

EUROFINS CZ, s.r.o.

Head office: Radiová 1285/7, Hostivař, 102 00 Praha 10

Address: Tuřanka 115, 627 00 BRNO

Eurofins Food & Feed Testing
Czech Republic s.r.o.
Radiová 1285/7
102 00 Praha 10 – Hostivař ®
IČO: 27449408, DIČ: CZ27449408**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, Radiová 1285/7, Hostivař,
102 00 Praha 10**Order No.:** 023/BR/2021**Customer:** HEMP SAPA s.r.o., Křižovnická 86/6, 110 00 Praha 1, IČ: 06116329**Test performer:** Doc. MUDr. Jarmila Rulcová, CSc.**Test No.:** 018-E-2022**Test date:** 03.01.2022 - 19.01.2022**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	PL	Z	45
002	ŠT	Z	22
003	MB	Z	22
004	RD	M	19
005	NM	Z	47
006	ŠS	Z	29
007	BŽ	Z	25
008	MO	Z	62
009	ŠM	M	46

Test Report Epicutaneous Tests On Cosmetic Products

010	LH	Z	24
011	PR	M	51
012	PA	Z	20
013	PL	Z	40
014	MA	Z	39
015	BL	Z	62
016	ČM	Z	67
017	ŽV	Z	61
018	MK	Z	44
019	ChD	Z	52
020	HJ	M	66
021	VJ	Z	44
022	KJ	Z	26
023	KS	Z	47
024	KE	Z	37
025	JJ	Z	56

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
175	Hemp Body Butter	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 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: **175-Hemp Body Butter** 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 **175-Hemp Body Butter** 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: 19.1.2022


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Study performer: **Doc. MUDr. Jarmila Rulcová, CSc.**
Odborný dermatolog
Vedoucí testování

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Contract partner Eurofins CZ

INDIVIDUAL SKIN IRRITATION SCORES

Datum: 19.01.2022
 Číslo testu: 018-E-2022

SUBJECT	Sample				
175-Hemp Body Butter					
1	0				
2	0				
3	0				
4	0				
5	0				
6	0				
7	0				
8	0				
9	0				
10	0				
11	0				
12	0				
13	0				
14	0				
15	0				
16	0				
17	0				
18	0				
19	0				
20	0				
21	0				
22	0				
23	0				
24	0				
25	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

Processed by:  **Doc. MUDr. Jarmila Rybcova, ES, MSc.**
 Doc. MUDr. Jarmila Rybcova, ES, MSc., Jarmila Rybcova, s.r.o.
 Eurofins Food & Feed Testing
 Czech Republic s.r.o.
 Radiová 1265/7
 102-00 Praha 10
 IČO: 249449408
 Test performer: Dermatolog, Doc. MUDr. Jarmila Rybcova, CSc.
 The test was performed based on order form contract partner Eurofins CZ.