

Agencia Națională pentru Sănătatea Publică



CERTIFICAT
DE ÎNREGISTRARE DE STAT/AVIZARE SANITARĂ
AL PRODUSULUI BIOCID

Nr. 00048 data/luna/anul 15.06.2020 rectificat la 16.10.2020

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 – de la 50ml până la 5000ml

1.4 Conținut în substanțe active: Etanol 70 %

1.5 Categorii 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 interimar



Vasile GUȘTIUC



REPORT OF ANALYSIS No. 264672/20/JSHR

Client VIORICA COSMETIC SA 1 MESAGER MD-2069 CHISINAU		Sample description (according to declaration of Client) Cosmeplant GEL dezinfectant pentru maini Romanita 6.1. Lot: 29.05.2020 Data fabricatiei: 29.05.2020 Cantitatea: 1000 ml Data expirarii: 29.05.2023 Data prelevarii: 02.06.2020 Sample without any visible damages
Sample received:	2020-06-05	Order of 2020-06-04 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) ¹⁾	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.

¹⁾ 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, Gozdziów 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

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TESTING LABORATORY

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REPORT OF ANALYSIS No. 264674/20/JSHR

Client VIORICA COSMETIC SA 1 MESAGER MD-2069 CHISINAU		Sample description (according to declaration of Client) Cosmeplant GEL dezinfectant pentru maini Romanita 6.3. Lot: 29.05.2020 Data fabricatiei: 29.05.2020 Cantitatea: 1000 ml Data expirarii: 29.05.2023 Data prelevarii: 02.06.2020 Sample without any visible damages
Sample received:	2020-06-05	Order of 2020-06-04 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 ¹⁾	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.

¹⁾ 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

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

A) IDENTIFICATION OF THE SAMPLE:	
Name of the product	Cosmeplant GEL dezinfecant pentru maini Romanita Lot: 29.05.2020 Data fabricatiei: 29.05.2020 Cantitatea: 1000 ml Data expirarii: 29.05.2023 Data prelevării: 02.06.2020
The active substance	Ethanol 70% w/w, CAS: 64-17-5,
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	E. coli 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)
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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: 2.6×10^8 cfu/g

volunteer	Hand left/right	number of cfu per plate from dilution 10 ⁶								Reduction
		previ-values			post-values					
Nr		x10 ⁴	x10 ⁵	log x	x10 ⁴	x10 ⁵	log y	log z		
1	r	169	17	1.8	82	7	0	1.89		
1	r	177	15	6.24	77	6	0	4.35		
2	r	188	19	96	96	6	0	1.94		
2	r	196	21	6.29	81	8	0	4.34		
3	r	216	22	45	45	5	0	1.80		
3	r	222	24	6.34	86	9	0	4.55		
4	r	238	25	72	72	8	0	1.84		
4	r	247	26	6.39	83	7	0	4.55		
5	r	172	19	52	52	6	0	1.68		
5	r	169	18	6.24	45	5	0	4.55		
6	r	155	16	58	58	6	0	1.79		
6	r	180	21	6.23	66	5	0	4.44		
7	r	216	22	46	46	2	0	1.59		
7	r	210	18	6.33	39	2	0	4.74		
8	r	130	14	71	71	8	0	1.85		
8	r	148	15	6.14	69	7	0	4.30		
9	r	163	17	52	52	5	0	1.71		
9	r	172	18	6.23	50	5	0	4.52		
10	r	210	22	33	4	0	0	1.57		
10	r	180	18	6.29	41	4	0	4.72		
11	r	163	18	29	3	0	0	1.50		
11	r	177	15	6.23	35	2	0	4.73		
12	r	152	16	48	48	5	0	1.61		
12	r	164	15	6.20	37	2	0	4.59		
13	r	175	14	72	72	8	0	1.84		
13	r	168	13	6.23	65	7	0	4.39		
14	r	154	17	81	81	8	0	1.78		
14	r	130	14	6.16	45	5	0	4.37		
15	r	143	13	64	64	7	0	1.84		
15	r	196	20	6.22	73	8	0	4.38		
16	r	216	22	52	52	6	0	1.69		
16	r	247	26	6.36	36	4	0	4.72		
17	r	238	24	47	5	0	0	1.69		
17	r	258	26	6.39	50	5	0	4.71		
18	r	178	18	6.7	67	7	0	1.76		
18	r	183	17	6.26	50	4	0	4.50		
19	r	162	15	48	48	5	0	1.60		
19	r	150	14	6.19	33	4	0	4.59		
20	r	148	13	6.19	72	8	0	1.80		
20	r	163	14	6.19	54	6	0	4.50		
X _{avg}				6.26				1.74		
s				0.07				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
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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 264672/20/JSHR

Table 2. HYGIENIC HANDRUBS PROCEDURE WITH THE PRODUCT

PRODUCT P
TEST ORGANISM E. coli K12 NCTC 10538
NUMBER IN CONTAMINATION FLUID: 2.6×10^8 cfu/g

volunteer		number of cfu per plate from dilution 10 ⁶								
	Hand left/right	prev-values				post-values				Reduction
Nr		x10 ⁴	x10 ⁵	log x	x10 ⁴	x10 ⁵	log y	log z		
1	r	163	18	45	6	0	1.73	4.47		
1	r	152	13	5.20	59	5	0	4.40		
2	r	148	15	6.3	63	5	0	1.82	4.40	
2	r	188	14	71	6	0	1.82	4.40		
3	r	177	16	77	5	0	1.90	4.30		
3	r	165	15	6.23	85	10	1	4.30		
4	r	121	11	89	10	1	1.96	4.25		
4	r	172	18	6.16	35	8	0	1.86	4.30	
5	r	184	17	63	5	0	1.72	4.50		
5	r	179	15	6.25	46	3	0	4.50		
6	r	141	13	47	4	0	1.65	4.50		
6	r	160	12	6.17	42	5	0	4.50		
7	r	164	15	53	5	0	1.76	4.47		
7	r	176	16	6.23	61	7	0	1.76	4.47	
8	r	194	21	78	7	0	1.93	4.30		
8	r	172	16	6.20	35	8	0	1.82	4.30	
9	r	138	13	84	7	0	1.83	4.35		
9	r	165	17	6.18	54	4	0	1.82	4.35	
10	r	164	15	44	3	0	1.58	4.61		
10	r	150	14	6.19	36	3	0	4.61		
11	r	181	15	24	2	0	1.57	4.67		
11	r	172	13	5.7	8	0	1.75	4.43		
12	r	163	15	6.18	61	7	0	1.75	4.43	
12	r	145	11	52	4	0	1.75	4.43		
13	r	146	15	48	5	0	1.71	4.45		
13	r	155	14	6.18	55	6	0	1.71	4.45	
14	r	189	21	69	7	0	1.85	4.44		
14	r	197	23	72	8	0	1.85	4.44		
15	r	142	13	64	5	0	1.76	4.40		
15	r	147	18	6.17	52	4	0	1.76	4.40	
16	r	132	16	59	6	0	1.82	4.29		
16	r	120	14	5.11	75	8	0	1.82	4.29	
17	r	145	20	44	5	0	1.78	4.49		
17	r	197	24	6.28	82	9	0	1.78	4.49	
18	r	155	16	63	5	0	1.72	4.45		
18	r	146	13	6.17	47	3	0	1.72	4.45	
19	r	134	12	52	6	0	1.68	4.42		
19	r	122	10	44	3	0	1.85	4.42		
20	r	134	11	6.18	69	7	0	1.77	4.42	
20	r	171	21	78	5	0	1.77	4.42		
X _{avg}				6.20				6.16		
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
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Table 3. LIST OF COMPUTED IG VALUES AND IG REDUCTIONS

volunteer	R 2-propanol 60% (V/V)			P		
	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	1.89	4.55	6.23	1.90	4.32
4 R-P	6.39	1.69	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	1.75	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	1.64	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	1.68	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	1.75	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	1.60	4.39	6.18	1.85	4.34
X ₂₀	6.26	1.74	4.52	6.20	1.77	4.43
X10(R-P)	6.25	1.77	4.48	6.21	1.78	4.43
X10(P-R)	6.26	1.70	4.56	6.19	1.76	4.43

Criteria:
Rs (R-P) = 4.48 - 4.43 = 0.05
Rs (P-R) = 4.56 - 4.43 = 0.13
Abs = 0.05 - 0.13 = -0.08 < 2
logx(R) = 6.26 > 5
logx(P) = 6.20 > 5
logz (P), logz (R) > 3

Validation conditions of neutralizer and methods have been satisfied

Date: 06.07.2020
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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
2	4,34	4,40	-0,06	0,35
3	4,55	4,32	0,23	0,27
4	4,55	4,20	0,35	0,23
5	4,55	4,53	0,02	0,22
6	4,44	4,52	-0,09	0,17
7	4,74	4,47	0,27	0,17
8	4,30	4,34	-0,04	0,16
9	4,52	4,35	0,17	0,11
10	4,72	4,61	0,11	0,07
11	4,73	4,67	0,07	0,05
12	4,59	4,43	0,16	0,05
13	4,39	4,46	-0,08	0,02
14	4,37	4,44	-0,07	-0,02
15	4,38	4,40	-0,02	-0,04
16	4,72	4,29	0,43	-0,06
17	4,71	4,49	0,22	-0,07
18	4,50	4,45	0,05	-0,08
19	4,59	4,42	0,17	-0,09
20	4,35	4,34	0,05	-0,12
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								
2	0,35	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	-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							
19	-0,09	0,17							
20	-0,12								

Date: 05.07.2020

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager
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Table 6. WILCOXON'S 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: 05.07.2020

Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager
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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 264674/20/JSHR

A) IDENTIFICATION OF THE SAMPLE	
Name of the product	Cosmeplant GEL dezinfecant pentru maini Romanita 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) TEST METHOD AND ITS VALIDATION	
	PN-EN 1650:2013 – Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeastcidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1)
Neutralizer	Polisorbate 80- 30 g/l, saponine- 3 g/l, cysteine- 1g/l, histidine- 1g/l, sodium thiosulfate 7,5g/l
C) EXPERIMENTAL CONDITIONS	
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

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

TABLE 1. RESULTS OF THE TEST

TEST ORGANISM	VALIDATION SUBSTRATE				VALIDATION				VALIDATION			
	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC
<i>Candida albicans</i> ATCC 10231	120	120	120	120	120	120	120	120	120	120	120	120
<i>Aspergillus brasiliensis</i> ATCC 16404	120	120	120	120	120	120	120	120	120	120	120	120
Media	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml
TEST ORGANISM	TEST SUBSTRATE				TEST				TEST			
	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC
<i>Candida albicans</i> ATCC 10231	120	120	120	120	120	120	120	120	120	120	120	120
<i>Aspergillus brasiliensis</i> ATCC 16404	120	120	120	120	120	120	120	120	120	120	120	120
Media	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml
TEST ORGANISM	TEST SUBSTRATE				TEST				TEST			
	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC	ATC
<i>Candida albicans</i> ATCC 10231	120	120	120	120	120	120	120	120	120	120	120	120
<i>Aspergillus brasiliensis</i> ATCC 16404	120	120	120	120	120	120	120	120	120	120	120	120
Media	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml	200 µg/ml

Date: 16.07.2020
Authorized by: Agnieszka Erber, Cosmetics Microbiology Laboratory Manager
Approved by: Hanna Wachowska, Laboratory Director (Approved with qualified electronic signature)
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REPORT OF ANALYSIS No. 264673/20/JSHR

Client VIORICA COSMETIC SA 1 MESAGER MD-2069 CHISINAU		Sample description: according to declaration of Client Cosmeplant GEL dezinfectant pentru maini Romanita 6.2. Lot: 29.05.2020 Data fabricatiei: 29.05.2020 Cantitatea: 250 ml Data expirarii: 02.06.2023 Data prelevarii: 02.06.2020 Sample without any visible damages
Sample received:	2020-06-05	Order of 2020-06-04 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 bactericidal activity of chemical disinfectants and antiseptics ¹⁾	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: <i>Pseudomonas aeruginosa</i> ATCC 15442, <i>Escherichia coli</i> ATCC 10536, <i>Staphylococcus aureus</i> ATCC 6538, <i>Enterococcus faecalis</i> ATCC 10541

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

THE END OF THE REPORT

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Laboratory: Tyty 41-100, Gdansk 1

The results relate to the analysed samples only. Unless otherwise specified, the 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 EN ISO 9001:2015. 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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J.S. HAMILTON POLAND Sp. z o.o.

TESTING LABORATORY

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




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

A) IDENTIFICATION OF THE SAMPLE	
Name of the product	Cosmeplant GEL dezinfectant pentru maini Romanita 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) TEST METHOD AND ITS VALIDATION	
Method	PN-EN 1276:2010/AC:2010 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)
Neutralizer	Polisorbate 80- 30 g/l, saponine- 3 g/l, cysteine- 1g/l, histidine- 1g/l, sodium thiosulfate 7,5g/l
C) EXPERIMENTAL CONDITIONS	
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

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

TABLE 1. RESULTS OF THE TEST

TEST ORGANISM		VALUES IN VOLUME % ETHANOL			VALUES IN VOLUME % ETHANOL			VALUES IN VOLUME % ETHANOL		
		0,01%	50%	80%	0,01%	50%	80%	0,01%	50%	80%
<i>Escherichia coli</i> ATCC 10536		10	10	10	10	10	10	10	10	10
<i>Staphylococcus aureus</i> ATCC 6538		10	10	10	10	10	10	10	10	10
<i>Pseudomonas aeruginosa</i> ATCC 15442		10	10	10	10	10	10	10	10	10
<i>Enterococcus hirae</i> ATCC 10541		10	10	10	10	10	10	10	10	10
Control		10	10	10	10	10	10	10	10	10

TEST ORGANISM		VALUES IN VOLUME % ETHANOL			VALUES IN VOLUME % ETHANOL			VALUES IN VOLUME % ETHANOL		
		0,01%	50%	80%	0,01%	50%	80%	0,01%	50%	80%
<i>Escherichia coli</i> ATCC 10536		10	10	10	10	10	10	10	10	10
<i>Staphylococcus aureus</i> ATCC 6538		10	10	10	10	10	10	10	10	10
<i>Pseudomonas aeruginosa</i> ATCC 15442		10	10	10	10	10	10	10	10	10
<i>Enterococcus hirae</i> ATCC 10541		10	10	10	10	10	10	10	10	10

TEST ORGANISM		VALUES IN VOLUME % ETHANOL			VALUES IN VOLUME % ETHANOL			VALUES IN VOLUME % ETHANOL		
		0,01%	50%	80%	0,01%	50%	80%	0,01%	50%	80%
<i>Escherichia coli</i> ATCC 10536		10	10	10	10	10	10	10	10	10
<i>Staphylococcus aureus</i> ATCC 6538		10	10	10	10	10	10	10	10	10
<i>Pseudomonas aeruginosa</i> ATCC 15442		10	10	10	10	10	10	10	10	10
<i>Enterococcus hirae</i> ATCC 10541		10	10	10	10	10	10	10	10	10

Date: 16.07.2020

Authorized by: Agnieszka Ertler, Cosmetics Microbiology Laboratory Manager

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

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