REPORT OF ANALYSIS No. L77878/22/JSHCR

Client: **Aromara d.o.o., 10292 Harmica, Ulica Ivana Perkovca 19**		Sample description *(according to declaration of the Client)* 3650/22 INVIZZ, 50mL Datum proizvodnje: 28.06.2022. RT: 06/2024 KONTROLNI BR.: 0647609
Sample received on:	28.07.2022	
Report issued on:	09.09.2022	

Dermatological test CLOSED TEST EXPANDED

Prepared by: Magdalena Wierzba, Senior Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
{Iwona Świniańska, Project Manager (qualified electronic signature)

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

J.S. HAMILTON POLAND Sp. z o.o.
ul. Chwaszczyńska 180, 81-571 Gdynia, Poland, tel. +48 58 766 99 00

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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

Prepared by: Magdalena Wierzba, Senior Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
{Iwona Świniańska, Project Manager (qualified electronic signature)

J.S. HAMILTON POLAND Sp. z o.o.
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Prepared by: Magdalena Wierzba, Senior Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
{Iwona Świniańska, Project Manager (qualified electronic signature)

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1. BASIS OF THE STUDY

Test sample delivered by the Client.
The qualitative composition of the product delivered by the Client.
The results of microbiological purity of the product provided by the Client (or declaration from the Client about microbiological purity) does 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	Liquid
Color	Transparent
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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{Iwona Świniańska, Project Manager (qualified electronic signature)

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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 allergy. 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 and 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 the appropriate concentration is applied onto the Finn Chamber® fixed on Scanpor® by SmartPractice® and then fixed to the arm or interscapular area with the use of a sticking patch. Finn Chamber® is a patch test device which provides good occlusion because of the chamber design. The chamber is made of aluminum, the 8 mm inner diameter provides a 50 mm2 area and about 20 microlitre volume. Finn Chambers on Scanpor are available in strips of 10 (2x5) chambers. Simultaneously, to objectify the results of the study and in order to exclude possible reading errors connected with dermal irritations two control samples (control sample called "blind" and control sample with water) are used. The purpose of this study is to exclude possible reading errors connected with dermal irritations. The results of the study are presented in section 10 of this report. The dermatologist removes the patch 48h after the application and examines the skin response 30 minutes after removal. 72h after the application, the dermatologist examines the skin again for a response. If irritations appear or persist 72h after the application, an additional examination takes place after 96 hours. Determining the response of the skin, 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 and environmental conditions, etc.

7. DATE OF THE STUDY

06.09.2022 – 09.09.2022

Prepared by: Magdalena Wierzba, Senior Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
{Iwona Świniańska, Project Manager (qualified electronic signature)

J.S. HAMILTON POLAND Sp. z o.o.
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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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{Iwona Świniańska, Project Manager (qualified electronic signature)

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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	06.09.2022	63	M	II
2	CIE.MA	06.09.2022	61	F	II
3	DUR.MI	06.09.2022	62	F	II
4	WOJ.JU	06.09.2022	23	F	II
5	JES.KA	06.09.2022	41	F	II
6	JES.MA	06.09.2022	64	F	II
7	URB.BA	06.09.2022	64	F	II
8	KAS.VA	06.09.2022	66	F	II
9	NOW.DA	06.09.2022	28	M	II
10	MAC.PA	06.09.2022	37	M	II
11	WIS.KI	06.09.2022	25	F	II
12	CIB.KA	06.09.2022	36	M	II
13	IWA.AN	06.09.2022	43	F	II
14	JAS.AR	06.09.2022	36	M	II
15	CZE.MI	06.09.2022	67	F	II
16	LEJ.AN	06.09.2022	41	M	II
17	KLU.JO	06.09.2022	45	F	II
18	STA.MA	06.09.2022	24	F	II
19	JOZ.SL	06.09.2022	63	M	II
20	POL.EL	06.09.2022	58	F	II
21	WIC.DA	06.09.2022	29	M	II
22	MIC.BA	06.09.2022	55	F	II
23	TRE.MI	06.09.2022	56	F	II
24	JER.DA	06.09.2022	54	F	II
25	KOR.MA	06.09.2022	31	M	II
		Min	23	**No. F**	**phototype I**
		Max	67	16	0
		Average	47	**No. M**	**phototype II**
				9	25
					phototype III
					0
					phototype IV
					0

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

Prepared by: Magdalena Wierzba, Senior Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
{Iwona Świniańska, Project Manager (qualified electronic signature)

J.S. HAMILTON POLAND Sp. z o.o.
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Table 2

No. of subject	Identification of subject	Begining of the study	Age	Sex	Phototype
1	RAD.MA	06.09.2022	50	F	II
2	HER.EW	06.09.2022	69	F	II
3	SIE.AG	06.09.2022	44	F	II
4	ZAL.IZ	06.09.2022	43	F	II
5	ROM.DO	06.09.2022	45	F	II
6	JAG.MA	06.09.2022	62	F	II
7	SOS.AG	06.09.2022	32	F	II
8	LIS.DA	06.09.2022	35	F	II
9	SKU.IW	06.09.2022	44	F	II
10	DUD.IR	06.09.2022	65	F	II
11	SZY.UR	06.09.2022	36	F	II
12	BER.AN	06.09.2022	50	F	II
13	SZR.MA	06.09.2022	45	F	II
14	SZY.MA	06.09.2022	49	F	II
15	SEK.EL	06.09.2022	69	F	II
16	ARB.LU	06.09.2022	43	F	II
17	KIZ.MA	06.09.2022	41	F	II
18	KUL.SY	06.09.2022	22	F	II
19	MAN.MA	06.09.2022	47	F	II
20	OST.IZ	06.09.2022	40	F	II
21	TAR.AG	06.09.2022	58	F	II
22	ROZ.AG	06.09.2022	40	F	II
23	FOT.IW	06.09.2022	44	F	II
24	MAT.RE	06.09.2022	69	F	II
25	KUR.MA	06.09.2022	51	F	II
		Min	22	**No. F**	**phototype I**
		Max	69	25	0
		Average	48	**No. M**	**phototype II**
				0	25
					phototype III
					0
					phototype IV
					0

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

9.2. TABLE OF SKIN RESPONSE

Prepared by: Magdalena Wierzba, Senior Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
{Iwona Świniańska, Project Manager (qualified electronic signature)

J.S. HAMILTON POLAND Sp. z o.o.
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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 a negative history of allergy

Prepared by: Magdalena Wierzba, Senior Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
{Iwona Świniańska, Project Manager (qualified electronic signature)

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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 a positive history of allergy

Prepared by: Magdalena Wierzba, Senior Technician
Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
{Iwona Świniańska, Project Manager (qualified electronic signature)

J.S. HAMILTON POLAND Sp. z o.o.
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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 sume 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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{Iwona Świniańska, Project Manager (qualified electronic signature)

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12. CONCLUSION

The patch test study was performed under dermatological control on a group of 50 volunteers, including 25 volunteers positive history of allergy/atopy(sensitive skin). The study allows to conclude that product INVIZZ used by volunteers, that 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 NOT IRRITATING.

Prepared by: Magdalena Wierzba, Senior Technician
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{Iwona Świniańska, Project Manager (qualified electronic signature)

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13. SIGNATURES

Senior Technician	**Magdalena Wierzba**	
Dermatologist - venereologist	**Karolina Osiecka (2487308)**	
Project Manager	**Iwona Świniańska**	

*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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Authorized by: Karolina Osiecka (2487308), Dermatologist - venereologist
{Iwona Świniańska, Project Manager (qualified electronic signature)

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