

Copy No.: 1
Issue No.: 1

Test report No. S379/2019

**SKIN IRRITATION ASSESSMENT
CBVIT ACTIVE HEMP SHAMPOO**

Sample ID: S379/2019

Sample name: **CBVIT ACTIVE HEMP SHAMPOO**

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

Page: 1
From pages: 6

Incoming date:
9.12.2019

Delivery date:
16.12.2019

Hodonín, 16.12.2019

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Ing. Jana Štřelová, Head of Laboratory
.....

Description: *Skin irritation assessment*

Sample ID: S379/2019
Sample name: **CBVIT ACTIVE HEMP SHAMPOO**
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
Page: 2

Subject of testing:

Skin irritation assessment on volunteers

Identification of the sample:

Name of the product:

CBVIT ACTIVE HEMP SHAMPOO

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:

semitransparent shampoo of amber color

Amount:

100 ml

Storage conditions:

lab temperature

Composition:

Aqua, Sodium Coco-Sulfate, Lauryl Glucoside, Glycerin, Almond Oil Glycereth-8 Esters, Alcohol Denat., Citric Acid, CBD Isolate, Cannabis Sativa Leaf Extract, Aloe Barbadensis Leaf Juice, Urtica Dioica Extract, Lavandula Angustifolia Herb Extract, Malva Sylvestris Leaf Extract, Arctium Lappa Root Extract, Humulus Lupulus Extract, Humulus Lupulus Cone Extract, Mentha Piperita Extract, Tilia Vulgaris Flower Extract, Aspalathus Linearis Extract, Euphrasia Officinalis Extract, Chlorella Vulgaris Extract, Citrus Limon Peel Oil, Lavandula Angustifolia Oil, Hydrolyzed Wheat Protein, Decyl Glucoside, Dicaprylyl Ether, Glyceryl Oleate, Hydrolyzed Algin, Biosaccharide Gum-1, Maris Aqua, Sodium Chloride, Limonene, Glyceryl Cyprylate, Sodium Anisate, Sodium Levulinate, Potassium Sorbate, Sodium Benzoate, Benzoic Acid

Description: Skin irritation assessment

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Page: 3

Experimental conditions:

Testing of skin irritation

Period of analysis:	SOP-M-14-10 (ČSN EN ISO 10993-10) 29.11.-2.12.2019
Test temperature:	human skin temperature (36.7 ± 0.2 °C)
Test method:	on volunteers
Moisturising solution:	-
Amount of sample:	30 x 200 µl
Contact time:	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 SHAMPOO) 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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 Batch No: 271119/1
 Page: 5

Positive control: 20% Sodium laurylsulphate

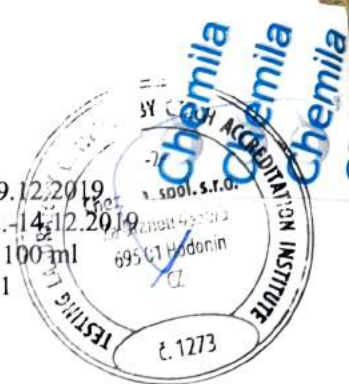
Volunteer			Reading the test					Reaction yes/ no
			Contact time: 15 min/ 30 min/ 1 h/ 2 h/ 3 h/ 4 h					
			Classification of skin reaction after:					
No	Age	Sex	0 h	2 h	24h	48h	72h	
1	45	F	000112	000112	000111	000001	000000	YES
2	40	F	001111	000111	000112	000111	000011	YES
3	39	F	000112	000111	000011	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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Page: 6



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 SHAMPOO** 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 SHAMPOO** is not skin irritant.

Hodonín, 16.12.2019

