

## EUROFINS CZ, s.r.o.

Head office: Praha 9 – Hloubětín, Poděbradská 186/56, PSČ 198 00

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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.:** 025/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.:** 193-E-2019

**Test date:** 29.10.2019 – 14.11.2019

### 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	ŠT	Z	19
002	BN	Z	34
003	HH	Z	55
004	HŽ	Z	24
005	NL	M	31
006	PM	M	27
007	MM	M	41
008	ŠM	M	24
009	FV	M	57

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Test Report Epicutaneous Tests On Cosmetic Products

010	MH	Z	35
011	TM	Z	60
012	KJ	M	63
013	VJ	Z	41
014	ZO	Z	43
015	ČK	M	64
016	ŠM	Z	46
017	HO	Z	55
018	PO	M	28
019	PZ	Z	23
020	ČJ	M	45
021	KZ	Z	57
022	DK	M	26
023	PK	Z	19
024	VL	M	64
025	DD	M	18

Key: M – male, F – female

**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
302	<b>Active Hemp Body Butter</b>	<b>JUT</b>
303	<b>Active Hemp Body Milk</b>	<b>JUT</b>
304	<b>Active Hemp Body Oil</b>	<b>JUT</b>
305	<b>Active Hemp Ointment</b>	<b>JUT</b>
306	<b>Active Hemp Shampoo</b>	<b>JOT</b>

**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: **302-Active Hemp Body Butter; 303-Active Hemp Body Milk; 304-Active Hemp Body Oil; 305-Active Hemp Ointment** was applied on the left 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: **306-Active Hemp Shampoo** was applied in diluted form - water to 10% solution - with pad on volar side of the right forearm 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.....  $I_{KI} \geq 5.0$

**D) Conclusions**

Tested cosmetic products **302-Active Hemp Body Butter; 303-Active Hemp Body Milk; 304-Active Hemp Body Oil; 305-Active Hemp Ointment; 306-Active Hemp Shampoo** were 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: 14.11.2019

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

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Study performer: Doc. MUDr. Jarmila Rulcová, CSc

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Contract partner Eurofins CZ

## INDIVIDUAL SKIN IRRITATION SCORES

Date: 14.11.2019  
 Test No.: 193-E-2019

SUBJECT	Sample					
	302-Active Hemp Body Butter;	303-Active Hemp Body Milk;	304-Active Hemp Body Oil;	305-Active Hemp Ointment;	306-Active Hemp Shampoo	
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	25	25	25	10	0
Sum of score	0	0	0	0	0	0
Average	0,0	0,0	0,0	0,0	0,0	0
Standard deviation	0,0	0,0	0,0	0,0	0,0	0

Odborný dermatolog  
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 Doc. MUDr. Jarmila Rulcová, CSc.  
 Test performer: Dermatolog Doc. MUDr. Jarmila Rulcová, CSc.  
 The test was performed based on order from contract partner Eurofins CZ.