

PATCH TEST REPORT
Report Nr. A 23/09/0279

Извештај за тест за закрпи
Извештај бр. А 23/09/0279

FACE SERUM

Tested By | Тестирано од

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The test results refer only to the tested sample, for the composition and information provided responsibility lays on Principal. The report can only be copied in whole.

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STUDY OBJECTIVE

Assessment of skin tolerance of a cosmetic product after a single application during 48 hours occlusive patch on 10 volunteers.

CUSTOMER INFORMATION

Applicant: İNSİTU YEŞİL TEKNOLOJİLER SAN. VE TİC. A.Ş.
Address: PAZAR MAH. CUMHURİYET MEY. BELEDİYE İŞHANI SİTESİ NO:12
İÇ KAPI NO: 119 GÖLHİSAR / BURDUR
Related Person: -
Contact: -

SAMPLE INFORMATION

Sample Description: FACE SERUM
Brand: -
Appearance: A homogeneous, liquid.
Package: Original Package
Amount: 50 ml
Production Date: -
Expiry Date: -
Lot / Serial No: -
Manufacturer: İNSİTU YEŞİL TEKNOLOJİLER SAN. VE TİC. A.Ş.
Receipt Date: 25.09.2023
Study Period: 27.09.2023 – 02.10.2023

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TEST INFORMATION

Test Method: Single application - 48 Hours occlusive patch tests
Time(s) Of Assessment: 1 hour after patch removal, then after 24 & 48 hours (72 hours)

Panel: 20 healthy adult volunteers

Application Area: On the back

Quantity Of Product: 0.1 g

Methodology Abstract:

The tested product in commercial form in an amount of 0.1g was applied to paper flake (Whatmann 3), which were attached with a porous hypoallergenic (surgical) patch on the shoulders on the straight side or on the back.

Treatment sites are assessed before the first application of test material (baseline) and after treatment at 30 minutes after patch removal. Negative controls are used to facilitate evaluation. Skin reactions are scored throughout the test by the same experienced assessor, a dermatologist, who made the baseline assessment and under the same lighting source, following a pre-defined scoring scale. The quantification of the skin irritation is given through a numeric scale (erythema, oedema, dryness/desquamation, vesicles). The average irritant score of the product to be tested is calculated from the average of the quotations obtained for each volunteer, allowing to rank the product from "non irritant to very irritant".

Characteristics of volunteers and test results are presented in Table 1.

Related Regulations

1. Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of November 30, 2009 regarding cosmetic products.
2. Cosmetic Europe – The Personal Care Association (formerly COLIPA) Guidelines "Product test Guidelines for the Assessment of Human Skin Compatibility 1997"

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In the tested group of 10 people, there were no positive reactions, which proves that the tested product does not have irritating or sensitizing properties.

The test results are presented in Table 1.

Volunteer Tested Person Nr.	Age	Sex	Skin Type	Test Results After 24h	Test Results After 48h
1	28	M	N	(-)	(-)
2	33	W	D	(-)	(-)
3	31	W	D	(-)	(-)
4	27	M	N	(-)	(-)
5	29	W	D	(-)	(-)
6	38	M	N	(-)	(-)
7	32	W	N	(-)	(-)
8	33	W	D	(-)	(-)
9	26	M	D	(-)	(-)
10	29	M	D	(-)	(-)

Sex: W: Woman M: Man	Body Skin Type N: Normal, D: Dry, S: Sensitive, L: Normal with a tendency to oily around the seborrhic of the torso
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<p>Skin condition assessment by a dermatologist</p> <p>0 or (-) - no reaction, 1 or (+/-) - weak erythema, 2 or (+) - erythema, 3 or (++) - erythema, papules, 4 or (+++) - erythema, slight edema, 5 or (++++) - erythema, infiltration, vesicles</p>

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IRRITATION INDEX (X_{sr})

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_{sr})	PRODUCT CLASSIFICATION
$X_{sr} < 0,5$	non-irritating
$0,5 < X_{sr} < 2,0$	slightly irritating
$2,0 < X_{sr} < 5,0$	moderately irritating
$5,0 \leq X_{sr}$	strongly irritating

Average irritation index for tested product: $X_{sr} = 0$, where $X_{sr} = (\text{sum of the scores}) / (\text{volunteers number})$

CONCLUSION

According to the experimental conditions of the study, the test product, can be considered as **NON-IRRITATING** regarding its primary skin tolerance.

Др. Угур КАЈАСИ

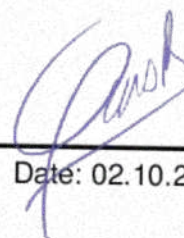
Principal Investigator | Dermatologist



Date: 02.10.2023

Дениз ЕЈСИЕР

Co-Investigator | Research Coordinator



Date: 02.10.2023

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