



CERTIFICAT
DE ÎNREGISTRARE DE STAT/AVIZARE SANITARĂ
AL PRODUSULUI BIOCID

Nr. 00047 data/luna/aniul 15.06.2020

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

Adresa juridică: str. Mesager, l. mun. Chișinău, Republica Moldova
Nr. de identificare de stat – codul fiscal 1002600033793

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

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” Soluție antibacteriană 70% Alcool Castravete

1. Date de identificare ale produsului:

1.1 Categoria de produs: biocid

- Grupa principală: I

- 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: lichid, ambalaj – 50ml, 200ml, 5000ml

1.4 Conținut în substanțe active: Etanol 70 %

1.5 Categori de utilizatori: Industrial, profesional, 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:

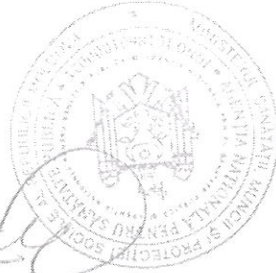
2.1 Firma: „Viorica –Cosmetic” S.A.

2.2 Adresa: str. Mesager, l. mun. Chișinău, Republica Moldova

Valabilitatea certificatului de înregistrare data/luna/aniul 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. 34 din 05.06.2020

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

Director



[Signature]

Nicolae FURTUNĂ



Ministerul Sănătății, Muncii și Protecției Sociale al Republicii Moldova
 Министерство Здравоохранения, Труда и Социальной Защиты Молдова
 Agenția Națională pentru Sănătate Publică
 Национальное Агентство Общественного Здравоохранения
 Centrul de Cercetări de Laborator (CLL)
 Национальный Лабораторный Центр
 Adresa Republica Moldova, 2028, mun. Chișinău, str. G. Asachi 67-A
 Юридический адрес: Печерьянка Молдова, 2028, гоп. Кишинев, ул. Георге Асаки 67-а
 Юридический адрес: Печерьянка Молдова, 2028, гоп. Кишинев, ул. Георге Асаки 67-а
 Tel. fax Телефон факс 57-45-01; 57-46-69; 57-45-05 Fax: 72-97-25;
 Accreditat în Sistemul Ministerului Sănătății, Muncii și Protecției Sociale a RM
 Аккредитованный в системе Министерства Здравоохранения, Труда и Социальной Защиты РМ
 №. 2293 din 24.10.2014 valabil pînă la 24.10.2019

RAPORT

a încercărilor de laborator

ОТЧЕТ ЛАБОРАТОРНЫХ ИСПЫТАНИЙ

№. 7145 din 15 11 2019

„VIORICA-COSMETIC” SA

1. Denumirea întreprinderii/organizației (beneficiar)
 Наименование предприятия/организации (заказчик)

2. Adresa juridică
 Юридический адрес
 Chișinău, str. Mesager, 1

3. Denumirea mostrei, data producerii
 Наименование образца (побыл), дата изготовления
 Gel antibacterian Cosmeplant

4. Producătorul (firma, organizația, instituția)
 Изготовитель (фирма, предприятие, организация)
 „VIORICA-COSMETIC” SA

5. Data și ora prelevării
 Время и дата отбора
 10 ora 00 min „11” 2019

6. Date suplimentare
 Дополнительные сведения
 N.P./funcția
 ф.И.О., должность
 Mostra a fost prelevată de beneficiar

Condițiile de transportare
 Условия доставки
 auto

7. D.N. la producție
 Издана продукция
 Livrat în LTA
 доставлен в ИЛТ
 11 ora 30 min „11” 2019

8. D.N. privind reglementarea volumului cercetărilor de laborator și apărerea lor
 НДЛ регламентирующие объем лабораторных исследований и их защиту
 HG nr.1207 din 02.11.2016

№ n/n	Parametrii cercetării	Rezultate cercetător, unități de măsură	Неопределенность измерения	Incetitudinea de măsurare	Nivelul maxim admisibil, unități de măsură	DN a metodelor de investigație
1	№ m/n	Результаты исследований	Единицы измерения	Неопределенность измерения	Величина допустимого уровня	НДЛ на методы исследования
2	Parametrii cercetării	Rezultate cercetător, unități de măsură	Неопределенность измерения	Incetitudinea de măsurare	Nivelul maxim admisibil, unități de măsură	DN a metodelor de investigație

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

1. Cercetările toxicologice: ТОКСИКОЛОГИЧЕСКИЕ ИССЛЕДОВАНИЯ:

Mostra a sosit
 Образец поступил
 12 ora
 min „11”
 11 2019

Codul
 Код
 7145.2.1.1.19

№ de înregistrare
 в реестре
 1206
 Nr. №.
 1206
 procesul – verbal
 протокол неформальный
 din 15.11.2019

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

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

St. Constantinovici, medic igienist

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

Amenđament:

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

*- Parametrii cercetați nu sunt incluși în Domeniul de acreditare CIL, aprobat MOLDAC
*- Определенные показатели не включены в Область аккредитации ИИЛ MOLDAC

Ф.И.О., должность

Numе, prenume, funcția Șef Direcție diagnostic de laborator în sănătate publică **AIA HALACU**

semnatura



FORMA NR. 1 DE ÎMBĂLĂCĂL
 Formă nr. 1
 Apud. de S.S.RM
 Valabilă din 2014
 Nr. 878 din 31.12.2014

RAPORT
al Încercărilor de Laborator
 ОТЧЕТ ЛАБОРАТОРНЫХ ИСПЫТАНИЙ
 Nr. 10809 din 19 06 2020

1. Denumirea întreprinderii, organizației (beneficiar) _____
 Наименование предприятия, организации (заказчик) _____
 codul 2728.3.1.1.2020
2. Adresa juridică _____
 Юридический адрес _____
3. Denumirea mostrei, data producerii Soluție antimicrobiană, 70% alcool Cășăveștii, seria K05mepilant
 Наименование образца (пробы), дата изготовления _____
 d. c. 2020, 500 ml, PET (ambalaj original)
4. Producătorul (firma, organizația, instituția) _____
 Изготовитель (фирма, предприятие, организация) _____
 țara Moldova
5. Data și ora prelevării _____
 Дата и время отбора _____
 țara _____ ora _____ min _____
 țara _____ ora _____ min _____
 țara _____ ora _____ min _____
6. Condițiile de transportare _____
 Условия доставки _____
7. Date suplimentare: proces-verbal de ordonare din 21.05.2020
 Дополнительные сведения _____
8. D.N. la producție: _____
 Д.Н. на производство _____
9. D.N. privind Reglementarea volumului cercetărilor de laborator și aprecierea lor _____
 Д.Н. относительно объема работ, сроков проведения и их оплаты _____

Cercetările microbiologice:

Municipiul Iași - Secțiunea

11.05.2020

Mostra a sosit ora min

25.05.19.06.2020

Mostra a investigat ora min

Nr. de înregistrare 87 în registre Nr. _____ în registre
 Percepământul Nr. _____ așezare
 Nr. _____ procesului - verbal
 (procedura reinstaurării)

Obiectul de cercetare și substanța activă	- Soluție antimicrobiană - substanța activă- alcool etilic 70%
Condiții de stocare	- Temperatură controlată
Concentrațiile restate a dezinfecțianților	- nediluat
Temp de contact de test	- 30 sec - 5 min
Microorganisme de testare:	- Pseudomonas aeruginosa ATCC 15442 - Staphylococcus aureus ATCC 6538 - Enterococcus hirae ATCC 10541 - Candida albicans ATCC 10231
Neutralizant:	- Soluție de Tween 80 (50g/l), lecitină (5g/l), fosfatul de sodiu (5g/l)
Diluant:	- Soluție de clorură de sodiu cu tiponit 0,1%
Substanța de referință (strain organic):	- Albamina de bovină (5g/l) (condiții de curățenie) - Mediu Agar tiponit soia (pentru bacterii) - Mediu Sabouraud agar cu dextransă (pentru drojii)
Mediile de cultură:	- (35±1) °C pentru bacterii - (30±1) °C pentru drojii
Temperaturi de incubare	- Metoda de control utilizată:
Documentul de referință:	SMI SR EN 13727+A1:2014 Antiseptic și dezinfectant chimice. Incercarea cantitativă a suspensiilor pentru evaluarea activității bactericide în domeniul medical. Metoda de încercare și cerințe (fază 2, etapă 1) SMI SR EN 13624:2014 Antiseptice și dezinfectante chimice. Incercarea cantitativă a suspensiilor pentru evaluarea activității fungicide sau levuricide în domeniul medical. Metoda de încercare și cerințe (fază 2, etapă 1)

Rezultatele de încercare

Microorganismul de testare: Staphylococcus aureus ATCC 6538

Validare și controale

Suspensie de validare (N _{VB})	V _{CI} = 116 x = 122		V _{CI} = 190 x = 180		Controlul condițiilor experimentale (A)	Controlul neutralizării (B)	Validarea modelului (C)	Concentrația produsului - mediu	v = 1,55
	V _{CD} = 127	V _{CD} = 169	V _{CD} = 156	V _{CD} = 165					
Suspensia de validare (N _{VB})	D _A Nu		D _A Nu		180 ≥ 61 (0,5x N _{VB}) ?	163 ≥ 61 (0,5x N _{VB}) ?	155 ≥ 61 (0,5x N _{VB}) ?	D _A Nu	
	V _{CI} = 139		V _{CI} = 107		30 ≤ 23 (N _{VB} / 100) ≤ 160 ?	30 ≤ 23 (N _{VB} / 100) ≤ 160 ?	30 ≤ 23 (N _{VB} / 100) ≤ 160 ?	D _A Nu	

Suspensia de încercare și încercarea

Suspensia de încercare (N și N ₀)	N		V _{CI}		V _{CD}		N = 212 x 10 ⁷ ± 9,33	V _{CI}	V _{CD}
	10 ⁷	10 ⁸	214	213	18	22			
	10 ⁷	10 ⁸	214	213	18	22	7,17 ≤ 9,33 ≤ 9,73	N ₀ = 8,100 ± 2,2 x 10 ⁷ ± 7,32	D _A Nu
	10 ⁷	10 ⁸	214	213	18	22	7,17 ≤ 9,33 ≤ 9,73	N ₀ = 8,100 ± 2,2 x 10 ⁷ ± 7,32	D _A Nu

Microorganismul de testare: Pseudomonas aeruginosa ATCC 15443

Validare și controale

Suspensie de validare (N _{VB})	V _{CI} = 207 x = 206		V _{CI} = 225 x = 216		Controlul condițiilor experimentale (A)	Controlul neutralizării (B)	Validarea modelului (C)	Concentrația produsului - mediu	v = 1,78
	V _{CD} = 204	V _{CD} = 206	V _{CD} = 230	V _{CD} = 245					
Suspensia de validare (N _{VB})	D _A Nu		D _A Nu		216 ≥ 103 (0,5x N _{VB}) ?	238 ≥ 103 (0,5x N _{VB}) ?	178 ≥ 103 (0,5x N _{VB}) ?	D _A Nu	
	V _{CI} = 97		V _{CI} = 94		30 ≤ 96 (N _{VB} / 100) ≤ 160 ?	30 ≤ 96 (N _{VB} / 100) ≤ 160 ?	30 ≤ 96 (N _{VB} / 100) ≤ 160 ?	D _A Nu	

Suspensia de încercare și încercarea

Suspensia de încercare (N și N ₀)	N		V _{CI}		V _{CD}		N = 222 x 10 ⁷ ± 9,33	V _{CI}	V _{CD}
	10 ⁷	10 ⁸	257	213	7	12			
	10 ⁷	10 ⁸	257	213	7	12	9,17 ≤ 9,33 ≤ 9,70 ?	N ₀ = 8,100 ± 2,2 x 10 ⁷ ± 7,35	D _A Nu
	10 ⁷	10 ⁸	257	213	7	12	9,17 ≤ 9,33 ≤ 9,70 ?	N ₀ = 8,100 ± 2,2 x 10 ⁷ ± 7,35	D _A Nu

Validare și control

Microorganismul de testare: Enterococcus hirae ATCC 16541

Suspensie de validare (N ₉₀)		Controlul condițiilor experimentale (A)		Controlul neutralității (B)		Validarea metodei (C)	
V _{C1}	97	V _{C1}	315	V _{C1}	508	V _{C1}	354
V _{C2}	108	V _{C2}	352	V _{C2}	318	V _{C2}	344
D _a	Nu	D _a	Nu	D _a	Nu	D _a	Nu
30 ≤ 103 (N _v /100) ≤ 160 ?	302 ± 52 (0,5x N _{v0}) ?	313 ± 52 (0,5x N _{v0}) ?	349 ± 52 (0,5x N _{v0}) ?	104	104	30 ≤ 104 (N _v /1000) ≤ 160 ?	30 ≤ 104 (N _v /1000) ≤ 160 ?
Suspensia de validare (N ₉₀)		Suspensia de încercare (N și N ₀)		Suspensia de încercare (N și N ₀)		Suspensia de încercare (N și N ₀)	
V _{C1} =105 V _{C2} =101		N = 188 × 10 = lg 9,27 N ₀ = N/100 = 1,88 × 10 ² = lg 7,27		N = 188 × 10 = lg 9,27 N ₀ = N/100 = 1,88 × 10 ² = lg 7,27		N = 188 × 10 = lg 9,27 N ₀ = N/100 = 1,88 × 10 ² = lg 7,27	

Validare și control

Microorganismul de testare: Candida albicans ATCC 10231

Suspensie de validare (N ₉₀)		Controlul condițiilor experimentale (A)		Controlul neutralității (B)		Validarea metodei (C)	
V _{C1}	92	V _{C1}	124	V _{C1}	116	V _{C1}	81
V _{C2}	83	V _{C2}	136	V _{C2}	117	V _{C2}	84
D _a	Nu	D _a	Nu	D _a	Nu	D _a	Nu
30 ≤ 89 (N _v /100) ≤ 160 ?	125 ± 63 (0,5x N _{v0}) ?	117 ± 43 (0,5x N _{v0}) ?	83 ± 45 (0,5x N _{v0}) ?	104	104	30 ≤ 104 (N _v /1000) ≤ 160 ?	30 ≤ 104 (N _v /1000) ≤ 160 ?
Suspensia de validare (N ₉₀)		Suspensia de încercare (N și N ₀)		Suspensia de încercare (N și N ₀)		Suspensia de încercare (N și N ₀)	
V _{C1} =103 V _{C2} =101		N = 191 × 10 = lg 8,28 N ₀ = N/100 = 1,91 × 10 ² = lg 6,28		N = 191 × 10 = lg 8,28 N ₀ = N/100 = 1,91 × 10 ² = lg 6,28		N = 191 × 10 = lg 8,28 N ₀ = N/100 = 1,91 × 10 ² = lg 6,28	

Validare și control

Microorganismul de testare: Candida albicans ATCC 10231

Suspensie de validare (N ₉₀)		Controlul condițiilor experimentale (A)		Controlul neutralității (B)		Validarea metodei (C)	
V _{C1}	92	V _{C1}	124	V _{C1}	116	V _{C1}	81
V _{C2}	83	V _{C2}	136	V _{C2}	117	V _{C2}	84
D _a	Nu	D _a	Nu	D _a	Nu	D _a	Nu
30 ≤ 89 (N _v /100) ≤ 160 ?	125 ± 63 (0,5x N _{v0}) ?	117 ± 43 (0,5x N _{v0}) ?	83 ± 45 (0,5x N _{v0}) ?	104	104	30 ≤ 104 (N _v /1000) ≤ 160 ?	30 ≤ 104 (N _v /1000) ≤ 160 ?
Suspensia de validare (N ₉₀)		Suspensia de încercare (N și N ₀)		Suspensia de încercare (N și N ₀)		Suspensia de încercare (N și N ₀)	
V _{C1} =103 V _{C2} =101		N = 191 × 10 = lg 8,28 N ₀ = N/100 = 1,91 × 10 ² = lg 6,28		N = 191 × 10 = lg 8,28 N ₀ = N/100 = 1,91 × 10 ² = lg 6,28		N = 191 × 10 = lg 8,28 N ₀ = N/100 = 1,91 × 10 ² = lg 6,28	

Explicatii:
Vc - numar pe ml (o placă sau mai multe)
x - media lui Vc1 și Vc2
R - reducția (lgR) = lgN0 - lgNa

Concluzie: Soluție antibacteriană pe baza de alcool etilic 70% posedă o reducere a microorganismelor de referință *E. aeruginosa*, *E. hinc* și *S. aureus* mai mare de lg 5 și a microorganismului de referință *C. albicans* mai mare de lg 4.
Conform SM SR EN 13727+A1:2014 și SM SR EN 13624:2014 Soluție antibacteriană pe baza de alcool etilic 70% a demonstrat o acțiune bactericidă și levuricidă pentru dezinfectarea igienică a mâinilor și suprafețelor în condiții de curățenie și timp de contact 30 secunde și 5 minute.

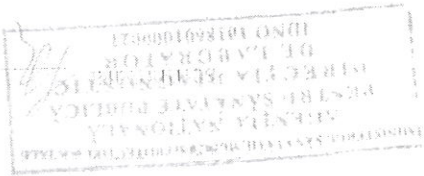
Concluzie:

N.P., funcția persoanei responsabile de formarea raportului
Ф.И.О. должностное лицо ответственного за оформление отчета

Medic-microbiolog - *Svetlana Prudnicova*

Șef de laborator microbiologie sanitară - *Svetlana Prudnicova*
Ф.И.О. и название учреждения

Șef direcției diagnostice de laborator - *Ala Halca*
Ф.И.О. учреждения



Amendament: Rezultatul se referă numai la proba analizată. Este strict interzis reproducerea parțială a rezultatului.
Примечание: Результат распространяется только на анализированную пробу. Запрещается воспроизведение результатов.

REPORT OF ANALYSIS NO. 264544/20/JSHR



Client	VIORICA COSMETIC SA 1 MESAGER MD-2069 CHISINAU		
Sample received:	2020-06-05	Report dated:	2020-07-07
Analysis completed:	2020-07-07	Order of 2020-06-04	The samples were delivered by Client
Sample description (according to declaration of Client)	Solutie dezinfectanta pentru maini PRODIZ 1.1. 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		

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, Gozdzikow 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 IAC-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



A) IDENTIFICATION OF THE SAMPLE:	
Name of the product	Solutie dezinfectanta pentru maini PRODIZ Lot: 29.05.2020 Data fabricatiei: 29.05.2020 Cantitatea: 1000 ml Data expirarii: 29.05.2023 Data prelevarii: 02.06.2020
The active substance	Ethanol, CAS: 64-17-5, 80 m/m%
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: 07.07.2020

 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 prior written consent of J.S. Hamilton Poland Sp. z o.o.
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ENCLOSURE NO. 1 TO REPORT OF ANALYSIS NO. 264544/20/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: 2.2×10^8 cfu/g

Nr	Hand	prevalences			log x	log y	log z
		$\times 10^4$	$\times 10^5$	$\times 10^6$			
Reduction	volunteer	number of cfu per plate from dilution 10x			log x	log y	log z
		$\times 10^2$	$\times 10^1$	$\times 10^0$			
1	1	175	19	96	6,22	1,95	4,27
2	1	145	18	102	6,19	2,06	4,13
2	1	159	21	133	6,30	1,89	4,41
3	1	182	22	81	6,30	1,89	4,41
3	1	210	23	77	6,30	1,89	4,41
4	1	223	25	65	6,37	1,65	4,73
4	1	245	26	32	6,37	1,65	4,73
5	1	197	21	28	6,31	1,56	4,76
5	1	218	18	47	6,31	1,56	4,76
6	1	174	16	69	6,21	1,86	4,35
6	1	158	12	75	6,21	1,86	4,35
7	1	164	15	83	6,20	1,82	4,37
7	1	152	14	56	6,20	1,82	4,37
8	1	156	13	52	6,24	1,77	4,47
8	1	192	23	66	6,24	1,77	4,47
9	1	174	18	73	6,20	1,91	4,29
9	1	144	13	94	6,20	1,91	4,29
10	1	152	17	103	6,16	1,96	4,20
10	1	139	11	81	6,16	1,96	4,20
11	1	248	26	45	6,40	1,82	4,58
11	1	251	22	96	6,40	1,82	4,58
12	1	213	23	30	6,35	1,45	4,91
12	1	237	25	27	6,35	1,45	4,91
13	1	185	21	45	6,30	1,58	4,72
13	1	216	23	31	6,30	1,58	4,72
14	1	172	18	72	6,23	1,75	4,48
14	1	166	14	42	6,23	1,75	4,48
15	1	142	13	67	6,17	1,77	4,40
15	1	155	16	55	6,17	1,77	4,40
16	1	254	26	46	6,39	1,58	4,81
16	1	233	24	32	6,39	1,58	4,81
17	1	221	22	41	6,34	1,47	4,87
17	1	219	23	20	6,34	1,47	4,87
18	1	167	18	34	6,20	1,47	4,74
18	1	154	13	26	6,20	1,47	4,74
19	1	238	25	71	6,36	1,80	4,56
19	1	222	20	54	6,36	1,80	4,56
20	1	247	28	66	6,41	1,87	4,53
20	1	259	31	88	6,41	1,87	4,53
Xavg	s	6,28	0,08			1,75	4,53
						0,18	0,23

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: 07.07.2020

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ENCLOSURE NO. 1 TO REPORT OF ANALYSIS NO. 264544/20/JSHR

Table 2. HYGIENIC HANDRUB PROCEDURE WITH THE PRODUCT

PRODUCT P
 TEST ORGANISM: *E. coli* K12 NCTC 10538
 NUMBER IN CONTAMINATION FLUID: $2,2 \times 10^8$ cfu/g

volunteer	number of cfu per plate from dilution 10x				Reduction
	Hand	prevalues	postvalues		
Nr	left/right	$\times 10^{-4}$	$\times 10^{-5}$	$\log x$	$\times 10^{-1}$
					$\log y$
1	r	162	15	6,19	39
	l	149	17	54	5
2	r	110	13	6,11	71
	l	149	18	56	8
3	r	205	21	6,34	93
	l	228	25	48	4
4	r	168	14	6,30	73
	l	241	26	56	5
5	r	291	24	6,43	65
	l	256	28	61	5
6	r	119	12	6,17	48
	l	183	15	76	8
7	r	132	14	6,23	68
	l	221	23	92	7
8	r	128	14	6,16	55
	l	162	18	49	4
9	r	241	22	6,36	58
	l	223	24	58	8
10	r	148	11	6,20	45
	l	169	18	36	5
11	r	217	20	6,35	81
	l	233	23	76	5
12	r	254	28	6,37	98
	l	215	23	92	8
13	r	187	21	6,26	44
	l	177	20	57	6
14	r	199	15	6,26	63
	l	165	18	63	5
15	r	235	17	6,37	47
	l	245	23	28	2
16	r	187	18	6,31	33
	l	217	24	50	5
17	r	154	14	6,19	75
	l	156	16	68	8
18	r	133	14	6,14	48
	l	146	13	39	4
19	r	169	18	6,22	56
	l	158	17	28	2
20	r	177	16	6,21	71
	l	151	14	49	5
X _{avg}		6,26		0,09	
s		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: 07.07.2020

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 Table 3. LIST OF COMPUTED I_G VALUES AND I_G REDUCTIONS

	volunteer	R 2-propanol 60% (V/V)	P
Nr			
1 R-P	6,22	1,95	4,27
2 R-P	6,19	2,06	4,13
3 R-P	6,30	1,89	4,41
4 R-P	6,37	1,65	4,73
5 R-P	6,31	1,56	4,76
6 R-P	6,21	1,86	4,35
7 R-P	6,20	1,82	4,37
8 R-P	6,24	1,77	4,47
9 R-P	6,20	1,91	4,29
10 R-P	6,16	1,96	4,20
11 R-P	6,40	1,82	4,58
12 R-P	6,35	1,45	4,91
13 R-P	6,30	1,58	4,72
14 R-P	6,23	1,75	4,48
15 R-P	6,17	1,77	4,40
16 R-P	6,39	1,58	4,81
17 R-P	6,34	1,47	4,87
18 R-P	6,20	1,47	4,74
19 R-P	6,36	1,80	4,56
20 R-P	6,41	1,87	4,53
X ²⁰	6,28	1,75	4,53
X10(R-P)	6,28	1,75	4,54
X10 (P-R)	6,27	1,75	4,52
log z		log x	log y
1 R-P	6,22	1,95	4,27
2 R-P	6,19	2,06	4,13
3 R-P	6,30	1,89	4,41
4 R-P	6,37	1,65	4,73
5 R-P	6,31	1,56	4,76
6 R-P	6,21	1,86	4,35
7 R-P	6,20	1,82	4,37
8 R-P	6,24	1,77	4,47
9 R-P	6,20	1,91	4,29
10 R-P	6,16	1,96	4,20
11 R-P	6,40	1,82	4,58
12 R-P	6,35	1,45	4,91
13 R-P	6,30	1,58	4,72
14 R-P	6,23	1,75	4,48
15 R-P	6,17	1,77	4,40
16 R-P	6,39	1,58	4,81
17 R-P	6,34	1,47	4,87
18 R-P	6,20	1,47	4,74
19 R-P	6,36	1,80	4,56
20 R-P	6,41	1,87	4,53
X ²⁰	6,28	1,75	4,53
X10(R-P)	6,28	1,75	4,54
X10 (P-R)	6,27	1,75	4,52
log z		log x	log y
1 R-P	6,22	1,95	4,27
2 R-P	6,19	2,06	4,13
3 R-P	6,30	1,89	4,41
4 R-P	6,37	1,65	4,73
5 R-P	6,31	1,56	4,76
6 R-P	6,21	1,86	4,35
7 R-P	6,20	1,82	4,37
8 R-P	6,24	1,77	4,47
9 R-P	6,20	1,91	4,29
10 R-P	6,16	1,96	4,20
11 R-P	6,40	1,82	4,58
12 R-P	6,35	1,45	4,91
13 R-P	6,30	1,58	4,72
14 R-P	6,23	1,75	4,48
15 R-P	6,17	1,77	4,40
16 R-P	6,39	1,58	4,81
17 R-P	6,34	1,47	4,87
18 R-P	6,20	1,47	4,74
19 R-P	6,36	1,80	4,56
20 R-P	6,41	1,87	4,53
X ²⁰	6,28	1,75	4,53
X10(R-P)	6,28	1,75	4,54
X10 (P-R)	6,27	1,75	4,52
log z		log x	log y
1 R-P	6,22	1,95	4,27
2 R-P	6,19	2,06	4,13
3 R-P	6,30	1,89	4,41
4 R-P	6,37	1,65	4,73
5 R-P	6,31	1,56	4,76
6 R-P	6,21	1,86	4,35
7 R-P	6,20	1,82	4,37
8 R-P	6,24	1,77	4,47
9 R-P	6,20	1,91	4,29
10 R-P	6,16	1,96	4,20
11 R-P	6,40	1,82	4,58
12 R-P	6,35	1,45	4,91
13 R-P	6,30	1,58	4,72
14 R-P	6,23	1,75	4,48
15 R-P	6,17	1,77	4,40
16 R-P	6,39	1,58	4,81
17 R-P	6,34	1,47	4,87
18 R-P	6,20	1,47	4,74
19 R-P	6,36	1,80	4,56
20 R-P	6,41	1,87	4,53
X ²⁰	6,28	1,75	4,53
X10(R-P)	6,28	1,75	4,54
X10 (P-R)	6,27	1,75	4,52
log z		log x	log y
1 R-P	6,22	1,95	4,27
2 R-P	6,19	2,06	4,13
3 R-P	6,30	1,89	4,41
4 R-P	6,37	1,65	4,73
5 R-P	6,31	1,56	4,76
6 R-P	6,21	1,86	4,35
7 R-P	6,20	1,82	4,37
8 R-P	6,24	1,77	4,47
9 R-P	6,20	1,91	4,29
10 R-P	6,16	1,96	4,20
11 R-P	6,40	1,82	4,58
12 R-P	6,35	1,45	4,91
13 R-P	6,30	1,58	4,72
14 R-P	6,23	1,75	4,48
15 R-P	6,17	1,77	4,40
16 R-P	6,39	1,58	4,81
17 R-P	6,34	1,47	4,87
18 R-P	6,20	1,47	4,74
19 R-P	6,36	1,80	4,56
20 R-P	6,41	1,87	4,53
X ²⁰	6,28	1,75	4,53
X10(R-P)	6,28	1,75	4,54
X10 (P-R)	6,27	1,75	4,52
log z		log x	log y
1 R-P	6,22	1,95	4,27
2 R-P	6,19	2,06	4,13
3 R-P	6,30	1,89	4,41
4 R-P	6,37	1,65	4,73
5 R-P	6,31	1,56	4,76
6 R-P	6,21	1,86	4,35
7 R-P	6,20	1,82	4,37
8 R-P	6,24	1,77	4,47
9 R-P	6,20	1,91	4,29
10 R-P	6,16	1,96	4,20
11 R-P	6,40	1,82	4,58
12 R-P	6,35	1,45	4,91
13 R-P	6,30	1,58	4,72
14 R-P	6,23	1,75	4,48
15 R-P	6,17	1,77	4,40
16 R-P	6,39	1,58	4,81
17 R-P	6,34	1,47	4,87
18 R-P	6,20	1,47	4,74
19 R-P	6,36	1,80	4,56
20 R-P	6,41	1,87	4,53
X ²⁰	6,28	1,75	4,53
X10(R-P)	6,28	1,75	4,54
X10 (P-R)	6,27	1,75	4,52
log z		log x	log y
1 R-P	6,22	1,95	4,27
2 R-P	6,19	2,06	4,13
3 R-P	6,30	1,89	4,41
4 R-P	6,37	1,65	4,73
5 R-P	6,31	1,56	4,76
6 R-P	6,21	1,86	4,35
7 R-P	6,20	1,82	4,37
8 R-P	6,24	1,77	4,47
9 R-P	6,20	1,91	4,29
10 R-P	6,16	1,96	4,20
11 R-P	6,40	1,82	4,58
12 R-P	6,35	1,45	4,91
13 R-P	6,30	1,58	4,72
14 R-P	6,23	1,75	4,48
15 R-P	6,17	1,77	4,40
16 R-P	6,39	1,58	4,81
17 R-P	6,34	1,47	4,87
18 R-P	6,20	1,47	4,74
19 R-P	6,36	1,80	4,56
20 R-P	6,41	1,87	4,53
X ²⁰	6,28	1,75	4,53
X10(R-P)	6,28	1,75	4,54
X10 (P-R)	6,27	1,75	4,52

Criteria:
 $R_s (R-P) = 4,54 - 4,52 = 0,02$
 $R_s (P-R) = 4,52 - 4,52 = 0$
 $Abs = 0,02 < 2$
 $\log(x(R)) = 6,28 > 5$
 $\log(x(P)) = 6,26 > 5$
 $\log z (P), \log z (R) > 3$

Validation conditions of neutralizer and methods have been satisfied

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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
18	47	40
19	53	46
20	60	52
21	68	59
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 0,14 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: 07.07.2020

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REPORT OF ANALYSIS NO. 267768/20/JSHR



Client	VIOERICA COSMETIC SA		
	1 MESAGER		
	MD-2069 CHISINAU		
Report dated:	2020-07-06	Sample received: 2020-06-08	
Analysis completed:	2020-07-06	Sample received: 2020-06-08	
Order of 2020-06-06	The samples were delivered by Client		
Sample description (according to declaration of Client)	Soluție dezinfectantă pentru mâini! COSMEPLANT cu extract natural de Castravete 7.1. Tip proba/lot 29.05.2020 Data fabricației! 29.05.2020 Cantitatea 1000 ml Data expirării! 29.05.2023 Data prelevării! 02.06.2020 Sample without any visible damages		

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

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 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



A) IDENTIFICATION OF THE SAMPLE:	
Name of the product	Soluție dezinfectantă pentru mâini COSMEPLANT cu extract natural de Castravete Tip proba/lot: 29.05.2020 Data fabricației: 29.05.2020 Cantitatea: 1000 ml Data expirării: 29.05.2023 Data prelevării: 02.06.2020
The active substance	Ethanol CAS: 64-17-5, 70%
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: 06.07.2020

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ENCLOSURE NO. 1 TO REPORT OF ANALYSIS NO. 267768/20/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: $2,7 \times 10^8$ ctu/g

volunteer	Hand		prevalues		postvalues		Reduction
	left/right	$\times 10^{-4}$	$\times 10^{-5}$	log x	$\times 10^{-1}$	$\times 10^{-2}$	
1	r	152	16	6,24	61	7	4,39
2	l	180	15	6,22	74	8	4,42
2	l	156	13	6,22	55	4	4,42
3	r	174	15	6,14	49	5	4,39
3	l	198	21	6,17	53	6	4,39
4	r	110	10	6,17	29	3	4,57
4	l	136	14	6,10	47	5	4,57
5	r	118	12	6,10	72	8	4,34
5	l	112	13	6,04	95	10	4,34
6	r	104	11	6,04	84	9	4,08
6	l	136	14	6,18	69	7	4,34
7	r	168	17	6,18	73	5	4,34
7	l	88	10	5,98	46	4	4,34
8	l	100	12	5,98	28	3	4,43
8	r	126	13	5,98	66	7	4,43
9	r	72	8	5,98	41	5	4,26
9	l	88	10	6,06	20	3	4,26
10	r	146	16	6,06	16	1	4,80
10	l	88	10	5,91	70	7	4,09
11	r	88	10	5,91	65	5	4,09
11	l	74	8	6,27	55	6	4,59
12	r	180	20	6,27	55	6	4,59
12	l	60	8	5,86	69	8	4,00
13	r	84	10	5,86	78	5	4,00
13	l	192	21	6,24	85	7	4,44
14	r	151	18	6,24	46	5	4,44
14	l	104	12	5,95	44	5	4,40
15	r	72	10	5,95	28	3	4,40
15	l	184	20	6,34	35	4	4,72
16	r	252	27	6,34	49	5	4,72
16	l	108	11	6,06	51	6	4,43
17	r	120	13	6,06	35	3	4,43
17	l	144	15	6,20	44	4	4,61
18	r	174	18	6,20	37	2	4,61
18	l	232	24	6,30	78	8	4,46
19	r	168	17	6,30	62	5	4,46
19	l	248	26	6,22	65	4	4,64
20	r	112	12	6,22	23	3	4,64
	Xavg	6,12		0,14			4,42
	S						0,21

log x-logarithm of the average value of the initial left and right hand
 log y-logarithm of the average value of the final left and right hand
 log z-logarithm reduction
 x 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. 267768/20/JSHR

Table 2. HYGIENIC HANDRUB PROCEDURE WITH THE PRODUCT

 PRODUCT P
 TEST ORGANISM: *E. coli* K12 NCTC 10538
 NUMBER IN CONTAMINATION FLUID: 2.7×10^8 cfu/g

volunteer	number of cfu per plate from dilution 10x				Reduction
	Hand	left/right	$\times 10^{-1}$	$\times 10^{-2}$	
1	188	139	14	0	0
2	164	104	11	0	0
3	160	155	16	0	0
4	184	152	16	0	0
5	136	100	11	0	0
6	132	101	10	0	0
7	105	139	15	0	0
8	154	176	16	0	0
9	136	152	14	0	0
10	196	152	21	0	0
11	213	177	23	0	0
12	182	196	22	0	0
13	235	220	21	0	0
14	146	130	15	0	0
15	215	244	23	0	0
16	258	265	28	0	0
17	145	187	16	0	0
18	159	125	13	0	0
19	146	112	15	0	0
20	169	150	18	0	0
\bar{X}_{avg}	6,20	6,20	13	0	0
s	0,10	0,13	0,17	0,13	0,17

log x-logarithm of the average value of the initial left and right hand
 log y-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

Nr	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	1,86	4,39	6,21	1,72	4,49
2 R-P	6,22	1,80	4,42	6,12	1,61	4,51
3 R-P	6,14	1,75	4,39	6,20	1,92	4,28
4 R-P	6,17	1,60	4,57	6,23	1,78	4,44
5 R-P	6,10	1,77	4,34	6,07	1,72	4,35
6 R-P	6,04	1,95	4,08	6,06	1,59	4,47
7 R-P	6,18	1,85	4,34	6,08	1,72	4,36
8 R-P	5,98	1,55	4,43	6,21	1,78	4,43
9 R-P	5,98	1,72	4,26	6,16	1,90	4,26
10 R-P	6,06	1,25	4,80	6,24	1,66	4,57
11 R-P	5,91	1,82	4,09	6,29	1,51	4,78
12 R-P	6,27	1,69	4,59	6,28	1,69	4,58
13 R-P	5,86	1,86	4,00	6,35	1,84	4,51
14 R-P	6,24	1,79	4,44	6,14	1,69	4,44
15 R-P	5,95	1,55	4,40	6,36	1,44	4,92
16 R-P	6,34	1,62	4,72	6,42	1,81	4,61
17 R-P	6,06	1,63	4,43	6,22	1,89	4,33
18 R-P	6,20	1,59	4,61	6,15	1,83	4,32
19 R-P	6,30	1,84	4,46	6,11	1,58	4,53
20 P-R	6,22	1,59	4,64	6,20	1,56	4,65
X ²⁰	6,12	1,70	4,42	6,20	1,71	4,49
X10(R-P)	6,11	1,75	4,36	6,22	1,69	4,53
X10 (P-R)	6,14	1,66	4,48	6,19	1,73	4,45

Criteria:

Rs (R-P) = 4,36 - 4,53 = - 0,17
 Rs (P-R) = 4,48 - 4,45 = 0,03
 Abs = - 0,17 - 0,03 = - 0,20 < 2
 logx(R) = 6,12 > 5
 logx(P) = 6,20 > 5
 logz (P), logz (R) > 3

Validation conditions of neutralizer and methods have been satisfied

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

volunteer	log RF		P	R-P	high to low difference	Range +/-
	R	P				
1	4,39	4,49	-0,10	0,28		
2	4,42	4,51	-0,09	0,23		
3	4,39	4,28	0,11	0,13		
4	4,57	4,44	0,13	0,11		
5	4,34	4,35	-0,01	0,10		
6	4,08	4,47	-0,39	0,10		
7	4,34	4,36	-0,03	0,00		
8	4,43	4,43	-0,01	0,00		
9	4,26	4,26	0,00	0,00		
10	4,80	4,57	0,23	-0,01		
11	4,09	4,78	-0,69	-0,01		
12	4,59	4,58	0,00	-0,01		
13	4,00	4,51	-0,51	-0,03		
14	4,44	4,44	0,00	-0,08		
15	4,40	4,92	-0,52	-0,09		
16	4,72	4,61	0,10	-0,10		
17	4,43	4,33	0,10	-0,39		
18	4,61	4,32	0,28	-0,51		
19	4,46	4,53	-0,08	-0,52		
20	4,64	4,65	-0,01	-0,69		
	sum range (+): 45			sum range (-): 165		

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

1	0,28	0,26	0,23	0,13	0,11	0,10	0,10	0,00	0,00
2	0,23	0,18	0,13	0,12	0,11	0,10	0,05	0,00	0,00
3	0,13	0,18	0,13	0,12	0,11	0,10	0,05	0,00	0,00
4	0,11	0,20	0,17	0,12	0,11	0,10	0,05	0,00	0,00
5	0,10	0,19	0,17	0,12	0,11	0,10	0,05	0,00	0,00
6	0,10	0,19	0,17	0,12	0,11	0,10	0,05	0,00	0,00
7	0,00	0,14	0,12	0,07	0,06	0,05	0,05	0,00	0,00
8	0,00	0,14	0,12	0,07	0,06	0,05	0,05	0,00	0,00
9	0,00	0,14	0,12	0,07	0,06	0,05	0,05	0,00	0,00
10	-0,01	0,14	0,11	0,06	0,05	0,05	0,05	0,00	0,00
11	-0,01	0,14	0,11	0,06	0,05	0,05	0,05	0,00	0,00
12	-0,01	0,14	0,11	0,06	0,05	0,05	0,05	0,00	0,00
13	-0,03	0,13	0,10	0,05	0,04	0,04	0,04	0,01	0,01
14	-0,08	0,10	0,08	0,03	0,02	0,02	0,01	0,01	0,01
15	-0,09	0,10	0,07	0,02	0,01	0,01	0,01	0,01	0,01
16	-0,10	0,09	0,07	0,02	0,01	0,01	0,01	0,01	0,01
17	-0,39	-0,06	-0,08	-0,13					
18	-0,51	-0,12	-0,14						
19	-0,52								
20	-0,69								

Date: 06.07.2020

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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
18	47	40
19	53	46
20	60	52
21	68	59
22	75	66

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 0,05 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.

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REPORT OF ANALYSIS NO. 267769/20/JSHR



Client	VIORICA COSMETIC SA
	1 MESAGER
	MD-2069 CHISINAU
Sample received:	2020-06-08
Analysis completed:	2020-07-19
Report dated:	2020-07-19
Sample description (according to declaration of Client)	Soluție dezinfectantă pentru mâini! COSMEPLANT cu extract natural de Castravete 7.2. Tip proba/lot 29.05.2020 Data fabricației! 29.05.2020 Cantitatea 1000 ml Data expirării! 29.05.2023 Data prelevării! 02.06.2020 Sample without any visible damages
Order of 2020-06-06	The samples were delivered by Client

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 80% shows bactericidal activity at 60 second, 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.

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

THE END OF THE REPORT

Authorized by: Agnieszka Eber, Cosmetics Microbiology Laboratory Manager
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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



A) IDENTIFICATION OF THE SAMPLE	
Soluție dezinfectantă pentru mâini COSMEPLANT cu extract natural de Castravete Tip proba/lot: 29.05.2020 Data fabricației: 29.05.2020 Cantitatea: 1000 ml Data expirării: 29.05.2023 Data prelevării: 02.06.2020	Name of the product
Ethanol CAS: 64-17-5, 70%	Active substance
B) TEST METHOD AND ITS VALIDATION	
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)	Method
Polisorbate 80- 30 g/l, saponine- 3 g/l, cysteine- 1g/l, histidine- 1g/l, sodium thiosulfate 7,5g/l	Neutralizer
C) EXPERIMENTAL CONDITIONS	
0,01%, 50%, 80%	Product test concentrations (%V/V)
20°C	Test temperature
60 seconds	Contact time
Clean conditions: 0,3g/l bovine albumin	Interfering substance
Sterile hard water	Product diluent
37±1°C	Temperature of incubation
<i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Escherichia coli</i> ATCC 10536 <i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541	Identification of the bacterial and fungal strains used:

Date: 19.07.2020

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ENCLOSURE NO. 1 TO REPORT OF ANALYSIS NO. 267769/20/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 SUSPENSION			VALIDATION A		
	VC1	VC2	Nv	N ₆₀	VC1	VC2
<i>Escherichia coli</i> ATCC 10536	121	124	1225	123	114	116
<i>Staphylococcus aureus</i> ATCC 6538	134	131	1325	133	121	120
<i>Pseudomonas aeruginosa</i> ATCC 15442	126	131	1285	129	116	110
<i>Enterococcus hirae</i> ATCC 10541	112	111	1115	112	96	94
criteria	300 ≤ Nv ≤ 1600			A ≥ 0.5N ₆₀ acceptable		
				B ≥ 0.5N ₆₀ acceptable		
				C ≥ 0.5N ₆₀ acceptable		

TEST ORGANISM	TEST SUSPENSION					
	N	VC1	VC2	Na	lg Na	lg R
<i>Escherichia coli</i> ATCC 10536	206	204	21	20	2.1E+08	8.31
<i>Staphylococcus aureus</i> ATCC 6538	231	236	23	24	2.3E+08	8.37
<i>Pseudomonas aeruginosa</i> ATCC 15442	251	256	25	26	2.5E+08	8.40
<i>Enterococcus hirae</i> ATCC 10541	233	231	24	23	2.3E+08	8.37
criteria	1.5*10 ⁸ ≤ N ≤ 5*10 ⁸			8.17 ≤ logN ≤ 8.70		
				1.5*10 ⁷ ≤ N ₆₀ ≤ 5*10 ⁷		
				7.17 ≤ logN ₆₀ ≤ 7.70		

TEST ORGANISM	0.01%											
	N	VC1	VC2	Na	lg Na	lg R	VC1	VC2	Na	lg Na	lg R	VC1
<i>Escherichia coli</i> ATCC 10536	2.1E+08	>330	>330	>3300	>3.52	<3.79	>330	>330	>3300	>3.52	<3.79	0
<i>Staphylococcus aureus</i> ATCC 6538	2.3E+08	>330	>330	>3300	>3.52	<3.85	0	<140	>3300	>3.52	<3.79	0
<i>Pseudomonas aeruginosa</i> ATCC 15442	2.5E+08	>330	>330	>3300	>3.52	<3.88	>330	>330	>3300	>3.52	<3.88	0
<i>Enterococcus hirae</i> ATCC 10541	2.3E+08	>330	>330	>3300	>3.52	<3.85	0	<140	>3300	>3.52	<3.88	0
criteria	lg R ≥ 5											

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REPORT OF ANALYSIS NO. 267770/20/JSHR

Client	VIORICA COSMETIC SA	MD-2069 CHISINAU
Sample received:	2020-06-08	
Analysis completed:	2020-07-19	
Report dated:	2020-07-19	
Sample description (according to declaration of Client)	Soluție dezinfectantă pentru mâini COSMPLANT cu extract natural de Castravete 7.2. Tip proba/lot 29.05.2020 Data fabricației 29.05.2020 Cantitatea 1000 ml Data expirării 29.05.2023 Data prelevării 02.06.2020 Sample without any visible damages	
Order of 2020-06-06	The samples were delivered by Client	

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: <i>Candida albicans</i> ATCC 10231, <i>Aspergillus brasiliensis</i> ATCC 16404.

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: Tychy 43-100, Gozdziów 1

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* Test method accredited: # Test performed by external provider



A) IDENTIFICATION OF THE SAMPLE	
Name of the product	natural de Castravete Tip proba/lot: 29.05.2020 Data fabricației: 29.05.2020 Cantitatea: 1000 ml Data expirării: 29.05.2023 Data prelevării: 02.06.2020
Active substance	Ethanol CAS: 64-17-5, 70%
B) TEST METHOD AND ITS VALIDATION	
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)	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

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HAMILTON

ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 267770/20/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	Nv	N ₀	VC1	VC2	A	VC1	VC2	B	VC1	VC2	C	VC1	VC2	C	
<i>Candida albicans</i> ATCC 10231	126	122	1240	124	97	91	94	84	86	85	71	73	72				
<i>Aspergillus brasiliensis</i> ATCC 16404	107	104	1055	106	86	88	87	76	77	76,5	60	61	61				
criteria	300 < N _v < 1600 30 < N ₀ < 160						acceptable	A ≥ 0,5 * N ₀			acceptable	B ≥ 0,5 * N ₀			C ≥ 0,5 * N ₀		
TEST ORGANISM	VALIDATION SUSPENSION						TEST SUSPENSION			TEST SUSPENSION			TEST SUSPENSION				
<i>Candida albicans</i> ATCC 10231	-5	-5	-6	-6	N	Ig N	N ₀	Ig N ₀									
	222	224	22	23	2,2E+07	7,35	2,2E+06	6,35									
<i>Aspergillus brasiliensis</i> ATCC 16404	>165	>165	31	35	3,3E+07	7,52	3,3E+06	6,52									
criteria	1,5*10 ⁵ ≤ N ≤ 5*10 ⁷						acceptable			1,5*10 ⁵ ≤ N ₀ ≤ 5*10 ⁶			acceptable				
	7,17 ≤ Ig N ≤ 7,70						acceptable			6,17 ≤ Ig N ₀ ≤ 6,70			acceptable				
TEST ORGANISM	0.01%						50%			80%			80%				
<i>Candida albicans</i> ATCC 10231	N	VC1	VC2	Na	Ig Na	Ig R	VC1	VC2	Na	Ig Na	Ig R	VC1	VC2	Na	Ig Na	Ig R	
		>330	>330	>3300	>3,52	<2,83	0	0	<140	<2,15	>4,20	0	0	<140	<2,15	>4,20	
<i>Aspergillus brasiliensis</i> ATCC 16404	Ig R ≥ 4	>165	>165	>1650	>3,22	<3,30	64	60	520	2,79	3,73	0	0	<140	<2,15	>4,37	

Date: 19.07.2020

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