TEST REPORT No. 134856/23/GDA

Client: **Aromara d.o.o., Ulica Ivana Perkovca 19, 10292 Harmica Sample No 2**		Description of the sample *(as per Client's declaration)* Revolution Roll-On Rose delight 30ml, šifra proizvoda: 420-038-0010
Sample reception date:	17.04.2023	
Test report date:	12.05.2023	

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

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Paulina Maciszka, Project Manager

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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 (formerly COLIPA) Guidelines: "Product Test Guidelines for the Assessment of Human Skin Compatibility 1997";

Cosmetics Europe — The Personal Care Association (formerly COLIPA) Guidelines for the Evaluation of the Efficacy of Cosmetic Products 2008.

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1. BASIS OF THE STUDY

The test sample was delivered by the Client.
The qualitative composition of the product was delivered by the Client.
The results of microbiological purity of the product provided by the Client (or the Client's declaration concerning microbiological purity) do not apply to low microbiological risk products.

The Client is responsible for compliance with the declared qualitative composition and microbiological purity of the product sample sent for testing.

2. OBJECT OF THE STUDY

Parameter	Description
Appearance	Dense liquid
Color	Transparent, yellow
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 Client before the start of the study.

4. PURPOSE OF THE STUDY

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

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5. DESCRIPTION OF VOLUNTEERS

The volunteers (50 people) were healthy, 25 people with negative and 25 people with positive history of allergies. The selection of the group included the criteria of inclusion and exclusion. General inclusion criteria: healthy men and women over 18 years old, phototype: I-IV on Fitzpatrick scale, Caucasians, skin without irritations or changes requiring pharmacological treatment. General exclusion criteria: volunteers who use any treatment on the skin area subject to the study, volunteers exhibiting or having a known history of acute or chronic dermatological, medical and/or physical conditions that could influence the outcome of the study, pregnant or breastfeeding women or women planning a pregnancy during the study. None of the volunteers reported documented oversensitivity or history of adverse reactions to individual ingredients of the product tested. All the volunteers fulfilled the requirements of inclusion for tests and signed the Informed Consent Form (ICF). Additionally, they were informed on the purpose, methodology of the study and possible adverse effects. The skin at the application spot (arms or interscapular area) was healthy, without lesions. The volunteers were advised to exercise caution in handling the applied contact tests.

6. TESTING METHODOLOGY

The preparation in an appropriate concentration is applied onto filter paper discs of 12 mm diameter, manufactured by SmartPractice® and then fixed to the arm or interscapular area with the use of a sticking patch. At the same time, in order to guarantee objective results of the study and to exclude possible reading errors connected with dermal irritations, two control samples (control sample called "blind" and control sample containing water) are used. The dermatologist removes the patch 24 hours after the application and examines the skin reaction 30 minutes after the removal. 48 hours after the application, the dermatologist examines the skin again for a reaction. If irritations appear or persist 48 hours after the application, an additional examination takes place after 72 hours. While determining the skin reaction, the dermatologist assesses the irritating and sensitising effects of the tested product.
The study results may be influenced by factors such as lifestyle, stress, diet, environmental conditions, etc.

7. DATE OF THE STUDY

09.05.2023 – 12.05.2023

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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	CIE.JA	08.05.2023	64	M	II
2	CIE.MA	08.05.2023	62	F	II
3	PAŁ.MA	08.05.2023	37	F	II
4	ŻUR.AL	08.05.2023	67	F	II
5	STE.LI	08.05.2023	61	F	II
6	PIÓ.MA	08.05.2023	66	F	II
7	BOC.AL	08.05.2023	44	F	II
8	STA.KA	08.05.2023	29	F	II
9	FLI.AN	08.05.2023	35	F	II
10	PAC.NA	08.05.2023	23	F	II
11	JAG.KA	08.05.2023	21	F	II
12	KIE.MA	08.05.2023	26	F	II
13	SER.NA	08.05.2023	26	F	II
14	MAM.AG	08.05.2023	26	F	II
15	WEN.MO	08.05.2023	25	F	II
16	ZAW.AG	08.05.2023	41	F	II
17	FUS.MO	08.05.2023	28	F	II
18	PIS.PI	08.05.2023	45	M	II
19	CYB.MA	08.05.2023	62	F	II
20	CZE.AG	08.05.2023	37	F	II
21	SKO.MA	08.05.2023	42	F	II
22	WIC.AD	08.05.2023	26	F	II
23	TRE.MI	08.05.2023	56	F	II
24	MAZ.AN	08.05.2023	60	M	II
25	KOZ.JO	08.05.2023	51	F	II
		Min	21	**No. F**	**phototype I**
		Max	67	22	0
		Average	42	**No. M**	**phototype II**
				3	25
					phototype III
					0
					phototype IV
					0

Table 1. Characteristics of volunteers with negative history of allergies

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Table 2

No. of subject	Identification of subject	Begining of the study	Age	Sex	Phototype
1	BAR.KA	08.05.2023	44	F	II
2	BER.AN	08.05.2023	52	F	II
3	ŻAL.IZ	08.05.2023	44	F	II
4	JAG.MA	08.05.2023	63	F	II
5	SIE.AG	08.05.2023	45	F	II
6	AND.AN	08.05.2023	63	F	II
7	SZY.MA	08.05.2023	51	F	II
8	SKU.IW	08.05.2023	45	F	II
9	BOV.AN	08.05.2023	54	F	II
10	MŁY.MI	08.05.2023	65	F	II
11	SOS.AG	08.05.2023	34	F	II
12	ROZ.AG	08.05.2023	40	F	II
13	ARB.AL	08.05.2023	22	F	II
14	SIK.GR	08.05.2023	68	F	II
15	SZR.MA	08.05.2023	51	F	II
16	KAL.GR	08.05.2023	64	F	II
17	KUR.MA	08.05.2023	51	F	II
18	ŻAG.JO	08.05.2023	45	F	II
19	SZY.UR	08.05.2023	36	F	II
20	TRO.MA	08.05.2023	44	F	II
21	PŁO.BO	08.05.2023	59	F	II
22	TAR.AG	08.05.2023	57	F	II
23	PIO.AN	08.05.2023	51	F	II
24	KLI.KA	08.05.2023	30	F	II
25	DUD.IR	08.05.2023	63	F	II
		Min	22	**No. F**	**phototype I**
		Max	68	25	0
		Average	50	**No. M**	**phototype II**
				0	25
					phototype III
					0
					phototype IV
					0

Table 2. Characteristics of volunteers with positive history of allergies

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9.2. TABLE OF SKIN RESPONSE

Table 3

No.	Evaluation after 48 hours of product application		Evaluation after 72 hours of product application		Evaluation after 96 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	Examination skipped	
2	0	0	0	0	Examination skipped	
3	0	0	0	0	Examination skipped	
4	0	0	0	0	Examination skipped	
5	0	0	0	0	Examination skipped	
6	0	0	0	0	Examination skipped	
7	0	0	0	0	Examination skipped	
8	0	0	0	0	Examination skipped	
9	0	0	0	0	Examination skipped	
10	0	0	0	0	Examination skipped	
11	0	0	0	0	Examination skipped	
12	0	0	0	0	Examination skipped	
13	0	0	0	0	Examination skipped	
14	0	0	0	0	Examination skipped	
15	0	0	0	0	Examination skipped	
16	0	0	0	0	Examination skipped	
17	0	0	0	0	Examination skipped	
18	0	0	0	0	Examination skipped	
19	0	0	0	0	Examination skipped	
20	0	0	0	0	Examination skipped	
21	0	0	0	0	Examination skipped	
22	0	0	0	0	Examination skipped	
23	0	0	0	0	Examination skipped	
24	0	0	0	0	Examination skipped	
25	0	0	0	0	Examination skipped	

Table 3. Results for volunteers with negative history of allergies

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Table 4

No.	Evaluation after 48 hours of product application		Evaluation after 72 hours of product application		Evaluation after 96 hours of product application	
	Erythema	Edema	Erythema	Edema	Erythema	Edema
1	0	0	0	0	Examination skipped	
2	0	0	0	0	Examination skipped	
3	0	0	0	0	Examination skipped	
4	0	0	0	0	Examination skipped	
5	0	0	0	0	Examination skipped	
6	0	0	0	0	Examination skipped	
7	0	0	0	0	Examination skipped	
8	0	0	0	0	Examination skipped	
9	0	0	0	0	Examination skipped	
10	0	0	0	0	Examination skipped	
11	0	0	0	0	Examination skipped	
12	0	0	0	0	Examination skipped	
13	0	0	0	0	Examination skipped	
14	0	0	0	0	Examination skipped	
15	0	0	0	0	Examination skipped	
16	0	0	0	0	Examination skipped	
17	0	0	0	0	Examination skipped	
18	0	0	0	0	Examination skipped	
19	0	0	0	0	Examination skipped	
20	0	0	0	0	Examination skipped	
21	0	0	0	0	Examination skipped	
22	0	0	0	0	Examination skipped	
23	0	0	0	0	Examination skipped	
24	0	0	0	0	Examination skipped	
25	0	0	0	0	Examination skipped	

Table 4. Results for volunteers with positive history of allergies

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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 48 hours of product application		Evaluation after 72 hours of product application		Evaluation after 96 hours of product application	
	Erythema	**Edema**	**Erythema**	**Edema**	**Erythema**	**Edema**
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
$X_{av} < 0.50$	Non irritating
$0.50 \leq X_{av} < 2.00$	Slightly irritating
$2.00 \leq X_{av} < 5.00$	Moderately irritating
$5.00 \leq X_{av}$	Highly irritating

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12. CONCLUSION

The patch test study was performed under dermatological control on a group of 50 volunteers, including 25 volunteers with positive history of allergies/atopy (sensitive skin). The study allows to conclude that product Revolution Roll-On Rose delight used by volunteers, who didn't report documented oversensitivity or a history of adverse reactions to individual ingredients of the tested product, is well tolerated by the skin. In the tested group of volunteers there were no irritations or allergic reactions. The product meets the requirements of compatibility test with the skin (Skin Compatibility Test) and can be classified as NON IRRITATING.

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13. SIGNATURES

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

*The Client 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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