

Cracow, July 17<sup>th</sup>, 2020

**THE STUDY FOR THE VERIFICATION OF THE GOOD CUTANEOUS COMPATIBILITY OF A  
COSMETIC INVESTIGATIONAL PRODUCT AFTER A SINGLE APPLICATION TO THE SKIN OF  
THE BACK AND UNDER OCCLUSIVE PATCH FOR 48 H, IN THE ADULT SUBJECT)**

Test number:

**22/06/20/D/7**

**BIOBELLİNDÄ SASY ANTİPERSPIRANT DEO ROLL-ON FOR WOMEN**

name of the Principal:

***BIOBELLİNDÄ KOZMETİK VE TEMİZLİK ÜRÜNLERİ PAZARLAMA A.Ş.***

We confirm the quality, efficacy and safety

## **1. BASIS OF TEST IMPLEMENTATION**

- Order received on June 22<sup>nd</sup>, 2020 with the assigned number 22/06/20/D/7
- Samples of the product delivered by the Principal
- Confirmation of positive results of microbiological researches – attached by the Principal
- Quality composition of the product provided by the Principal:

INCI: *Deionize water, Aluminum Chlorohydrate, Steareth-2, C12-15 Alkyl Benzoate, Undecane Tridecane, Steareth-20, Perfume, Phenoxyethanol, Ethylhexylglycerin, Propylene Glycol, Octenidine HCl, Linalool.*

## **2. STUDY TYPE**

Compatibility (single patch test), under Dermatological Control.

## **3. STUDY OBJECTIVE**

To verify the good cutaneous compatibility of a cosmetic investigational product after a single application, to the skin of the back and under occlusive patch for 48 hours, in the adult subject.

## **4. STUDY RELEVANCE**

Cutaneous irritation can be defined as an attack to skin integrity, with lesions to the epidermis and coming from an inflammatory reaction of the dermis, expressed by macroscopy visible phenomena, mainly redness (erythema), up to edema. In Man, the study called "Single Patch Test" (occlusive application of a product to the skin, for 48 hours), allows to check, in 20 subjects, the good cutaneous compatibility (absence of any primary cutaneous irritation) after a single application followed by a macroscopic examination performed according to a given numerical scale.

## **5. LEGAL BASE OF THE 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 (1964r. and later changes)

## **6. INCLUSION CRITERIA**

Number of subjects: 20

Sex: male or female

Age: 18 to 71 years old

## **7. METHODOLOGY**

### **Application modalities of the investigational product:**

- Area: back, between the hips and the shoulders
- Quantity: a small amount (occlusive patch "Small Finn Chambers on Scanpor")
- Application conditions: investigational product as supplied, under occlusive patch
- Frequency and duration: single application, for about 48 hours

### **Evaluation modalities:**

- Observation, about 30 minutes after removal of the patches: readings done compared to those obtained with the "negative" control (patch alone)

- Cutaneous irritation quantification, according to a given numerical scale (erythema, edema, papulae/vesicles/bullae/pustules, dryness/desquamation, detergent effect, reflectivity), by the method of the differences (product-control).

## 8. DATA ANALYSIS

Determination of the index of Primary Cutaneous Irritation (P.C.I.); mean of the weighted sum of scoring obtained on the whole panel (erythema: factor 1; edema, papulae: factor 2; dryness, detergent effect, reflectivity: factor 0,5).

## 9. DURATION OF RESEARCH

Beginning of observation: June 26<sup>th</sup> 2020

End of observation: July 16<sup>th</sup> 2020

## RESULTS

Tab. 1 Patch test results

No.	Identification number	Sex	Age	Test result	
				48 h	Skin type
1	22/06/20/D/7-1	F	71	(-)	normal
2	22/06/20/D/7-2	F	51	(-)	normal
3	22/06/20/D/7-3	F	64	(-)	normal
4	22/06/20/D/7-4	F	58	(-)	normal
5	22/06/20/D/7-5	F	25	(-)	normal
6	22/06/20/D/7-6	F	64	(-)	normal
7	22/06/20/D/7-7	F	57	(-)	normal
8	22/06/20/D/7-8	F	22	(-)	normal
9	22/06/20/D/7-9	F	63	(-)	normal
10	22/06/20/D/7-10	F	56	(-)	normal
11	22/06/20/D/7-11	F	21	(-)	normal
12	22/06/20/D/7-12	F	30	(-)	normal
13	22/06/20/D/7-13	M	30	(-)	normal
14	22/06/20/D/7-14	F	18	(-)	normal
15	22/06/20/D/7-15	F	18	(-)	normal
16	22/06/20/D/7-16	F	30	(-)	normal
17	22/06/20/D/7-17	M	30	(-)	normal
18	22/06/20/D/7-18	F	30	(-)	normal
19	22/06/20/D/7-19	F	27	(-)	normal
20	22/06/20/D/7-20	M	27	(-)	normal

F – female

M – male

## RESULTS OF OBSERVATIONS AND EXAMINATIONS

SUBJ. N°	ERYTHEMA	EDEMA	PAPULAE/VESICLES/BULLAE/PUSTULES	DRYNESS/DESQUAMATION	DETERGENT EFFECT	REFLECTIVITY
01	0	0	0	0	0	0
02	0	0	0	0	0	0
03	0	0	0	0	0	0
04	0	0	0	0	0	0
05	0	0	0	0	0	0
06	0	0	0	0	0	0
07	0	0	0	0	0	0
08	0	0	0	0	0	0
09	0	0	0	0	0	0
10	0	0	0	0	0	0
11	0	0	0	0	0	0
12	0	0	0	0	0	0
13	0	0	0	0	0	0
14	0	0	0	0	0	0
15	0	0	0	0	0	0
16	0	0	0	0	0	0
17	0	0	0	0	0	0
18	0	0	0	0	0	0
19	0	0	0	0	0	0
20	0	0	0	0	0	0
Weighting	1	2	2	0.5	0.5	0.5

<b>WEIGHTED TOTAL</b>	<b>0</b>
<b>PRIMARY CUTANEOUS IRRITATION INDEX (P.C.I. #)</b>	<b>0</b>

*#= weighted total / number of subjects*

**Other observation: -**

**Nothing to report.**

## **RESULT:**

In 20 subjects, the results of patch tests were negative, which means that the product does not cause irritation or allergy reaction in those subjects.

## **CONCLUSION:**

1. Having conducted patch tests, one may state that the cosmetic product "BIOBELLINDA SASY ANTIPERSPIRANT DEO ROLL-ON FOR WOMEN" does not give irritant or allergenic reaction.
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.

**This report support "Dermatologically tested" and "Non-Irritant".**

*Signature of the person responsible  
for the report*

*Signature of the person responsible  
for dermatological evaluation*

*Signature of the  
approving person*

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DERMATOLOGIST AND VENEROLOGIST  
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Copy 1 (the Principal)  
Copy of the copy 1 (Skin Lab INTERNATIONAL Ltd.)