HAMILTON

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TEST REPORT No. 455216/23/INT

Client: **"ECOCHIM-GRUP" S.R.L. str. Nationala, or. Ungheni, Republica Moldova**		Description of the sample *(as per Client's declaration)*
Sample reception date:	24.08.2023	Dezinfectant Universal "Bio-Dez" Lot/Batch: - Production date: 05.08.2023 Expiration date: 05.08.2026 Sampling date: 23.08.2023 Sampling quantity: 1x 200ml Sample temperature: 17°C Reception hour: 12:30 Responsible for sampling: Crestinov Alexandr Sample condition with no objections
Test report date:	08.09.2023	

Dermatological test - Open test (25 subjects with allergological history, 25 subjects, without allergological history)

Prepared by: Natalia Dawidowicz, Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
Paulina Maciszka, Project Manager (qualified electronic signature)

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THE STUDY IS COMPLIANT WITH:

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

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Laboratory: ul. Bajana 3D, 80-463 Gdańsk

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1. BASIS OF THE STUDY

- Samples delivered by the Sponsor.
- The qualitative composition of the product delivered by the Sponsor.
- The results of microbiological purity of the product provided by the Sponsor (or declaration from the Sponsor about microbiological purity).

The Sponsor is responsible for conformity with the declared quality composition of the product as well as for the microbiological purity test of the delivered samples.

2. OBJECT OF THE STUDY

Parameter	Description
Appearance	Liquid
Colour	Blue
Fragrance	Characteristic for raw materials (or fragrance composition)
Packaging	Replacement packaging containing the name and sample number for testing

3. QUALITATIVE COMPOSITION OF THE PRODUCT

The qualitative composition was delivered to the Laboratory by the Sponsor before the start of the study.

4. PURPOSE OF THE STUDY

The purpose of the study was to assess irritating properties (skin tolerance) of the product on a healthy adult skin, with applied patch test.

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5. DESCRIPTION OF STUDY SUBJECTS

The study subjects (25 people) were healthy, with negative history of allergy. General inclusion criteria for the selection of study subjects were the following: healthy men and women over 18 years old, phototype: I-IV on Fitzpatrick scale, Caucasians, skin without irritations and changes requiring pharmacological treatment. General exclusion criteria were the following: volunteers who at the time used any treatment on the skin area subject to the study, volunteers exhibiting or having a known history of acute or chronic dermatological, medical and/or physical conditions that could influence the outcome of the study, pregnant or breastfeeding women or women planning a pregnancy during the study. None of the study subjects reported documented oversensitivity or history of adverse reactions to individual ingredients of the product tested. All the study subjects fulfilled the requirements of inclusion for tests and signed the Informed Consent Form (ICF). Additionally, they were informed on the purpose, methodology of the study and possible adverse effects. The skin at the application area (arms or interscapular area) was healthy, without lesions. The study subjects were advised to exercise caution in handling the applied contact tests.

6. TESTING METHODOLOGY

The preparation in the appropriate concentration was applied onto to the skin on the forearm in the area of 3x3 cm. The reading of skin response was performed 15 minutes, 30 minutes, 1 hour, and 24 hours after the test application. Simultaneously, to assure the objectivity of the results of the study and in order to exclude possible reading errors connected with dermal irritations one sample control (control sample with water) was carried out. The results of the study are presented in section 10 of this report. If irritations appeared or persisted 24h after the application, an additional examination took place after 48 hours. Determining the response of the skin, the dermatologist assessed the irritating and sensitising effects of the tested product. The study results might have been influenced by factors such as lifestyle, stress, diet and environmental conditions, etc.

7. DATE OF THE STUDY

05.09.2023 – 08.09.2023

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8. EVALUATION PARAMETERS

EVALUATION PARAMETERS OF SKIN REACTION	
Erythema	**Classification point**
No erythema	0
Light erythema	0.5
Erythema and/or papules	1
Erythema and/or papules and/or vesicles	2
Erythema and/or papules and/or vesicles and/or blisters	3
Erythema Bullous and/or ulcerative reaction and/or papules and/or vesicles and/or blisters	4
Edema	**Classification point**
No edema	0
Very light edema (hardly visible)	1
Light edema	2
Moderate edema (about 1mm raised skin)	3
Strong edema (extended swelling even beyond the application area)	4

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9. RESULTS

9.1. CHARACTERISTICS OF VOLUNTEERS

Table 1

No. of subject	Identification of subject	Begining of the study	Age	Sex	Phototype
1	CHY.AG	05.09.2023	26	F	II
2	DAW.NA	05.09.2023	24	F	II
3	BIE.IZ	05.09.2023	34	F	II
4	KOC.KR	05.09.2023	54	M	II
5	KRZ.EW	05.09.2023	37	F	II
6	ZAM.PA	05.09.2023	32	F	II
7	JAG.KR	05.09.2023	32	M	II
8	URB.BA	05.09.2023	65	F	II
9	TRE.MI	05.09.2023	57	F	II
10	BOC.AL	05.09.2023	44	F	II
11	FLI.AN	05.09.2023	35	F	II
12	PAC.NA	05.09.2023	24	F	II
13	KIE.MA	05.09.2023	26	F	II
14	ZAW.AG	05.09.2023	41	F	II
15	FUS.MO	05.09.2023	28	F	II
16	MAM.AG	05.09.2023	24	F	II
17	WEN.MO	05.09.2023	25	F	II
18	WOD.KA	05.09.2023	34	F	II
19	KOS.DO	05.09.2023	23	F	II
20	NOW.AR	05.09.2023	51	M	II
21	SEP.JA	05.09.2023	42	M	II
22	PIS.PI	05.09.2023	46	M	II
23	JER.DA	05.09.2023	56	F	II
24	MUS.NA	05.09.2023	37	F	II
25	BEC.EL	05.09.2023	58	F	II
		Min	23	**No. F**	**phototype I**
		Max	65	20	0
		Average	38	**No. M**	**phototype II**
				5	25
					phototype III
					0
					phototype IV
					0

Table 1. Characteristics of volunteers with a negative history of allergy

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Table 2

No. of subject	Identification of subject	Begining of the study	Age	Sex	Phototype
1	CIE.MA	05.09.2023	62	F	II
2	SZY.UR	05.09.2023	37	F	II
3	TRO.MA	05.09.2023	44	F	II
4	SKU.IW	05.09.2023	45	F	II
5	SZY.MA	05.09.2023	51	F	II
6	ARB.YU	05.09.2023	22	F	II
7	KOR.DO	05.09.2023	48	F	II
8	GAN.MA	05.09.2023	59	F	II
9	TAR.AG	05.09.2023	58	F	II
10	RAT.EM	05.09.2023	38	F	II
11	PIO.EL	05.09.2023	53	F	II
12	KWI.BO	05.09.2023	68	F	II
13	WYS.BE	05.09.2023	35	F	II
14	ARB.AL	05.09.2023	22	F	II
15	ARB.LU	05.09.2023	45	F	II
16	ZAL.IZ	05.09.2023	44	F	II
17	SLE.AG	05.09.2023	45	F	II
18	GOR.AG	05.09.2023	22	F	II
19	WAN.SY	05.09.2023	25	F	II
20	SZE.KA	05.09.2023	22	F	II
21	HIR.HA	05.09.2023	47	F	II
22	RAD.MA	05.09.2023	57	F	II
23	MAN.MA	05.09.2023	48	F	II
24	HAN.AN	05.09.2023	23	F	II
25	ROZ.AG	05.09.2023	41	F	II
		Min	22	**No. F**	**phototype I**
		Max	68	25	0
		Average	42	**No. M**	**phototype II**
				0	25
					phototype III
					0
					phototype IV
					0

Table 2. Characteristics of volunteers with a positive history of allergy

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9.2. TABLE OF SKIN RESPONSE

Table 3

No.	Evaluation after 15 minutes of product application		Evaluation after 30 minutes of product application		Evaluation after 1 hour of product application		Evaluation after 24 hours of product application		Evaluation after 48 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	0	0	0	0	Examination skipped	
2	0	0	0	0	0	0	0	0	Examination skipped	
3	0	0	0	0	0	0	0	0	Examination skipped	
4	0	0	0	0	0	0	0	0	Examination skipped	
5	0	0	0	0	0	0	0	0	Examination skipped	
6	0	0	0	0	0	0	0	0	Examination skipped	
7	0	0	0	0	0	0	0	0	Examination skipped	
8	0	0	0	0	0	0	0	0	Examination skipped	
9	0	0	0	0	0	0	0	0	Examination skipped	
10	0	0	0	0	0	0	0	0	Examination skipped	
11	0	0	0	0	0	0	0	0	Examination skipped	
12	0	0	0	0	0	0	0	0	Examination skipped	
13	0	0	0	0	0	0	0	0	Examination skipped	
14	0	0	0	0	0	0	0	0	Examination skipped	
15	0	0	0	0	0	0	0	0	Examination skipped	
16	0	0	0	0	0	0	0	0	Examination skipped	
17	0	0	0	0	0	0	0	0	Examination skipped	
18	0	0	0	0	0	0	0	0	Examination skipped	
19	0	0	0	0	0	0	0	0	Examination skipped	
20	0	0	0	0	0	0	0	0	Examination skipped	
21	0	0	0	0	0	0	0	0	Examination skipped	
22	0	0	0	0	0	0	0	0	Examination skipped	
23	0	0	0	0	0	0	0	0	Examination skipped	
24	0	0	0	0	0	0	0	0	Examination skipped	
25	0	0	0	0	0	0	0	0	Examination skipped	

Table 3. Results for volunteers with a negative history of allergy

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Table 4

No.	Evaluation after 15 minutes of product application		Evaluation after 30 minutes of product application		Evaluation after 1 hour of product application		Evaluation after 24 hours of product application		Evaluation after 48 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	0	0	0	0	Examination skipped	
2	0	0	0	0	0	0	0	0	Examination skipped	
3	0	0	0	0	0	0	0	0	Examination skipped	
4	0	0	0	0	0	0	0	0	Examination skipped	
5	0	0	0	0	0	0	0	0	Examination skipped	
6	0	0	0	0	0	0	0	0	Examination skipped	
7	0	0	0	0	0	0	0	0	Examination skipped	
8	0	0	0	0	0	0	0	0	Examination skipped	
9	0	0	0	0	0	0	0	0	Examination skipped	
10	0	0	0	0	0	0	0	0	Examination skipped	
11	0	0	0	0	0	0	0	0	Examination skipped	
12	0	0	0	0	0	0	0	0	Examination skipped	
13	0	0	0	0	0	0	0	0	Examination skipped	
14	0	0	0	0	0	0	0	0	Examination skipped	
15	0	0	0	0	0	0	0	0	Examination skipped	
16	0	0	0	0	0	0	0	0	Examination skipped	
17	0	0	0	0	0	0	0	0	Examination skipped	
18	0	0	0	0	0	0	0	0	Examination skipped	
19	0	0	0	0	0	0	0	0	Examination skipped	
20	0	0	0	0	0	0	0	0	Examination skipped	
21	0	0	0	0	0	0	0	0	Examination skipped	
22	0	0	0	0	0	0	0	0	Examination skipped	
23	0	0	0	0	0	0	0	0	Examination skipped	
24	0	0	0	0	0	0	0	0	Examination skipped	
25	0	0	0	0	0	0	0	0	Examination skipped	

Table 4. Results for volunteers with a positive history of allergy

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10. CALCULATED VALUES

The following calculated values present the sum of negative reaction (erythema and edema) defined as Average Irritation Index (X_{av}).

	Evaluation after 15 minutes of product application	Evaluation after 30 minutes of product application	Evaluation after 1 hour of product application	Evaluation after 24 hours of product application	Evaluation after 48 hours of product application
The sum of negative reaction (the sum of classification points)	0,00	0,00	0,00	0,00	Examination skipped
X_{av}	0,00				

11. INTERPRETATION

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

Average irritation index (xav)	Class
$\mathbf{X_{av}} < 0.50$	Not irritating
$0.50 \leq \mathbf{X_{av}} < 2.00$	Slightly irritating
$2.00 \leq \mathbf{X_{av}} < 5.00$	Moderately irritating
$5.00 \leq \mathbf{X_{av}}$	Highly irritating

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12. CONCLUSION

The patch test study was performed under dermatological control on a group of 25 volunteers. The study allowed the investigators to conclude that product Dezinfectant Universal "Bio-Dez" used by volunteers that didn't report documented oversensitivity or a history of adverse reactions to individual ingredients of the tested product, was well tolerated by the skin. In the tested group of volunteers there were no irritations or allergic reactions. The product meets the requirements of compatibility test with the skin (Skin Compatibility Test) and can be classified as NOT IRRITATING.

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13. SIGNATURES

Technician	**Natalia Dawidowicz**	
Dermatologist - venereologist	**Karolina Osiecka (2487308)**	
Project Manager	**Paulina Maciszka**	

*The Sponsor is responsible for conformity with the declared quality composition as well as microbiological purity of the delivered samples.
Attention: The released opinion of dermatological compatibility does not apply to people who are allergic to any ingredient of the tested product.

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