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Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to CSN EN ISO/IEC 17025:2018.

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Issue No.: 1

Test report No. S378/2019

SKIN IRRITATION ASSESSMENT CBVIT ACTIVE HEMP BODY MILK

Sample ID: S378/2019

Sample name: **CBVIT ACTIVE HEMP BODY MILK**

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

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

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

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From pages: 6

Incoming date:
9.12.2019

Delivery date:
16.12.2019

Hodonín, 16.12.2019



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Ing. Jana Šlitrová, Head of Laboratory

Description: *Skin irritation assessment*

Sample ID: S378/2019
Sample name: **CBVIT ACTIVE HEMP BODY MILK**
Sampled: by client
Sampling point: CBVIT Ltd., London, UK
Client: CBVIT Ltd., London, UK

Sample delivered: 9.12.2019
Testing date: 11.12.-14.12.2019
Delivered amount: 100 ml
Batch No: 271119/1
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Subject of testing:

Skin irritation assessment on volunteers

Identification of the sample:

Name of the product:	CBVIT ACTIVE HEMP BODY MILK
Batch number:	271119/1
Date of manufacture:	28.11.2019
Expiry date:	not available
Manufacturer:	CBVIT Ltd., CN:08467027, Crown House, 27 Old Gloucester Street, WC1N 3AX London, UK
Incoming date:	9.12.2019
Appearance of the product:	greenish body milk
Amount:	100 ml
Storage conditions:	lab temperature
Composition:	Aqua, Glycerin, Coco-Caprylate/Caprates, Butyrospermum Parkii Butter, Cannabis Sativa Seed Oil, Cocos Nucifera Oil, Glyceryl Stearate, Glyceryl Stearate Citrate, Squalane, Olea Europaea Fruit Oil, Cetyl Alcohol, CBD Isolate, Cannabis Sativa Leaf Extract, Cannabis Sativa Flower Oil, Hydrogenated Olive Oil Unsaponifiables, Tocopheryl Acetate, Xanthan Gum, Sodium Phytate, Alcohol, Linalool, Limonene, Citronellol, Sodium Anisate, Sodium Benzoate, Sodium Levulinate, Citric Acid, Sodium Hydroxide, Chlorophyllin-Copper Complex

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Experimental conditions:

Period of analysis:

Test temperature:

Test method:

Moisturising solution:

Amount of sample:

Contact time:

Testing of skin irritation

SOP-M-14-10 (ČSN EN ISO 10993-10)

29.11.-2.12.2019

human skin temperature (36.7 ± 0.2 °C)

on volunteers

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30 x 200 µl

15 min, 30 min, 1 h, 2h, 3h, 4 h

Test procedure:

The volunteers are selected according to CIOMS 2002 instructions and approved by ethical committee of Chemila, spol. s r.o. The selection is based on voluntariness, working on the assumption of meeting the requirements of the study and informed consent. More than one third of volunteers were of the same-sex (female). The test was performed on 30 volunteers.

The material (200 µl of the CBVIT ACTIVE HEMP BODY MILK) was applied inside the patch test chamber. The patch test was applied on the upper part of the arm for the contact time. After removal of the patch test, the skin is rinsed and wiped under the running water. Reading of the test is performed immediately and after (1 ± 0.1) h to (2 ± 1) h, (24 ± 2) h, (48 ± 2) h and (72 ± 2) h after the removal of the sample.

Further on the patch test was applied the positive control **20 % sodium dodecylsulphate** (SDS) in the amount of 0.4 ml. The patch test was applied on the upper part of the arm for the contact time. After removal of the patch test, the skin is rinsed and wiped under the running water. Reading of the test is performed immediately and after (1 ± 0.1) h to (2 ± 1) h, (24 ± 2) h, (48 ± 2) h and (72 ± 2) h after the removal.

The standard:

ČSN EN ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

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Positive control: 20% Sodium laurylsulphate

Volunteer			Reading the test					Reaction yes/ no
			Contact time: 15 min/ 30 min/ 1 h/ 2 h/ 3 h/ 4 h					
			Classification of skin reaction after:					
No	Age	Sex	0 h	2 h	24h	48h	72h	
1	45	F	000112	000112	000111	000001	000000	YES
2	40	F	001111	000111	000112	000111	000011	YES
3	39	F	000112	000111	000011	000000	000000	YES
4	40	F	001111	000112	000011	000001	000001	YES
5	54	F	000111	000112	000111	000011	000000	YES
6	42	F	000011	000112	000011	000001	000000	YES
7	43	F	000001	000111	000111	000001	000000	YES
8	50	F	000111	001112	000011	000001	000000	YES
9	44	F	000001	000111	000011	000001	000000	YES
10	47	F	011122	001112	001112	000011	000001	YES
11	53	F	000111	000011	000011	000001	000000	YES
12	37	F	000112	000112	000111	000011	000001	YES
13	34	F	001111	011111	000111	000011	000000	YES
14	27	F	000112	000111	000111	000011	000001	YES
15	44	F	000112	000111	000011	000001	000000	YES
16	35	F	000112	000011	000011	000001	000001	YES
17	47	F	000122	000112	000111	000011	000011	YES
18	49	F	000011	000111	000012	000011	000001	YES
19	69	F	000011	001111	000111	000001	000001	YES
20	45	F	000112	000111	000011	000011	000001	YES
21	42	F	000001	000012	000011	000001	000000	YES
22	46	M	011111	011112	000111	000011	000001	YES
23	42	M	000112	001112	001111	000111	000011	YES
24	45	M	000112	001111	000011	000001	000000	YES
25	54	M	000111	000111	000111	000011	000000	YES
26	54	M	000111	001222	000112	000111	000011	YES
27	51	M	000011	000011	000001	000000	000000	YES
28	36	M	000011	000111	000111	000011	000000	YES
29	49	M	001112	000111	000011	000001	000000	YES
30	29	M	000122	000112	000112	000111	000011	YES
Total number of reaction			0/2/6/22/27/30	0/2/8/26/30/30	0/0/2/16/29/30	0/0/0/4/15/28	0/0/0/0/5/14	30/30

Performed by: Bc. Iva Čížová, Deputy Manager of Microbiological Laboratory

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Discussion:

0 from 30 volunteers reacted on tested product.
30 from 30 volunteers reacted on positive control.
According to Fisher test (by P-value = 0,05) the skin irritation was significantly less frequent on tested product than on positive kontrol.

Interpretation:

The goal was to determine, whether the tested product **CBVIT ACTIVE HEMP BODY MILK** is skin irritant after exposition. That was achieved by comparison of number of volunteers, which reacted on tested product, with the number of volunteers, which reacted on positive control.

Material, which causes the skin irritation on the significantly smaller number of volunteers than the positive control, **cannot be considered as skin irritant.**

Conclusion:

The product **CBVIT ACTIVE HEMP BODY MILK** is not skin irritant.

Hodonín, 16.12.2019



Mgr. Mária Horáková, Ph.D. Leader of Study