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Expertise

Examination of the Product

"EcoSparc 105"

Concentration: undiluted

by Human Patch Test (Cosmetic Trial)

Sponsor
oelheld GmbH
Ulmer Str. 135-139
70188 Stuttgart
Germany

Performing Laboratory
Derma Consult GmbH
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Study Details

Type of study.....: Determination of irritating effects to the skin with an occlusive patch test.
Study Period.....: November/December 2009
Study Director....: Dr. med. H. Prieur
Test subjects.....: 50 (22-61 years; sex distribution non-standardized)
24 normal healthy, 5 eczema, 2 allergy and 19 subjects with sensitive skin
Test site.....: Back
Concentration.....: Undiluted
Controls.....: SDS (1% in water), water

Summary Results

All participants completed the study. Under the test conditions, SDS (1% in water) caused positive reactions in 16 subjects. The negative control water showed no reactions. None of the subjects showed any reaction to the test product. On the basis of the test results and under the test conditions, the product

"EcoSparc 105"

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

Signature:

Dr. med. H. Prieur
Dermatologist - Allergist

Signature:

Dr. Hans-Peter Nissen
Chemist – Ph.D.

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Methodology

Introduction

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

Description

All the work described in this expertise was conducted 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, 5 eczema patients, 2 allergy patients, 19 subjects with sensitive skin) between the ages of 22 to 61. 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 participating in the study.
Participants could withdraw from the study at any time without giving reason. During the test period, the subjects refrained from using other substances on the test areas.

Inclusion criteria

- informed volunteers
- age ≥ 18 years

Exclusion criteria

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

Procedure

The product was applied in a concentration as outlined above in square test-chambers (Haye`s Test Chambers - Haye's Service B.V., The Netherlands) 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.

The 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

Erythema	0: no E., 1: slight E., 2: significant E., 3: pronounced E., 4: strong E.
Fissure	0: no F., 1: minimal F., 2: significantly perceptible F., 3: pronounced F., 4: ulceration
Scaling	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 on a per subject base for the test product are attached in tabulated form.

Literature

Jan E. Wahlberg, Magnus Lindberg:
"Patch Testing" in
P.J. Frosch, T. Menné & J.-P. Lepoittevin (eds.),
Contact Dermatitis 4th Edition
Springer-Verlag, Berlin Heidelberg, Germany (2006), pp. 365-390

Appendix: test protocol

03.12.2009 **Product: EcoSparc 105**

PROTOCOL

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	S	0	0	0	0	0	0
5	A	0	0	0	0	0	0
6		0	0	0	0	0	0
7	S	0	0	0	0	0	0
8		0	0	0	0	0	0
9		0	0	0	0	0	0
10	S	0	0	0	0	0	0
11	S	0	0	0	0	0	0
12	A	0	0	0	0	0	0
13		0	0	0	0	0	0
14		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		0	0	0	0	0	0
19		0	0	0	0	0	0
20	S	0	0	0	0	0	0
21	S	0	0	0	0	0	0
22		0	0	0	0	0	0
23		0	0	0	0	0	0
24	S	0	0	0	0	0	0
25		0	0	0	0	0	0
26		0	0	0	0	0	0
27	S	0	0	0	0	0	0
28	E	0	0	0	0	0	0
29		0	0	0	0	0	0
30	S	0	0	0	0	0	0
31		0	0	0	0	0	0
32		0	0	0	0	0	0
33	S	0	0	0	0	0	0
34	E	0	0	0	0	0	0
35		0	0	0	0	0	0
36	S	0	0	0	0	0	0
37		0	0	0	0	0	0
38		0	0	0	0	0	0
39		0	0	0	0	0	0
40		0	0	0	0	0	0
41	S	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	E	0	0	0	0	0	0
46	E	0	0	0	0	0	0
47	S	0	0	0	0	0	0
48		0	0	0	0	0	0
49	S	0	0	0	0	0	0
50	S	0	0	0	0	0	0
SUM		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