



MINISTERUL SĂNĂTĂȚII AL REPUBLICII MOLDOVA
AGENȚIA NAȚIONALĂ PENTRU SĂNĂTATE PUBLICĂ



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

**CERTIFICAT
DE ÎNREGISTRARE DE STAT**

Nr.	B-0263/2025
din	03.09.2025

I. Denumirea comercială a produsului în Republica Moldova
DEZINFECTANT UNIVERSAL BIO-DEZ

Alte denumiri comerciale

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

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

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

S.R.L. ECHOCHIM-GRUP, str. Nationala, 119, or. Ungheni, Republica Moldova

IV. Date de identificare a produsului

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

Certificatul de înregistrare este valabil până la data: 18.12.2026.

În conformitate cu Hotărârea Guvernului nr. 344 din 10.06.2020 s-a decis ca următorul produs biocid poate fi fabricat sau comercializat și 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

Digitally signed by Guștiuc Vasile
Date: 2025.09.24 15:47:32 EEST
Reason: MoldSign Signature
Location: Moldova

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Vasile Gustiuc



Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:39:39 EEST
Reason: MoldSign Signature
Location: Moldova

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Anexa 1
la certificatul nr. B-0263/2025 din 03.09.2025 pentru înregistrare de stat a
produsului biocid

I. Denumirea comercială a produsului în Republica Moldova

DEZINFECTANT UNIVERSAL BIO-DEZ

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

<i>Denumirea chimică (IUPAC, ISO sau alte)</i>	<i>Nr. CE</i>	<i>Nr. CAS</i>	<i>Cantitatea în produs</i>
Alcool etilic	200-578-6	64-17-5	72-76%
Clorură de benzalconiu	270-325-2	68424-85-1	0,024-0,029%

VII. Forma de condiționare

lichid/gel

VIII. Modul de ambalare (tipul, capacitatea)

recipient din plastic de 0,05L până la 5L

IX. Domeniul și aria de utilizare

1. Domeniul de utilizare

2. Aria de aplicare

Dezinfectanți. Igiena umană. Dezinfectanți și algicide care nu sunt destinate aplicării directe la oameni sau animale. Dezinfecția igienică și chirurgicală a mâinilor. Dezinfecția instrumentelor medicale și suprafețelor. Dezinfectarea echipamentelor, recipientelor, ustensilelor de consum, suprafețelor sau conductelor folosite pentru producția, transportul, depozitarea sau consumul produselor alimentare sau al hranei pentru animale.

X. Eficacitate

<i>Activitatea</i>	<i>Metoda de testare/protocolul de testare</i>	<i>Specia/tulpina</i>	<i>Concentrații</i>	<i>Timp de acțiune</i>
Bactericidă (Hygienic Handrub)	EN 1500:2013	Escherichia coli K12	100%/3 mlx1	60 sec
Bactericidă (Hygienic Handwash)	PN-EN 1499:2013-07	E.coli K12 NCTC 10538	100%	30 sec
Bactericidă (Surgical Handrub)	EN 12791:2016+A1:2017	Pseudomonas aeruginosa Staphylococcus aureus Enterococcus hirae Escherichia coli K12 Candida albicans	100%, 2x7ml	2x45 sec
Bactericidă în condiții de murdărie	EN 13727:2012+A2:2015	Pseudomonas aeruginosa Staphylococcus aureus Enterococcus hirae Escherichia coli K12	97%;80%	60sec
Bactericidă în condiții de murdărie	PN EN 13697+A1:2019-08	Staphylococcus aureus Enterococcus hirae Pseudomonas aeruginosa	100%, 50%	60 sec

		Escherichia coli		
Bactericidă în condiții de murdărie	PN EN 1276:2019-12	Escherichia coli Pseudomonas aeruginosa Staphylococcus aureus Enterococcus hirae	80%;50%	60 sec
Bactericidă în condiții de murdărie	EN 13727:2012+A2:2015	Pseudomonas aeruginosa Staphylococcus aureus Enterococcus hirae Escherichia coli K12 Staphylococcus aureus MRSA Enterococcus faecium	97%;80%;50%	60sec
Bactericidă în condiții de murdărie	UNE-EN 14561:2007	Pseudomonas aeruginosa Staphylococcus aureus Enterococcus hirae	100%	60sec
Bactericidă în condiții de murdărie	PN-EN 13697+A1:2019-08	Staphylococcus aureus Enterococcus hirae Pseudomonas aeruginosa Escherichia coli	100%;50%	60sec
Dermatological test	Nr.455216/23/INT Nr. 390310/25/INT			
Fungicidă în condiții de murdărie	EN13624:2022	Candida albicans Aspergillus brasiliensis	97%	90 sec
Fungicidă în condiții de murdărie	PN EN 1650:2008+A1:2013-08	Candida albicans Aspergillus brasiliensis	50%;80%	60sec
Fungicidă în condiții de murdărie	PN EN 13697+A1:2019-08	Candida albicans Aspergillus brasiliensis	50%;100%	60 sec
Fungicidă în condiții de murdărie	EN 13624:2022	Aspergillus brasiliensis Candida albicans	80%	90 sec
Fungicidă în condiții de murdărie	PN EN 13697+A1:2019	Aspergillus brasiliensis Candida albicans	nedil	60 sec
Fungicidă/levurcidă în condiții de murdărie	PN EN 1650:2008+A1:2013-08	Candida albicans Aspergillus brasiliensis	80%;50%	60sec
Levuricidă în condiții de murdărie	EN13624:2022			

		Candida albicans	80%	90sec
Levuricidă în condiții de murdărie	PN EN 13697+A1:2019	Candida albicans	nedil	60 sec
Levuricidă în condiții de murdărie	EN 13624:2014	Candida albicans	80%;50%	60 sec
Levuricidă în condiții de murdărie	EN 14562:2007	Candida albicans	100%	60 sec
Levuricidă/Fungicidă în condiții de murdărie	EN 14562:2007	Candida albicans Aspergillus brasiliensis	100%	90 sec
Micobactericidă/Tubercul ocidă în condiții de murdărie	EN 14348:2005	Mycobacterium avium Mycobacterium terrae	80%;50%	60 sec
Micobactericidă/Tubercul ocidă în condiții de murdărie	UNE-EN 14563:2009	Mycobacterium avium Mycobacterium terrae	100%	60 sec
Virucidă în condiții de murdărie	UNE-EN 14476:2014+A2:2019	Poliovirus type 1 Adenovirus type 5 Murine Norovirus	80%	60 sec

XI. Indicații de utilizare

<i>Metoda de aplicare</i>	<i>Concentrația soluției de lucru</i>	<i>Timpul de acțiune</i>
Dezinfecția mâinilor prin frecare	nediluat/3ml	60 sec
prin imersiune, înmuiere, irigare cu ștergerea suprafețelor	nediluat	60 sec, 90 sec.
imersie, pulverizare, stropire, ștergere cu laveta	activitate: bactericidă, fungicidă, virucidă, micobactericidă, nediluat	60 sec
dezinfecția mâinilor prin spălare	nediluat/3 ml	30 sec
dezinfectia chirurgicala mainilor prin frecare	nediluat 100%, 2x7 ml	2x45 sec

XII. Etichetarea produsului biocid

Simboluri și indicarea pericolelor	GHS02.GHS07.PERICOL
Fraze de risc (R) și/sau Pictograme de pericol (H)	H225:Lichid și vapori foarte inflamabili
Fraze de prudență (S) și/sau Fraze de precauție (P)	P102: A nu se lăsa la îndemâna copiilor

XIII. Categoria de utilizatori

Profesionali, Populație, Industriali,

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

pentru utilizatorii profesionali se interzice reambalarea produsului la capacități mai mici în vederea comercializării. După deschiderea unui recipient eficacitatea produsului scade semnificativ.



REPORT OF ANALYSIS No. 136987/21/JSHR/Z2

Replaces Report of Analysis No. 136987/21/JSHR of 2021-04-14

Client ECOCHEM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU		Sample description (according to declaration of Client) DEZINFECTANT UNIVERSAL "BIO-DEZ"	
		Sample quantity: 2 pcs x 1 L Production date: 26.01.2021 Expiration date: 26.01.2024 Sampling date: 22.02.2021 Sample temperature: 15°C Reception hour: 15:00 Responsible for sampling: Crestinov Alexandr	
Sample received:	2021-03-18	Sample condition with no objections Order of 2021-03-09 The samples were delivered by Client	
Analysis completed (the date of performance of the laboratory activity):	2021-04-14		
Report dated:	2021-07-27		

Test	Method	Unit	Result
* Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2) 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 60 seconds.

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

Identification of the change: test result

THE END OF THE REPORTDigitally signed by Crestinov Evghenii
Date: 2025.10.21 09:39:43 EEST
Reason: MoldSign Signature
Location: Moldova

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Authorized by:

Approved by: Hanna Wachowska, Laboratory Director (Approved with electronic signature)

Laboratory: Tychy 43-100, Goździków 1

The results relate to the analysed samples only. Unless otherwise specified given expanded measurement uncertainty was estimated for the coverage factor $k=2$ at 95% confidence level. Sampling uncertainty has not been taken into consideration. Unless otherwise specified when conformity is stated J.S. Hamilton Poland Sp. z o.o. applies the simple acceptance decision rule in accordance with ILAC-G8:09/2019. This Report cannot be reproduced partially without a prior written consent of J.S. Hamilton Poland Sp. z o.o. Responsibility of J.S. Hamilton Poland Sp. z o.o. is restricted exclusively to the results and statements presented in original copy of the Report. The service confirmed by this Report is subject to the General Terms and Conditions of Services of J.S. Hamilton Poland Sp. z o.o. published on www.hamilton.com.pl

* Test method accredited; # Test performed by external provider

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Form PO-10/02a of 20.01.2020

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

ul. Chwaszczyńska 180, 81-571 Gdynia, Poland, tel. +48 58 766 99 00



ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 136987/21/JSR/Z2

A) IDENTIFICATION OF THE SAMPLE:	
Name of the product	DEINFECTANT UNIVERSAL "BIO-DEZ" Sample quantity: 2 pcs x 1 L Production date: 26.01.2021 Expiration date: 26.01.2024 Sampling date: 22.02.2021 Sample temperature: 15°C Reception hour: 15:00 Responsible for sampling: Crestinov Alexandr
The active substance	Ethyl alcohol 72-76% CAS 64-17-5 CE 200-578-6 Benzalkonium chloride 0,024-0,029% CAS 68424-85-1 CE 270-325-2 Methylthioninium chloride 0,00024% CAS 61-73-4 and 200-515-2
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, saponine 30g/l, histidine 1g/l, cysteine 1g/l
C) EXPERIMENTAL CONDITIONS:	
Product test concentrations (%V/V)	100%
Test temperature	20°C
Contact time	3ml of the preparation for 60s
Incubation temperature	36±1 °C
Test-organism	<i>E. coli</i> K12 NCTC 10538

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory
 Approved by: Hanna Wachowska, Laboratory Director (*Approved with qualified electronic signature*)

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 136987/21/JSR/Z2

Table 1. PROCEDURE FOR REFERENCE HYGIENIC HANDRUB

PRODUCT: Standard 2-propanol 60% (V/V)

TEST ORGANISM: *E. coli* K12 NCTC 10538

NUMBER IN CONTAMINATION FLUID: $2,4 \times 10^8$ cfu/ml

volunteer		number of cfu per plate from dilution 10x							Reduction
Nr	Hand left/right	prevalues			postvalues				
		x10 ⁻⁴	x10 ⁻⁵	log x	x10 ⁰	x10 ⁻¹	x 10 ⁻²	log y	
1	l	288	29		61	7	0		
	r	247	22	6,42	33	3	0	1,65	4,77
2	l	167	17		51	5	0		
	r	291	28	5,81	36	4	0	1,63	4,18
3	l	175	11		42	5	0		
	r	275	25	6,33	29	2	0	1,54	4,79
4	l	220	21		30	3	0		
	r	192	19	6,31	68	6	0	1,65	4,66
5	l	164	15		37	3	0		
	r	301	33	6,35	52	5	0	1,64	4,71
6	l	200	20		23	2	0		
	r	198	18	6,30	37	4	0	1,46	4,83
7	l	287	22		60	6	0		
	r	288	29	6,45	42	5	0	1,70	4,75
8	l	298	28		31	4	0		
	r	213	21	6,40	58	5	0	1,63	4,77
9	l	283	23		34	3	0		
	r	311	33	5,96	51	5	0	1,62	4,34
10	l	313	32		53	6	0		
	r	251	25	6,45	36	4	0	1,65	4,80
11	l	175	18		54	5	0		
	r	295	22	6,35	47	3	0	1,69	4,66
12	l	183	19		72	7	0		
	r	171	17	5,74	36	4	0	1,71	4,03
13	l	206	22		29	2	0		
	r	317	33	6,41	49	5	0	1,57	4,84
14	l	295	28		55	6	0		
	r	279	25	6,45	64	7	0	1,78	4,68
15	l	248	22		72	7	0		
	r	256	26	6,40	66	6	0	1,84	4,56
16	l	301	31		46	5	0		
	r	261	26	6,45	27	3	0	1,55	4,90
17	l	259	24		41	4	0		
	r	271	28	6,42	22	1	0	1,47	4,96
18	l	259	22		61	6	0		
	r	288	23	6,43	33	3	0	1,65	4,78
19	l	223	21		35	4	0		
	r	205	20	6,33	45	5	0	1,60	4,72
20	l	297	28		54	6	0		
	r	257	24	5,90	28	3	0	1,59	4,31
X _{sr}				6,28				1,63	4,65
S				0,23				0,09	0,25

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 sr- overall average of log x, log y, log z

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory

Approved by: Hanna Wachowska, Laboratory Director (*Approved with qualified electronic signature*)

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 136987/21/JSR/Z2

Table 2. HYGIENIC HANDRUB PROCEDURE WITH THE PRODUCT

PRODUCT P 136987/21/JSR

TEST ORGANISM: *E. coli* K12 NCTC 10538

NUMBER IN CONTAMINATION FLUID: $2,4 \times 10^8$ cfu/ml

volunteer		number of cfu per plate from dilution 10x							Reduction
Nr	Hand left/right	prevalues			postvalues				
		x10 ⁻⁴	x10 ⁻⁵	log x	x10 ⁰	x10 ⁻¹	x 10 ⁻²	log y	
1	l	132	14		103	11	1		
	r	224	21	6,24	92	9	0	1,98	4,26
2	l	>330	125		89	7	0		
	r	304	31	6,27	78	4	0	1,68	4,59
3	l	144	15		97	9	0		
	r	132	11	6,14	78	5	0	1,93	4,21
4	l	328	34		87	8	0		
	r	>330	85	6,20	99	9	0	1,89	4,32
5	l	164	11		116	11	2		
	r	132	12	6,16	99	8	0	2,03	4,13
6	l	>330	121		61	3	0		
	r	320	32	6,27	83	9	0	1,67	4,60
7	l	328	33		61	4	0		
	r	288	29	6,49	71	7	0	1,81	4,68
8	l	>330	58		91	9	0		
	r	>330	22	5,51	72	6	0	1,82	3,69
9	l	336	36		79	8	0		
	r	>330	21	5,90	106	12	2	1,96	3,94
10	l	296	28		74	7	0		
	r	>330	41	6,02	85	9	0	1,90	4,12
11	l	228	21		93	8	0		
	r	104	11	6,19	80	5	0	1,93	4,26
12	l	>330	48		107	11	1		
	r	200	20	5,97	94	9	0	1,98	4,00
13	l	248	25		112	14	2		
	r	212	22	6,36	113	11	1	2,06	4,31
14	l	>330	48		89	8	0		
	r	255	22	6,02	91	9	0	1,95	4,07
15	l	278	28		99	7	0		
	r	169	17	6,34	67	6	0	1,77	4,57
16	l	178	11		104	11	1		
	r	255	25	6,32	69	7	0	1,93	4,39
17	l	274	28		79	8	0		
	r	231	24	6,40	107	12	2	1,97	4,44
18	l	225	22		92	9	0		
	r	183	19	6,31	66	7	0	1,89	4,42
19	l	199	17		53	5	0		
	r	252	23	6,35	89	8	0	1,83	4,51
20	l	266	22		97	9	0		
	r	231	21	6,39	68	7	0	1,91	4,48
X _{sr}				6,19				1,89	4,30
S				0,22				0,10	0,25

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_{sr}- overall average of log x, log y, log z

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory

Approved by: Hanna Wachowska, Laboratory Director (*Approved with qualified electronic signature*)

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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	6,42	1,65	4,77	6,24	1,99	4,25
2	R-P	5,81	1,63	4,18	6,27	1,91	4,36
3	R-P	6,33	1,54	4,79	6,14	1,93	4,21
4	R-P	6,31	1,65	4,66	6,20	1,96	4,24
5	R-P	6,35	1,64	4,71	6,16	2,03	4,13
6	P-R	6,30	1,46	4,83	6,27	1,84	4,43
7	P-R	6,45	1,70	4,75	6,49	1,81	4,68
8	P-R	6,40	1,63	4,77	5,51	1,90	3,61
9	P-R	5,96	1,62	4,34	5,90	1,96	3,94
10	P-R	6,45	1,65	4,80	6,02	1,90	4,12
11	R-P	6,35	1,69	4,66	6,19	1,93	4,26
12	R-P	5,74	1,71	4,03	5,97	2,00	3,97
13	R-P	6,41	1,57	4,84	6,36	2,06	4,31
14	R-P	6,45	1,78	4,68	6,02	1,95	4,07
15	R-P	6,40	1,84	4,56	6,34	1,90	4,43
16	P-R	6,45	1,55	4,90	6,32	1,93	4,39
17	P-R	6,42	1,47	4,96	6,40	1,97	4,44
18	P-R	6,43	1,65	4,78	6,31	1,89	4,42
19	P-R	6,33	1,60	4,72	6,35	1,83	4,51
20	P-R	5,90	1,59	4,31	6,39	1,91	4,48
X ₂₀		6,28	1,63	4,65	6,19	1,93	4,26
X ₁₀ (R-P)		6,26	1,67	4,59	6,19	1,97	4,22
X ₁₀ (P-R)		6,31	1,59	4,72	6,20	1,90	4,30

Criteria:

 $R_s(R-P) = 4,59 - 4,22 = 0,37$
 $R_s(P-R) = 4,72 - 4,30 = 0,42$
 $Abs = 0,37 - 0,42 = -0,05 < 2$
 $\log x(R) = 6,28 > 5$
 $\log x(P) = 6,19 > 5$
 $\log z(P), \log z(R) > 3$

Validation conditions of neutralizer and methods have been satisfied

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory

Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

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

volunteer	log RF		difference R-P	difference high to low	Range +/-
	R	P			
1	4,77	4,25	0,52	1,16	1
2	4,18	4,36	-0,18	0,68	2
3	4,79	4,21	0,59	0,61	3
4	4,66	4,24	0,42	0,59	4
5	4,71	4,13	0,58	0,58	5
6	4,83	4,43	0,40	0,53	6
7	4,75	4,68	0,07	0,52	7
8	4,77	3,61	1,16	0,52	8
9	4,34	3,94	0,40	0,51	9
10	4,80	4,12	0,68	0,42	10
11	4,66	4,26	0,40	0,40	11
12	4,03	3,97	0,06	0,40	12
13	4,84	4,31	0,53	0,40	13
14	4,68	4,07	0,61	0,36	14
15	4,56	4,43	0,13	0,21	15
16	4,90	4,39	0,51	0,13	16
17	4,96	4,44	0,52	0,07	17
18	4,78	4,42	0,36	0,06	18
19	4,72	4,51	0,21	-0,17	-19
20	4,31	4,48	-0,17	-0,18	-20
sum of ranks (+): 171					
sum of ranks (-): 39					

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

	1,16	0,68	0,61	0,59	0,58	0,53	0,52	0,52	0,51
1	1,16								
2	0,68	0,92							
3	0,61	0,89	0,65						
4	0,59	0,87	0,63	0,60	0,59				
5	0,58	0,87	0,63	0,59	0,58	0,58			
6	0,53	0,85	0,61	0,57	0,56	0,55	0,53		
7	0,52	0,84	0,60	0,57	0,56	0,55	0,53	-0,52	
8	0,52	0,84	0,60	0,56	0,55	0,55	0,53	-0,52	-0,52
9	0,51	0,83	0,59	0,56	0,55	0,54	0,52	-0,52	-0,51
10	0,42	0,79	0,55	0,52	0,50	0,50	0,48	-0,47	-0,47
11	0,40	0,78	0,54	0,51	0,49	0,49	0,47	-0,46	-0,46
12	0,40	0,78	0,54	0,51	0,49	0,49	0,47	-0,46	-0,46
13	0,40	0,78	0,54	0,50	0,49	0,49	0,47	-0,46	
14	0,36	0,76	0,52	0,49	0,47	0,47	0,45		
15	0,21	0,69	0,45	0,41	0,40	0,39			
16	0,13	0,65	0,41	0,37	0,36				
17	0,07	0,62	0,38	0,34					
18	0,06	0,61	0,37						
19	-0,17	0,50							
20	-0,18								

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory

Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 136987/21/JSR/Z2

Table 6. WILCOXON'S T-MATCHED 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 0,55 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.

Date: 27.07.2021

Authorized by: Daria Depa, Senior Specialist Analyst, Cosmetics Microbiology Laboratory

Approved by: Hanna Wachowska, Laboratory Director (*Approved with qualified electronic signature*)

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REPORT OF ANALYSIS No. 80248/21/ROBCH

Client ECOCHIM-GRUP SRL OR. OTACI, STR. VOITOVICI 21 2059 CHIȘINĂU		Sample number: 80248/21/ROBCH Sample description (according to declaration of Client) DEZINFECTANT UNIVERSAL "BIO-DEZ" Lot: - Data fabricatie: 01.10.2021 Data expirarii: 01.10.2024 Data prelevării: - Cantitate prelevata: 2 x 500 ml Responsabil prelevare: CRESTINOV ALEXANDR Ora receptiei probei: 15:30 Temperatura receptie proba: 15°C Sample condition with no objections Order of 11.10.2021 Sampling and delivery were carried out by client.	
Sample received:	11.10.2021		
Tests performed:	21.10.2021		
Tests completed:	13.12.2021		
Report dated:	13.12.2021		

Test	Method	Unit	Result
# * Fungicidal activity in medical area. 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).	EN 13624:2014	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/21/B0644, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

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Elaborated by: Mariana Ilinca, Manager of Microbiological Laboratory
Authorized by: Mariana Ilinca, Manager of Microbiological Laboratory
Approved by: Alina-Roxana Mihai, General Manager (Approved with qualified electronic signature)

Laboratory: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevării probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercarii. Daca nu se specifica altfel, incertitudinea de masurare a fost estimata pentru coeficientul K= 2 si nivel de încredere 95%. Fara aprobarea scrisa a laboratorului acest raport de incercare nu poate fi reprodus decat integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se refera exclusiv la rezultatele si declaratiile prezentate in raportul original. Opiniile si interpretarile continute in prezentul raport de incercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare va rugam sa solicitati Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

* Test method accredited # Test performed by external provider

o Non accredited methods



A) IDENTIFICATION OF THE SAMPLE	
Name of the product/Details about the product	DEZINFECTANT UNIVERSAL "BIO-DEZ" Expiration date: 01.10.2024. Manufacturer (supplier): Ecochim-Grup SRL. Storing conditions: Dry, without sun, 5-25 Celsius degree. Conditions of use: Hygienic handrub, surface disinfection, medical instruments disinfection, surgical handrub
Active compound/s and its concentration/s	Ethyl alcohol 72-76%, CAS 64-17-5 and CE 200-578-6. Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2, Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2
Concentrations requested for the assay	Pure (80%).
B) TEST METHOD	
Performed in accredited contracted partner laboratory, Scope of Accreditation Nr. 648/LE1286 Report Registration No. D/21/B0644 Quantitative evaluation assay of yeasticidal activity under dirty conditions, in the medical area (phase 2, step 1), with product Desinfectant Universal "Bio-Dez", (UNE-EN 13624: 2014 Standard).	UNE-EN 13624:2014 Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of the fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1). AENOR.
Testing method	Procedure DESIN-1058-b // EN 13624:2014
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of order with test conditions	21.10.2021
Date of reception of the sample	25.10.2021
Aspect of the received product	Blue liquid in plastic package
D) METHOD OF ASSAY AND ITS VALIDATION (UNE-EN 13624: 2014 Standard)	
Method used	Dilution-neutralization
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 bisulphite 2.5 g/L, soy lecithin 7 g/L, polysorbate-80 5 g/L, glycine 1 g/L, l-histidine 1 g/L and Saponin 30 g/L.
E) EXPERIMENTAL CONDITIONS	
Assay period	2021/11/08 to 2021/11/14.
Solvent of the product used in the assay	Sterile distilled water.
Product concentrations for the assay	Pure (80%), 50%, 0.1%
Aspect of the dilutions of the product	Pure (80%) and 50% blue liquid; 0.1% transparent.
Contact time	60 seconds
Assay temperature	+20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L and erythrocytes 3 mL/L.
Stability of the mixture (interfering substance and product diluted in sterile distilled water)	Stable
Temperature of incubation	+30°C ± 1°C
Identification of the strain used	<i>Candida albicans</i> CECT-1394 (ATCC 10231)

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Page 1 of 3

Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80248/21/ROBCH**Results of the assay**

- Assay of validation See tables 1 and 2.
- Evaluation of yeasticidal activity..... See table 3.
- Number of replicates per assay organism 1.

Special remarks

- All controls and validation were between the basic limits.
- At least one concentration of the sample showed a log reduction lower than 4 log.
- At least one concentration of the sample showed a log reduction higher than 4 log.
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.
- No precipitate formed during the test procedure (the test mixtures were homogeneous).

Conclusion

The product **Desinfectant Universal“Bio-Dez”**, batch not indicated, when is pure (80%), shows yeasticidal activity after 60 seconds at $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), for the reference strain *Candida albicans* (CECT 1394 = ATCC 10231), when tested as required by the **UNE-EN 13624: 2014 Standard**.

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

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 the Good Laboratory Practices (GLPs) as well and the final report contains the primary data obtained.

Reference

- **UNE-EN 13624 : 2014**. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of the fungicidal or yeasticidal activity in the medical area. Test method and requirements (phase 2, step 1). AENOR.

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Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 80248/21/ROBCH
Results of the assay with *Candida albicans* (CECT 1394 = ATCC 10231).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 1.-Validation and controls.

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of neutralizer (B)			Validation of the method (C) Sample concentration: Pure (80%)		
V_{C1}	86	$\bar{X}=90$	V_{C1}	72	$\bar{X}=74$	V_{C1}	75	$\bar{X}=73$	V_{C1}	66	$\bar{X}=63.5$
V_{C2}	94		V_{C2}	76		V_{C2}	71		V_{C2}	61	
$30 \leq x \text{ of } N_{V0} \leq 160?$ Yes			$x \text{ of } A \text{ es } \geq 0,5 \bar{X} \text{ de } N_{V0}?$ Yes			$x \text{ of } B \text{ es } \geq 0,5 \bar{X} \text{ de } N_{V0}, \text{ or } 0.0005 N_{VB}?$ Yes			$x \text{ of } C \text{ es } \geq 0.5 \bar{X} \text{ of } N_{V0}?$ Yes		
Suspension of validation (N_{VB})			$V_{C1}: 79 \quad V_{C2}: 77$			$\bar{X}=78$ $30 \leq x \text{ de } N_{VB}/1000 \leq 160?$ Yes					

Table 2. -Suspension of the assay.

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$\bar{X}_{wm} = 3.35 \times 10^7$
	10^{-5}	>330	>330	$\lg N = 7.53$ $N_0 = N/10$
	10^{-6}	32	35	$\lg N_0 = 6.53$ $6.17 \leq \lg N_0 \leq 6.70? \text{ Yes}$

Table 3.-Results of the activity assays with the sample.

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (\bar{X} \times 10 \text{ or } \bar{X}_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 6.53$)	Time of contact (seconds)
Pure (80%)	Na^0	<14	<14	<2.15	>4.38	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>4.38	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.01	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); $\bar{X}_{wm}$ = ponderated mean of $\bar{X}$.

$\bar{X}$ = mean of V_{C1} and V_{C2} (duplicate of 1 + 2); R (reduction): ($\lg R = \lg N_0 - \lg Na$).

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*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 08.12.2021

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)



RAPORT DE INCERCARE NR. 34692/23/ROBCH/Z1

Inlocuieste Raportul de Incercare Nr. 34692/23/ROBCH din 07.11.2023

Client ECOCHIM-GRUP SRL OR. UNGHENI, STR. NAȚIONALĂ 119 - REPUBLICA MOLDOVA		Numărul eșantionului: 34692/23/ROBCH Descriere obiect de incercat (conform cu declaratia Clientului) Dezinfectant Universal "Bio-Dez" Lot: - Cantitate prelevata:500 ml Responsabil prelevare: Cristinov Alexandr Ora receptiei probei: 08:00 Temperatura receptie proba: 15°C Sample condition with no objections	
Data primirii obiectului de incercat:	17.05.2023	Comanda numar 5331/23/ROBCH din 17.05.2023 Probele au fost prelevate si livrate de catre Client.	
Data finalizarii incercarii:	07.11.2023		
Data eliberarii raportului:	19.01.2024		

Parametrii de testare	Metoda de testare	Unitate de masura	Rezultat
# * Quantitative suspension test for the evaluation of bactericidal activity in medical area ¹⁾	EN 13727:2012+A2:2015	-	Test efectuat de catre subcontractor.; rezultatele se regasesc integral in raportul Nr D/23/B0419, primit de la subcontractor. Rezultatele analizelor sunt incluse in anexa nr 1 la raportul de analiza.

¹⁾ Modificare efectuata: se ataseaza raportul de incercare Nr D23/B0840, primit de la subcontractor, raport care include rezultatele incercarii solicitate.

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Location: Moldova

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Preluare date de catre: Mariana Ilinca, Sef Laborator Microbiologie
Validat de: Mariana Ilinca, Sef Laborator Microbiologie
Autorizat de: Alina-Roxana Mihai, Manager General (Aprobat cu semnatura electronica)

Laborator: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevarii probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercarii. Daca nu se specifica altfel, incertitudinea de masurare a fost estimata pentru coeficientul K= 2 si nivel de incredere 95%. Fara aprobarea scrisa a laboratorului acest raport de incercare nu poate fi reprodus decat integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se refera exclusiv la rezultatele si declaratiile prezentate in raportul original. Opiniile si interpretarile continute in prezentul raport de incercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare va rugam sa solicitati Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

* Metoda de testare acreditata # Test efectuat de catre subcontractor

o Incercari neacreditate



ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

A) IDENTIFICATION OF THE SAMPLE	
Name of the product/Details about the product	Dezinfectant Universal “Bio-Dez”. Manufacturer(supplier): Ecochim-Grup Condition of use: Instrument disinfection, surface disinfection, Hygienic handrub, surgical handrub.
Active(s) Substance(s) and its concentration(s)	Ethyl alcool 72-76%, CAS 64-17-5 and CE 200-578-6 Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2 Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
Concentration ordered for the assay	97%, 80%.
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report No.: D/23/B0419– Quantitative evaluation assay of the bactericidal activity in the medical area (phase 2, step 1), with the product “Dezinfectant Universal “Bio-Dez””. (EN 13727: 2012 + A2: 2015 Standard)	EN 13727: 2012 + A2: 2015. Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in Medicine. Test method and requirements (phase 2, step 1).
Testing method	EN 13727: 2012 + A2: 2015 Standard
Methods of assay and its validation UNE-EN 13727: 2012 + A2: 2015 Standard	
Method	Dilution-neutralization.
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 bisulphite 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.
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	2023/05/18.
Date of reception of order with test conditions	2023/08/30.
Aspect of the received product	Blue liquid in plastic container.
D) EXPERIMENTAL CONDITIONS	
Assay period	2023/10/11 to 2023/10/15.
Solvent of the product used in the assay	Sterile distilled water.
Product concentrations for the assay	97%, 80%, 50% and 0.1%.
Aspect of the dilutions of the product	97%, 80% and 50% blue liquid; 0.1% transparent liquid..
Contact time	60 seconds.
Assay temperature	20°C ± 1°C
Interfering substance	Bovine serum albumin 3 g/L + erythrocytes 3 mL/L.
Stability of the mixture (interfering substance and product diluted in sterile distilled water)	97% flocs formation; 80%, 50% and 0.1% stable.
Incubation temperature	+36°C ± 1°C
Identification of the strains used:	– <i>Pseudomonas aeruginosa</i> CECT-116 (ATCC-15442). – <i>Staphylococcus aureus</i> CECT-239 (ATCC-6538). – <i>Enterococcus hirae</i> CECT-4081 (ATCC-10541). – <i>Escherichia coli</i> K12 (CECT 433 = NCTC 10538).

Laboratory: Bucharest 041914, 8 Berceni Street.

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 07.11.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

Results of the assay

- Assay of validation See tables 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 22 and 23.
- Evaluation of bactericidal activity See tables 3, 6, 9, 12, 15, 18, 21 and 24.
- Number of replicates per assay organism. 1.

Special remarks

- All controls and validation were between the basic limits.
- For a valid test, at least one concentration must show a log reduction lower than 5 log, and at least one concentration must show a log reduction equal or higher than 5 log.
- Flocs formation is observed during the test procedure at 97%.
- The client requests the complete test including the concentration of 80% as the maximum concentration. It also requests the modified method (97%) additionally.

Conclusion

The product **Dezinfectant Universal "Bio-Dez"**, batch 34692/23/ROBCH, when it is pure (97%) (modified method) and 80%, concentrations requested by the client, **shows bactericidal activity** after 60 seconds at $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), for the reference strains *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442), *Staphylococcus aureus* (CECT 239 = ATCC 6538), *Enterococcus hirae* (CECT 4081 = ATCC 10541) and *Escherichia coli* K12 (CECT 433 = NCTC 10538), when tested according to **EN 13727: 2012 + A2: 2015 Standard**.

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

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Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Page 2 of 10

Date: 07.11.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 1.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 80%		
V_{C1}	44	$X=42$	V_{C1}	36	$X=35$	V_{C1}	38	$X=$	V_{C1}	32	$X=33$
V_{C2}	40		V_{C2}	34		V_{C2}	37	37.5	V_{C2}	34	
$30 \leq X \text{ of } N_{V0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			V_{C1} : 40 V_{C2} : 39			$X=39.5$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$ Yes					

Table 2.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.68 \times 10^8$, $\lg N = 8.22$ $N_0 = N/10$; $\lg N_0 = 7.22$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	164	171	
	10^{-7}	18	16	

Table 3.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.22$)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.07	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.07	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.70	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

Laboratory: Bucharest 041914, 8 Berceni Street.

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Enclosure no. 1 subcontracted tests

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PGL 09 F 04 Ed. 1 Rev. 0

Date: 07.11.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Pseudomonas aeruginosa* (CECT 116 = ATCC 15442) following the modified method (97%).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 4.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 97%		
V_{C1}	42	$\bar{X}=41$	V_{C1}	37	$\bar{X}=36$	V_{C1}	31	$\bar{X}=32$	V_{C1}	30	$\bar{X}=31$
V_{C2}	40		V_{C2}	35		V_{C2}	33		V_{C2}	32	
$30 \leq X \text{ of } N_{V0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			V_{C1} : 43 V_{C2} : 45			$\bar{X}=44$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$ Yes					

Table 5.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.86 \times 10^9$, $\lg N = 9.27$ $N_0 = N/100$; $\lg N_0 = 7.27$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-7}	189	183	
	10^{-8}	20	18	

Table 6.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10^6 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.27$)	Time of contact (sec)
97%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			

Explanations:

Vc = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Date: 07.11.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Staphylococcus aureus* (CECT 239 = ATCC 6538).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 7.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 80%		
V_{C1}	48	$\bar{X}=49$	V_{C1}	47	$\bar{X}=46$	V_{C1}	48	$\bar{X}=46$	V_{C1}	40	$\bar{X}=42$
V_{C2}	50		V_{C2}	45		V_{C2}	44		V_{C2}	44	
$30 \leq X \text{ of } N_{V0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			$V_{C1}: 52 \quad V_{C2}: 56$			$\bar{X}=54$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$ Yes					

Table 8.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.84 \times 10^8$, $\lg N = 8.27$ $N_0 = N/10$; $\lg N_0 = 7.27$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	177	189	
	10^{-7}	20	19	

Table 9.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.27$)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.75	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Date: 07.11.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Staphylococcus aureus* (CECT 239 = ATCC 6538) following the modified method (97%).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 10.-Validation and controls

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 97%		
V_{C1}	51	$X=52$	V_{C1}	46	$X=48$	V_{C1}	50	$X=52$	V_{C1}	39	$X=40$
V_{C2}	53		V_{C2}	50		V_{C2}	54		V_{C2}	41	
$30 \leq X \text{ of } N_{v0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{v0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{v0}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{v0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{vB})			$V_{C1}: 56 \quad V_{C2}: 58$			$X=57$ $30 \leq x \text{ of } N_{vB}/1000 \leq 160?$ Yes					

Table 11.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.97 \times 10^9$, $\lg N = 9.29$ $N_0 = N/100$; $\lg N_0 = 7.29$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-7}	190	201	
	10^{-8}	22	20	

Table 12.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10^6 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.29$)	Time of contact (sec)
97%	Na^0	<14	<14	<2.15	>5.14	60
	Na^{-1}	<14	<14			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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PGL 09 F 04 Ed. 1 Rev. 0

Date: 07.11.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Enterococcus hirae* (CECT 4081 = ATCC 10541).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 13.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 80%		
V_{C1}	47	$\bar{X}=49$	V_{C1}	40	$\bar{X}=$	V_{C1}	47	$\bar{X}=$	V_{C1}	45	$\bar{X}=44$
V_{C2}	51		V_{C2}	44	42	V_{C2}	42	44.5	V_{C2}	43	
$30 \leq X \text{ of } N_{V0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			$V_{C1}: 50 \quad V_{C2}: 52$			$\bar{X}=51$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$ Yes					

Table 14.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.88 \times 10^8$, $\lg N = 8.27$ $N_0 = N/10$; $\lg N_0 = 7.27$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	181	192	
	10^{-7}	20	21	

Table 15.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10^6 / X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.27$)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.75	60
	Na^{-1}	>330	>330			

Explanations:

V_C = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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PGL 09 F 04 Ed. 1 Rev. 0

Date: 07.11.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Enterococcus hirae* (CECT 4081 = ATCC 10541), following the modified method (97%).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 16.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 97%		
V_{C1}	46	$\bar{X}=47$	V_{C1}	40	$\bar{X}=42$	V_{C1}	42	$\bar{X}=44$	V_{C1}	37	$\bar{X}=36$
V_{C2}	48		V_{C2}	44		V_{C2}	46		V_{C2}	35	
$30 \leq X \text{ of } N_{V0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			$V_{C1}: 51 \quad V_{C2}: 53$			$\bar{X}=52$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$ Yes					

Table 17.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.84 \times 10^9$, $\lg N = 9.27$ $N_0 = N/100$; $\lg N_0 = 7.27$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-7}	179	188	
	10^{-8}	20	18	

Table 18.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10^6 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.27$)	Time of contact (sec)
97%	Na^0	<14	<14	<2.15	>5.12	60
	Na^{-1}	<14	<14			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Date: 07.11.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Escherichia coli* K12 (CECT 433 = NCTC 10538).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 19.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 80%		
V_{C1}	47	$X=46$	V_{C1}	40	$X=$	V_{C1}	39	$X=38$	V_{C1}	41	$X=42$
V_{C2}	45		V_{C2}	39	39.5	V_{C2}	37		V_{C2}	43	
$30 \leq X \text{ of } N_{V0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			$V_{C1}: 45 \quad V_{C2}: 41$			$X=43$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$ Yes					

Table 20.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$X_{wm} = 1.72 \times 10^8$, $\lg N = 8.24$ $N_0 = N/10$; $\lg N_0 = 7.24$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	168	175	
	10^{-7}	19	17	

Table 21.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.24$)	Time of contact (sec)
80%	Na^0	<14	<14	<2.15	>5.09	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.09	60
	Na^{-1}	<14	<14			
0.1%	Na^0	>330	>330	>4.52	<2.72	60
	Na^{-1}	>330	>330			

Explanations:

V_C = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 34692/23/ROBCH

Results of the assay (Bactericidal suspension) with *Escherichia coli* K12 (CECT 433 = NCTC 10538), following the modified method (97%).

Seeding: Pour plates. No. of plates: 1 /mL.

Table 22.-Validation and controls

Suspension of validation (N_{V0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: 97%		
V_{C1}	42	$\bar{X}=43$	V_{C1}	36	$\bar{X}=37.5$	V_{C1}	33	$\bar{X}=34.5$	V_{C1}	37	$\bar{X}=36$
V_{C2}	44		V_{C2}	39		V_{C2}	36		V_{C2}	35	
$30 \leq X \text{ of } N_{V0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{V0}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{V0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{VB})			$V_{C1}: 40 \quad V_{C2}: 39$			$\bar{X}=39.5$ $30 \leq x \text{ of } N_{VB}/1000 \leq 160?$ Yes					

Table 23.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{C1}	V_{C2}	$\bar{X}_{wm} = 1.74 \times 10^9$, $\lg N = 9.24$ $N_0 = N/100$; $\lg N_0 = 7.24$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-7}	180	165	
	10^{-8}	19	18	

Table 24.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{C1}	V_{C2}	$\lg Na = \lg (X \times 10 \text{ o } \bar{X}_{wm} \times 10)$	$\lg R$ ($\lg N_0 = 7.24$)	Time of contact (sec)
97%	Na^0	<14	<14	<2.15	>5.09	60
	Na^{-1}	<14	<14			

Explanations:

V_c = number per mL (one or two plates); $\bar{X}_{wm}$ = weighted mean of X .

X = mean of V_{C1} and V_{C2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)



Instituto Valenciano de Microbiología

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



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No. 2/23-C.VAL. General Directorate of
Pharmacy and Medical Devices of the Health
Department of the Valencian Region. Spain

**Quantitative evaluation assay of the bactericidal activity
in the medical area (phase 2, step 1),
with the product “Dezinfectant Universal “Bio-Dez”” with deviations from the standard.
(EN 13727: 2012 + A2: 2015 Standard)**

Report

Registration No.: D/23/B0840.

1. **Laboratory identification** Instituto Valenciano de Microbiología.
2. **Client identification** J.S. HAMILTON ROMANIA SRL.
Address Sos Berceni, Nr 8, sector 4, Bucuresti.
Romania.
3. **Sample identification** (information provided by the client)
 - Product name **Dezinfectant Universal “Bio-Dez”.**
 - Batch number 34692/23/ROBCH.
 - Expiration date Not indicated.
 - Manufacturer /supplier SRL “ Ecochim-Grup ”
 - Store conditions Not indicated.
 - Conditions of use Instrument disinfection, surface disinfection,
Hygienic handrub, surgical handrub.
 - Diluent of the product recommended by
the manufacturer Not indicated.
 - Active(s) Substance(s) and its
concentration (s) Ethyl alcohol 72-76%, CAS 64-17-5 and CE
200-578-6, Benzalkonium chloride 0.024-
0.029%, CAS: 68424-85-1 and CE 270-325-2
Methylthionibium chloride 0.00024%, CAS
61-73-4 and 200-515-2.
 - Concentrations ordered for the assay Ready to use.

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

DESIN-1031-b //EN 13727: 2012 + A2: 2015 Version 8 (2019-10-02)

DESIN-1031.5-b//EN 13727:2012+A2:2015- Additional bacteria Version 3 (2023-03-02)

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Registration No.: D/23/B0840

Instituto Valenciano de Microbiología

4. Information about sample reception

- Date of reception of the sample 2023/05/18.
- Date of reception of order with test conditions 2023/11/24.
- Aspect of the received sample..... Blue transparent liquid received in plastic container.

5. Method of assay and its validation (EN 13727: 2012 + A2: 2015 Standard)

- Method used Dilution-neutralization.
- 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 bisulphite 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.

6. Experimental conditions

- Assay period (including prior preparation of the strains)..... 2023/12/13 to 2023/12/17.
- Solvent of the product used in the assay ... Sterile distilled water.
- Product concentrations for the assay Pure (80%), 50% and 0.1%.
- Aspect of the dilutions of the product Pure (80%), and 50% bluish transparent liquid; 0.1% transparent liquid.
- Contact time 60 seconds.
- Assay temperature $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- Interfering substance Bovine serum albumin 3 g/L + erythrocytes 3mL/L.
- Stability of the mixture (interfering substance and product diluted in sterile distilled water) Stable.
- Incubation temperature $+36^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- Identification of the strains used:
 - *Staphylococcus aureus* MRSA (ATCC 33592).
 - *Enterococcus faecium* (ATCC 6057 = CECT 8108).

7. Results of the assay

- Assay of validation See tables 1, 2, 4 and 5.
- Evaluation of bactericidal activity See tables 3 and 6.
- Number of replicates per assay organism. 1.

8. Special remarks

- All controls and validation were between the basic limits.
- For a valid test, at least one concentration must show a log reduction lower than 5 log, and at least one concentration must show a log reduction equal or higher than 5 log.
- No precipitation was observed during the assay procedure (the mixtures were homogenous).
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.

9. Conclusion

The product **Dezinfectant Universal “Bio-Dez”**, batch 34692/23/ROBCH, when it is pure (80%), concentration requested by the client, **shows bactericidal activity** after 60 seconds at $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3mL/L), for the reference strains *Staphylococcus aureus* MRSA (ATCC 33592) and *Enterococcus faecium* (ATCC 6057 = CECT 8108), when tested according to **EN 13727: 2012 + A2: 2015 Standard, with deviations from the standard due to not testing all mandatory microorganisms.**

With the results obtained with the product **Dezinfectant Universal “Bio-Dez”**, batch 34692/23/ROBCH, **it cannot be concluded** that the product has general bactericidal activity, but only that it has activity against *Staphylococcus aureus* MRSA and *Enterococcus faecium*.

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), January 4, 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 the Good Laboratory Practices (GLPs) as well and the final report contains the primary data obtained.

MONTOYA VIECO,
ELENA (FIRMA)

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

TEMPRANO LOPEZ
ANA - 47374856P

Signed. Encarnación Esteban.
Technical Director
(Quality Assurance Director)
Signed by delegation by Ana Temprano

Reference

- **EN 13727: 2012 + A2: 2015.** Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in Medicine. Test method and requirements (phase 2, step 1).

DESIN-1031-b //EN 13727: 2012 + A2: 2015 Version 8 (2019-10-02)

DESIN-1031.5-b//EN 13727:2012+A2:2015- Additional bacteria Version 3 (2023-03-02)

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Registration No.: D/23/B0840

Instituto Valenciano de Microbiología

Results of the assay (Bacterial suspension) with *Staphylococcus aureus* MRSA (ATCC 33592).

Method: Dilution-neutralization; Seeding: Pour plate; No. of plates: 1/mL.

Table 1.-Validation and controls

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: Pure (80%)		
V_{c1}	83	$X=87$	V_{c1}	71	$X=77$	V_{c1}	89	$X=$	V_{c1}	77	$X=$
V_{c2}	91		V_{c2}	83		V_{c2}	100	94.5	V_{c2}	80	78.5
$30 \leq X \text{ of } N_{v0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{v0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{v0} \text{ or } 0.0005 N_{vB}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{v0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{vB})			V_{c1} : 100 V_{c2} : 112			$X=106$ $30 \leq X \text{ of } N_{vB}/1000 \leq 160?$ Yes					

Table 2.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{c1}	V_{c2}	$X_{wm} = 2.70 \times 10^8$, $\lg N = 8.43$ $N_0 = N/10$; $\lg N_0 = 7.43$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	>330	>330	
	10^{-7}	24	30	

Table 3.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{c1}	V_{c2}	$\lg Na = \lg (X \times 10^6 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0=7.43$)	Time of contact (sec)
Pure (80%)	Na^0	<14	<14	<2.15	>5.28	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.28	60
	Na^{-1}	<14	<14			
0.1 %	Na^0	>330	>330	>4.52	<2.91	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{c1} and V_{c2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$).

Results of the assay (Bacterial suspension) with *Enterococcus faecium* (ATCC 6057 = CECT 8108).

Method: Dilution-neutralization; Seeding: Pour plate; No. of plates: 1/mL.

Table 4.-Validation and controls

Suspension of validation (N_{v0})			Control of experimental conditions (A)			Control of the neutralization (B)			Validation of the method (C) Sample concentration: Pure (80%)		
V_{c1}	58	$X=60$	V_{c1}	57	$X=$	V_{c1}	54	$X=58$	V_{c1}	50	$X=$
V_{c2}	62		V_{c2}	56	56.5	V_{c2}	62		V_{c2}	57	53.5
$30 \leq X \text{ of } N_{v0} \leq 160?$			$X \text{ of } A \text{ is } \geq 0.5 X \text{ of } N_{v0}?$			$X \text{ of } B \text{ is } \geq 0.5 X \text{ of } N_{v0} \text{ or } 0.0005 N_{vB}?$			$X \text{ of } C \text{ is } \geq 0.5 X \text{ of } N_{v0}?$		
Yes			Yes			Yes			Yes		
Suspension of validation (N_{vB})			$V_{c1}: 68 \quad V_{c2}: 64$			$X=66$ $30 \leq X \text{ of } N_{vB}/1000 \leq 160?$ Yes					

Table 5.-Suspension of the assay

Suspension of assay (N and N_0)	N	V_{c1}	V_{c2}	$X_{wm} = 2.45 \times 10^8$, $\lg N = 8.39$ $N_0 = N/10$; $\lg N_0 = 7.39$ $7.17 \leq \lg N_0 \leq 7.70?$ Yes
	10^{-6}	>330	>330	
	10^{-7}	26	23	

Table 6.-Results of the activity assays with the sample

Concentrations of the sample (%)	Dilutions steps	V_{c1}	V_{c2}	$\lg Na = \lg (X \times 10 \text{ o } X_{wm} \times 10)$	$\lg R$ ($\lg N_0=7.39$)	Time of contact (sec)
Pure (80%)	Na^0	<14	<14	<2.15	>5.24	60
	Na^{-1}	<14	<14			
50%	Na^0	<14	<14	<2.15	>5.24	60
	Na^{-1}	<14	<14			
0.1 %	Na^0	>330	>330	>4.52	<2.87	60
	Na^{-1}	>330	>330			

Explanations:

V_c = number per mL (one or two plates); X_{wm} = weighted mean of X .

X = mean of V_{c1} and V_{c2} (duplicate of 1 + 2);

Logarithmic reduction R : ($\lg R = \lg N_0 - \lg Na$)

RAPORT DE INCERCARE NR. 60363/23/ROBCH

Client ECOCHIM-GRUP SRL OR. UNGHENI, STR. NAȚIONALĂ 119 - REPUBLICA MOLDOVA		Numărul eșantionului: 60363/23/ROBCH Descriere obiect de încercat (conform cu declarația Clientului) Dezinfectant Universal "Bio-Dez" Lot: - Data fabricației: 05.08.2023 Data expirare: 05.08.2026 Data receptiei probei: 23.08.2023 Cantitate prelevată: 500 ml Responsabil prelevare: Cristinov Alexandr Ora receptiei probei: 12:30 Temperatura receptie proba: 17°C Sample condition with no objections Comanda din 24.08.2023 Probele au fost prelevate și livrate de către Client.
Data primirii obiectului de încercat:	24.08.2023	
Data începerii încercării:	30.08.2023	
Data finalizării încercării:	22.11.2023	
Data eliberării raportului:	22.11.2023	

Parametrii de testare	Metoda de testare	Unitate de masura	Rezultat
# * Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1) ¹⁾	EN 14348: 2005	-	Rezultatul încercării se regăsește în raportul de încercare nr. D/23/B0672 primit de la subcontractor și anexat acestui raport.

¹⁾ Încercare efectuată de către subcontractor cu Certificat de acreditare Nr. 648/LE1286.

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:39:55 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ



Responsabil încercare: Mariana Ilinca, Șef Laborator Microbiologie
Validat de: Mariana Ilinca, Șef Laborator Microbiologie
Autorizat de: Manager general Mihai Alina-Roxana (Aprobat cu semnatura electronica)

Laborator: București 041914, sos. Berceni nr.8

Responsabilitatea eșantionării/ prelevării probelor aparține solicitantului. Rezultatele se referă numai la obiectul supus încercării. Dacă nu se specifică altfel, incertitudinea de măsurare a fost estimată pentru coeficientul $K=2$ și nivel de încredere 95%. Fără aprobarea scrisă a laboratorului acest raport de încercare nu poate fi reprodus decât integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se referă exclusiv la rezultatele și declarațiile prezentate în raportul original. Opiniile și interpretările conținute în prezentul raport de încercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare vă rugăm să solicitați Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

* Metoda de testare acreditată # Test efectuat de către subcontractor

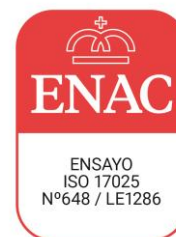
o Încercări neacreditate





Instituto Valenciano de Microbiología

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



Test with the certificate of GLPs
(Good Laboratory Practices)
No. 2/21-C.VAL. General Directorate of
Pharmacy and Medical Devices of the Health
Department of the Valencian Region. Spain

Mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants (phase 2, step 1), with the product “Dezinfectant Universal “Bio-Dez””. (EN 14348: 2005 Standard)

Report

Registration No.: D/23/B0672.

- 1. Laboratory identification** Instituto Valenciano de Microbiología.
- 2. Client identification** J.S. HAMILTON ROMANIA SRL.
Address SOS BERCENI, NR 8, SECTOR 4
BUCURESTI, ROMANIA, 041914.
- 3. Sample identification** (information provided by the client)
 - Product name **Dezinfectant Universal “Bio-Dez”.**
 - Batch number 60363/23/ROBCH.
 - Expiration date 05.08.2026.
 - Manufacturer/Supplier SRL “Ecochim-Grup”.
 - Keeping conditions Not indicated.
 - Condition for use Hygienic handrub, Instrument disinfection,
surface disinfection.
 - Diluent recommended by the manufacturer ... Not indicated.
 - Active compound/s and its concentration/s ... Ethyl alcohol 72-76%, CAS 64-17-5 and CE
200-578-6 Benzalkonium chloride 0.024-
0.029%, CAS 68424-85-1 and CE 270-325-
2 Methylthionibium chloride 0.00024%,
CAS 61-73-4 and 200-515-2.
 - Concentrations requested for the assay 80%

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

4. Information about sample reception

- Date of reception of the sample 2023/08/31.
- Date of reception of order with test conditions 2023/08/25.
- Aspect of the received samples..... Purple transparent liquid in plastic package.

5. Method of assay and its validation (EN 14348: 2005 Standard)

- Method used Dilution-neutralization.
- Neutralizer Tryptone 5 g/L, yeast extract 2.5 g/L, dextrose 10 g/L, sodium thioglycolate 1 g/L, sodium thiosulfate 1g/L, sodium bisulphite 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.

6. Experimental conditions

- Assay period (including prior preparation of the strains) 2023/09/28 to 2023/11/09.
- Solvent of the product used in the assay ... Sterile distilled water.
- Product concentrations for the assay 80%, 50% and 0.1%.
- Aspect of the dilutions of the product 80% purple transparent liquid;
50% blue transparent liquid;
0.1% transparent liquid.
- Contact time 60 seconds.
- Assay temperature 20°C ± 1°C.
- Interfering substance Bovine serum albumin 3 g/L and erythrocytes 3 mL/L.
- Stability of the mixture (interfering substance and product diluted in sterile distilled water) Stable.
- Temperature of incubation 36°C ± 1°C.
- Identification of the strains used
 - *Mycobacterium avium* (ATCC 15769).
 - *Mycobacterium terrae* (CECT 3028 = ATCC 15755).

7. Results of the assay

- Control and validation assays See tables 1, 2, 4 and 5.
- Evaluation of mycobactericidal activity See tables 3 and 6.
- Number of replicates for each assay microorganism 1.

8. Special remarks

- All controls and validation were between the basic limits.
- For a valid test, at least one concentration must show a reduction lower than 4 log and at least one concentration must show a reduction equal or higher than 4 log.
- The highest concentration that can be assayed in the test (80%) is due to the mixtures to perform the assay.

9. Conclusion

The product **Dezinfectant Universal “Bio-Dez”**, batch 60363/23/ROBCH, when it is pure (80%), concentration requested by the client, **shows mycobactericidal activity** after 60 seconds, at $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), against the strains *Mycobacterium avium* (ATCC 15769) and *Mycobacterium terrae* (CECT 3028 = ATCC 15755), when tested as required by **EN 14348: 2005 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), November 9, 2023.

MIGUEL FRANCO,
CLAUDIA (FIRMA)

Signed: Claudia Miguel.
Responsible Technician

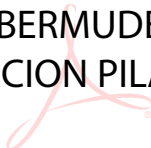
Quality Assurance Review:

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)

Reference

- **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. Test methods and requirements (phase 2, step 1).

Table 1.-Assay with *Mycobacterium avium* (ATCC 15769): Validation and controls.

Suspension of validation validation (N_{v0})			Control of experimental conditions (A)			Neutralizer (B)			Validation of the method (C) with sample concentration: 80%		
V_{C1}	97	$X = 100.5$	V_{C1}	98	$X = 96$	V_{C1}	92	$X = 95$	V_{C1}	93	$X = 91$
V_{C2}	104		V_{C2}	94		V_{C2}	98		V_{C2}	89	
30 ≤ X of N_{v0} ≤ 160? Yes			X of A is ≥ 0.5 x X of N_{v0} ? Yes			X of B is ≥ 0.5 x X of N_{v0} ? Yes			X of C is ≥ 0.5 x X of N_{v0} ? Yes		

Table 2.- Assay with *Mycobacterium avium* (ATCC 15769): Suspension of the assay.

Suspension of the assay (N y N_0)	N	Vc1	Vc2	$X_{wm} = 4.00 \times 10^9 = \lg = 9.60$ $N_0 = N/10 = \lg = 8.60$ $8.17 \leq N_0 \leq 8.70$? Yes
	10^{-7}	391	405	
	10^{-8}	44	41	

Table 3.- Assay with *Mycobacterium avium* (ATCC 15769).

Concentrations of the sample (%)	Dilutions	Vc1	Vc2	Lg Na = lg ($X \times 10^0$ o $X_{wm} \times 10$)	LgR ($\lg N_0 = 8.60$)	Time of contact (sec)
80 %	10^0	<14	<14	< 2.15	> 6.45	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
50 %	10^0	<14	<14	< 2.15	> 6.45	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
0.1 %	10^0	>660	>660	>6.82	<1.78	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			

Observations:

N 10^{-7} : 198 + 193; 202 + 203;

10^{-8} : 20 + 24; 19 + 22;

Na 80% 10^0 : 0 + 0; 0 + 0;

50% 10^0 : 0 + 0; 0 + 0;

0.1% 10^{-3} : >330 + >330; >330 + >330;

Nv0: 50 + 47; 55 + 49;

A: 46 + 52; 49 + 45;

B: 45 + 47; 49 + 49;

C: 48 + 45; 42 + 47;

Table 4.-Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755): Validation and controls.

Suspension of validation validation (N_{v0})			Control of experimental conditions (A)			Neutralizer (B)			Validation of the method (C) with sample concentration: 80%		
V_{c1}	79	$X = 80.5$	V_{c1}	66	$X = 68$	V_{c1}	75	$X = 77$	V_{c1}	67	$X = 69.5$
V_{c2}	82		V_{c2}	70		V_{c2}	79		V_{c2}	72	
30 ≤ X of N_{v0} ≤ 160? Yes			X of A is ≥ 0.5 x X of N_{v0} ? Yes			X of B is ≥ 0.5 x X of N_{v0} ? Yes			X of C is ≥ 0.5 x X of N_{v0} ? Yes		

Table 5.- Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755): Suspension of the assay.

Suspension of the assay (N y N_0)	N	V_{c1}	V_{c2}	$X_{wm} = 2.86 \times 10^9 = \lg = 9.46$ $N_0 = N/10 = \lg = 8.46$ $8.17 \leq N_0 \leq 8.70?$ Yes
	10^{-7}	295	275	
	10^{-8}	32	29	

Table 6.- Assay with *Mycobacterium terrae* (CECT 3028 = ATCC 15755).

Concentrations of the sample (%)	Dilutions	V_{c1}	V_{c2}	$\lg Na = \lg (X \times 10^9 \text{ o } X_{wm} \times 10)$	$\lg R (\lg N_0 = 8.46)$	Time of contact (sec)
80 %	10^0	<14	<14	<2.15	>6.31	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
50 %	10^0	<14	<14	<2.15	>6.31	60
	10^{-1}	<14	<14			
	10^{-2}	<14	<14			
	10^{-3}	<14	<14			
0.1%	10^0	>660	>660	>6.82	<1.64	60
	10^{-1}	>660	>660			
	10^{-2}	>660	>660			
	10^{-3}	>660	>660			

Observations:

N 10^{-7} : 150 + 145; 130 + 145;

10^{-8} : 17 + 15; 14 + 15;

Na 80% 10^0 : 0 + 0; 0 + 0;

50% 10^0 : 0 + 0; 0 + 0;

0.1% 10^{-3} : >330 + >330; >330 + >330;

N_{v0} : 40 + 39; 40 + 42;

A: 32 + 34; 34 + 36;

B: 39 + 36; 40 + 39;

C: 36 + 31; 35 + 37;

Explanations:

V_c : Counts per mL.

X_{wm} : weighted mean of X .

X : Values of V_{c1} and V_{c2} (1. + 2. duplicates); R : reduction ($\lg R = \lg N_0 - \lg Na$).



REPORT OF ANALYSIS No. 60362/23/ROBCH

Client ECOCHIM-GRUP SRL OR. UNGHENI, STR. NAȚIONALĂ 119 - REPUBLICA MOLDOVA		Sample number: 60362/23/ROBCH Sample description (according to declaration of Client) Dezinfectant Universal "Bio-Dez" Lot: - Data fabricatiei: 05.08.2023 Data expirare: 05.08.2026 Data receptiei probei: 23.08.2023 Cantitate prelevata: 500 ml Responsabil prelevare: Cristinov Alexandr Ora receptiei probei: 12:30 Temperatura receptie proba: 17°C Sample condition with no objections Order of 24.08.2023 Sampling and delivery were carried out by client.	
Sample received:	24.08.2023		
Tests performed:	30.08.2023		
Tests completed:	30.10.2023		
Report dated:	30.10.2023		

Test	Method	Unit	Result
# * Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of virucidal activity in the medical area	UNE-EN 14476:2014 + A2:2019	-	Test method performed by the subcontractor; the results are taken in full from the test report No D/23/V0259, issued by the subcontractor. The results of the analysis are listed starting with enclosure No1 to report of analysis.

Digitally signed by Crestinov Evghenii
Date: 2025.10.21 09:39:15 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ



Test responsible: Mariana Ilinca, Manager of Microbiological Laboratory
Validated by: Mariana Ilinca, Manager of Microbiological Laboratory
Authorized by: Alina-Roxana Mihai, General Manager (Approved with qualified electronic signature)

Laboratory: Bucuresti 041914, sos. Berceni nr.8

Responsabilitatea esantionarii/ prelevarii probelor apartine solicitantului. Rezultatele se refera numai la obiectul supus incercarii. Daca nu se specifica altfel, incertitudinea de masurare a fost estimata pentru coeficientul K= 2 si nivel de incredere 95%. Fara aprobarea scrisa a laboratorului acest raport de incercare nu poate fi reprodus decat integral. Responsabilitatea S.C. J.S. HAMILTON ROMANIA S.R.L. se refera exclusiv la rezultatele si declaratiile prezentate in raportul original. Opiniile si interpretarile continute in prezentul raport de incercare nu sunt acoperite de acreditarea RENAR. Pentru detalii suplimentare va rugam sa solicitati Certificatul de Acreditare la adresa de email bucharest@hamilton.com.pl

* Test method accredited # Test performed by external provider

ø Non accredited methods



ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

A) IDENTIFICATION OF THE SAMPLE	
Name of the product/Details about the product	DEZINFECTANT UNIVERSAL "BIO-DEZ" Manufacturer(supplier): Ecochim-Grup Condition of use: Instrument disinfection, surface disinfection, hygienic handrub.
Active(s) Substance(s) and its concentration(s)	Ethyl alcohol 72-76%, CAS 64-17-5 and CE 200-578-6, Benzalkonium chloride 0.024-0.029%, CAS 68424-85-1 and CE 270-325-2, Methylthionibium chloride 0.00024%, CAS 61-73-4 and 200-515-2.
Concentration ordered for the assay	80
B) TEST METHOD	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr. 648/LE1286 Report D/23/V0259. 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 "Dezinfectant Universal "Bio-Dez" (EN 14476: 2013 + A2: 2019 Standard)	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).
Testing method	Procedure DESIN-1078 (EN 14476: 2013 + A2: 2019 Standard).
C) INFORMATION ABOUT SAMPLE RECEPTION	
Date of reception of the sample	2023/08/30
Date of reception of order with test conditions	2023/09/04.
Aspect of the received product	Blue transparent liquid in plastic container with identification label.
D) EXPERIMENTAL CONDITIONS	
Assay period	2023/09/06 to 2023/09/21.
Assay temperature	37°C ± 1°C
Titration method	TCID50 (Tissue Culture Infective Dose 50%).
Product concentrations for the assay	80%, 50% and 0.1%
Contact time	60 seconds
Contact temperature	20°C ± 1°C
Procedure to stop product cytotoxicity	Molecular sieving (< 4 columns).
Procedure to stop product activity	Cooling with ice
Solvent of the product used in the assay	Sterile distilled water
Aspect of the dilutions of the product	Transparent
Stability of the mixture (interfering substance and product diluted in sterile hard water/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 stains and number of passes	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 passes)	Vero, ref: FTVE, working aliquot 4, passages 18 21, 22 and 25. Raw 264.7, Public Health England, working aliquot 4, passages 18, 21 and 25

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Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosure no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Date: 27.10.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH
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 $\log 10^{-7.50}$
 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 $\log 10^{-7.00}$
Adenovirus type 5 (ATCC VR-5)

Titre of the viral suspension for the virus control (at the requested test time)

 – Dirty conditions $\log 10^{-6.82}$
 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 $\log 10^{-6.32}$
Murine Norovirus (strain S99 Berlin)

Titre of the viral suspension for the virus control (at the requested test time)

 – Dirty conditions $\log 10^{-8.32}$
 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 $\log 10^{-7.82}$
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 $\log 10^{-3.08}$

Viral quantification in the reference test (formaldehyde) after 60 minutes and with

 Adenovirus type 5 $\log 10^{-2.75}$

Viral quantification in the reference test (formaldehyde) after 60 minutes and with

 Murine Norovirus $\log 10^{-4.99}$

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH
Confidence interval

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

- Dirty conditions $\log 10^{-7.50 \pm 0.37}$

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

- Dirty conditions $\log 10^{-6.82 \pm 0.41}$

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

- Dirty conditions $\log 10^{-8.32 \pm 0.42}$

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 $\log 10^{-8.23}$
- Viral quantification of Poliovirus type 1 with cells treated by the test solution with the test sample $\log 10^{-7.65}$
- Viral quantification of Adenovirus type 5 with cells not treated by the test solution with the test sample $\log 10^{-7.41}$
- Viral quantification of Adenovirus type 5 with cells treated by the test solution with the test sample $\log 10^{-6.74}$
- Viral quantification of Murine Norovirus with cells not treated by the test solution with the test sample $\log 10^{-8.66}$
- Viral quantification of Murine Norovirus with cells treated by the test solution with the test sample $\log 10^{-7.99}$

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

Control of the effectivity of the disinfectant suppression activity

- Viral quantification of Poliovirus type 1 after 30 minutes on bath ice without exposing the virus to the test sample $\log 10^{-7.41}$
- Viral quantification of Poliovirus type 1 exposing the virus to the test sample and incubated 30 minutes on ice bath $\log 10^{-6.99}$
- Viral quantification of Adenovirus type 5 after 30 minutes on bath ice without exposing the virus to the test sample $\log 10^{-7.08}$
- Viral quantification of Adenovirus type 5 exposing the virus to the test sample and incubated 30 minutes on ice bath $\log 10^{-6.83}$

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

- Viral quantification of Murine Norovirus after 30 minutes on bath ice without exposing the virus to the test sample $\log 10^{-8.25}$
- Viral quantification of Murine Norovirus exposing the virus to the test sample and incubated 30 minutes on ice bath $\log 10^{-7.74}$

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

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	$\geq 7.00 \pm 0.37$ TCID ₅₀ Shows	2.84 ± 0.56 TCID ₅₀ Does not show	0.01 ± 0.49 TCID ₅₀ Does not show
Adenovirus type 5	$\geq 6.32 \pm 0.41$ TCID ₅₀ Shows	5.07 ± 0.48 TCID ₅₀ Shows	0.07 ± 0.48 TCID ₅₀ Does not show
Murine Norovirus	$\geq 7.82 \pm 0.42$ TCID ₅₀ Shows	5.58 ± 0.56 TCID ₅₀ Shows	0.08 ± 0.54 TCID ₅₀ Does not show

Virucidal activity exists when the titre of virus shows a reduction ≥ 4 log.

TCID₅₀: Tissue Culture Infectious Dose 50%.

9.2 Tables of results and graphics

See tables 1 to 6 and figures 1 to 3.

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH**Conclusion**

The product “Dezinfectant Universal “Bio-Dez”, batch 60362/23/ROBCH, at 80% concentration, under dirty conditions (bovine serum albumin 3 g/L and erythrocytes 3 mL/L), requested by the client and during 60 seconds of contact time and 20°C of temperature, shows activity against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus, when the activity is assayed according with the EN 14476: 2013 + A2: 2019 Standard.

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

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

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

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH
Table 1. Results of activity of the test sample with Poliovirus type 1 (ATCC VR-192) under test conditions requested by the client.

Assay	Concentration	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after...				Reduction with the confidence interval of 95 %
				0 min	60 sec	30 min	60 min	
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	0.50	-	0.50	-	-	$\geq 7.00 \pm 0.37$
	50%		0.50	-	4.66	-	-	2.84 ± 0.56
	0.1%		0.50		7.49			0.01 ± 0.49
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	NA	7.58	7.50	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.50	NR	NR	4.99	3.08	NA
Virus control formaldehyde	0.7% (w:v)	NA	NA	7.58	NR	NR	7.32	NA
Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) log ₁₀ ^{-0.58}								
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 ^{-0.42}								
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.								

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

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 + 3 mL/L erythrocytes	60 sec	0000	0000	0000	0000	0000	0000	0000	0000	NR	NR	NR	
				0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	
	4444			4444	4444	3240	0002	0200	0000	NR	NR	NR	NR		
	50%		60 sec	4444	4444	4444	0403	3010	0000	0000	NR	NR	NR		
				4444	4444	4444	4432	0020	0000	0000	0000	0000	0000	0000	
	4444			4444	4444	4444	4444	4444	3241	0000	0000	0000	NR		
0.1%	60 sec	4444	4444	4444	4444	4444	4444	4444	0344	0200	0000	0000	NR		
		4444	4444	4444	4444	4444	4444	4444	3032	0001	0000	0000	NR		
Cytotoxicity		80%	3 g/L BSA + 3 mL/L erythrocytes	NA	0000	0000	0000	0000	0000	0000	0000	NR	NR	NR	
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	0	4444	4444	4444	4444	4444	4444	3244	0000	0000	NR	NR	
				4444	4444	4444	4444	4444	4444	3021	0220	0000	0000	NR	
				4444	4444	4444	4444	4444	4444	3044	0003	0000	0000	NR	
			60 sec	4444	4444	4444	4444	4444	4444	3204	0010	0000	0000	NR	NR
				4444	4444	4444	4444	4444	4444	4310	0000	0000	0000	NR	NR
				4444	4444	4444	4444	4444	4444	0233	2020	0000	0000	0000	NR
Formal- dehyde	0.7% (w:v)	NA	30 min	4444	4444	4444	4444	0030	0000	0000	NR	NR	NR		
				4444	4444	4444	4444	2004	0020	0000	0000	NR	NR	NR	
				4444	4444	4444	4444	4030	0000	0000	0000	NR	NR	NR	
			60 min	4444	4444	0302	0000	0000	0000	0000	NR	NR	NR		
				4444	4444	2304	0000	0000	0000	0000	NR	NR	NR		
				4444	4444	0002	0100	0000	0000	0000	NR	NR	NR		
Control of formaldehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + 3 mL/L erythrocytes	NA	0000	0000	0000	0000	0000	0000	0000	NR	NR	NR		
Virus control formal- dehyde	0.7% (w:v)	NA	0	4444	4444	4444	4444	4444	4444	0321	1000	0000	0000		
				4444	4444	4444	4444	4444	4444	0044	2000	0000	0000		
				4444	4444	4444	4444	4444	4444	4342	3020	0000	0000		
			60 min	4444	4444	4444	4444	4444	4444	0321	0000	0000	0000		
				4444	4444	4444	4444	4444	4444	0404	2000	0000	0000		
				4444	4444	4444	4444	4444	4444	4303	0020	0000	0000		
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	NR	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	
			Cells treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	NR
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	NR
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	NR
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + 3 mL/L erythrocytes	Without sample	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	NR	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	
			With sample	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	NR
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	NR
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	NR

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;

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

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

Assay	Concentration	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after...				Reduction with the confidence interval of 95 %
				0 min	60 sec	30 min	60 Min	
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	0.50	-	0.50	-	-	$\geq 6.32 \pm 0.41$
	50%		0.50	-	1.75	-	-	5.07 ± 0.48
	0.1%		0.50	-	6.75	-	-	0.07 ± 0.48
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	NA	6.91	6.82	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.50	NR	NR	3.49	2.75	NA
Virus control formaldehyde	0.7% (w:v)	NA	NA	7.16	NR	NR	6.98	NA
Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) log ₁₀ ^{-0.67} 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 ^{-0.25}								
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.								

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

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

Assay	Concentration	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}												
				1	2	3	4	5	6	7	8	9	10			
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	60 sec	0000	0000	0000	0000	0000	0000	0000	0000	NR	NR	NR		
				0000	0000	0000	0000	0000	0000	0000	0000	0000	0000	0000		
	50%		60 sec	4433	0010	0000	0000	0000	0000	0000	0000	NR	NR	NR		
				2113	3002	0000	0000	0000	0000	0000	0000	0000	0000	0000		
	0.1%		60 sec	4444	4444	4444	4444	4444	4433	0003	0000	NR	NR	NR		
				4444	4444	4444	4444	4444	1234	1000	0000	0000	0000	0000		
Cytotoxicity	80%	3 g/L BSA + 3 mL/L erythrocytes	NA	0000	0000	0000	0000	0000	0000	0000	NR	NR	NR			
				0000	0000	0000	0000	0000	0000	0000						
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	0	4444	4444	4444	4444	4444	3244	2004	0100	NR	NR			
				4444	4444	4444	4444	4444	4302	0423	0000	0000	0000			
			60 sec	4444	4444	4444	4444	4444	3201	0023	0000	NR	NR			
				4444	4444	4444	4444	4444	4443	0102	0000	0000	0000			
				4444	4444	4444	4444	4444	3440	0200	0001	0000	0000			
				4444	4444	4444	4444	4444	3402	0001	0000	0000	0000			
Formal-dehyde	0.7% (w:v)	NA	30 min	4444	4444	0303	2000	0000	0000	NR	NR	NR				
				4444	4444	2033	1000	0000	0000	0000	0000	0000				
			60 min	4444	3334	0202	0000	0000	0000	NR	NR	NR				
				4444	2444	0010	0000	0000	0000	0000	0000	0000				
				4444	3442	0000	0000	0000	0000	0000	0000	0000				
				4444	3402	0001	0000	0000	0000	0000	0000	0000				
Control of formal-dehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + 3 mL/L erythrocytes	NA	0000	0000	0000	0000	0000	0000	NR	NR	NR				
				0000	0000	0000	0000	0000	0000	0000	0000	0000				
				0000	0000	0000	0000	0000	0000	0000	0000	0000				
				0000	0000	0000	0000	0000	0000	0000	0000	0000				
				0000	0000	0000	0000	0000	0000	0000	0000	0000				
				0000	0000	0000	0000	0000	0000	0000	0000	0000				
Virus control formal-dehyde	0.7% (w:v)	NA	0	4444	4444	4444	4444	4444	4444	0402	0000	0000	0000			
				4444	4444	4444	4444	4444	4444	4444	3030	0010	0000	0000		
			60 min	4444	4444	4444	4444	4444	4444	4444	4040	0020	0000	0000		
				4444	4444	4444	4444	4444	4444	4344	4020	0000	0000	0000		
				4444	4444	4444	4444	4444	4444	4340	0200	0010	0000	0000		
				4444	4444	4444	4444	4444	2433	3200	0010	0000	0000	0000		
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0CCC	0000	NR	NR		
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC		
			Cells treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	NR	NR
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC		
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + 3 mL/L erythrocytes	Without sample	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0000	NR	NR		
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC		
			With sample	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	NR	NR
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC		

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.

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8 Berceni Street, 041902 Bucharest, Romania

Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

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Date: 27.10.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

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

Assay	Concentration	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after...				Reduction with the confidence interval of 95 %
				0 min	60 sec	30 min	60 min	
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	0.50	-	0.50	-	-	$\geq 7.82 \pm 0.42$
	50%		0.50	-	2.74	-	-	5.58 ± 0.56
	0.1%		0.50	-	8.24	-	-	0.08 ± 0.54
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	NA	8.41	8.32	-	-	NA
Formaldehyde	0.7% (w.v)	NA	0.50	NR	NR	5.74	4.99	NA
Virus control formaldehyde	0.7% (w.v)	NA	NA	8.50	NR	NR	8.32	NA
Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells) log10 ^{-0.67}								
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 ^{-0.43}								
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.								

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ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

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

Assay	Concentration	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}											
				1	2	3	4	5	6	7	8	9	10		
Test sample	80%	3 g/L BSA + 3 mL/L erythrocytes	60 sec	0000	0000	0000	0000	0000	0000	0000	0000	NR	NR	NR	
				0000	0000	0000	0000	0000	0000	0000	0000				
	0000			0000	0000	0000	0000	0000	0000	0000					
	50%		60 sec	4444	3244	0020	0000	0000	0000	0000	NR	NR	NR		
				4444	3020	0122	0000	0000	0000	0000	0000				
	4444			2244	0030	0000	0000	0000	0000	0000					
0.1%	60 sec	4444	4444	4444	4444	4444	4444	4444	0302	0000					
		4444	4444	4444	4444	4444	4444	4444	4444	2010	0000				
4444		4444	4444	4444	4444	4444	4444	4444	3212	0002	NR				
Cytotoxicity	80%	3 g/L BSA + 3 mL/L erythrocytes	NA	0000	0000	0000	0000	0000	0000	0000	NR	NR	NR		
				0000	0000	0000	0000	0000	0000	0000					
				0000	0000	0000	0000	0000	0000	0000					
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	0	4444	4444	4444	4444	4444	4444	4444	4444	0323	0020		
				4444	4444	4444	4444	4444	4444	4444	4444	0404	0000	NR	
				4444	4444	4444	4444	4444	4444	4444	4444	3302	0210		
			60 sec	4444	4444	4444	4444	4444	4444	4444	3244	3213	0002		
				4444	4444	4444	4444	4444	4444	4444	4444	2030	0200	NR	
				4444	4444	4444	4444	4444	4444	4444	2013	2203	0010		
Formaldehyde	0.7% (w:v)	NA	30 min	4444	4444	4444	4444	3344	0200	0000					
				4444	4444	4444	4444	0334	0202	0000	NR	NR	NR		
				4444	4444	4444	4444	4444	0100	0000					
			60 min	4444	4444	4444	4444	0030	0000	0000					
				4444	4444	4444	4444	4020	0100	0000	NR	NR	NR		
				4444	4444	4444	4444	2200	0000	0000					
Control of formaldehyde cytotoxicity	0.7% (w:v)	3 g/L BSA + 3 mL/L erythrocytes	NA	0000	0000	0000	0000	0000	0000	0000	NR	NR	NR		
				0000	0000	0000	0000	0000	0000	0000					
				0000	0000	0000	0000	0000	0000	0000					
Virus control formaldehyde	0.7% (w:v)	NA	0	4444	4444	4444	4444	4444	4444	4444	4444	3042	0000	0000	
				4444	4444	4444	4444	4444	4444	4444	4444	4040	1000	0000	
				4444	4444	4444	4444	4444	4444	4444	4444	4433	0102	0000	
			60 min	4444	4444	4444	4444	4444	4444	4444	2002	0000	0000		
				4444	4444	4444	4444	4444	4444	4444	4244	0302	0120	0000	
				4444	4444	4444	4444	4444	4444	4444	3330	2434	0100	0000	
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	NR	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC		
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC		
			Cells treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0000	NR
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0000	
Effectiveness control of the disinfectant suppression activity	NA	3 g/L BSA + 3 mL/L erythrocytes	Without sample	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	NR	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC		
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC		
			With sample	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0000	0000
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0000	0000
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0000	NR

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.

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Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

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

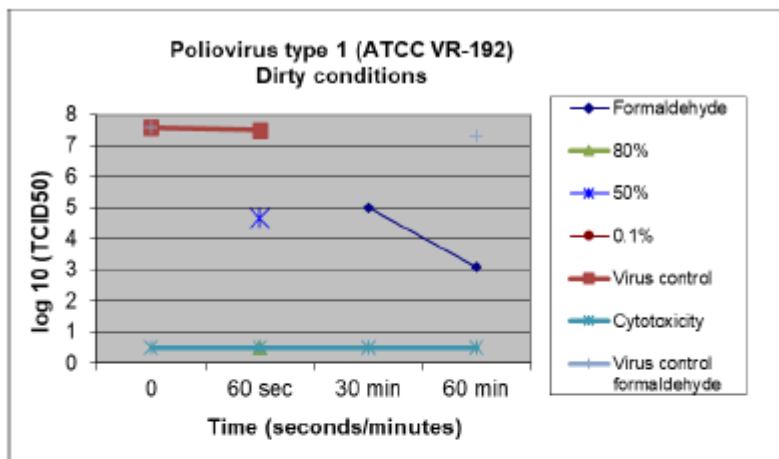
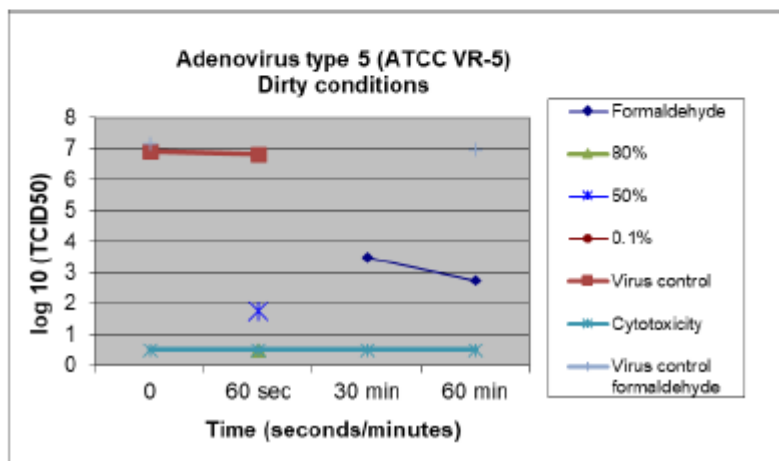


Figure 2. Results of the activity of the test sample under test conditions requested by the client with Adenovirus type 5 (ATCC VR-5).



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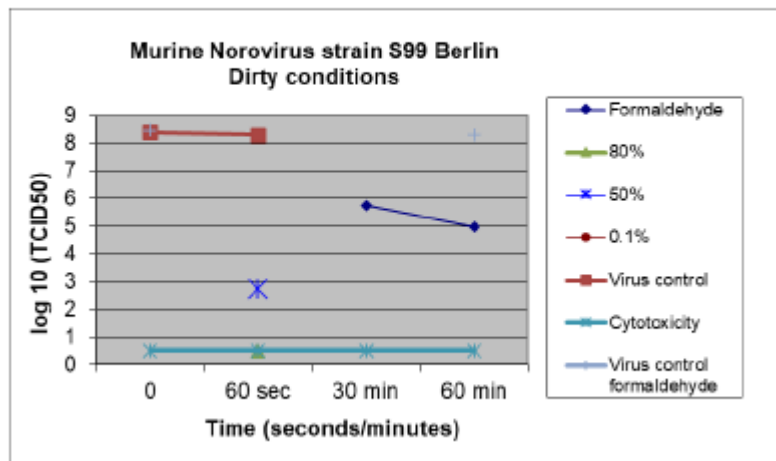
Date: 27.10.2023

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

ENCLOSURE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 60362/23/ROBCH

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



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REPORT No. 390310/25/INT

Sponsor: ECOCHIM-GRUP S.R.L., UNGHENI CITY, NATIONALA 119 STREET		Investigational product (according to declaration of the Sponsor) DISINFECTANT „BIO-DEZ,, UNIVERSAL 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 1
		Sample status: no objections Sample received from the Sponsor
Sample reception date:	06.06.2025	
Start of study:	10.06.2025	
End of study:	13.06.2025	
Report date:	16.06.2025	

**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 09:39:23 EEST
Reason: MoldSign Signature
Location: Moldova

MOLDOVA EUROPEANĂ



REPORT No. 390310/25/INT**THE STUDY IS COMPLIANT WITH:**

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

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REPORT No. 390310/25/INT**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.

REPORT No. 390310/25/INT**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

REPORT No. 390310/25/INT
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

REPORT No. 390310/25/INT
8. RESULTS
8.1. CHARACTERISTICS OF VOLUNTEERS
Table 1

No. of subject	Identification of subject	Beginning 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

REPORT No. 390310/25/INT
Table 2

No. of subject	Identification of subject	Beginning 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

REPORT No. 390310/25/INT
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

REPORT No. 390310/25/INT
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 sum of classification points)	0,00	0,00	0,00	0,00	Examination skipped
X_{av}	0,00				

10. INTERPRETATION

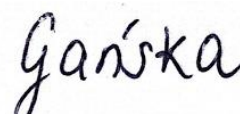
The average irritation index (X_{av}) was calculated. The product was then classified according to the following table:

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

REPORT No. 390310/25/INT**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 „BIO-DEZ,, UNIVERSAL 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.

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*Accredited study

THE END OF THE REPORT