Cracow, August 11th, 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:

13/07/20/D/18

BİOBELLİNDA SASY IŞILTILI VÜCUT SPREYİ

name of the Principal:

BİOBELLİNDA KOZMETİK VE TEMİZLİK ÜRÜNLERİ PAZARLAMA A.Ş.

We confirm the quality, efficacy and safety

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1. BASIS OF TEST IMPLEMENTATION

- Order received on July 13th, 2020 with the assigned number 13/07/20/D/18
- Series: 0
- Samples of the product delivered by the Principal
- Quality composition of the product provided by the Principal:

INCI: *Alcohol denat, deionize water, parfume , glycerin, Crylates/C10-30 alkyl acrylate crosspolymer, d panthenol, triethanolamine, Synthetic Fluorphlogopite, CI 77891, CI 77491, tın oxide, 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: 19 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: July 20th 2020
End of observation: August 11th 2020

RESULTS

Tab. 1 Patch test results

No.	Identification number	Sex	Age	Test result	
				48 h	Skin type
1	13/07/20/D/18-1	F	25	(-)	normal
2	13/07/20/D/18-2	F	28	(-)	normal
3	13/07/20/D/18-3	F	23	(-)	normal
4	13/07/20/D/18-4	F	19	(-)	normal
5	13/07/20/D/18-5	F	32	(-)	normal
6	13/07/20/D/18-6	F	33	(-)	normal
7	13/07/20/D/18-7	M	33	(-)	normal
8	13/07/20/D/18-8	F	33	(-)	normal
9	13/07/20/D/18-9	F	26	(-)	normal
10	13/07/20/D/18-10	F	30	(-)	normal
11	13/07/20/D/18-11	F	56	(-)	normal
12	13/07/20/D/18-12	F	56	(-)	normal
13	13/07/20/D/18-13	F	31	(-)	normal
14	13/07/20/D/18-14	M	30	(-)	normal
15	13/07/20/D/18-15	F	30	(-)	normal
16	13/07/20/D/18-16	F	71	(-)	normal
17	13/07/20/D/18-17	M	51	(-)	normal
18	13/07/20/D/18-18	F	49	(-)	normal
19	13/07/20/D/18-19	F	20	(-)	normal
20	13/07/20/D/18-20	F	26	(-)	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

WEIGHTED TOTAL	**0**

PRIMARY CUTANEOUS IRRITATION INDEX (P.C.I. #)	**0**

#= 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 "BİOBELLİNDA SASY IŞILTILI VÜCUT SPREYİ" 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".

Signed by / Podpisano przez:
Magdalena Kędziora
Skin Lab International Sp. z o.o.
Date / Data: 2020-08-20 14:10

Signature of the person responsible for the report

Elektronicznie podpisany przez BARBARA WNUK

Signature of the person responsible for dermatological evaluation

Doctor of medicine Barbara Wnuk
DERMATOLOGIST AND VENEROLOGIST
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Signed by / Podpisano przez:
Sylwia Filipek
Skin Lab International Sp. z o.o.
Date / Data: 2020-08-29 10:49

Signature of the approving person