x10^{0}$	$x10^{-1}$	$x\ 10^{-2}$	log y	log z
	l	>330	82		111	11	1		
1	r	>330	90	6,89	132	13	1	2,08	4,81
	l	>330	38		87	9	1		
2	r	>330	46	6,58	115	13	2	2,00	4,58
	l	>330	104		158	16	2		
3	r	>330	64	6,87	121	12	1	2,14	4,73
	l	>330	64		81	8	2		
4	r	>330	40	6,66	69	7	1	1,87	4,79
	l	>330	46		139	14	1		
5	r	160	18	6,42	102	10	1	2,08	4,34
	l	>330	74		51	5	0		
6	r	>330	50	6,74	41	4	0	1,63	5,11
	l	141	15		81	8	1		
7	r	139	14	6,15	70	7	1	1,88	4,27
	l	>330	48		55	6	1		
8	r	>330	54	6,67	79	8	1	1,82	4,84
	l	>330	144		104	10	1		
9	r	>330	66	6,95	81	9	2	1,96	4,98
	l	>330	54		69	8	1		
10	r	>330	37	6,61	43	4	1	1,74	4,87
	l	143	16		44	4	0		
11	r	133	13	6,14	37	4	1	1,61	4,54
	l	310	30		48	6	1		
12	r	>330	37	6,51	66	7	1	1,78	4,73
	l	212	21		39	4	1		
13	r	157	16	6,26	30	3	1	1,53	4,73
	l	251	25		67	7	2		
14	r	297	30	6,44	70	7	1	1,84	4,60
	l	>330	42		59	7	1		
15	r	>330	34	6,54	41	4	0	1,69	4,84
	l	>330	111		118	15	2		
16	r	>330	162	7,09	159	17	3	2,14	4,94
	l	>330	39		81	10	1		
17	r	>330	34	6,52	64	6	1	1,86	4,66
	l	>330	35		97	10	1		
18	r	>330	59	6,62	123	12	1	2,04	4,58
	l	>330	42		111	11	1		
19	r	>330	74	6,70	157	16	2	2,12	4,58
	l	>330	147		191	19	2		
20	r	>330	169	7,16	212	22	2	2,30	4,85
$x_{śr}$				6,62				1,91	4,72
s				0,28				0,21	0,21

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

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ANNEX NO. 1 TO THE TEST REPORT NO 167489/24/INT

Table 3. LIST OF COMPUTED IG VALUES AND IG REDUCTIONS

volunteer		R 2-propanol 60% (V/V)			P		
Nr		log x	log y	log z	log x	log y	log z
1	R-P	6,79	2,30	4,48	6,89	2,08	4,81
2	R-P	6,61	1,72	4,89	6,58	2,00	4,58
3	R-P	7,00	2,06	4,94	6,87	2,14	4,73
4	R-P	6,49	1,78	4,71	6,66	1,87	4,79
5	R-P	6,37	1,85	4,52	6,42	2,08	4,34
6	P-R	6,65	2,03	4,62	6,74	1,63	5,11
7	P-R	6,39	1,61	4,78	6,15	1,88	4,27
8	P-R	6,29	1,61	4,67	6,67	1,82	4,84
9	P-R	7,04	2,11	4,94	6,95	1,96	4,98
10	P-R	6,85	1,93	4,91	6,61	1,74	4,87
11	R-P	6,47	1,72	4,75	6,14	1,61	4,54
12	R-P	6,32	1,69	4,63	6,51	1,78	4,73
13	R-P	6,42	1,60	4,82	6,26	1,53	4,73
14	R-P	6,97	2,10	4,87	6,44	1,84	4,60
15	R-P	6,69	2,00	4,69	6,54	1,69	4,84
16	P-R	6,37	1,88	4,50	7,09	2,14	4,94
17	P-R	6,97	2,13	4,84	6,52	1,86	4,66
18	P-R	6,83	1,80	5,03	6,62	2,04	4,58
19	P-R	6,58	1,70	4,88	6,70	2,12	4,58
20	P-R	6,70	2,04	4,66	7,16	2,30	4,85
X_{20}		**6,64**	1,88	4,76	**6,62**	1,91	4,72
X10(R-P)		6,61	1,88	**4,73**	6,53	1,86	**4,67**
X10 (P-R)		6,67	1,88	**4,78**	6,72	1,95	**4,77**

Criteria:
Rs (R-P) = 4,73-4,67=0,06
Rs (P-R)= 4,78-4,77=0,01
Abs= 0,06-0,01=0,05 <2
logx(R)= 6,64>5
logx(P)= 6,62>5
logz (P), logz (R) >3

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 (the qualified electronic signature)

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ANNEX NO. 1 TO THE TEST REPORT NO 167489/24/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	4,48	4,81	-0,33	0,51	1
2	4,89	4,58	0,32	0,45	2
3	4,94	4,73	0,21	0,32	3
4	4,71	4,79	-0,08	0,30	4
5	4,52	4,34	0,18	0,27	5
6	4,62	5,11	-0,49	0,22	6
7	4,78	4,27	0,51	0,21	7
8	4,67	4,84	-0,17	0,18	8
9	4,94	4,98	-0,04	0,18	9
10	4,91	4,87	0,04	0,09	10
11	4,75	4,54	0,22	0,04	11
12	4,63	4,73	-0,10	-0,04	-12
13	4,82	4,73	0,09	-0,08	-13
14	4,87	4,60	0,27	-0,10	-14
15	4,69	4,84	-0,15	-0,15	-15
16	4,50	4,94	-0,45	-0,17	-16
17	4,84	4,66	0,18	-0,19	-17
18	5,03	4,58	0,45	-0,33	-18
19	4,88	4,58	0,30	-0,45	-19
20	4,66	4,85	-0,19	-0,49	-20
sum of ranks (+): 66					
sum of ranks (-): 144					

Annex date: 17.04.2024

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

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ANNEX NO. 1 TO THE TEST REPORT NO 167489/24/INT

Table 5. SORTING OF INDIVIDUAL DIFFERENCES AND COMPUTATION FOR HODGES-LEHMANN 97,5% UPPER CONFIDENCE LIMITS FOR THE DIFFERENCE IN lg BETWEEN R-P

		0,51	0,45	0,32	0,30	0,27	0,22	0,21	0,18	0,18
1	0,51	0,51								
2	0,45	0,48	0,45							
3	0,32	0,41	0,38	0,32						
4	0,30	0,40	0,37	0,31	0,30					
5	0,27	0,39	0,36	0,29	0,28	0,27				
6	0,22	0,36	0,33	0,27	0,26	0,24	0,22			
7	0,21	0,36	0,33	0,26	0,25	**0,24**	0,21	-0,21		
8	0,18	0,35	0,32	0,25	0,24	0,22	0,20	-0,19	-0,18	
9	0,18	0,34	0,32	0,25	0,24	0,22	0,20	-0,19	-0,18	-0,18
10	0,09	0,30	0,27	0,20	0,19	0,18	0,15	-0,15	-0,14	-0,04
11	0,04	0,28	0,25	0,18	0,17	0,16	0,13	-0,13	-0,11	-0,02
12	-0,04	0,23	0,20	0,14	0,13	0,11	0,09	-0,08	-0,07	
13	-0,08	0,22	0,19	0,12	0,11	0,09	0,07	-0,06		
14	-0,10	0,20	0,17	0,11	0,10	0,08	0,06			
15	-0,15	0,18	0,15	0,08	0,07	0,06				
16	-0,17	0,17	0,14	0,07	0,06					
17	-0,19	0,16	0,13	0,06						
18	-0,33	0,09	0,06							
19	-0,45	0,03								
20	-0,49									

Table 6. 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	**0,025**	0,01
18	47	**40**	32
19	53	**46**	27
20	60	**52**	43
21	68	**59**	49
22	75	**66**	56

For the designated level of significance 0,025 for n=20 the value read from the table 6 is 52.
Hence c = 52+1 =53.
For the distribution of 53 Table 5 assigns a value of 0,24 which is less than the agreed inferiority margin of 0,6.
Therefore, the hypothesis of inferiority of PP compared to the reference RP is rejected.
The test preparation (PP) is non-inferior to RP.

Annex date: 17.04.2024

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

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

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ENSAYO
ISO 17025
Nº648 / LE1286

Test with the certificate of GLPs (Good Laboratory Practices) No. 2/23-C.VAL. General Directorate of Pharmacy and Medical Devices of the Health Department of the Valencian Region. Spain

Efficacy assay for surgical hands disinfection, with the product "Disinfectant «GamaDez»". (EN 12791: 2016 + A1: 2017 Standard)

Report
Registration No.: D/24/B0435.

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

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

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

- Name of the product …..……..……..… **Disinfectant «GamaDez».**
- Batch number ..…..……..…… Not indicated.
- Expiration date ….……..……..... 2027/07/08.
- Manufacturer/supplier …..…….. ECOCHIM – GRUP S.R.L.
- Storing conditions ……. Not indicated.
- Active compound/s and its concentration/s …..…….…….. Ethyl alcool 72%, CAS 64-17-5 and CE 200-578-6; Isopropyl alcohol 1%, CAS 67-63-0, CE 200-661-7.
- Condition for use ….……..……. Surgical hand disinfection.
- Requested test concentration……..…. Pure.

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

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:43:20 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

4. Information about sample reception

- Date of reception of the sample ……..……. 2024/07/09.
- Date of reception of order with test conditions ...…….…… 2024/07/09.
- Aspect of the received sample ……..…….. Transparent liquid received in plastic packaging.

5. Method of assay and its validation

EN 12791: 2016 + A1: 2017 Standard.
Validation following EN 13727: 2012 + A2: 2015 and EN 13624: 2021 Standards.

6. Composition of the neutralizer and results of its validation performed by the suspension assay for phase 2/step 2

- Neutralizer …….. Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1 g/L, sodium bisulfite 2.5 g/L, soya lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and saponin 30 g/L.

7. Experimental conditions

- Period of assay (including prior preparation of the strain) ……..……... 2024/07/21 to 2024/08/08.
- Diluent used ……..... Not applicable.
- Concentration of the product in the assay.. Pure.
- Aspect of product dilutions ……..……... Not applicable.
- Time/s of contact ……..……..... 90 seconds.
- Temperature/s of the assay ……..…….. +20ºC ± 1 ºC.
- Stability of the mixture ……..... Not applicable.
- Temperature of incubation ……. +36ºC ± 1 ºC.

8. Description of method of use of "P" (product of assay)

- Volume …… 6 mL (2 x 3 mL).
- Duration of contact ..…… 90 seconds (2 x 45 seconds).
- Method of application ...……. 2 applications of ready to use product, 3 mL for each application (6 mL total). 45 seconds for each application (90 seconds total). Pre-wetting is not required. Rinsing off the product is not required.

9. Criteria according to Guideline EN 12791: 2016+ A1: 2017

To comply with the EN 12791 standard, the mean reduction for immediate effect and 3 h effect of a product shall at least be not statistically inferior to that achieved by a specified reference product (60% volume concentration of propan-1-ol). To demonstrate additionally a sustained effect, the mean reduction for the 3 h effect of a product shall be statistically superior to that achieved by the reference product.

Statistical analysis is performed to calculate the higher limit of the unilateral 97.5% confidence interval of Hodges-Lehman for the difference of the reduction logarithms between the reference product (**RP**) (a 60% aqueous solution [v:v] of propanol-1), and the product of assay (**PP**), to calculate the inferiority hypothesis of the assay product with respect to the reference product (60% propanol-1). If the result obtained is superior or equal to 0.75 for the immediate effect, or 0.85 for the effect at 3 hours, the activity of the assay product is lower than the reference product (**RP**). If the result obtained is inferior to 0.75 or 0.85 for the immediate and 3 hours effect, respectively, the activity of the assay product is not inferior to the reference product.

To demonstrate additionally a sustained effect (long-term effect), a statistical evaluation with the Wilcoxon test with a value of P = 0.01 must be performed and demonstrate that the mean reduction for the 3 h effect of a product (**PP**) is superior to that achieved by the reference product (**RP**).

10. Results of the controls and their validation

- Validation ……. See tables 8, 9, 10, 11 and 12.
- Results of the controls and their validation..…… All controls and their validation were within their basic limits.

11. Conclusion

The product of assay **Disinfectant «GamaDez»**, batch not indicated, when it is pure (100%), and applying a total volume of 6 mL for 90 seconds, in two applications (3 mL every 45 seconds), has a value of the upper limit of the 97.5% confidence interval **lower** than 0.75 and consequently, it can be concluded that the mean reduction for the immediate effect of the test product **is not statistically significantly lower** than that obtained with the reference product and, therefore, it **complies** with the requirements of the rule for **immediate effect**. At 3 hours, it has value of the upper limit of the 97.5% confidence interval **lower** than 0.85, consequently, it can be concluded that the mean reduction for the effect at 3 hours of the test product **is not statistically significantly lower** than that obtained with the reference product and, therefore, it **complies** with the requirements of the standard **for the effect 3 hours after application**, when tested according to **EN 12791: 2016 + A1: 2017** standard.

The test product **Disinfectant «GamaDez»**, batch not indicated, **is suitable** for use as a product for surgical hand disinfection in accordance with **EN 12791: 2016 + A1: 2017** standard.

The test product **Disinfectant «GamaDez»**, batch not indicated, **does not show** sustained effect (long-term effect), since the average reduction obtained with the test product for the effect after 3 hours after application **is not statistically significantly higher** than that obtained with the reference product after 3 hours. hours of application, when tested according to **EN 12791 :2016 +A1:2017** standard.

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

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), August 22, 2024.

GARCIA DE LOMAS
LATIN, JAIME (FIRMA)

Signed. Jaime García de Lomas.
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.

MONTOYA VIECO, ELENA (FIRMA)

Signed. Elena Montoya.
Responsible for the Laboratory Area
(Study Director)

ESTEBAN BERMUDEZ, ENCARNACION PILAR (FIRMA)

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

References

- **EN 12791: 2016 + A1: 2017**. Antiseptics and chemical disinfectants. Surgical disinfection of hands. Method of assay and requirements (phase 2/step 2).
- **EN 13727: 2012 + A2: 2015**. Chemical antiseptics and disinfectants. Quantitative suspension test for the evaluation of bactericidal activity in the medical area. Test method and requirements (Phase 2. stage 1).
- **EN 13624: 2021**. Chemical antiseptics and disinfectants. Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in Medicine. Test method and requirements (phase 2. stage 1).

Experimental results for "RP" (Reference Product) and "PP" (P**roduct of assay**).

Table 1.- Reference surgical hands disinfection procedure – experimental results.

Product: Reference (propanol-1 60%, concentration in volume).
Date of the experiment: **First assay,** subjects 17 to 24, date 2024/07/23.
Second assay, subjects 1 to 8, date 2024/07/30.
Third assay, subjects 9 to 16, date 2024/08/06.
Application: Number of 3 mL volumes aliquots required to maintain the hands wet for 3 minutes.

Voluntarios			**Number of UFC per plate of dilution 10^x**								
			Initial counts			**Final counts**					
						Immediate			**3 hours**		
OA	**Nº (App.)**	**t**	**-1**	**-2**	**-3**	**Pure**	**-1**	**-2**	**Pure**	**-1**	**-2**
PP-RP	1(3)	inm	>330	>330	303	>330	318	34	>330	>330	46
		3h	>330	71	7						
PP-RP	2(3)	inm	>330	>330	132	>330	164	18	>330	>330	253
		3h	>330	299	35						
PP-RP	3(3)	inm	>330	250	30	>330	>330	115	>330	>330	58
		3h	>330	>330	54						
PP-RP	4(3)	inm	>330	>330	203	>330	>330	261	>330	262	28
		3h	>330	>330	131						
PP-RP	5(3)	inm	>330	>330	312	>330	131	15	>330	>330	248
		3h	>330	>330	292						
PP-RP	6(5)	inm	>330	>330	107	>330	>330	300	>330	>330	269
		3h	>330	>330	211						
PP-RP	7(3)	inm	>330	>330	137	>330	>330	52	>330	>330	147
		3h	>330	>330	191						
PP-RP	8(3)	inm	>330	>330	57	>330	291	32	>330	>330	210
		3h	>330	249	28						
PP-RP	9(3)	inm	>330	>330	88	>330	>330	169	>330	>330	275
		3h	>330	>330	175						
PP-RP	10(3)	inm	>330	>330	104	>330	48	6	>330	121	14
		3h	>330	>330	142						
PP-RP	11(5)	inm	>330	>330	164	>330	>330	86	>330	>330	257
		3h	>330	>330	242						
PP-RP	12(4)	inm	>330	>330	280	>330	205	25	>330	>330	46
		3h	>330	>330	303						
PP-RP	13(2)	inm	>330	302	37	>330	>330	50	>330	133	16
		3h	>330	>330	46						
PP-RP	14(3)	inm	>330	>330	192	>330	>330	104	>330	>330	302
		3h	>330	>330	269						
PP-RP	15(3)	inm	>330	>330	317	>330	>330	115	>330	>330	231
		3h	>330	>330	250						

PP-RP	16(3)	inm	>330	>330	275	>330	185	21	>330	>330	283
		3h	>330	>330	296						
RP-PP	17(3)	inm	>330	>330	172	>330	202	22	>330	70	9
		3h	>330	>330	201						
RP-PP	18(3)	inm	>330	>330	160	>330	94	11	>330	>330	269
		3h	>330	>330	174						
RP-PP	19(4)	inm	>330	>330	101	>330	134	16	>330	>330	303
		3h	>330	>330	146						
RP-PP	20(3)	inm	>330	>330	294	>330	>330	160	>330	>330	315
		3h	>330	>330	315						
RP-PP	21(4)	inm	>330	>330	67	>330	208	24	>330	>330	277
		3h	>330	>330	71						
RP-PP	22(3)	inm	>330	>330	302	>330	>330	188	>330	>330	308
		3h	>330	>330	285						
RP-PP	23(5)	inm	>330	190	20	260	35	5	>330	238	27
		3h	>330	>330	44						
RP-PP	24(4)	inm	>330	>330	296	>330	60	9	>330	251	28
		3h	>330	>330	320						

Nº: Volunteer number; **App**: Number of product applications; **OA**: Order of application; **RP**: Reference; **PP**: Test product. **t**: time; **imm**: immediate; **h**: hours.

Table 2.-Surgical hand disinfection procedure with the test product.

Product: Test product (**PP**): **Disinfectant «GamaDez».**
Date of the experiment: **First assay,** subjects 9 to 16, date 2024/07/23.
Second assay, subjects 17 to 24, date 2024/07/30.
Third assay, subjects 1 to 8, date 2024/08/06.
Application: 2 applications of ready to use product, 3 mL for each application (6 mL total). 45 seconds for each application (90 seconds total). Pre-wetting is not required. Rinsing off the product is not required.

Subject			Number of UFC per plate of dilution 10^x								
			Initial counts			Final counts					
						Immediate			3 hours		
OA	Nº	t	-1	-2	-3	Puro	-1	-2	Puro	-1	-2
PP-RP	1	inm	>330	>330	108	>330	175	21	>330	>330	49
		3h	>330	>330	320						
PP-RP	2	inm	>330	>330	72	>330	>330	257	>330	>330	285
		3h	>330	>330	296						
PP-RP	3	inm	>330	>330	68	>330	59	8	>330	>330	75
		3h	>330	>330	57						
PP-RP	4	inm	>330	>330	189	>330	133	14	>330	>330	258
		3h	>330	>330	148						
PP-RP	5	inm	>330	>330	304	>330	>330	50	>330	>330	292
		3h	>330	>330	221						
PP-RP	6	inm	>330	>330	247	>330	>330	298	>330	>330	268
		3h	>330	>330	128						
PP-RP	7	inm	>330	>330	270	>330	>330	285	>330	>330	315
		3h	>330	>330	188						
PP-RP	8	inm	>330	>330	118	>330	>330	321	>330	>330	265
		3h	>330	>330	68						
PP-RP	9	inm	>330	>330	287	>330	>330	287	>330	>330	264
		3h	>330	>330	312						
PP-RP	10	inm	>330	>330	103	>330	>330	97	>330	>330	231
		3h	>330	>330	121						
PP-RP	11	inm	>330	>330	269	>330	>330	270	>330	>330	318
		3h	>330	>330	292						
PP-RP	12	inm	>330	>330	319	>330	>330	287	>330	>330	324
		3h	>330	>330	282						
PP-RP	13	inm	>330	>330	159	>330	>330	142	>330	>330	224
		3h	>330	>330	51						
PP-RP	14	inm	>330	>330	260	>330	>330	282	>330	>330	308
		3h	>330	>330	271						
PP-RP	15	inm	>330	>330	303	>330	260	33	>330	>330	230
		3h	>330	>330	263						

PP-RP	16	inm	>330	>330	277	>330	>330	289	>330	>330	255
		3h	>330	>330	158						
RP-PP	17	inm	>330	>330	87	>330	>330	71	>330	>330	253
		3h	>330	>330	139						
RP-PP	18	inm	>330	>330	57	>330	166	23	>330	>330	270
		3h	>330	>330	136						
RP-PP	19	inm	>330	>330	103	>330	>330	51	>330	>330	295
		3h	>330	>330	253						
RP-PP	20	inm	>330	>330	301	>330	>330	314	>330	>330	255
		3h	>330	>330	128						
RP-PP	21	inm	>330	>330	161	>330	>330	252	>330	>330	279
		3h	>330	>330	158						
RP-PP	22	inm	>330	>330	318	>330	>330	285	>330	>330	199
		3h	>330	>330	308						
RP-PP	23	inm	>330	>330	180	>330	>330	280	>330	>330	201
		3h	>330	>330	296						
RP-PP	24	inm	>330	>330	278	>330	>330	306	>330	>330	273
		3h	>330	>330	315						

Nº: Volunteer number; **App**: Number of product applications; **OA**: Order of application; **RP**: Reference; **PP**: Test product. **t**: time; **imm**: immediate; **h**: hours.

Table 3.- List of logarithm values used and logarithm of the reduction factors of the experimental results with the reference product (propanol-1 60%, concentration in volume)

Subject No. and sequence		Immediate effect			Effect at 3 hours		
		Log x	log y	log z	log x	log y	log z
1	PP→RP	5.48	3.51	1.97	3.85	3.66	0.19
2	PP→RP	5.12	3.22	1.90	4.48	4.40	0.08
3	PP→RP	4.41	4.06	0.35	4.73	3.76	0.97
4	PP→RP	5.31	4.42	0.89	5.12	3.42	1.70
5	PP→RP	5.49	3.12	2.37	5.47	4.39	1.08
6	PP→RP	5.03	4.48	0.55	5.32	4.43	0.89
7	PP→RP	5.14	3.72	1.42	5.28	4.17	1.11
8	PP→RP	4.76	3.47	1.29	4.40	4.32	0.08
9	PP→RP	4.94	4.23	0.71	5.24	4.44	0.80
10	PP→RP	5.02	2.68	2.34	5.15	3.09	2.06
11	PP→RP	5.21	3.93	1.28	5.38	4.41	0.97
12	PP→RP	5.45	3.32	2.13	5.48	3.66	1.82
13	PP→RP	4.49	3.70	0.79	4.66	3.13	1.53
14	PP→RP	5.28	4.02	1.26	5.43	4.48	0.95
15	PP→RP	5.50	4.06	1.44	5.40	4.36	1.04
16	PP→RP	5.44	3.27	2.17	5.47	4.45	1.02
17	RP→PP	5.24	3.31	1.93	5.30	2.85	2.45
18	RP→PP	5.20	2.97	2.23	5.24	4.43	0.81
19	RP→PP	5.00	3.13	1.87	5.16	4.48	0.68
20	RP→PP	5.47	4.20	1.27	5.50	4.50	1.00
21	RP→PP	4.83	3.32	1.51	4.85	4.44	0.41
22	RP→PP	5.48	4.27	1.21	5.45	4.49	0.96
23	RP→PP	4.28	2.43	1.85	4.64	3.38	1.26
24	RP→PP	5.47	2.78	2.69	5.51	3.40	2.11
X		5,13	3.57	1.56	5.10	4.02	1.08
S		0,36	0.58	0.63	0.44	0.55	0.62
N		24	24	24	24	24	24
X (PP-RP)		5,11	3.53	1.58	5.02	4.03	0.99
S (PP-RP)		0,37	0.59	0.62	0.47	0.52	0.65
N (PP-RP)		16	16	16	16	16	16
X (RP-PP)		4,94	3.65	1.52	5.28	4.00	1.27
S (RP-PP)		0,54	0.52	0.63	0.27	0.61	0.47
N (RP-PP)		8	8	8	8	8	8

Log x = Logarithm of the initial value. **Log y** = Logarithm of the initial value. **Log z** = Logarithm of reduction factor.	**X** = Overall mean of log x; log y; log z **S** = Standard deviation. **N** = Number of values (= subjects) in each column.

Table 4.- List of logarithm values and logarithms of the reduction factors of the experimental results with the test product.

Subject No. and sequence		Immediate effect			Effect at 3 hours		
		Log x	log y	log z	log x	log y	log z
1	PP→RP	5.03	3.25	1.78	5.51	3.69	1.82
2	PP→RP	4.86	4.41	0.45	5.47	4.45	1.02
3	PP→RP	4.83	2.77	2.06	4.76	3.88	0.88
4	PP→RP	5.28	3.13	2.15	5.17	4.41	0.76
5	PP→RP	5.48	3.70	1.78	5.34	4.47	0.87
6	PP→RP	5.39	4.47	0.92	5.11	4.43	0.68
7	PP→RP	5.43	4.45	0.98	5.27	4.50	0.77
8	PP→RP	5.07	4.51	0.56	4.83	4.42	0.41
9	PP→RP	5.46	4.46	1.00	5.49	4.42	1.07
10	PP→RP	5.01	3.99	1.02	5.08	4.36	0.72
11	PP→RP	5.43	4.43	1.00	5.47	4.50	0.97
12	PP→RP	5.50	4.46	1.04	5.45	4.51	0.94
13	PP→RP	5.20	4.15	1.05	4.71	4.35	0.36
14	PP→RP	5.41	4.45	0.96	5.43	4.49	0.94
15	PP→RP	5.48	3.43	2.05	5.42	4.36	1.06
16	PP→RP	5.44	4.46	0.98	5.20	4.41	0.79
17	RP→PP	4.94	3.85	1.09	5.14	4.40	0.74
18	RP→PP	4.76	3.24	1.52	5.13	4.43	0.70
19	RP→PP	5.01	3.71	1.30	5.40	4.47	0.93
20	RP→PP	5.48	4.50	0.98	5.11	4.41	0.70
21	RP→PP	5.21	4.40	0.81	5.20	4.45	0.75
22	RP→PP	5.50	4.45	1.05	5.49	4.30	1.19
23	RP→PP	5.26	4.45	0.81	5.47	4.30	1.17
24	RP→PP	5.44	4.49	0.95	5.50	4.44	1.06
X S N		5.25 0.24 24	4.07 0.54 24	1.18 0.46 24	5.26 0.24 24	4.37 0.19 24	0.89 0.29 24
X (PP-PP) S (PP-PP) N (PP-PP)		5.19 0.26 16	3.99 0.61 16	1.20 0.51 16	5.24 0.23 16	4.34 0.23 16	0.90 0.32 16
X (RP-RP)		5.37	4.23	1.14	5.28	4.43	0.86
S (RP-RP)		0.17	0.37	0.37	0.27	0.07	0.23
N (RP-RP)		8	8	8	8	8	8

Log x = Logarithm of the initial value. **Log y** = Logarithm of the initial value. **Log z** = Logarithm of reduction factor.	**X** = Overall mean of log x; log y; log z **S** = Standard deviation. **N** = Number of values (= subjects) in each column.

Table 5.-Individual differences of the decimal logarithms of the reduction factors between RP and PP for the "immediate effect" and the "3 hours effect".

Subject Nº.	Log_{10} for immediate effect			Log_{10} for 3 hours effect		
	RP	PP	Difference RP-PP	RP	PP	Difference RP-PP
1	1.97	1.78	0.19	0.19	1.82	-1.63
2	1.90	0.45	1.45	0.08	1.02	-0.94
3	0.35	2.06	-1.71	0.97	0.88	0.09
4	0.89	2.15	-1.26	1.70	0.76	0.94
5	2.37	1.78	0.59	1.08	0.87	0.21
6	0.55	0.92	-0.37	0.89	0.68	0.21
7	1.42	0.98	0.44	1.11	0.77	0.34
8	1.29	0.56	0.73	0.08	0.41	-0.33
9	0.71	1.00	-0.29	0.80	1.07	-0.27
10	2.34	1.02	1.32	2.06	0.72	1.34
11	1.28	1.00	0.28	0.97	0.97	0.00
12	2.13	1.04	1.09	1.82	0.94	0.88
13	0.79	1.05	-0.26	1.53	0.36	1.17
14	1.26	0.96	0.30	0.95	0.94	0.01
15	1.44	2.05	-0.61	1.04	1.06	-0.02
16	2.17	0.98	1.19	1.02	0.79	0.23
17	1.93	1.09	0.84	2.45	0.74	1.71
18	2.23	1.52	0.71	0.81	0.70	0.11
19	1.87	1.30	0.57	0.68	0.93	-0.25
20	1.27	0.98	0.29	1.00	0.70	0.30
21	1.51	0.81	0.70	0.41	0.75	-0.34
22	1.21	1.05	0.16	0.96	1.19	-0.23
23	1.85	0.81	1.04	1.26	1.17	0.09
24	2.69	0.95	1.74	2.11	1.06	1.05
X	1.56	1.18	0.38	1.08	0.89	0.19
S	0.63	0.46	0.83	0.62	0.29	0.73
N	24	24	24	24	24	24

Table 6.- Calculation of the confidence limit of 97.5% using the Hodges-Lehmann method for the "immediate effect".

	Ordination RP-PP	1.74	1.45	1.32	1.19	1.09	1.04	0.84	0.73	0.71	0.70	0.59	0.57
1	1.74	1.74											
2	1.45	1.60	1.45										
3	1.32	1.53	1.39	1.32									
4	1.19	1.47	1.32	1.26	1.19								
5	1.09	1.42	1.27	1.21	1.14	1.09							
6	1.04	1.39	1.25	1.18	1.12	1.07	1.04						
7	0.84	1.29	1.15	1.08	1.02	0.97	0.94	0.84					
8	0.73	1.24	1.09	1.03	0.96	0.91	0.89	0.79	0.73				
9	0.71	1.23	1.08	1.02	0.95	0.90	0.88	0.78	0.72	0.71			
10	0.70	1.22	1.08	1.01	0.95	0.90	0.87	0.77	0.72	0.71	0.70		
11	0.59	1.17	1.02	0.96	0.89	0.84	0.82	0.72	0.66	0.65	0.65	0.59	
12	0.57	1.16	1.01	0.95	0.88	0.83	0.81	0.71	0.65	0.64	0.64	0.58	0.57
13	0.44	1.09	0.95	0.88	0.82	0.77	0.74	0.64	0.59	0.58	0.57	0.52	0.51
14	0.30	1.02	0.88	0.81	0.75	0.70	0.67	0.57	0.52	0.51			
15	0.29	1.02	0.87	0.81	0.74	0.69	0.67	0.57	0.51				
16	0.28	1.01	0.87	0.80	0.74	0.69	0.66	0.56	0.51				
17	0.19	0.97	0.82	0.76	0.69	0.64	0.62	0.52					
18	0.16	0.95	0.81	0.74	0.68	0.63	0.60						
19	-0.26	0.74	0.60	0.53									
20	-0.29	0.73	0.58	0.52									
21	-0.37	0.69	0.54										
22	-0.61	0.57											
23	-1.26												
24	-1.71												

Critical value 82: 0.74

Table 7.- Calculation of the confidence limit of 97.5% using the Hodges-Lehmann method for the "3 hours effect".

	Ordination RP-PP	1.71	1.34	1.17	1.05	0.94	0.88	0.34	0.30	0.23	0.21	0.21	0.11
1	1.71	1.71											
2	1.34	1.53	1.34										
3	1.17	1.44	1.26	1.17									
4	1.05	1.38	1.20	1.11	1.05								
5	0.94	1.33	1.14	1.06	1.00	0.94							
6	0.88	1.30	1.11	1.03	0.97	0.91	0.88						
7	0.34	1.03	0.84	0.76	0.70	0.64	0.61	0.34					
8	0.30	1.01	0.82	0.74	0.68	0.62	0.59	0.32	0.30				
9	0.23	0.97	0.79	0.70	0.64	0.59	0.56	0.29	0.27	0.23			
10	0.21	0.96	0.78	0.69	0.63	0.58	0.55	0.28	0.26	0.22	0.21		
11	0.21	0.96	0.78	0.69	0.63	0.58	0.55	0.28	0.26	0.22	0.21	0.21	
12	0.11	0.91	0.73	0.64	0.58	0.53	0.50	0.23	0.21	0.17	0.16	0.16	0.11
13	0.09	0.90	0.72	0.63	0.57	0.52	0.49	0.22	0.20	0.16	0.15	0.15	0.10
14	0.09	0.90	0.72	0.63	0.57	0.52	0.49	0.22	0.20	0.16	0.15	0.15	0.10
15	0.01	0.86	0.68	0.59	0.53	0.48	0.45	0.18	0.16	0.12	0.11	0.11	
16	0.00	0.86	0.67	0.59	0.53	0.47	0.44	0.17	0.15	0.12	0.11	0.11	
17	-0.02	0.85	0.66	0.58	0.52	0.46	0.43	0.16	0.14	0.11			
18	-0.23	0.74	0.56	0.47	0.41	0.36	0.33						
19	-0.25	0.73	0.55	0.46	0.40	0.35	0.32						
20	-0.27	0.72	0.54	0.45	0.39	0.34	0.31						
21	-0.33	0.69	0.51	0.42	0.36	0.31	0.28						
22	-0.34	0.69	0.50	0.42	0.36	0.30	0.27						
23	-0.94	0.39	0.20	0.12									
24	-1.63												

Critical value 82: 0.53

Evaluation of the prolonged effect - Results of the statistical treatment of the data by means of the unilateral Wilcoxon signed-rank test.

To carry out the statistical test, the raised hypotheses are:

H_0: There is not a significant difference between the log reduction obtained with the PP and the RP at 3 hours.
H_1: The log reduction, obtained with PP for the effect after 3 hours, **is significantly higher** than the reduction obtained after 3 hours with the RP.

- Critical value for unilateral test with p = 0.01 for 24 pairs with differences ≠ 0 (table 8): 69.
- Value of the statistic ***W*** obtained when comparing the logarithmic reduction after 3 hours of PP and RP: 98.5.

Since the obtained statistic ***W*** (98.5) is higher than the tabulated critical value (69), the null hypothesis (**H_0**) is accepted and it is considered that the reduction obtained with the test product for the effect after 3 hours, **is not significantly higher** than the reduction obtained after 3 hours with the reference product, therefore, **the test product does not show a prolonged effect.**

Table 8.- Wilcoxon contrast of the ranges with signs for the paired samples: critical values for the lower sums of the ranges with sign (+) or (-) at different signification values.

Number of pairs with differences ≠ 0	**Signification values**		
	***P* = 0.025** Unilateral	***P* = 0.01** Unilateral	**2*P* = 0.01** bilateral
23	73	62	54
24	81	69	61
25	89	76	68
26	98	84	75

Table 8.-Validation and controls with *Escherichia coli* K12 (CECT 433 = NCTC 10538).

Suspension of validation *(Nv$_0$)*			**Control of experimental conditions *(A)***			**Control of neutralizer *(B)***			**Validation of the method *(C)* Pure**		
V_{C1}	89	X= 91	V_{C1}	90	X= 87.5	V_{C1}	91	X= 88.5	V_{C1}	86	X= 80
V_{C2}	93		V_{C2}	85		V_{C2}	86		V_{C2}	74	
30 ≤ X of Nv_0 ≤ 160? Yes			X of A is ≥ 0.5 X of Nv_0? Yes			X of B is ≥ 0.5 X of Nv_0 or Nv_B/1.000? Yes			X of C is ≥ 0.5 X of Nv_0? Yes		
Suspension of validation *(Nv$_B$)*			V_{C1} 94 V_{C2} 102			X = 98 30 ≤ X of Nv_B/1.000 ≤ 160? Yes					

Table 9.- Validation and controls with *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442).

Suspension of validation *(Nv$_0$)*			**Control of experimental conditions *(A)***			**Control of neutralizer *(B)***			**Validation of the method *(C)* Pure**		
V_{C1}	59	X= 54.5	V_{C1}	52	X= 49.5	V_{C1}	55	X= 52	V_{C1}	54	X= 51
V_{C2}	50		V_{C2}	47		V_{C2}	49		V_{C2}	48	
30 ≤ X of Nv_0 ≤ 160? Yes			X of A is ≥ 0.5 X of Nv_0? Yes			X of B is ≥ 0.5 X of Nv_0 or Nv_B/1.000? Yes			X of C is ≥ 0.5 X of Nv_0? Yes		
Suspension of validation *(Nv$_B$)*			V_{C1} 62 V_{C2} 56			X = 59 30 ≤ X of Nv_B/1.000 ≤ 160? Yes					

Table 10.- Validation and controls with *Staphylococcus aureus* (CECT 239 = ATCC 6538).

Suspension of validation *(Nv$_0$)*			**Control of experimental conditions *(A)***			**Control of neutralizer *(B)***			**Validation of the method *(C)* Pure**		
V_{C1}	63	X= 62	V_{C1}	56	X= 53.5	V_{C1}	59	X= 58	V_{C1}	44	X= 42.5
V_{C2}	61		V_{C2}	51		V_{C2}	57		V_{C2}	41	
30 ≤ X of Nv_0 ≤ 160? Yes			X of A is ≥ 0.5 X of Nv_0? Yes			X of B is ≥ 0.5 X of Nv_0 or Nv_B/1.000? Yes			X of C is ≥ 0.5 X of Nv_0? Yes		
Suspension of validation *(Nv$_B$)*			V_{C1} 65 V_{C2} 58			X = 61.5 30 ≤ X of Nv_B/1.000 ≤ 160? Yes					

Table 11.- Validation and controls with *Enterococcus hirae* (CECT 4081 = ATCC 10541).

Suspension of validation *(Nv_0)*			**Control of experimental conditions *(A)***			**Control of neutralizer *(B)***			**Validation of the method *(C)*** **Pure**		
Vc_1	51	X= 47.5	V_{C1}	50	X= 48	V_{C1}	41	X= 44.5	V_{C1}	39	X= 37
Vc_2	44		V_{C2}	46		V_{C2}	48		V_{C2}	35	
$30 \leq X$ of $Nv_0 \leq 160$? Yes			X of A is ≥ 0.5 X of Nv_0? Yes			X of B is ≥ 0.5 X of Nv_0 or $Nv_B/1.000$? Yes			X of C is ≥ 0.5 X of Nv_0? Yes		
Suspension of validation *(Nv_B)*			Vc_1 54 Vc_2 50			X = 52 $30 \leq X$ of $Nv_B/1.000 \leq 160$? Yes					

Table 12.- Validation and controls with *Candida albicans* (CECT 1394 = ATCC 10231).

Suspension of validation *(Nv_0)*			**Control of experimental conditions *(A)***			**Control of neutralizer *(B)***			**Validation of the method *(C)*** **Pure**		
Vc_1	69	X= 66.5	V_{C1}	61	X= 64.5	V_{C1}	62	X= 61	V_{C1}	56	X= 52.5
Vc_2	64		V_{C2}	68		V_{C2}	60		V_{C2}	49	
$30 \leq X$ of $Nv_0 \leq 160$? Yes			X of A is ≥ 0.5 X of Nv_0? Yes			X of B is ≥ 0.5 X of Nv_0 or $Nv_B/1.000$? Yes			X of C is ≥ 0.5 X of Nv_0? Yes		
Suspension of validation *(Nv_B)*			Vc_1 70 Vc_2 61			X = 65.5 $30 \leq X$ of $Nv_B/1.000 \leq 160$? Yes					

Explanations:
Vc = counts per mL (one or more plates).
X = measurement of Vc_1 and Vc_2 (duplicate 1 + 2)

Nordic Tersus
Laboratory

Test report no. 134024hd

EVALUATION OF MYCOBACTERICIDAL ACTIVITY (EN 14348)

Name of the product: DISINFECTANT "GAMADEZ"
Batch number: 15.02.2024
Date of test report: 03/05/2024

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

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:43:26 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

EAK
EN ISO/IEC 17025
L263

Nordic Tersus
Laboratory

Test report No. 134024hd

EVALUATION OF MYCOBACTERICIDAL ACTIVITY (EN 14348)

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:	*Mycobacterium terrae* ATCC 15755 *Mycobacterium avium* ATCC 15769
Testing method:	EVS-EN 14348:2005 Chemical disinfectants and antiseptics- Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants (phase 2, step 1)
Testing date:	12.04.2024 – 03.05.2024
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 issue: 03.05.2024

** - 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 (suspension test)

EVS-EN 14348:2005; Phase 2, step 1
Membrane filtration method
Product diluent: Glass-distilled water
Appearance of product solutions: Transparent, colourless liquid
Test organism: *Mycobacterium avium* ATCC 15769
Test temperature: +20° C; Incubation temperature: +37 ± 1° C
Interfering substance: 3 g/l bovine albmin solution + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 12.04.2024
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}	$\bar{x}$
122	139	130.5	157	165	161	177	145	161	164	160	162
$30 \leq \bar{x}\ N_{vo} \leq 160$? 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}	$\bar{x}_{wm} = 5.00 \times 10^9$; $\log N = 9.70$
N and N_0	10^{-7}	>330	>330	$N_0 = N/10$; $\log N_0 = 8.70$
	10^{-8}	58	42	$8.17 \leq \log N_0 \leq 8.70$; yes X; no □

Experimental results Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	log Na	logR	Contact time	Conditions
80.0%	10^0	<14	<14	<2.15	>6.55	30 sec	Dirty
	10^{-1}	<14	<14				
	10^{-2}	<14	<14				
	10^{-3}	<14	<14				
50.0%	10^0	>660	>660	>4.82	<3.88	30 sec	Dirty
	10^{-1}	>660	>660				
	10^{-2}	>660	>660				
	10^{-3}	>660	>660				
10.0%	10^0	>660	>660	>4.82	<3.88	30 sec	Dirty
	10^{-1}	>660	>660				
	10^{-2}	>660	>660				
	10^{-3}	>660	>660				

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 (suspension test)

EVS-EN 14348:2005; Phase 2, step 1
Membrane filtration method
Product diluent: Glass-distilled water
Appearance of product solutions: Transparent, colourless liquid
Test organism: *Mycobacterium terrae* ATCC 15755
Test temperature: +20° C; Incubation temperature: +37 ± 1° C
Interfering substance: 3 g/l bovine albmin solution + 3 ml/l sheep blood erythrocytes
Nordic Tersus Laboratory LLC.
Date of test: 12.04.2024
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}	$\bar{x}$
34	26	30	36	37	36.5	42	37	39.5	32	49	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}	$\bar{x}_{wm} = 1.52 \times 10^9$; $\log N = 9.18$
N and N_0	10^{-7}	108	198	$N_0 = N/10$; $\log N_0 = 8.18$
	10^{-8}	11	18	$8.17 \leq \log N_0 \leq 8.70$; yes X; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	log Na	logR	Contact time	Conditions
80.0%	10^0	<14	<14	<2.15	>6.03	30 sec	Dirty
	10^{-1}	<14	<14				
	10^{-2}	<14	<14				
	10^{-3}	<14	<14				
50.0%	10^0	>660	>660	>4.82	<3.36	30 sec	Dirty
	10^{-1}	>660	>660				
	10^{-2}	>660	>660				
	10^{-3}	>660	>660				
10.0%	10^0	>660	>660	>4.82	<3.36	30 sec	Dirty
	10^{-1}	>660	>660				
	10^{-2}	>660	>660				
	10^{-3}	>660	>660				

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 ($R= N_0/ Na$; $LogR=Log N_0 - Log\ Na$)

Appendix 3

Interpretation:

The ready to use disinfection product **DISINFECTANT "GAMADEZ"** (batch no. 15.02.2024) was tested according to the test method EVS-EN 14348:2005. The test was performed at 20 °C ± 1 °C, under dirty conditions during the contact time of 30 seconds. The membrane filtration method was used for testing the product's effectiveness against the reference strains *Mycobacterium terrae* ATCC 15755 and *Mycobacterium avium* ATCC 15769. Under dirty conditions the tested ready to use product was effective against all the reference strains tested within 30 seconds.

Conclusion:

The surviving count of mycobacterial reference strains showed at least 4 lg reduction meaning that **according to EVS-EN 14348:2005 under dirty conditions the sample of the ready to use product DISINFECTANT "GAMADEZ" has mycobacterial activity within 30 seconds.**

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

This is the end of the test report.

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Kerda Treksler
Microbiologist
Date of issue: 03.05.2024

Instituto Valenciano de Microbiología

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Nº648 / LE1286

Test with the certificate of GLPs
(Good Laboratory Practices)
No. 2/23-C.VAL. General Directorate of
Pharmacy and Medical Devices of the Health
Department of the Valencian Region. Spain

Quantitative suspension test for the evaluation of virucidal activity in the medical area (phase 2, step 1), against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus with the product "Disinfectant «GamaDez»" (EN 14476: 2013 + A2: 2019 Standard)

Report
Registration No.: D/24/V066.

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

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

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

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

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

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:43:31 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

4. Information about sample reception

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

5. Testing method

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

6. Experimental conditions

- Assay period ..……... 2024/03/20 to 2024/04/05.
- Titration method ....……... $TCID_{50}$ (Tissue Culture Infective Dose 50%).
- Incubation temperature ……. 37ºC ± 1ºC.
- Product concentrations for the assay .... 80%, 50% and 0.1%.
- Contact time ..……..... 30 seconds.
- Contact temperature ..……... 20ºC ± 1ºC.
- Procedure to stop product cytotoxicity . Molecular sieving (< 4 columns).
- Procedure to stop product activity ..…. Cooling with ice.
- Solvent of the product used in the assay ……... Sterile distilled water.
- Aspect of the dilutions of the product ... Transparent.
- Stability of the mixture (interfering substance and product diluted in sterile distilled water) ……...……...…… Stable.
- Interfering substance:
  - Dirty conditions in the presence of bovine serum albumin 3 g/L and erythrocytes 3 mL/L.
- Identification of the origin of viral strains and number of passages ……. Poliovirus type 1 (ATCC VR-192) aliquot: 2023/03/23 passage 2.
  Adenovirus type 5 (ATCC VR-5) aliquot: 2022/06/10 passage 2.
  Murine Norovirus (strain S99 Berlin) aliquot: 2022/06/22 passage 2.
- Cell lines (name, origin, number of passages) ……...…… Vero, ref: FTVE, working aliquot 11, passages 11, 13 and 16.

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

7. Validation of assay results

Poliovirus type 1 (ATCC VR-192)

Titre of the viral suspension for the virus control (at the requested test time)
- Dirty conditions ..... $\log 10^{-6.91}$

Cytotoxicity level (80%) ..... $\log 10^{-0.50}$

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):
- Dirty conditions ..... $\log 10^{-6.41}$

Adenovirus type 5 (ATCC VR-5)

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

Cytotoxicity level (80%) ..... $\log 10^{-0.50}$

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):
- Dirty conditions ..... $\log 10^{-6.00}$

Murine Norovirus (strain S99 Berlin)

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

Cytotoxicity level (80%) ..... $\log 10^{-0.50}$

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):
- Dirty conditions ..... $\log 10^{-7.33}$

Reference test (formaldehyde 1.4%)

Cytotoxicity level of formaldehyde 0.7% ..... $\log 10^{-0.50}$

Viral quantification in the reference test (formaldehyde) after 60 minutes and with Poliovirus type 1 ..... $\log 10^{-4.41}$

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

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

Confidence interval

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

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

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

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

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

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

Reduction with the confidence interval of 95% ..... See tables 1, 3 and 5.

Sensitivity of cells to virus

- Viral quantification of Poliovirus type 1 with cells not treated by the test solution with the test sample ……...……..……..... $\log 10^{-8.00}$
- Viral quantification of Poliovirus type 1 with cells treated by the test solution with the test sample ……..... $\log 10^{-7.49}$

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

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

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

  Note: only can be used to determine the infectivity of cells, those dilutions which: a) show a low degree of cellular destruction (< 25% of cell monolayer) and b) produce a reduction of the title of the virus < 1 $\log_{10}$.

Control of the effectivity of the disinfectant suppression activity

- Viral quantification of Poliovirus type 1 after 30 minutes on bath ice without exposing the virus to the test sample ……. $\log 10^{-7.16}$
- Viral quantification of Poliovirus type 1 exposing the virus to the test sample and incubated 30 minutes on ice bath ……... $\log 10^{-6.83}$

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

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

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

8. Special remarks

- All controls and validation were between the basic limits.
- To be accepted the assay, at least one concentration of the product must show a log reduction equal or higher than 4 log, and at least one concentration must show a log reduction lower than 4 log.

9. Assay results

9.1 Description of the results under the requested test conditions

Virus of assay	Test concentrations, reduction obtained with the confidence interval of 95% and virucidal activity		
	80%	50%	0.1%
Poliovirus type 1	4.75 ± 0.57 $TCID_{50}$ Shows	1.59 ± 0.58 $TCID_{50}$ Does not show	0.01 ± 0.59 $TCID_{50}$ Does not show
Adenovirus type 5	≥ 6.00 ± 0.37 $TCID_{50}$ Shows	4.75 ± 0.45 $TCID_{50}$ Shows	0.09 ± 0.46 $TCID_{50}$ Does not show
Murine Norovirus	≥ 7.33 ± 0.28 $TCID_{50}$ Shows	5.17 ± 0.51 $TCID_{50}$ Shows	0.09 ± 0.51 $TCID_{50}$ Does not show

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

9.2 Tables of results and graphics

See tables 1 to 6 and figures 1 to 3.

10. Conclusion

The product **"Disinfectant «GamaDez»"**, batch **not indicated**, at **80%** concentration, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), requested by the client and during 30 seconds of contact time and 20ºC of temperature, **shows** activity against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus, when the activity is assayed according with the **EN 14476: 2013 + A2: 2019 Standard.**

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

Note 1: The results obtained correspond to the sample received in this laboratory.
Note 2: The information that depend on the information received from the client and are not facilitated by the same one, shown as "not indicated".

Use of the ENAC mark: The ENAC "mark" can only be used by the holder of the accreditation. Its use in packaging, installations, shop windows, advertising or other documentation format other than that issued by the accredited entity (IVAMI) is not allowed.

Bétera (Valencia), April 10, 2024.

FERNANDEZ FUENTES, MIGUEL ANGEL (FIRMA)
Signed. Miguel Ángel Fernández.
Responsible Technician
(Investigator)

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials and reagents, following as well the Good Laboratory Practices (GLPs) and the final report contains the primary data obtained.

ROS ESTELLES, NOELIA (FIRMA)

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

ESTEBAN BERMUDEZ, ENCARNACION PILAR (FIRMA)

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

Reference

- **EN 14476: 2013 + A2: 2019 Standard**. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of virucidal activity in the medical area. Test method and requirements (phase 2/step1).

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

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

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

Control of the effectiveness of the disinfectant suppression activity (difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension)…….. $\log 10^{-0.33}$

NA: not applicable; NR: not realized.
Times recommended by Standard for surfaces: maximum 5 or 60 minutes.
Times recommended by Standard for instruments: maximum 60 minutes.
Times recommended by Standard for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds.
PBS: phosphate buffered saline; BSA: bovine serum albumin.
Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.

Table 2. Results of the activity of the test sample, with Poliovirus type 1 (ATCC VR-192) (Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concen-tration	Interfering substance	Time of contact (sec/min)	Dilutions (log10)[a,b]									
				1	2	3	4	5	6	7	8	9	10
Test sample	80%	3 g/L BSA + erythrocytes 3 mL/L	30 sec	4444 4444 4444	0340 2040 0332	0000 0000 0100	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	50%		30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0424 3304 0022	0000 0000 2010	0000 0000 0000	NR	NR	NR
	0.1%		30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4434 4340 4334	0202 0003 2200	0000 0000 0010	0000 0000 0000	0000 0000 0000
Cytotoxicity	80%	3 g/L BSA + erythrocytes 3 mL/L	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control	NA	3 g/L BSA + erythrocytes 3 mL/L	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2013 0202 0010	0000 0000 0000	0000 0000 0000	0000 0000 0000
			30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4304 0243 0442	0230 0200 2302	0000 0000 0210	0000 0000 0000	0000 0000 0000
Formaldehyde	0.7% (w:v)	NA	30 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0020 1022 0100	0000 0000 0000	NR	NR	NR
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	3402 0402 2320	0000 0010 0201	0000 0000 0000	0000 0000 0000	NR	NR	NR
Control of formaldehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + erythrocytes 3 mL/L	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control formaldehyde	0.7% (w:v)	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3002 0030 2200	0000 0000 1000	0000 0000 0000
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4430 4243 4424	0023 0200 0020	0020 0000 0000	0000 0000 0000
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	C0C0 0C0C 0CC0	0000 0000 0000	0000 0000 0000
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCC0 C0CC 0CC0	C0CC 000C 0000	0000 0000 0000	0000 0000 0000
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + erythrocytes 3 mL/L	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0C0C 00C0 CC0C	0000 0CC0 0000	0000 0000 0000	0000 0000 0000
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	C00C 00C0 C000	0000 0000 0000	0000 0000 0000	0000 0000 0000

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.
C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).
0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline.
sec: seconds; min: minutes.

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

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

Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) ……..……..……. $\log10^{-0.31}$
Control of the effectiveness of the disinfectant suppression activity (difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension)…….……...……..... $\log10^{-0.34}$

NA: not applicable; NR: not realized.
Times recommended by Standard for surfaces: maximum 5 or 60 minutes.
Times recommended by Standard for instruments: maximum 60 minutes.
Times recommended by Standard for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds.
PBS: phosphate buffered saline; BSA: bovine serum albumin.
Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.

Table 4. Results of the activity of the test sample, with Adenovirus type 5 (ATCC VR-5) (Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concen-tration	Interfering substance	Time of contact (sec/min)	Dilutions (log10)[a,b]									
				1	2	3	4	5	6	7	8	9	10
Test sample	80%	3 g/L BSA + erythrocytes 3 mL/L	30 sec	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	50%		30 sec	4444 4444 4444	0102 0020 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	0.1%		30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2430 4220 4333	0000 0000 2000	0000 0000 0000	0000 0000 0000	0000 0000 0000
Cytotoxicity	80%	3 g/L BSA + erythrocytes 3 mL/L	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control	NA	3 g/L BSA + erythrocytes 3 mL/L	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0001 0200 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000
			30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4240 2440 0223	0000 0020 2100	0000 0000 0000	0000 0000 0000	0000 0000 0000
Formaldehyde	0.7% (w:v)	NA	30 min	4444 4444 4444	4444 4444 4444	0030 2003 0402	0000 0001 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
			60 min	4444 4444 4444	3344 0204 4034	0100 0200 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Control of formaldehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + erythrocytes 3 mL/L	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control formaldehyde	0.7% (w:v)	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0020 0102 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3342 4220 3334	0002 1000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	000C 0000 0C0C	0000 0000 0000	0000 0000 0000
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	C00C 00C0 CCC0	0000 C0C0 0000	0000 0000 0000	0000 0000 0000
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + erythrocytes 3 mL/L	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	00CC 0CC0 0CC0	0000 0000 0000	0000 0000 0000	0000 0000 0000
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC 00CC CC0C	000C 0C00 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.
C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).
0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline.
sec: seconds; min: minutes.

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

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

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

Control of the effectiveness of the disinfectant suppression activity (difference between decimal logarithm of titre without exposing the virus to the sample and of the test suspension)…….……..... $\log10^{-0.34}$

NA: not applicable; NR: not realized.
Times recommended by Standard for surfaces: maximum 5 or 60 minutes.
Times recommended by Standard for instruments: maximum 60 minutes.
Times recommended by Standard for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds.
PBS: phosphate buffered saline; BSA: bovine serum albumin.
Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.

Table 6. Results of the activity of the test sample, with Murine Norovirus strain S99 Berlin (Assay of titration with 12 wells), under test conditions requested by the client.

Assay	Concen-tration	Interfering substance	Time of contact (sec/min)	Dilutions (log10)[a,b]									
				1	2	3	4	5	6	7	8	9	10
Test sample	80%	3 g/L BSA + erythrocytes 3 mL/L	30 sec	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	50%		30 sec	4444 4444 4444	4403 4424 0033	2030 0220 0000	0000 0001 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
	0.1%		30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4243 0404 4044	0302 0020 0320	0010 0000 0000	0000 0000 0000
Cytotoxicity	80%	3 g/L BSA + erythrocytes 3 mL/L	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control	NA	3 g/L BSA + erythrocytes 3 mL/L	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0001 2100 2020	0000 0000 0000	0000 0000 0000
			30 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	1020 0102 0000	0000 0000 0000	0000 0000 0000
Formaldehyde	0.7% (w:v)	NA	30 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3334 2434 2444	1220 0020 0100	0000 0000 0000	NR	NR	NR
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0300 1020 3011	0000 0000 0000	0000 0000 0000	NR	NR	NR
Control of formaldehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + erythrocytes 3 mL/L	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR	NR
Virus control formaldehyde	0.7% (w:v)	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0000 2003 0120	0000 0000 0000
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3420 4340 2433	0000 2002 0210	0000 0000 0000
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	00C0 0C00 CCC0	0000 0000 0000
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	00C0 CCC0 C0C0	0000 00C0 00CC	0000 0000 0000
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + erythrocytes 3 mL/L	Without sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	0CC0 C0C0 C0C0	0000 0000 0000	0000 0000 0000
			With sample	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCC0 CCC0 CCCC	CC0C 000C 0000	0000 0000 0000	0000 0000 0000

a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.
C = cytopathic effect with presence of virus (in this case and according to Standard does not take into account the degree of cytopathic effect only, the presence or absence of the same).
0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline.
Sec: seconds; min: minutes.

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

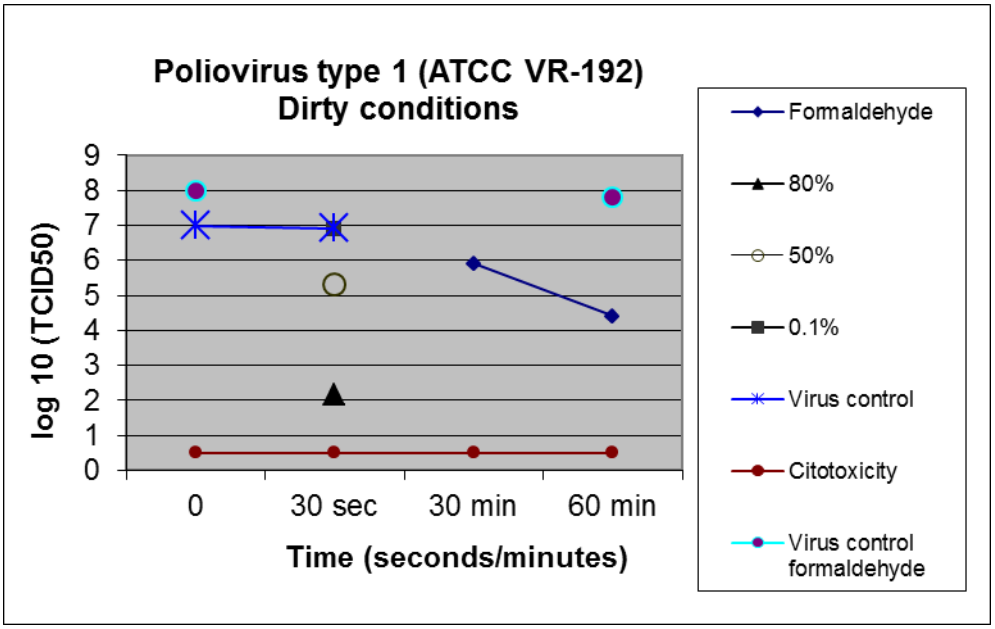


Figure 2. Results of the activity of the test sample under test conditions requested by the client with Adenovirus type 5 (ATCC VR-5).

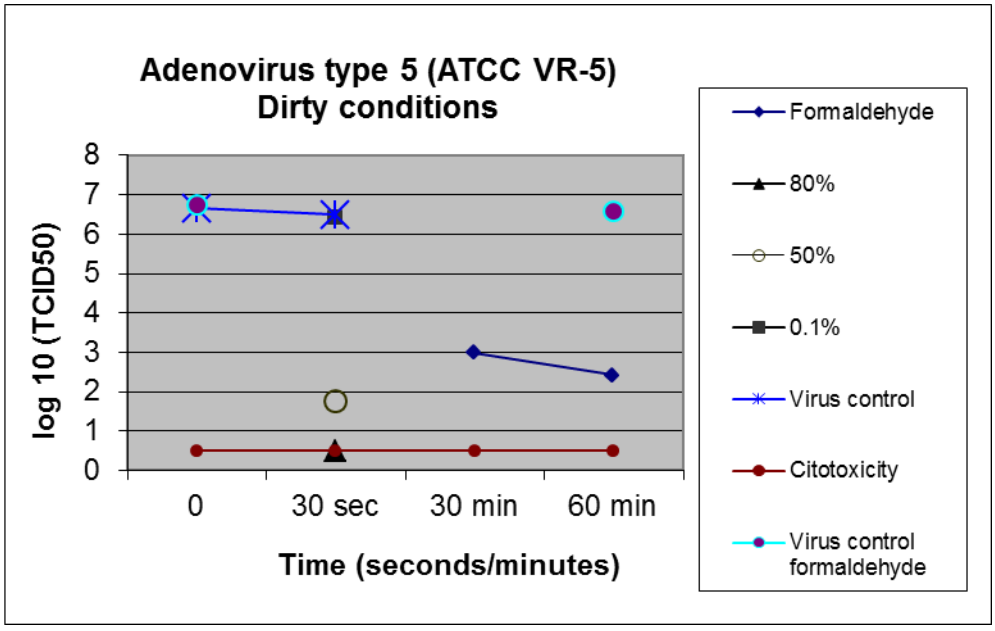
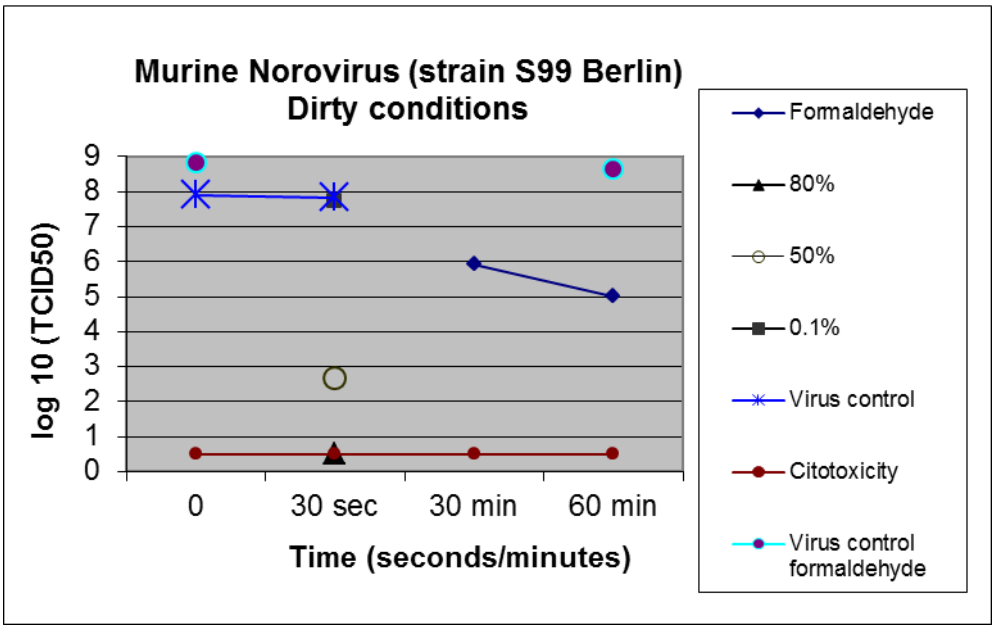


Figure 3. Results of the activity of the test sample under test conditions requested by the client with Murine Norovirus strain S99 Berlin.



Nordic Tersus
Laboratory

Test report no. 125024hd

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

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

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

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:43:38 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

EAK
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

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Kerda Treksler
Microbiologist
Date of test report: 24.04.2024

** - Data provided by the customer*

Nordic Tersus Laboratory OÜ
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Appendix 1

TEST RESULTS (yeasticidal suspension test)

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

Validation and controls

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

Test suspension and test

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

Experimental results

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

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

Appendix 2

TEST RESULTS (yeasticidal suspension test)

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

Validation and controls

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

Test suspension and test

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

Experimental results

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

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

Appendix 3

Interpretation:

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

Conclusion:

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

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

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Kerda Treksler
Microbiologist
Date of test report: 24.04.2024

Nordic Tersus
Laboratory

Test report no. 124024hd

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

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

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

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:42:47 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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Nordic Tersus
Laboratory

Test report No. 124024hd

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

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

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NORDIC TERSUS LABORATORY OÜ

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Kerda Treksler
Microbiologist

Date of test report: 22.04.2024

** - Data provided by the customer*

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Appendix 1

TEST RESULTS (bactericidal suspension test)

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

Validation and controls

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

Test suspension and test

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

Experimental results

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

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

Appendix 2

TEST RESULTS (bactericidal suspension test)

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

Validation and controls

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

Test suspension and test

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

Experimental results

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

Explanations:

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

Appendix 3

TEST RESULTS (bactericidal suspension test)

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

Validation and controls

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

Test suspension and test

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

Experimental results

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

Explanations:

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

Appendix 4

TEST RESULTS (bactericidal suspension test)

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

Validation and controls

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

Test suspension and test

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

Experimental results

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

Explanations:

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

Appendix 5

TEST RESULTS (bactericidal suspension test)

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

Validation and controls

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

Test suspension and test

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

Experimental results

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

Explanations:

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

Appendix 6

TEST RESULTS (bactericidal suspension test)

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

Validation and controls

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

Test suspension and test

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

Experimental results

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

Explanations:

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

Appendix 7

Interpretation:

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

Conclusion:

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

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

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

.....

Kerda Treksler
Microbiologist
Date of test report: 22.04.2024

HAMILTON

AB 079

REPORT No. 390311/25/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** 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 2
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)

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:42:55 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

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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	Gel
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** 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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