

REPORT OF ANALYSIS No. 453243/18/JSHH/Z1

(Replaces the report no 453243/18/CGDA made on 09.11.2018)

Client: TINATI NATURAL Kft, Szőló utca 32, 1034 Budapest		Sample description (<i>according to declaration of the Client</i>) I'm so sensitive Regenerating facial cream
Sample received:	09.10.2018	
Report dated:	23.11.2018	

Dermatological test HYPOALLERGY

THE NATURAL
COSMETICS COMPANY

Prepare: Katarzyna Rulska, Technician
Authorize: Karolina Osiecka (2487308), Dermatologist - venereologist (qualified electronic signature)
Marta Rosińska, Cosmetic Laboratory Manager (qualified electronic signature)

Laboratory: ul. Bajana 3D, 80-463 Gdańsk, Poland
The results relate to the analysed samples only.

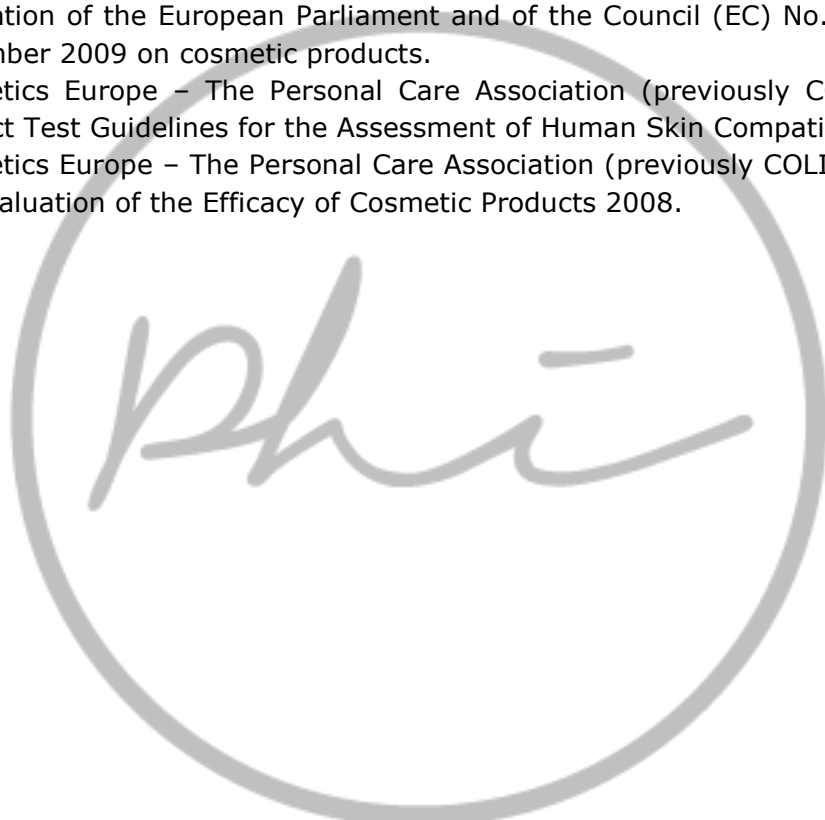
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SCOPE OF TESTS COMPLIANT WITH:

- 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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12. Conclusion.
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1. THE 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 STUDY:

Parameter	Description
Appearance	Emulsion
Color	White
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. AIM OF THE TEST:

The aim of the study was to assess the 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 allergy. The selection of the group included the criteria of inclusion and exclusion. None of the volunteers reported documented oversensitivity or a history of adverse reactions to individual ingredients of the tested product. All volunteers fulfilled the requirements of inclusion for tests and signed an informed consent form. Additionally they were advised of the purpose, methodology of the test and possible adverse effects. The skin at the application spot (arms or interscapular area) was healthy, without lesions. The participants were advised to use caution in handling the applied contact tests.

6. TESTING METHODOLOGY:

The preparation in the useful concentration is applied into a filter paper discs of 12 mm diameter, manufactured by SmartPractice® and then fixed to the arm or interscapular area using sticking patch. In a parallel time to objectify the results of studies two control samples: control sample name: "blind" and control sample with water are carried out. The purpose of this test is to exclude possible reading errors connected with the dermal irritation. The results of the studies are presented in section 10. The dermatologist removes the patch after 48h since the application and checks the skin response 30 minutes after removal. After 24h from last verification the dermatologist checks again for a skin response. If it is necessary, the skin response is observed also after 96 hours. Reading the response of the skin, the dermatologist assesses the irritating and sensitising effects of the tested product. The test results may be influenced by such factors as: the lifestyle, stress, diet and environmental conditions etc.

7. DATE OF PERFORMANCE OF THE STUDY:

05.11.2018 – 09.11.2018

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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

No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype	
1	DYG.HA	05.11.2018	67	F	II	
2	SYT.GR	05.11.2018	65	F	II	
3	NAG.SY	05.11.2018	41	F	II	
4	KUR.EW	05.11.2018	62	F	II	
5	WIE.MA	05.11.2018	49	F	II	
6	NAW.SY	05.11.2018	43	F	II	
7	KRO.DO	05.11.2018	48	F	III	
8	WOL.DI	05.11.2018	25	F	II	
9	STR.DO	05.11.2018	52	F	II	
10	RUT.AL	05.11.2018	56	F	III	
11	RUT.MI	05.11.2018	32	M	II	
12	KAP.YU	05.11.2018	20	F	II	
13	JUR.TE	05.11.2018	69	F	II	
14	OBA.KA	05.11.2018	39	F	II	
15	GAP.MO	05.11.2018	41	F	II	
16	MLY.MI	05.11.2018	60	F	II	
17	KOP.AN	05.11.2018	67	M	II	
18	STE.DA	05.11.2018	27	F	II	
19	SMI.MA	05.11.2018	29	F	III	
20	KUR.AN	05.11.2018	45	F	II	
21	STA.JO	05.11.2018	38	F	II	
22	ANT.ZO	05.11.2018	63	F	II	
23	ZRO.HA	05.11.2018	24	F	II	
24	KRZ.KL	05.11.2018	23	F	II	
25	CIE.EW	05.11.2018	34	F	II	
			Min	20	No. F	phototype I
			Max	69	23	0
			Average	45	No. M	phototype II
					2	22
						phototype III
						3
						phototype IV
						0

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No. of subject	Identification of subject	Beginning of the study	Age	Sex	Phototype	
1	SIK.SO	05.11.2018	24	F	II	
2	MAK.MO	05.11.2018	30	F	II	
3	SZY.MA	05.11.2018	46	F	II	
4	WYS.MA	05.11.2018	31	F	II	
5	DUD.IR	05.11.2018	62	F	II	
6	PNI.JU	05.11.2018	25	F	III	
7	SOB.MA	05.11.2018	69	F	II	
8	BAR.GR	05.11.2018	47	F	II	
9	BAL.EL	05.11.2018	60	F	II	
10	MIS.IW	05.11.2018	52	F	II	
11	MIS.AN	05.11.2018	22	F	II	
12	BER.AN	05.11.2018	48	F	III	
13	ZAB.AN	05.11.2018	59	F	II	
14	RAD.MA	05.11.2018	46	F	II	
15	KAL.GR	05.11.2018	60	F	II	
16	JAB.MA	05.11.2018	27	F	II	
17	PAL.MA	05.11.2018	33	F	III	
18	JAW.LU	05.11.2018	30	M	II	
19	BRU.AN	05.11.2018	24	F	II	
20	MEZ.SE	05.11.2018	30	M	II	
21	JAR.DA	05.11.2018	23	F	II	
22	KRO.AL	05.11.2018	53	F	II	
23	GRA.EL	05.11.2018	54	F	II	
24	CZE.NA	05.11.2018	27	F	II	
25	SZC.PA	05.11.2018	26	F	II	
			Min	22	No. F	phototype I
			Max	69	23	0
			Average	40	No. M	phototype II
					2	22
						phototype III
						3
						phototype IV
						0

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9.2. TABLE OF SKIN RESPONSE

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

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

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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}).

	Result 48 hours after product application	Result 72 hours after product application	Result 96 hours after product application
The sum of negative reaction (the sum of classification points)	0,00	0,00	0,00
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 (x_{av})	Class
$x_{av} < 0,50$	Not 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

12. CONCLUSION:

The patch test study was performed under dermatological control on a group of 50 volunteers, with 25 volunteers positive history of allergy/atopy (sensitive skin). . The study allows to conclude, that product **I'M SO SENSITIVE REGENERATING FACIAL CREAM** used by persons, for whom allergy to any of its ingredients hasn't been documented, is good tolerated by the skin. In the tested group of volunteers there were no irritations or allergic reactions. The product meets the requirements for products called "hypoallergenic" and requirements of compatibility test with atopic and sensitive skin (Skin Compatibility Test) and can be classified as **NOT IRRITATING**.

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13. SIGNATURES:

Technician	Katarzyna Rulska	
Dermatologist - venereologist	Karolina Osiecka (2487308)	
Cosmetic Laboratory Manager	Marta Rosińska	

*The Client is responsible for conformity with the declared quality composition as well as microbiological cleanliness of the delivered samples.

Attention: Released opinion of dermatological safety does not apply people who are allergic to any ingredient of the tested product.

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