REPORT FROM DERMATOLOGICAL TEST – h-RIPT* method

Date of report:		23.06.2022
Sample number / test number:		25/05/22/D/18
Information given by the Principal	Sample name:	**LIFE BY FAKİR BEBEK ÇAMAŞIR YUMUŞATICISI**
	Identification number given by Principal (series / production date / internal number):	PD:12.03.2022
	Product composition / INCI:	Dıhydrogenated tallow hydroxyethylmonıum methosulfate, Calcıum chlorıde,Benzisothiazolinone, Methylisothiazolinone,Mixture.
	Principal / Responsible person:	SARUHAN KİMYA VE TEMİZLİK ÜRÜNLERİ SAN. TİC. A.Ş. VELİMEŞE OSB MAHALLESİ 233 SOKAK NO:33/1 ERGENE/TEKİRDAĞ
Beginning of research:		02.06.2022
Completion of research:		22.06.2022
Comments on sample state / deviation:		NONE
Volunteers group:		30 volunteers
Skin type:		sensitive

1. BASIS FOR RESEARCH IMPLEMENTATION

- Order form and test samples delivered by Principal
- Confirmation of microbiological purity / microbiological insensitivity

The Principal is responsible for compliance with the declared quality composition of the samples sent for testing.

2. PURPOSE OF RESEARCH

Product evaluation in terms of irritating and sensitizing properties.

3. LEGAL BASE OF RESEARCH

- Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 of November 30, 2009, relating to cosmetic products.
- Cosmetics Europe- The Personal Care Association Guidelines „Product test Guidelines for the Assessment of Human Skin Compatibility 1997".
- WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (1964 - 2013).
- The Act on Cosmetic Products, October 4, 2018, Journal of Laws No. 2018 item 2227.
- Test procedure by SKINLAB P.S.A.: PO-08 Research Implementation.
- Instruction by SKINLAB P.S.A.: I02/PO-08 Dermatological test – patch test.
- Instruction by SKINLAB P.S.A.: I04/PO-08 Scheme for assessing skin reactions - product classification.

4. VOLUNTEERS SELECTION

Volunteers participating in the research were selected on the basis of:

- Current European and Polish law
- Cosmetics Europe- The Personal Care Association
- Declaration of Helsinki (1964-2013)
- Test procedure by SKINLAB P.S.A.: PO-08 Research Implementation
- Instruction by SKINLAB P.S.A.: I01/PO-08 Volunteers qualification for the study

All volunteers selected for the study met the requirements for inclusion in the study and signed consent to voluntary participation in the study, and were informed about the purpose of the study, how it was conducted and about possible side effects. During the entire study, the volunteers were under the constant care of a dermatologist.

5. METHODS OF RESEARCH

The test was performed in accordance with the research procedure of SKINLAB P.S.A. (PO-08 Research implementation) under the supervision of a dermatologist. The research model is the skin test according to Jadassohn-Bloch modified by Rudzki. The test consisted in a triple application of the product to a selected area of the skin, and then observing the condition of the skin at intervals. The recording of the results and the classification of the product is made on the basis of the point classification (0-4) of the skin reaction (I04 / PO-08). Qualification, sample application and readings take place at SKINLAB P.S.A. in Cracow.

6. RESULTS

6.1. VOLUNTEERS IDENTIFICATION AND READINGS FROM THE TEST - POINT CLASSIFICATION

VOLUNTTER IDENTIFICATION NUMBER	SEX F – female M - male	AGE	RESULT					
			AFTER 1st APPLICATION		AFTER 2nd APPLICATION		AFTER 3rd APPLICATION	
			Erythema	Edema/ Swelling	Erythema	Edema/ Swelling	Erythema	Edema/ Swelling
1	F	46	0	0	0	0	0	0
2	F	59	0	0	0	0	0	0
3	F	61	0	0	0	0	0	0
4	F	27	0	0	0	0	0	0
5	F	24	0	0	0	0	0	0
6	F	40	0	0	0	0	0	0
7	F	47	0	0	0	0	0	0
8	F	48	0	0	0	0	0	0
9	F	33	0	0	0	0	0	0
10	F	73	0	0	0	0	0	0
11	F	49	0	0	0	0	0	0
12	F	31	0	0	0	0	0	0
13	F	38	0	0	0	0	0	0
14	F	21	0	0	0	0	0	0
15	F	23	0	0	0	0	0	0
16	F	66	0	0	0	0	0	0
17	F	28	0	0	0	0	0	0
18	F	23	0	0	0	0	0	0
19	F	42	0	0	0	0	0	0
20	F	47	0	0	0	0	0	0
21	F	31	0	0	0	0	0	0
22	F	31	0	0	0	0	0	0
23	F	56	0	0	0	0	0	0
24	F	56	0	0	0	0	0	0
25	F	44	0	0	0	0	0	0
26	M	32	0	0	0	0	0	0
27	F	33	0	0	0	0	0	0
28	F	50	0	0	0	0	0	0
29	F	55	0	0	0	0	0	0
30	F	26	0	0	0	0	0	0

6.2. IRRITATION INDEX ($x_{śr}$)

The average irritation index is calculated from the sum of the scores for erythema and edema. Based on the irritation index, the product is classified according to the scale.

AVERAGE IRRITATION INDEX ($x_{śr}$)	PRODUCT CLASSIFICATION
$x_{śr} < 0,5$	non-irritating
$0,5 < x_{śr} < 2,0$	slightly irritating
$2,0 < x_{śr} < 5,0$	moderately irritating
$5,0 \leq x_{śr}$	strongly irritating

Average irritation index for tested product: $x_{śr} = 0$, where $x_{śr} = \frac{\text{sum of the scores}}{\text{volunteers number}}$

7. CONCLUSION

A dermatological study conducted on volunteers who were not allergic to any of the ingredients of the tested product confirms that the tested product is well tolerated by the skin, as it did not show any irritating or allergenic properties. The product can be classified as **NON-IRRITATING.**

8. RESULTS AUTHORIZATION

Report authorised by:	Anna Kszczanowicz-Kierzkowska R&D Coordinator	*Signed with qualified electronical signature*
Report approved by:	Doctor of medicine BARBARA WNUK DERMATOLOGIST AND VENEROLOGIST KR 5562935	*Signed with qualified electronical signature*

-------- END OF THE REPORT --------

**The h-RIPT (Human Repeat Insult Patch Test) method is performed for products with a hypoallergenic declaration. However, the test result itself does not confirm the product declaration, but it is only a component needed to define the product as hypoallergenic. The Principal is responsible for meeting the requirements for a hypoallergenic product. The laboratory is not responsible for declaring the nature of the product based on the presented results.*