Certified translation from the Czech language

NATIONAL INSTITUTE OF PUBLIC HEALTH
contributory organisation
Šrobárova 48
Prague 10
100 42

YOUR LETTER REF. NO.:
AS OF:
OUR REF. NO.: 19 February 2018
Ref. no.: 688/2018
ATTENDED TO BY: **CTZB 187-688/18-67, EX 180267**
TEL. FAX: MUDr. Dagmar Jírová, CSc.
E-MAIL: 2 6708 2439
dagmar.jirova@szu.cz
DATE:

LABORA Novy
Dvur
Dobrá Voda 20
264 01 Toužim

28 FEBRUARY 2018

EXPERT OPINION concerning the performed test to determine skin tolerance of a cosmetic product in a specific group of persons.

SUBJECT OF APPLICATION:
As concerns your request as of 19 February 2018 regarding assessment of the clinical study of product CREME APAISANTE, we would like to inform you as follows:

SUBMITTED SAMPLE: CREME APAISANTE

Manufacturer: Labora s.r.o., Dobrá Voda 20, 264 01 Toužim - Czech Republic

SUBMITTED DOCUMENTATION:
Qualitative and quantitative composition of the product.

PERFORMED TEST:
The test to determine skin tolerance of a cosmetic product in a specific group of persons was carried out by MUDr. Andrea Vocilková, Vocilkovi s.r.o., Na Malovance 6, 169 00 Prague 6 in the period from 12 January to 2 February 2018. The test was carried out according to the Cosmetic Product Test Guidelines for Assessment of Human Skin Compatibility, COLIPA, Bruxelles, 1997 (COLIPA = The European Cosmetic, Toiletry and Perfumery Association).

EXPERT EVALUATION:
Evaluation of the outcomes of the test to determine skin tolerance of a cosmetic product in a specific group of persons was carried out by MUDr. Dagmar Jírová, CSc., National Reference Centre for Cosmetics, Institute of Public Health, Prague 10 under no. CTZB 187-688/18-67.

CONCLUSION:
CREME APAISANTE is a product suitable for daily care for skin in patients with atopy and psoriasis where it may serve to care for dry and irritable skin and to maintain it in a good condition.

stamp:
NATIONAL INSTITUTE OF PUBLIC HEALTH
Centre of Toxicology and Health Safety
Šrobárova 48, 100 42 Prague 10

[signature]
MUDr. Dagmar Jírová, CSc.
Head
Centre of Toxicology and Health Safety

TEST REPORT
DETERMINATION OF THE SKIN TOLERANCE OF A COSMETIC PRODUCT IN A SPECIFIC GROUP OF PERSONS

The test was assessed by:
National Reference Centre for Cosmetics, National Institute of Public Health, Šrobárova 48, 100 42 Prague 10.

Clinical performance of the Study:
MUDr. Andrea Vocilková, Vocilkovi s.r.o., Na Malovance 6, 169 00 Prague 6

Client: **Labora s.r.o.**
Dobrá Voda 20
364 01 Toužim

Date of study: 12 January - 2 February 2018
Reference number: CTZB 187-688/18-67

The test was performed in compliance with: Cosmetic Product Test Guidelines for Assessment of Human Skin Compatibility, Colipa, Bruxelles 1997 (COLIPA = The European Cosmetic, Toiletry and Perfumery Association).

Study target: To confirm tolerance and benefits for skin care in patients with atopy and psoriasis.

TEST REPORT

TESTED SAMPLE (indic. VZ)

VZ 1: CREME APAISANTE

SAMPLE PREPARATION
The sample was applied without any modification.

TEST SUBJECTS

Selection of the test subjects (probands) and the testing procedure are governed by the principles established in the International ethical guidelines for health-related research involving humans (CIOMS, Geneva 2002). The Study was carried out with an approval of the Ethical Committee of the National Institute of Public Health in Prague.

Selection of the subjects was carried out by a dermatologist based on their personal and

family history and an actual dermatological evaluation of their skin condition (an overview is attached in Table No. 1). All volunteers have complied with the conditions to be enrolled to the Study, filled in the study participant questionnaire and signed an individual informed consent to take part in the Study. An individual consent of the persons under 18 was requested by means of their parents who filled in the study participant questionnaire and confirmed signing of a consent of their children's participation in the Study. All Study documents are confidential. The Study included 20 participants and they all completed the Study.

Table No. 1: Set of test subjects

Test person number	Initials	Age	Sex	Diagnosis
1	BB	39	F	L209
2	LB	36	F	L209
3	TCH	12	M	L209
4	LK	41	F	L209
5	PL	38	F	L400
6	JV	31	M	L209
7	LV	30	F	L209
8	AV	30	F	L209
9	ZŠ	34	F	L209
10	PK	40	M	L400
11	SD	57	F	L400
12	JV	61	M	L400
13	VM	67	F	L209
14	RŠ	46	M	L400
15	OV	34	M	L209
16	AS	12	F	L209
17	AZ	43	F	L209
18	IB	63	F	L400
19	ZČ	72	M	L400
20	TW	32	M	L400

L209 - atopic dermatitis

L400 - psoriasis vulgaris

TEST METHODOLOGY

A precondition for the Study initiation comprised availability of the product safety information.

The Study included:

- A test of normal use - a user test.

The subjects were notified in writing of the course of the Study and the way of the product application.

USER TEST

The tested product was applied at the places where eczema usually occurs, i.e. in the elbow pit of one hand, or at the place of occurring psoriasis on the limbs, with the frequency of 1 to 2 applications of 100 ml per day. The product was applied in small amounts that got absorbed within approx. 1 minute. Non-treated, anatomically corresponding parts of the body served as check points.

During the entire Study volunteers did not use any other cosmetic products on the tested and check points.

ASSESSMENT OF RESULTS BY THE PROBANDS

Evaluation of the skin condition before the Study initiation and after completion of the application was carried out by the probands. Evaluation included an overall assessment of the skin condition before the first application and after the last application of the product according to the classification provided in Table No. 2.

Table No. 2: Evaluation of the skin condition by the probands

Skin condition	Evaluation (grade)
much better than common products	1
slightly better than common products	2
the same as common products	3
slightly worse than common products	4
much worse than common products	5

ASSESSMENT OF THE RESULTS BY THE DERMATOLOGIST

Evaluation of the clinical condition of the skin before the Study initiation and after completion of the application was carried out by the dermatologist. Evaluation included an overall assessment of the skin condition before the first application and after the last application of the product according to the classification provided in Table No. 3.

Table No. 2: Evaluation of the skin condition by the dermatologist

Skin condition	Evaluation (grade)
very significant improvement	1
slight improvement	2
without any changes	3
slight worsening	4
completely unsatisfactory up to the point of necessity to terminate testing	5

RESULTS

Evaluation of the clinical condition of the skin after the test completion carried out by the probands and the dermatologist is provided in Tables No. 4 and 5.

Table No. 4: Evaluation of the skin condition by the probands - subjective evaluation

Skin condition	Evaluation (grade)	Number of persons
much better than common products	1	12
slightly better than common products	2	5
the same as common products	3	2
slightly worse than common products	4	1
much worse than common products	5	0

Table No. 5: Evaluation of the skin condition by the dermatologist

Skin condition	Evaluation (grade)	Number of persons
very significant improvement	1	3
slight improvement	2	11
without any changes	3	6
slight worsening	4	0
significant worsening (up to the need to suspend the application)	5	0

ASSESSMENT OF RESULTS

The user test results have confirmed highly beneficial tolerance of the product by all Study participants. During the test the dermatologist did not record any negative skin responses in the exposed persons. The persons enlisted in the Study did not indicate and subjective signs of intolerance of any of the products, i.e. burning, stinging or itching or other changes. The product significantly improves the skin condition.

ASSESSMENT BY THE PROBANDS

Twelve probands assessed the product effect as significantly better than with use of common products and 5 probands as slightly better than common products. Only 2 probands assessed the tested product effects as equal as other commonly available products and only 1 proband stated that according to their subjective evaluation the tested product is worse than other commonly available products. None of the test subjects participating in the Study assessed the product as much worse than commonly available products.

ASSESSMENT BY THE DERMATOLOGIST

Three volunteers recorded significant improvement of their skin condition and in 11 probands the dermatologist claimed a slight improvement of their skin condition after the tested product application. In six test subjects, the dermatologist did not record any changes at the places of application compared to the check points without the tested product application. None of the probands experienced a slight or significant worsening of the skin condition after the tested product application.

CONCLUSION

CREME APAISANTE is a product suitable for daily care for skin in patients with atopy and psoriasis where it may serve to care of dry and excitable skin to maintain it in a good condition.

Date: 28.02.2018

RNDr. Hana Bendová, Ph.D,
National Reference Centre for Cosmetics
Assessment of Results

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stamp:
NATIONAL INSTITUTE OF PUBLIC HEALTH PRAGUE
National Reference Centre
for Cosmetics

MUDr. Andrea Vocilková
Dermatology, expert in the field of occupational skin diseases, clinical performance of the Study

stamp:

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06 **493** **001**	Dermatologist's Office MUDr. Andrea Vocilkova, spol. s r.o. Makovského 1396/16b, 163 00 Prague 6 404 Dermatology and Venerology Tel.: +420 220 515 257