DR KOZIEJ
INSTYTUT BADAŃ KOSMETYKÓW

B – (300/07/2018)

THE REPORT FROM DERMATOLOGICAL RESEARCH OF COSMETICAL PRODUCT WITH HALF OPEN PATCH TEST

Product **MAIA MC ROSEWATER**

Responsible Person **BİR KOZMETİK HADİ TEBER**

Report number **B-0829/18**
Issue date **13.08.2018**

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1. RESEARCH BASIS

Order date	24.07.2018
Order number	300/07/2018
Research time frame	30.07.2018 - 10.08.2018
Report issue date	13.08.2018

CUSTOMER NAME
MACRO PROFESYONEL KOZMETİK DANIŞMANLIK VE ANALİZ HİZMETLERİ LTD. ŞTİ., Idealtepe Mah. Ali Riza Cevik Sok. No:15/4, Maltepe – Istanbul

RESPONSIBLE PERSON NAME	
Company name	BİR KOZMETİK HADİ TEBER
Address	

Product name	**MAIA MC ROSEWATER**
Ingredients	Rosa Damascena Flower Water

2. PRODUCT CHARACTERISTIC

Product Package	Supplementary – plastic container labeled with the name of the product
Product Appearance	Clear liquid with a perceptible scent
Product purpose	Rose Water

The responsible person is responsible for conformity with declared qualitative and quantitative composition and microbiological purity of the delivered research samples.

3. METHODOLOGY

- The study was conducted in accordance with Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetics.
- The study was conducted in accordance with recommendation of Cosmetics Europe – The Personal Care Association Guidelines:
  - product test guidelines for the Assessment of Human Skin Compatibility 1997
  - guidelines for the evaluation of the Efficacy of Cosmetic Products 2008.
- Patch tests according to Jadassohn-Bloch with Rudzki modifications were conducted under careful supervise of medical specialists – dermatologists. The assessment of the allergenic and irritant features was made on a group of 30 healthy volunteers no allergological history, familiarized with contraindications and recommendations for the study /not currently taking any medication that may have any effect on the result of the test/. The probands' selection, samples application and reading took place in Diagnostic Test in Bialystok. The tested preparation in commercial formulation was applied to chamber cell-petal patches of Finn Chamber® which are put around a vane. Patches are removed after 48 hours and the first reading is conducted. Another reading takes place 96 hours after insertion of the sample. A dermatologist based on the observations of skin reactions evaluates allergenic action of the conducted substance. Positive reaction (erythema) confirms allergenic properties of the formulation, negative reaction (no erythema) confirms the absence of allergenic properties of the formulation.

4. THE AIM OF STUDY

- The aim is to assess irritating and allergenic properties of the product in a healthy adult volunteer by single insert of patch test and the reading of skin reaction after 48 and 96 hours.

5. SUBJECT – VOLUNTEERS SELECTION

- The selection of probands – volunteers was conducted by a dermatologist according to the Declaration of Helsinki of 1964 (with subsequent amendments), Polish laws, Cosmetics Europe directives with applying inclusion and exclusion criteria. 30 people took part in the study who met the requirements for entering the study and agreed to informed consent to participate in the study. The skin at the selected area was normal, without any lesions. Subjects were informed not to use any kinds of antihistamines or pharmacological agents at the time of test, which may affect the tests' results.

6. RESULTS

Subject	Age	Skin type	Sex	Erythema	Oedema	Scaling
1	27	Dry	F	(0)	(0)	(0)
2	42	Normal	M	(0)	(0)	(0)
3	40	Mixed	F	(0)	(0)	(0)
4	34	Dry	M	(0)	(0)	(0)
5	47	Normal	F	(0)	(0)	(0)
6	50	Mixed	F	(0)	(0)	(0)
7	32	Dry	F	(0)	(0)	(0)
8	34	Dry	M	(0)	(0)	(0)
9	41	Normal	F	(0)	(0)	(0)
10	37	Mixed	F	(0)	(0)	(0)
11	46	Normal	F	(0)	(0)	(0)
12	35	Dry	M	(0)	(0)	(0)
13	39	Mixed	F	(0)	(0)	(0)
14	53	Dry	F	(0)	(0)	(0)
15	33	Normal	M	(0)	(0)	(0)
16	49	Normal	F	(0)	(0)	(0)
17	53	Dry	F	(0)	(0)	(0)
18	37	Mixed	M	(0)	(0)	(0)
19	42	Normal	F	(0)	(0)	(0)
20	29	Dry	M	(0)	(0)	(0)
21	31	Dry	F	(0)	(0)	(0)
22	46	Dry	M	(0)	(0)	(0)
23	38	Normal	M	(0)	(0)	(0)
24	50	Mixed	M	(0)	(0)	(0)
25	45	Normal	F	(0)	(0)	(0)
26	32	Normal	M	(0)	(0)	(0)
27	29	Dry	F	(0)	(0)	(0)
28	43	Mixed	M	(0)	(0)	(0)

29	35	Normal	F	(0)	(0)	(0)
30	40	Dry	F	(0)	(0)	(0)

Legend: E (erythema) - (0) – zero; (1) – weak; (2) – moderate; (3) – strong; (4) – very strong
O (oedema) - (0) – zero; (1) – weak; (2) – moderate; (3) – strong; (4) – very strong
S (scaling) - (0) – zero; (1) – weak; (2) – moderate; (3) – strong; (4) – very strong
(-) – negative result, (?) – questionable result
M – man, F – woman

RESULTS: In 30 subjects, the results of patch tests were negative**,** which means that the product does not cause irritation or allergy reaction in those subjects.

7. CONCLUSION

1. Having conducted patch tests, one may state that **MAIA MC ROSEWATER** does not have irritant or allergenic action.
2. The issued opinion does not apply to anybody with an allergy to any of the ingredients of the tested preparation.
3. The issued opinion does not include analysis of the composition of the product.
4. The tested preparation fulfills requirements for cosmetic products of declared specification, in regards to human health safety.

Stamp and Signature of investigator

Signature Not Verified Dokument podpisany przez dr n. med. Adam Wroński Data: 2018.08.14 14:48:58 CEST	Signature Not Verified Dokument podpisany przez dr n. med. Aleksander Wroński Data: 2018.08.14 14:49:21 CEST
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4. After the test, Diagnostic-Test does not store provided by the Customer research materials and samples of product tested.