

EUROFINS CZ, s.r.o.

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Test Report

Epicutaneous Tests On Cosmetic Products

For evaluation of skin compatibility according to COLIPA Product Test guidelines for the assessment of human skin compatibility (1997)

Sponsor/Contract partner: EUROFINS CZ s.r.o., IČ: 274 49 408, Poděbradská 186/56,
Praha 9 – Hloubětín, 198 00

Order No.: 030/BR/2019

Customer: CBVIT Ltd., CN:08467027, Crown House, 27 Old Gloucester Street,
WC1N 3AX London, UK

Test performer: Doc. MUDr. Jarmila Rulcová, CSc.

Test No.: 212-E-2019

Test date: 25.11.2019 – 11.12.2019

Type and objective of the test:

Test was performed according to Cosmetic Product Test Guidelines for the Assessment of Human Skin Compatibility COLIPA, Brussels (1997).

Aim of the test was the assessment of the safety of cosmetic products in relation to their expected usage.

1) Demographic data of participants

Subject No	Initials	Gender	Age
001	ŠV	Z	23
002	NM	M	43
003	DR	M	26
004	VP	Z	32
005	PJ	Z	54
006	PJ	M	47
007	NV	Z	29
008	SV	Z	59
009	ŠM	M	54

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010	PL	Z	37
011	HJ	Z	41
012	HM	Z	37
013	HI	Z	51
014	GL	Z	29
015	KK	Z	34
016	UJ	Z	41
017	MK	Z	42
018	PL	Z	42
019	KA	Z	43
020	PJ	M	56
021	KM	Z	61
022	VR	Z	43
023	KL	M	35
024	MT	Z	19
025	SH	Z	42

Criteria on participants:

1. Male or female
2. Age between 18 to 65 years
3. Written informed consent

Eliminating criteria:

1. Pregnancy or breast-feeding
2. Apparent illness
3. Usage of topic or systematic medicaments, which may interfere with test
4. Positive anamnesis of dermal or allergic affection
5. Cooperation on dermal test at last 4 months
6. Parallel cooperation on any type of test
7. Skin irritation in test area
8. Family member or employee of company providing testing

Informed consent:

All of the participants obtain informed consent form with test aim and method description. Signed informed consents are stored by test performer.

2) Tested products:

product code	product name	test type
350	ACTIVE HEMP FACE CREAM	JUT

Key:

JUT – Single application closed patch epicutaneous test under occlusion

JOT – single application open epicutaneous test

Study Design

Aim of the test was the assessment of the safety of cosmetic products – dermal tolerance - in relation to their expected usage.

JUT description:

Areas dedicated for application were cleaned with pad impregnated with 70% isopropyl alcohol and let dry on air. Occlusion patch LEUKOTEST BDF BEIERSDORF AG with tested product was applied (with syringe or pipette) on forearm, arm or back in amount of 0.07 to 0.10 ml. Subjects were instructed to keep the test areas dry. After 24 hours were patches removed and rest of material was wiped off with purified water and gentle swabbing. The skin reactions (erythema, redness, scaling and subjective reactions) were assessed after 30 minutes, then after 24 hours, 48 hours and 72 hours after patch removal. Primary skin irritation index IKI was set.

JOT description:

Used for rinse-off products. In cases of repeated daily application or at higher concentration of surfactants, where is cumulative effect expected or by children's usage, can test performer decide about using of JUT or repeated epicutaneous occlusion test.

Areas dedicated for application were cleaned with pad impregnated with 70% isopropyl alcohol and let dry on air. Product can be applied diluted or undiluted on inner forearm or arm. Product was applied with glass stick or pad during 15 to 30 minutes. The rest of product was rinsed off with purified water or gentle wiped off. The skin reactions (erythema, redness, scaling and subjective reactions) were assessed directly after removal of product, then after 24 hours and 48 hours after patch removal.

3) Study**a) Single application closed patch epicutaneous test under occlusion**

Occlusive patch with product: **350-ACTIVE HEMP FACE CREAM** was applied on the right half of back in an amount 0,07 – 0,10 ml. Subjects were instructed to keep the test areas dry. After 24 hours were patches removed and rest of material was wiped off with purified water and gentle swabbing. The skin

reactions (erythema, redness, scaling and subjective reactions) were assessed after 30 minutes, then after 24 hours, 48 hours and 72 hours after patch removal.

b) Single application open epicutaneous test

Product ... was applied with pad on ... during 30 minutes. The rest of product was rinsed off with purified water. The skin reactions were assessed directly after removal of product, then after 24 hours and 48 hours after patch removal.

1. Level 2 – erythema with oedema, redness
2. Level 3 or 4 – erythema with or without oedema, redness
3. Any type of non-expected skin reaction

Examination of skin state:

Test performer visually assessed tested area at standard light conditions. Each symptom has referred numerical classification.

Oedema creation

Symptom	Abbreviation	Evaluation
Fiery redness	V	5
Strong oedema (superelevation more than 1 mm)	E	4
Moderate strong oedema (superelevation not more than 1 mm)	P	3
Mild oedema (defined borders)	R	2
Slight, minimal oedema	F	1
Absence of oedema	D	0

Erythema creation

- 0 = no evidence of erythema
- 1 = slight redness, spotty and diffuse
- 2 = moderate, uniform erythema
- 3 = strong uniform erythema
- 4 = fiery redness, erythema

Evaluation is made with **primary skin irritation index** I_{KI} , which express sum average of skin reaction level for erythema and oedema at each interval for each subject and then calculation of average for all of the subjects.

Results:

- Non-irritating..... $I_{KI} < 0.5$
- Slightly irritating..... $I_{KI} \geq 0.5$
- Moderate irritating..... $I_{KI} \geq 3.0$
- Strong irritating to corrosive..... $I_{KI} \geq 5.0$

4) Conclusions

Tested cosmetic product **350-ACTIVE HEMP FACE CREAM** was assessed with regard to upper mentioned tests. There was no objective irritation reaction or subjective negative observation recorded during testing. Tested products may be recommended to intended use from the dermal skin tolerance point of view.

Date: 11.12.2019

Doc. MUDr. Jarmila Rulcová, CSc.
Odborný dermatolog
Vedoucí testování

Study performer: Doc. MUDr. Jarmila Rulcová, CSc

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INDIVIDUAL SKIN IRRITATION SCORES

Date: 11.12.2019
 Test No.: 212-E-2019

SUBJECT	Sample				
	1	2	3	4	5
350-ACTIVE HEMP FACE CREAM	0	0	0	0	0
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	0	0	0	0	0
5	0	0	0	0	0
6	0	0	0	0	0
7	0	0	0	0	0
8	0	0	0	0	0
9	0	0	0	0	0
10	0	0	0	0	0
11	0	0	0	0	0
12	0	0	0	0	0
13	0	0	0	0	0
14	0	0	0	0	0
15	0	0	0	0	0
16	0	0	0	0	0
17	0	0	0	0	0
18	0	0	0	0	0
19	0	0	0	0	0
20	0	0	0	0	0
21	0	0	0	0	0
22	0	0	0	0	0
23	0	0	0	0	0
24	0	0	0	0	0
25	0	0	0	0	0
n	25	0	0	0	0
Sum of score	0	0	0	0	0
Average	0,0	0,0	0,0	0,0	0,0
Standard deviation	0,0	0,0	0,0	0,0	0,0

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