Specialized Research Laboratory

REPORT FROM DERMATOLOGICAL TEST

Date of report:		31.08.2020
Sample number / test number:		07/08/20/D/6
Information given by the Principal	Sample name:	**BİOBELLİNDA NEMLENDİRİCİ EL VE TIRNAK BALMI**
	Identification number given by Principal (series / production date / internal number):	LOT:05 25.06.2020
	Product composition / INCI:	Prunus amygdalus dulcis oil, Deionized water, Polyglyceryl-2 Dipolyhydroxystearate, Hydrogenated Castor Oil, Glycerin, Coco-Glucoside (and) Glyceryl Oleate, Phenoxyethanol and ethylhexylglycerin, Tocopheryl Acetate (Vitamin E), Limon oil (Citrus Medica Limonum Peel Oil), d-panthenol, BHT, Limonene.
	Principal / Responsible person:	BİOBELLİNDA KOZMETİK VE TEMİZLİK ÜRÜNLERİ PAZARLAMA A.Ş.
Beginning of research:		12.08.2020
Completion of research:		31.08.2020
Comments on sample state / deviation:		NONE
Volunteers group:		20 volunteers
Skin type:		normal

Contact: Skin Lab International Sp. z o.o., Zacisze 6/7 St., 31-156 Kraków, tel: 797 700 986, 508 503 210.

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 Skin Lab International Sp. z o.o.: PO-08 Research Implementation.
- Instruction by Skin Lab International Sp. z o.o.: I02/PO-08 Dermatological test – patch test.
- Instruction by Skin Lab International Sp. z o.o.: 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 Skin Lab International Sp. z o.o.: PO-08 Research Implementation
- Instruction by Skin Lab International Sp. z o.o.: 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 Skin Lab International Sp. z o.o. (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 single 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 Skin Lab International Sp. z o.o. 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 48 h		AFTER 72 h	
			Erythema	Edema/ Swelling	Erythema	Edema/ Swelling
1	F	63	0	0	0	0
2	F	27	0	0	0	0
3	F	59	0	0	0	0
4	F	49	0	0	0	0
5	F	51	0	0	0	0
6	F	42	0	0	0	0
7	F	31	0	0	0	0
8	F	30	0	0	0	0
9	F	25	0	0	0	0
10	F	51	0	0	0	0
11	F	29	0	0	0	0
12	F	33	0	0	0	0
13	F	59	0	0	0	0
14	F	23	0	0	0	0
15	F	27	0	0	0	0
16	F	52	0	0	0	0
17	F	34	0	0	0	0
18	F	30	0	0	0	0
19	F	56	0	0	0	0
20	M	58	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
$2,0 < xśr < 5,0$	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:	Magdalena Kędziora Technologist, Cosmetic Product Specialist	*Signed with qualified electronical signature*
Report approved by:	Doctor of medicine BARBARA WNUK DERMATOLOGIST AND VENEROLOGIST KR 5562935	*Signed with qualified electronical signature*

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