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Date: 05.03.2004

EXPERTISE

Examination of the Product

“Callusan FORTE”

BL-F150/03

**Concentration: undiluted
by Human Patch Test**

Sponsor.....: Greppmayr Footcare GmbH
Gautinger Str. 40a
82061 Neuried
Germany

Performing Laboratory .: Derma Consult GmbH
Brunnenstr. 61
53347 Alfter
Germany

Study Director: Dr. med. H. Prieur
Study Period.....: March 2004

Summary

Type of study..... : Determination of irritating effects to the skin with an occlusive patch test.
Test subjects..... : 50
Test site : Back
Test concentration .. : undiluted
Result..... : No appreciable signs of irritation were observed.

manager: Dr. H. P. Nissen B. R. Nissen-Zoufal district court Bonn HRB 5272
bank: VR-Bank Bonn account: 6 106 665 018
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Introduction

The epicutaneous patch test allows us to assess the primary skin irritation potential of cosmetic-finished products and raw materials.

Methods

All the work described in this expertise was conducted according to Good Clinical Practice (CPMP Working Party on Efficacy of Medicinal Products Note for Guidance: Good Clinical Practice for Trials on Medicinal Products in the European Community -1990-CB-55-89-706-EN-C) and in accordance with the guidelines by COLIPA (Walker A.P. et al: Test Guidelines for Assessment of Skin Compatibility of Cosmetic Finished Products in Man. Food and Chemical Toxicology **34**, 1996, 651-660). Because it was a study with humans, it was carried out in accordance with the Declaration of Helsinki (1964) and subsequent revisions.

Experiments were carried out on 50 volunteers (24 normal healthy subjects, 8 eczema patients, 0 allergy patients, 18 subjects with sensitive skin) between the ages of 21 to 59. Sex distribution was not standardized. The volunteers were clearly informed, verbally and in writing, regarding the nature of the study, the timetable, constraints and possible risks. They gave their written informed consent before participation in the study.

Inclusion criteria

- informed volunteers
- age \geq 18 years

Non-inclusion criteria

- pregnant or lactating women
- blemishes, marks (tattoos, sunburn) which interfere with scoring
- any skin disease that may interfere with the aim of the study

Participants can withdraw from the study, if they will no longer wish to participate in the study. During the test period, the subjects refrained from using other substances on the test areas.

Procedure

The product was applied undiluted in square test-chambers (Haye`s Test Chambers; HAL Allergie GmbH, Düsseldorf) to the backs of the panellists for a period of 48 hours. Proper adherence of the test patches was assured by the inclusion of sodium dodecyl sulphate (SDS) in one concentration (1%) as positive control. Water was used as a negative control.

Treatment sites were assessed for the presence of irritation by a trained evaluator using a 5 point visual scoring scale at 48 h (30 min after patch removal) and 72 h after patch application.

Scoring scale

<u>Erythema</u>	0: no E., 1: slight E., 2: significant E., 3: pronounced E., 4: strong E.
<u>Fissure</u>	0: no F., 1: minimal F., 2: significantly perceptible F., 3: pronounced F., 4: ulceration
<u>Scaling</u>	0: no Sc., 1: minimal Sc., 2: moderate Sc., 3: significant Sc., 4: closed scale crust

Results

The test results outlining the data for erythema, scaling and fissure formation are attached. All participants completed the study. The results showed that, under the test conditions, SDS (1 % in water) caused positive reactions in 11 subjects. The negative control water showed no reactions. None of the subjects showed any reaction on the test product.

On the basis of the test results and under the test conditions, the product

**“Callusan FORTE”
(undiluted)**

is to be classified as 'harmless' as regards the possibility of skin irritation.

Literature

J.E. Wahlberg:
“Patch Testing” in
R.J.G. Rycroft, T. Menné, P.J. Frosch und C. Benezra (eds.),
Textbook of Contact Dermatitis
Springer-Verlag, Berlin (1992), p. 241-265

Appendix: test protocol

Signature:

Dr. med. H. Prieur Dermatologist - Allergist

Signature:

Dr. Hans-Peter Nissen Chemist – Ph.D.
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No.	Type	after 48 h			after 72 h		
		E	F	S	E	F	S
1	E	0	0	0	0	0	0
2		0	0	0	0	0	0
3	S	0	0	0	0	0	0
4		0	0	0	0	0	0
5		0	0	0	0	0	0
6		0	0	0	0	0	0
7		0	0	0	0	0	0
8	S	0	0	0	0	0	0
9		0	0	0	0	0	0
10	S	0	0	0	0	0	0
11		0	0	0	0	0	0
12	S	0	0	0	0	0	0
13	S	0	0	0	0	0	0
14	E	0	0	0	0	0	0
15		0	0	0	0	0	0
16		0	0	0	0	0	0
17	S	0	0	0	0	0	0
18	S	0	0	0	0	0	0
19	S	0	0	0	0	0	0
20	S	0	0	0	0	0	0
21		0	0	0	0	0	0
22	E	0	0	0	0	0	0
23		0	0	0	0	0	0
24		0	0	0	0	0	0
25		0	0	0	0	0	0
26	S	0	0	0	0	0	0
27		0	0	0	0	0	0
28	S	0	0	0	0	0	0
29		0	0	0	0	0	0
30		0	0	0	0	0	0
31	S	0	0	0	0	0	0
32		0	0	0	0	0	0
33	E	0	0	0	0	0	0
34		0	0	0	0	0	0
35	S	0	0	0	0	0	0
36	E	0	0	0	0	0	0
37		0	0	0	0	0	0
38		0	0	0	0	0	0
39	S	0	0	0	0	0	0
40		0	0	0	0	0	0
41	E	0	0	0	0	0	0
42	S	0	0	0	0	0	0
43	S	0	0	0	0	0	0
44		0	0	0	0	0	0
45	S	0	0	0	0	0	0
46	E	0	0	0	0	0	0
47	E	0	0	0	0	0	0
48	S	0	0	0	0	0	0
49		0	0	0	0	0	0
50		0	0	0	0	0	0
		0,0	0,0	0,0	0,0	0,0	0,0

Erythema (E): no E.: 0, slight E.: 1, clear E.: 2, severe E.: 3, very severe E.: 4
 Fissures (F): no F.: 0, minimal F.: 1, clearly visible F.: 2, distinct F.: 3, ulceration: 4
 Scales (S): no S.: 0, minimal S.: 1, clearly visible S.: 2, moderate S.: 3, distinct S.: 4

S: subjects with sensitive skin
 E: patients with eczema
 A: patients with allergy