

Agencia Națională pentru Sănătatea Publică



CERTIFICAT  
DE ÎNREGISTRARE DE STAT/AVIZARE SANITARĂ  
AL PRODUSULUI BIOCID

Nr. 00048 data/luna/anul 15.06.2020

Solicitant: For titular „Viorica –Cosmetic” S.A.

Adresa juridică: str. Mesager, 1, mun. Chișinău, Republica Moldova

Nr. de identificare de stat – codul fiscal 1002600033793

În conformitate cu HG nr. 564 din 10.09.09 și în baza ordinului ANSP nr.71 din 15.06.2020  
(nr., data/luna/anul)

emis în baza documentației înaintate, s-a decis că următorul produs biocid poate fi fabricat sau comercializat și utilizat în Republica Moldova, conform prevederilor legislației în vigoare.

**Denumirea comercială a produsului:** „COSMEPLANT” Gel antibacterian 70% Alcool Romanița

**1. Date de identificare ale produsului:**

**1.1 Categoria de produs:** biocid

- Grupa principală: 1

- Tip de produs: 1, 2

**1.2 Utilizare:** Pentru dezinfectia mâinilor, suprafețelor, obiectelor de inventar și a echipamentelor din domeniul sănătății publice.

**1.3 Forma de condiționare și ambalare:** gel, ambalaj – 50ml, 200ml, 5000ml

**1.4 Conținut în substanțe active:** Etanol 70 %

**1.5 Categoriile de utilizatori:** Industriali, profesionali, populație

**1.6 Informații privind reglementările aplicabile:** HG nr. 564 din 10.09.2009, Ordinul MS nr.299 din 06.05.2010 cu modificările ulterioare.

**2. Date de identificare ale producătorului:**

**2.1 Firma:** „Viorica –Cosmetic” S.A.

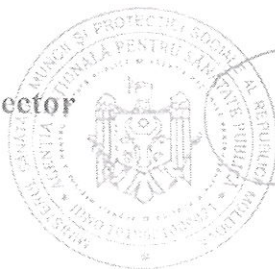
**2.2 Adresa:** str. Mesager, 1, mun. Chișinău, Republica Moldova

Valabilitatea certificatului de înregistrare data/luna/anul 15/06/2025

Compoziția, parametrii de calitate ai produsului și domeniul de utilizare sunt cei prevăzuți în documentația tehnică, care a stat la baza eliberării prezentului certificat, conform Raportului de evaluare nr. 35 din 05.06.2020

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

Director



Nicolae FURTUNĂ

**REPORT OF ANALYSIS No. 264672/20/JSHR**

<b>Client</b> <b>VIORICA COSMETIC SA</b> 1 MESAGER MD-2069 CHISINAU		<b>Sample description (according to declaration of Client)</b> <b>Cosmeplant GEL dezinfecant pentru maini Romanita 6.1. Lot: 29.05.2020</b> <b>Data fabricatiei: 29.05.2020</b> <b>Cantitatea: 1000 ml</b> <b>Data expirarii: 29.05.2023</b> <b>Data prelevarii: 02.06.2020</b> <b>Sample without any visible damages</b>	
Sample received:	2020-06-05	<b>Order of 2020-06-04</b> The samples were delivered by Client	
Analysis completed:	2020-07-06		
Report dated:	2020-07-06		

Test	Method	Unit	Result
* Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2) <sup>1)</sup>	PN-EN 1500:2013		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.

<sup>1)</sup> The results of the analysis in attachment No 1 to the report of analysis.

**THE END OF THE REPORT**

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager

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](http://www.hamilton.com.pl)

\* Test method accredited; # Test performed by external provider

Page 1 / 1

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. 264672/20/JSHR**

<b>A) IDENTIFICATION OF THE SAMPLE:</b>	
Name of the product	<b>Cosmeplant GEL dezinfektant pentru maini Romanita</b> <b>Lot: 29.05.2020</b> <b>Data fabricatiei: 29.05.2020</b> <b>Cantitatea: 1000 ml</b> <b>Data expirarii: 29.05.2023</b> <b>Data prelevarii: 02.06.2020</b>
The active substance	Ethanol 70% w/w, CAS: 64-17-5,
<b>B) TEST METHOD :</b>	
Method	<b>EN 1500:2013 Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2)</b>
Neutralizer	Polysorbate 80 30 g/l, saponine 30g/l, histidine 1g/l, cysteine 1g/l
<b>C) EXPERIMENTAL CONDITIONS:</b>	
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: 06.07.2020

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager

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

This enclosure is an inseparable part of the report of analysis and cannot be reproduced partially without a priori 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 an original copy of the enclosure.



**ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 264672/20/JSHR**

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:  $2,6 \times 10^8$  cfu/g

volunteer		number of cfu per plate from dilution 10x							Reduction	
Nr	Hand left/right	prevalues			postvalues				log y	log z
		$\times 10^{-4}$	$\times 10^{-5}$	log x	$\times 10^0$	$\times 10^{-1}$	$\times 10^{-2}$			
1	l	169	18		80	7	0			
	r	177	15	6,24	77	6	0	1,89	4,35	
2	l	189	19		96	9	0			
	r	196	21	6,29	81	8	0	1,94	4,34	
3	l	216	22		45	5	0			
	r	225	24	6,34	86	9	0	1,80	4,55	
4	l	238	25		72	8	0			
	r	247	26	6,39	65	7	0	1,84	4,55	
5	l	172	19		50	6	0			
	r	169	18	6,24	45	5	0	1,68	4,55	
6	l	155	16		59	6	0			
	r	180	21	6,23	66	5	0	1,79	4,44	
7	l	216	22		48	5	0			
	r	210	18	6,33	32	2	0	1,59	4,74	
8	l	130	14		71	8	0			
	r	148	15	6,14	69	7	0	1,85	4,30	
9	l	163	17		52	5	0			
	r	172	18	6,23	50	5	0	1,71	4,52	
10	l	210	22		33	4	0			
	r	180	19	6,29	41	4	0	1,57	4,72	
11	l	163	18		29	3	0			
	r	177	15	6,23	35	2	0	1,50	4,73	
12	l	152	16		46	5	0			
	r	164	15	6,20	37	2	0	1,61	4,59	
13	l	175	14		72	8	0			
	r	168	13	6,23	65	7	0	1,84	4,39	
14	l	154	17		81	8	0			
	r	132	14	6,16	45	5	0	1,78	4,37	
15	l	143	13		68	7	0			
	r	196	20	6,22	70	8	0	1,84	4,38	
16	l	214	22		52	6	0			
	r	247	26	6,36	36	4	0	1,64	4,72	
17	l	236	24		47	5	0			
	r	258	28	6,39	50	5	0	1,69	4,71	
18	l	179	18		67	7	0			
	r	183	17	6,26	50	4	0	1,76	4,50	
19	l	162	15		46	5	0			
	r	150	14	6,19	33	4	0	1,60	4,59	
20	l	148	13		72	8	0			
	r	163	14	6,19	54	6	0	1,80	4,39	
Xavg				6,26				1,74	4,52	
s				0,07				0,12	0,15	

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

Date: 06.07.2020

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager

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

This enclosure is an inseparable part of the report of analysis and cannot be reproduced partially without a priori 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 an original copy of the enclosure.

**ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 264672/20/JSHR**

Table 2. HYGIENIC HANDRUB PROCEDURE WITH THE PRODUCT

PRODUCT P

 TEST ORGANISM: *E. coli* K12 NCTC 10538

 NUMBER IN CONTAMINATION FLUID:  $2,6 \times 10^8$  cfu/g

volunteer		number of cfu per plate from dilution 10x							Reduction	
Nr	Hand left/right	prevalues			postvalues				log y	log z
		$\times 10^{-4}$	$\times 10^{-5}$	log x	$\times 10^0$	$\times 10^{-1}$	$\times 10^{-2}$			
1	l	163	18		45	6	0			
	r	152	13	6,20	59	8	0	1,73	4,47	
2	l	148	15		63	5	0			
	r	188	14	6,22	71	6	0	1,82	4,40	
3	l	177	16		77	5	0			
	r	162	15	6,23	85	10	1	1,90	4,32	
4	l	121	11		89	10	1			
	r	172	18	6,16	95	8	0	1,96	4,20	
5	l	188	17		63	5	0			
	r	173	15	6,25	46	3	0	1,72	4,53	
6	l	141	13		47	4	0			
	r	160	12	6,17	42	5	0	1,65	4,52	
7	l	164	15		53	5	0			
	r	176	16	6,23	61	7	0	1,76	4,47	
8	l	194	21		78	7	0			
	r	172	16	6,26	92	8	0	1,92	4,34	
9	l	138	13		84	7	0			
	r	165	17	6,18	56	4	0	1,83	4,35	
10	l	162	15		42	3	0			
	r	150	14	6,19	36	3	0	1,58	4,61	
11	l	181	15		24	2	0			
	r	172	13	6,24	57	8	0	1,57	4,67	
12	l	163	12		61	7	0			
	r	145	11	6,18	52	4	0	1,75	4,43	
13	l	146	15		48	5	0			
	r	155	14	6,18	55	6	0	1,71	4,46	
14	l	189	21		69	7	0			
	r	197	23	6,29	72	8	0	1,85	4,44	
15	l	142	15		64	5	0			
	r	147	18	6,17	55	4	0	1,76	4,40	
16	l	132	16		59	6	0			
	r	120	14	6,11	73	8	0	1,82	4,29	
17	l	182	20		46	5	0			
	r	197	24	6,28	82	9	0	1,79	4,49	
18	l	155	16		63	5	0			
	r	146	11	6,17	47	3	0	1,72	4,45	
19	l	134	12		52	6	0			
	r	122	10	6,10	44	3	0	1,68	4,42	
20	l	134	11		69	7	0			
	r	171	21	6,18	73	5	0	1,85	4,34	
x <sub>avg</sub>					6,20				1,77	4,43
s					0,05				0,10	0,11

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

Date: 06.07.2020

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager

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

This enclosure is an inseparable part of the report of analysis and cannot be reproduced partially without a priori 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 an original copy of the enclosure.

**ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 264672/20/JSHR**

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	6,24	1,89	4,35	6,20	1,73	4,47
2	R-P	6,29	1,94	4,34	6,22	1,82	4,40
3	R-P	6,34	1,80	4,55	6,23	1,90	4,32
4	R-P	6,39	1,84	4,55	6,16	1,96	4,20
5	R-P	6,24	1,68	4,55	6,25	1,72	4,53
6	P-R	6,23	1,79	4,44	6,17	1,65	4,52
7	P-R	6,33	1,59	4,74	6,23	1,76	4,47
8	P-R	6,14	1,85	4,30	6,26	1,92	4,34
9	P-R	6,23	1,71	4,52	6,18	1,83	4,35
10	P-R	6,29	1,57	4,72	6,19	1,58	4,61
11	R-P	6,23	1,50	4,73	6,24	1,57	4,67
12	R-P	6,20	1,61	4,59	6,18	1,75	4,43
13	R-P	6,23	1,84	4,39	6,18	1,71	4,46
14	R-P	6,16	1,78	4,37	6,29	1,85	4,44
15	R-P	6,22	1,84	4,38	6,17	1,76	4,40
16	P-R	6,36	1,64	4,72	6,11	1,82	4,29
17	P-R	6,39	1,69	4,71	6,28	1,79	4,49
18	P-R	6,26	1,76	4,50	6,17	1,72	4,45
19	P-R	6,19	1,60	4,59	6,10	1,68	4,42
20	P-R	6,19	1,80	4,39	6,18	1,85	4,34
X <sub>20</sub>		<b>6,26</b>	1,74	4,52	<b>6,20</b>	1,77	4,43
X10(R-P)		6,25	1,77	<b>4,48</b>	6,21	1,78	<b>4,43</b>
X10 (P-R)		6,26	1,70	<b>4,56</b>	6,19	1,76	<b>4,43</b>

Criteria:

$$R_s (R-P) = 4,48 - 4,43 = 0,05$$

$$R_s (P-R) = 4,56 - 4,43 = 0,13$$

$$Abs = 0,05 - 0,13 = -0,08 < 2$$

$$\log x(R) = 6,26 > 5$$

$$\log x(P) = 6,20 > 5$$

$$\log z (P), \log z (R) > 3$$

Validation conditions of neutralizer and methods have been satisfied

Date: 06.07.2020

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager

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

This enclosure is an inseparable part of the report of analysis and cannot be reproduced partially without a priori 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 an original copy of the enclosure.



**ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 264672/20/JSHR**

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

volunteer	log RF		difference	difference	Range +/-
	R	P	R-P	high to low	
1	4,35	4,47	-0,12	0,43	1
2	4,34	4,40	-0,06	0,35	2
3	4,55	4,32	0,23	0,27	3
4	4,55	4,20	0,35	0,23	4
5	4,55	4,53	0,02	0,22	5
6	4,44	4,52	-0,09	0,17	6
7	4,74	4,47	0,27	0,17	7
8	4,30	4,34	-0,04	0,16	8
9	4,52	4,35	0,17	0,11	9
10	4,72	4,61	0,11	0,07	10
11	4,73	4,67	0,07	0,05	11
12	4,59	4,43	0,16	0,05	12
13	4,39	4,46	-0,08	0,02	13
14	4,37	4,44	-0,07	-0,02	-14
15	4,38	4,40	-0,02	-0,04	-15
16	4,72	4,29	0,43	-0,06	-16
17	4,71	4,49	0,22	-0,07	-17
18	4,50	4,45	0,05	-0,08	-18
19	4,59	4,42	0,17	-0,09	-19
20	4,39	4,34	0,05	-0,12	-20
sum range (+): 91					
sum range (-): 119					

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

	0,43	0,35	0,27	0,23	0,22	0,17	0,17	0,16	0,11
1	0,43	0,43							
2	0,35	0,39	0,35						
3	0,27	0,35	0,31	0,27					
4	0,23	0,33	0,29	0,25	0,23				
5	0,22	0,33	0,29	0,25	0,23	0,22			
6	0,17	0,30	0,26	0,22	0,20	0,20	0,17		
7	0,17	0,30	0,26	0,22	0,20	0,20	0,17	-0,17	
8	0,16	0,30	0,26	0,22	0,20	0,19	0,17	-0,17	-0,16
9	0,11	0,27	0,23	0,19	0,17	0,17	0,14	-0,14	-0,14
10	0,07	0,25	0,21	0,17	0,15	0,15	0,12	-0,12	-0,12
11	0,05	0,24	0,20	0,16	0,14	0,14	0,11	-0,11	-0,11
12	0,05	0,24	0,20	0,16	0,14	0,14	0,11	-0,11	-0,11
13	0,02	0,23	0,19	0,15	0,13	0,12	0,10	-0,10	
14	-0,02	0,21	0,17	0,13	0,11	0,10	0,08		
15	-0,04	0,20	0,16	0,12	0,10	0,09			
16	-0,06	0,19	0,15	0,11	0,09				
17	-0,07	0,18	0,14	0,10					
18	-0,08	0,18	0,14						
19	-0,09	0,17							
20	-0,12								

Date: 06.07.2020

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager

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

This enclosure is an inseparable part of the report of analysis and cannot be reproduced partially without a priori 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 an original copy of the enclosure.

**ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 264672/20/JSHR**

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 0,20 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: 06.07.2020

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager

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

This enclosure is an inseparable part of the report of analysis and cannot be reproduced partially without a priori 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 an original copy of the enclosure.



## REPORT OF ANALYSIS No. 264673/20/JSHR

<b>Client</b> <b>VIORICA COSMETIC SA</b> 1 MESAGER MD-2069 CHISINAU	<b>Sample description</b> <i>(according to declaration of Client)</i> <b>Cosmeplant GEL dezinfectant pentru maini Romanita 6.2.</b> <b>Lot: 29.05.2020</b> <b>Data fabricatiei: 29.05.2020</b> <b>Cantitatea: 250 ml</b> <b>Data expirarii: 29.05.2023</b> <b>Data prelevarii: 02.06.2020</b> <b>Sample without any visible damages</b>
Sample received: <b>2020-06-05</b>	<b>Order of 2020-06-04</b> The samples were delivered by Client
Analysis completed: <b>2020-07-16</b>	
Report dated: <b>2020-07-16</b>	

Test	Method	Unit	Result
* Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics <sup>1)</sup>	PN-EN 1276:2010/AC:2010		Product diluted to 50% and 80% shows bactericidal activity at 60 seconds, 20°C, in clean conditions (0,3g/L bovine albumin) at reference strains: Pseudomonas aeruginosa ATCC 15442, Escherichia coli ATCC 10536, Staphylococcus aureus ATCC 6538, Enterococcus hirae ATCC 10541.

<sup>1)</sup> The results of the analysis in attachment No 1 to the report of analysis.

THE END OF THE REPORT

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager

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](http://www.hamilton.com.pl)

\* Test method accredited; # Test performed by external provider

Page 1 / 1

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. 264673/20/JSHR**

<b>A) IDENTIFICATION OF THE SAMPLE</b>	
Name of the product	<b>Cosmeplant GEL dezinfektant pentru maini Romanita</b> Lot: 29.05.2020 Data fabricatiei: 29.05.2020 Cantitatea: 250 ml Data expirarii: 29.05.2023 Data prelevarii: 02.06.2020
Active substance	Ethanol, CAS: 64-17-5, 70% w/w
<b>B) TEST METHOD AND ITS VALIDATION</b>	
Method	<b>PN-EN 1276:2010/AC:2010</b> <b>Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1)</b>
Neutralizer	Polisorbate 80- 30 g/l, saponine- 3 g/l, cysteine- 1g/l, histidine- 1g/l, sodium thiosulfate 7,5g/l
<b>C) EXPERIMENTAL CONDITIONS</b>	
Product test concentrations (%V/V)	0,01%, 50%, 80%
Test temperature	20°C
Contact time	60 seconds
Interfering substance	Clean conditions: 0,3g/l bovine albumin
Product diluent	Sterile hard water
Temperature of incubation	37±1°C
Identification of the bacterial and fungal strains used:	<i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Escherichia coli</i> ATCC 10536 <i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541

Date: 16.07.2020

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager

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

This enclosure is an inseparable part of the report of analysis and cannot be reproduced partially without a priori 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 an original copy of the enclosure.

## ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 264673/20/JSHR

TABLE 1. RESULTS OF THE TEST

0,3 g/l BOVINE ALBUMIN - CLEAN CONDITIONS  
 CONTACT TIME: 60 SECONDS  
 TEST TEMPERATURE: 20°C  
 PRODUCT TEST CONCENTRATIONS: 0,01%, 50%, 80%

TEST ORGANISM	VALIDATION SUSPENSION			VALIDATION A			VALIDATION B			VALIDATION C		
	VC1	VC2	N <sub>0</sub>	VC1	VC2	A	VC1	VC2	B	VC1	VC2	C
<i>Escherichia coli</i> ATCC 10536	131	132	1315	132	109	106	108	98	97	98	85	85
<i>Staphylococcus aureus</i> ATCC 6538	121	126	1235	124	112	111	112	103	106	105	91	92
<i>Pseudomonas aeruginosa</i> ATCC 15442	103	101	1020	102	98	96	97	86	86	86	79	79
<i>Enterococcus hirae</i> ATCC 10541	136	134	1350	135	124	125	125	114	117	116	93	91
criteria	300 ≤ N <sub>0</sub> ≤ 1600			A ≥ 0,5*N <sub>0</sub> acceptable			B ≥ 0,5*N <sub>0</sub> acceptable			C ≥ 0,5*N <sub>0</sub> acceptable		

TEST ORGANISM	TEST SUSPENSION					
	-6	-6	-7	-7	N	lg N <sub>0</sub>
<i>Escherichia coli</i> ATCC 10536	203	206	20	20	2,0E+08	8,31
<i>Staphylococcus aureus</i> ATCC 6538	216	217	21	21	2,2E+08	8,33
<i>Pseudomonas aeruginosa</i> ATCC 15442	251	255	25	26	2,5E+08	8,40
<i>Enterococcus hirae</i> ATCC 10541	236	235	23	24	2,4E+08	8,37
criteria	1,5*10 <sup>8</sup> ≤ N ≤ 5*10 <sup>8</sup> 8,17 ≤ logN ≤ 8,70    1,5*10 <sup>7</sup> ≤ N <sub>0</sub> ≤ 5*10 <sup>7</sup> 7,17 ≤ logN <sub>0</sub> ≤ 7,70					

TEST ORGANISM	N	0,01%						50%						80%					
		VC1	VC2	Na	lg Na	lg R	VC1	VC2	Na	lg Na	lg R	VC1	VC2	Na	lg Na	lg R			
<i>Escherichia coli</i> ATCC 10536	2,0E+08	>330	>330	>3300	>3,52	<3,79	0	0	0	<140	<2,15	>5,16	0	0	<140	<2,15	>5,16		
<i>Staphylococcus aureus</i> ATCC 6538	2,2E+08	>330	>330	>3300	>3,52	<3,81	0	0	0	<140	<2,15	>5,18	0	0	<140	<2,15	>5,18		
<i>Pseudomonas aeruginosa</i> ATCC 15442	2,5E+08	>330	>330	>3300	>3,52	<3,88	0	0	0	<140	<2,15	>5,25	0	0	<140	<2,15	>5,25		
<i>Enterococcus hirae</i> ATCC 10541	2,4E+08	>330	>330	>3300	>3,52	<3,85	0	0	0	<140	<2,15	>5,22	0	0	<140	<2,15	>5,22		
criteria	lg R ≥ 5																		

Date: 16.07.2020

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager  
 Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

This enclosure is an inseparable part of the report of analysis and cannot be reproduced partially without a priori 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 an original copy of the enclosure.



### REPORT OF ANALYSIS No. 264674/20/JSHR

<b>Client</b> <b>VIORICA COSMETIC SA</b> 1 MESAGER MD-2069 CHISINAU		<b>Sample description (according to declaration of Client)</b> <b>Cosmeplant GEL dezinfectant pentru maini Romanita 6.3.</b> <b>Lot: 29.05.2020</b> <b>Data fabricatiei: 29.05.2020</b> <b>Cantitatea: 1000 ml</b> <b>Data expirarii: 29.05.2023</b> <b>Data prelevarii: 02.06.2020</b> <b>Sample without any visible damages</b>	
Sample received:	2020-06-05	<b>Order of 2020-06-04</b> The samples were delivered by Client	
Analysis completed:	2020-07-16		
Report dated:	2020-07-16		

Test	Method	Unit	Result
* Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics <sup>1)</sup>	PN-EN 1650:2008+A1:2013-08		Product diluted to 80% shows fungicidal activity at 60 seconds, 20°C, in clean conditions (0,3g/L bovine albumin) at reference strains: Candida albicans ATCC 10231, Aspergillus brasiliensis ATCC 16404.

<sup>1)</sup> The results of the analysis in attachment No 1 to the report of analysis.

THE END OF THE REPORT

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager

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](http://www.hamilton.com.pl)

\* Test method accredited; # Test performed by external provider

Page 1 / 1

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. 264674/20/JSHR**

<b>A) IDENTIFICATION OF THE SAMPLE</b>	
Name of the product	<b>Cosmeplant GEL dezinfektant pentru maini Romanita</b> Lot: 29.05.2020 Data fabricatiei: 29.05.2020 Cantitatea: 1000 ml Data expirarii: 29.05.2023 Data prelevarii: 02.06.2020
Active substance	Ethanol, CAS: 64-17-5, 70% w/w
<b>B) TEST METHOD AND ITS VALIDATION</b>	
	<b>PN-EN 1650:2013 – Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1)</b>
Neutralizer	Polisorbate 80- 30 g/l, saponine- 3 g/l, cysteine- 1g/l, histidine- 1g/l, sodium thiosulfate 7,5g/l
<b>C) EXPERIMENTAL CONDITIONS</b>	
Product test concentrations	0,01%, 50%, 80%
Test temperature	20°C
Contact time	60 seconds
Interfering substances	Clean conditions: 0,3g/l bovine albumin
Product diluent	Hard water
Temperature of incubation	30°C ± 1°C
Identification of the bacterial and fungal strains used	<i>Candida albicans</i> ATCC 10231 <i>Aspergillus brasiliensis</i> ATCC 16404

Date: 16.07.2020

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager

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

This enclosure is an inseparable part of the report of analysis and cannot be reproduced partially without a priori 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 an original copy of the enclosure.

## ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 264674/20/JSHR

TABLE 1. RESULTS OF THE TEST

0.3 g/l BOVINE ALBUMIN - CLEAN CONDITIONS  
 CONTACT TIME: 60 SECONDS  
 TEST TEMPERATURE: 20°C  
 PRODUCT TEST CONCENTRATIONS: 0,01%, 50%, 80%

TEST ORGANISM	VALIDATION				VALIDATION A			VALIDATION B			VALIDATION C		
	VALIDATION SUSPENSION		N <sub>0</sub>		VC1	VC2	A	VC1	VC2	B	VC1	VC2	C
<i>Candida albicans</i> ATCC 10231	123	126	1245	125	113	111	112	95	96	95,5	81	80	81
<i>Aspergillus brasiliensis</i> ATCC 16404	95	98	985	97	85	86	86	76	77	76,5	66	64	65
criteria	300 < N <sub>0</sub> < 1600    30 < N <sub>0</sub> < 160				acceptable    A ≥ 0,5 * N <sub>0</sub>			acceptable    B ≥ 0,5 * N <sub>0</sub>			acceptable    C ≥ 0,5 * N <sub>0</sub>		
TEST ORGANISM	TEST SUSPENSION						50%			80%			
	N		0,01%		Na		Ig Na	VC1	VC2	Ig Na	VC1	VC2	Ig R
<i>Candida albicans</i> ATCC 10231	226	245	22	24	2,4E+07	7,37	2,4E+06	0	0	<2,15	0	0	>4,22
<i>Aspergillus brasiliensis</i> ATCC 16404	> 165	> 165	20	21	2,1E+07	7,31	2,1E+06	> 165	> 165	>3,22	0	0	>4,16
criteria	1,5*10 <sup>5</sup> ≤ N ≤ 5*10 <sup>7</sup>		acceptable		1,5*10 <sup>5</sup> ≤ N <sub>0</sub> ≤ 5*10 <sup>6</sup>		acceptable			acceptable			
	7,17 ≤ Ig N ≤ 7,70		acceptable		6,17 ≤ Ig N <sub>0</sub> ≤ 6,70		acceptable			acceptable			
TEST ORGANISM	N		0,01%		Na		Ig Na <th>VC1 <th>VC2 <th>Ig Na <th>VC1 <th>VC2 <th>Ig R</th> </th></th></th></th></th>	VC1 <th>VC2 <th>Ig Na <th>VC1 <th>VC2 <th>Ig R</th> </th></th></th></th>	VC2 <th>Ig Na <th>VC1 <th>VC2 <th>Ig R</th> </th></th></th>	Ig Na <th>VC1 <th>VC2 <th>Ig R</th> </th></th>	VC1 <th>VC2 <th>Ig R</th> </th>	VC2 <th>Ig R</th>	Ig R
<i>Candida albicans</i> ATCC 10231	2,4E+07	>330	>330	>3300	>3,52	<2,85	0	0	<140	<2,15	0	0	>4,22
<i>Aspergillus brasiliensis</i> ATCC 16404	2,1E+07	>165	>165	>1650	>3,22	<3,09	>165	>165	>1650	>3,22	0	0	>4,16
criteria	Ig R ≥ 4												

Date: 16.07.2020

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager  
 Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)

This enclosure is an inseparable part of the report of analysis and cannot be reproduced partially without a priori 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 an original copy of the enclosure.





MINISTERUL SANATATII  
COMISIA NATIONALA PENTRU PRODUSE BIOCID  
MINISTRY OF HEALTH  
NATIONAL COMMITTEE FOR BIOCIDAL PRODUCTS

Str. Dr. A. Leonte, Nr. 1 - 3, 050463 Bucuresti, ROMANIA  
Tel: \*(+40 21) 318 36 20, Secretariat tehnic: (+40 21) 311 86 20; Fax: (+40 21) 311 86 22



Data emiterii: 04.12.2020

## AVIZ

### Nr. 5297BIO/01/12.24

În conformitate cu Ordinul Ministrului Sănătății, al Ministrului Mediului și Pădurilor și al președintelui Autorității Naționale Sanitare Veterinare și pentru Siguranța Alimentelor nr. 10/368/11/2010, privind aprobarea procedurii de avizare a produselor biocide care sunt plasate pe teritoriul României, cu modificările și completările ulterioare și cu Ordinul Ministrului Sănătății, al Ministrului Mediului și Pădurilor și al Președintelui Autorității Naționale Sanitare Veterinare și pentru Siguranța Alimentelor nr. 637/2492/50/2012, privind aprobarea membrilor Comisiei Naționale pentru Produse Biocide și a regulamentului de organizare și funcționare a acesteia, cu modificările și completările ulterioare, în baza documentelor depuse în dosarul tehnic, CNPB, în sesiunea din data de 02.12.2020 a decis ca produsul biocid poate fi plasat pe piață în România, conform prevederilor legale în vigoare.

#### I. DENUMIREA COMERCIALĂ ÎN ROMÂNIA

COSMEPLANT GEL DEZINFECTANT PENTRU MĂINI ROMÂNIA

Alte denumiri comerciale, după caz

-

II. DATE DE IDENTIFICARE ALE PRODUCĂTORULUI (numele, adresa, țara, inclusiv punctul de lucru pentru producătorii din România)

Fabrica de parfumerie și cosmetică SA Viorica Cosmetic, Adresa: Mesager, 1. Chișinău, Moldova, 2069, Țara: Moldova

III. DATE DE IDENTIFICARE ALE SOLICITANTULUI (numele, adresa, țara)

Viorica Cosmetic S.R.L. Adresa: Calea Plevnei nr. 143, parter, Bloc Corp B, scara 1, ap. 4 Sectorul 6, BUCUREȘTI, Țara: România

IV. ÎNCADRAREA PRODUSULUI BIOCID (în conformitate cu anexa V la Regulamentul (UE) nr. 528/2012 al Parlamentului European și al Consiliului din 22 mai 2012 privind punerea la dispoziție pe piață și utilizarea produselor biocide, cu amendamentele ulterioare)

A. Grupa principală:	1
B. Tipul/Tipurile de produs:	1

#### V. DATE PRIVIND SUBSTANȚA ACTIVĂ / SUBSTANȚE

##### A. Substanțe chimice

Nr. crt.	Denumirea chimică (IUPAC, ISO sau altele)	Nr. CE	Nr. CAS	Concentrația în unități metrice
1.	Alcool etilic	200-578-6	64-17-5	70%

#### VI. FORMA DE CONDIȚIONARE:

Gel.

#### VII. MODUL DE AMBALARE (tipul, capacitate)

Flacoane / bidoane PE de capacități: 50 ml, 200 ml, 500 ml

# AVIZ Nr. 5297BIO/01/12.24

## VIII. DOMENIUL ȘI ARIA DE UTILIZARE

A. Domeniul de utilizare	Igiena umana.
B. Aria de aplicare	Dezinfectant pentru mâini, cu excepția utilizării în unități sanitare.

## IX. EFICACITATE



Activitatea	Metoda de testare/ Protocolul de testare	Specia / Tulpina	Concen trații	Timpi de acțiune
Bacterică	EN 1276, la 20°C, condiții de curățenie (0,3 g/L albumină bovină)	<i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Staphylococcus aureus</i> ATCC 6538 <i>Escherichia Coli</i> ATCC 10536 <i>Enterococcus hirae</i> ATCC 10541	80% 50%	60 secunde
	EN 1500	<i>Escherichia Coli</i> K12 NCTC 10538	100%	60 secunde
Fungică	EN 1650, la 20°C, condiții de curățenie (0,3 g/L albumină bovină)	<i>Candida albicans</i> ATCC 10231 <i>Aspergillus brasiliensis</i> ATCC 16404	80%	60 secunde

## X. INDICAȚII DE UTILIZARE

Metoda de aplicare	Concentrația soluției de lucru/ doza de aplicare	Timpul de acțiune
Frecare	Nediluat - 3 ml	60 secunde

## XI. ETICHETAREA PRODUSULUI BIOCID

A. Produs biocid cu substanțe active - substanțe chimice

Pictograme, simboluri și indicarea pericolului	 <b>GHS02</b>  <b>GHS 07</b>	Pericol!
Fraze de risc (H)	<b>H225:</b> Lichid și vapori foarte inflamabili. <b>H319:</b> Provoacă o iritare gravă a ochilor.	
Fraze de prudenta (P)	<b>P101:</b> Dacă este necesară consultarea medicului, țineți la îndemână recipientul sau eticheta produsului. <b>P102:</b> A nu se lăsa la îndemâna copiilor. <b>P103:</b> Citiți eticheta înainte de utilizare . <b>P210:</b> A se păstra departe de surse de căldură/scânteii/ flăcări deschise/ suprafețe încinse. Fumatul interzis. <b>P233:</b> Păstrați recipientul închis etanș. <b>P243:</b> Luați măsuri de precauție împotriva descărcărilor electrostatice. <b>P305+P351+P338:</b> ÎN CAZ DE CONTACT CU OCHII: clătiți cu atenție cu apă timp de mai multe minute. Scoateți lentilele de contact, dacă este cazul și dacă acest lucru se poate face cu ușurință. Continuați să clătiți. <b>P403+P235:</b> A se depozita într-un spațiu bine ventilat. A se păstra la rece. <b>P501:</b> Aruncați conținutul/containerul în acord cu regulamentele locale/regionale/naționale/ internaționale.	

## XII. CATEGORIA DE UTILIZATORI

Profesionali, populație.
--------------------------

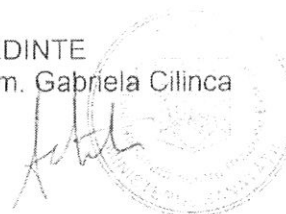
## XIII. RECOMANDARI/ RESTRICTII PRIVIND PROTECTIA SANATATII SI A FACTORILOR DE MEDIU

-
---

Avizul este valabil până la data: 31.12.2024.

Avizul conține – 2 pagini

PREȘEDINTE  
Dr. Chim. Gabriela Cilinca







**RAPORT**  
**a încercărilor de laborator**  
 ОТЧЕТ ЛАБОРАТОРНЫХ ИСПЫТАНИЙ

Nr. 7145 din 15 11 2019

1. Denumirea întreprinderii, organizația (beneficiar) ”VIORICA-COSMETIC”SA  
 Наименование предприятия, организации (заявитель)
2. Adresa juridică Chișinău, str. Mesager, 1  
 Юридический адрес
3. Denumirea mostrei, data producerii Gel antibacterian Cosmeplant  
 Наименование образца (пробы), дата изготовления
4. Producătorul (firma, organizația, instituția) ”VIORICA-COSMETIC”SA  
 Изготовитель (фирма, предприятие, организация)
- 11 țara Republica Moldova  
 страна
5. Data și ora prelevării 10 ora 00 min ”11” 11 2019  
 Время и дата отбора час мин
- N.P. funcția Mostra a fost prelevată de beneficiar  
 Ф.И.О., должность
- Condițiile de transportare auto  
 Условия доставки
- Livrat în LÎA 11 ora 30 min ”11” 11 2019  
 Доставлен в ИЛЦ час мин
6. Date suplimentare \_\_\_\_\_  
 Дополнительные сведения
7. D.N. la producție DNT a producătorului  
 ИД на продукцию
8. D.N. privind reglementarea volumului cercetărilor de laborator și aprecierea lor HG nr.1207 din 02.11.2016  
 ИД регламентирующие объем лабораторных исследований и их оценку

Nr. d/o № п/п	Parametrii cercetați Определяемые показатели	Rezultatele cercetărilor, unități de măsură Результаты исследований Единицы измерения	Incertitudinea de măsurare Неопределенность измерения	Nivelul maxim admisibil, unități de măsură Величина допустимого уровня	DN a metodelor de investigare ИД на методы исследований
1	2	3	4	5	6

\* Nota: La cererea clientului rezultatul încercării se eliberează cu incertitudinea de calcul extinsa cu coeficientul de acoperire k=2 și nivelul de încredere 95%.

**I. Cercetările toxicologice:**  
 ТОКСИКОЛОГИЧЕСКИЕ ИССЛЕДОВАНИЯ:

Mostra a sosit 12 ora \_\_\_\_\_ min ”11” 11 2019  
 Образец поступил час мин

Codul 7145.2.1.1.19  
 Код

Nr. de înregistrare 1206 în registru \_\_\_\_\_ Nr. 1206 procesului – verbal \_\_\_\_\_ din 15.11.2019  
 Регистрационный в журнале № протокола испытаний

1	2	3	4	5	6
1.	Determinarea proprietăților de iritare la animale de laborator	I cut = 0 p		nu se admit	POS 1.12



N.PP, funcția persoanei responsabile de oformarea raportului dat  
Ф.И.О. должность лица ответственного за оформление данного протокола

Șt. Constantinovici, medic igienist

Concluzie Заключение Proba investigată corespunde cerințelor HG nr.1207 din 02.11.2016  
la parametrii cercetați.

Amendament:

Rezultatul se referă numai la proba analizată. Este strict interzisă reproducerea parțială a rezultatului.  
Примечание: Результат распространяется только на анализируемую пробу. Частично воспроизведение результата строго запрещено

\*- Parametrii cercetați nu sunt incluși în Domeniul de acreditare CÎL aprobat MOLDAC

\*- Определяемые показатели не включены в Область аккредитации ИЛЦ MOLDAC

Nume, prenume, funcția Șef Direcție diagnostic de laborator în sănătate publică **Ala HALACU**  
Ф.И.О., должность

semnătura

