

Test report 250032

05.09.2004

- Human Patch Test -

Client:

Schomisch GmbH
Ms. Natalie Schomisch

Test report

Test parameter : singular, occlusive human patch test - 48 h

Client : Schomisch GmbH
Heinrich Nicolausstr. 31
87480 Weitnau-Seltmans

Reference : Ms Natalie Schomisch

Order date : 02.09.2004

Date of test report : 05.10.2004

Order no. : 250032

Test period : September 2004

Products : Leather

Sample no.	Sample designation
010/4269686	ECO-321 blazing red ecopell vegetabled tanned leather

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Schomisch GmbH, Weitnau-Seltmans

Sample No.: 010/4269686
Order No.: 250032

Number of test persons : number : 50
including : 21 21 normal healthy subjects
13 eczema patients
16 subjects with sensitive skin

age : 19 – 52
sexus : male and female

Test product : leather for garment/shoes

Number of application : singular

Test area : back,

Product quantity per test area : small pieces (~0.7 x 0.7)
25 Persons - rough side
25 Persons - smooth side

Contact time : 48 h under occlusion

Controls : 1. positive control : Sodium laurylsulfate (LDS) 1%ig in water
2. Negative control: water

Assessment : After 48 hours (30 minutes after removal of test chamber)
and after 72 h

Aim of the study

The aim of the study is to estimate the primary skin irritation potential under tightened test conditions (in vivo- human skin, under occlusion) after singular application.

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Test result

The results showed that under the chosen test conditions the SDS (1% in water) caused positive reactions on 13 panelists. The negative control water showed no reactions. None of the test persons showed any reaction on the leather product.

Based on the chosen test conditions and the test results the product

ECO-321 feuerrotes Leder (leather, blazing red)

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

Best regards

INSTITUT FRESENIUS AG

Uwe Aßmus

Gabriele Götttsch

Enclosure:

Method	(2 pages)
Demographische Daten	(2 pages)
Results	(3 x 2 pages)

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Method description:

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 consent before participating in the study. Participants could withdraw from the study at any time without giving reasons. During the test period, the panelists refrained from using other substances on the test areas.

Inclusion criteria:

- age: more than 18 years old.
- informed volunteers

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

The epicutaneous patch test allows us to assess the primary skin irritation potential. All the work described in this expertise was conducted according GLP directives and in accordance with the guidelines of the COLIPA working group (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). As it was a study with humans it was carried out in accordance with the declaration of Helsinki (1964) and subsequent revisions.

The product was cut in small pieces and applied in square test chambers (Haye's Test Chambers, Vertrieb: HAL Allergie GmbH, Düsseldorf) to the backs of the panelists for a period of 48 hours (25 persons had contact with the rough side, 25 persons had contact with the smooth side).

Water was used as a negative control, sodium lauryl sulfate (SLS 1%ig) was used as a positive control.

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Scoring scale:

The treatment site were assessed for the presence of irritation by a trained evaluator using a 5 point visual scoring scale after 48 h (30 minutes after patch removal) and 72 h after application.

Erythema	0	=	none Erythema
	1	=	slight Erythema
	2	=	significant Erythema
	3	=	pronounced Erythema
	4	=	strong Erythema
Fissure	0	=	none Fissure
	1	=	minimal Fissure
	2	=	significantly perceptible Fissure
	3	=	pronounced Fissure
	4	=	Ulceration
Scaling	0	=	none Scaling
	1	=	minimal Scaling
	2	=	moderate Scaling
	3	=	significant Scaling
	4	=	closed scale crust

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Demographic data of test persons

number of test persons	Skin
1	sensitive skin
2	sensitive skin
3	-
4	-
5	eczema
6	-
7	-
8	-
9	sensitive skin
10	sensitive skin
11	eczema
12	sensitive skin
13	-
14	eczema
15	eczema
16	sensitive skin
17	-
18	-
19	eczema
20	sensitive skin
21	-
22	eczema
23	-
24	eczema
25	sensitive skin

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Demographic data of test persons

number of Test person	Skin
26	-
27	sensitive skin
28	-
29	eczema
30	eczema
31	eczema
32	-
33	sensitive skin
34	sensitive skin
35	-
36	sensitive skin
37	sensitive skin
38	sensitive skin
39	-
40	-
41	eczema
42	eczema
43	sensitive skin
44	-
45	-
46	-
47	eczema
48	-
49	-
50	sensitive skin

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Product leather (results)

Test person No.	after 48 hours			after 72 hours		
	Erythema	Fissure	Scaling	Erythema	Fissure	Scaling
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	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	0	0	0	0	0	0
9	0	0	0	0	0	0
10	0	0	0	0	0	0
11	0	0	0	0	0	0
12	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	0	0	0	0	0	0
18	0	0	0	0	0	0
19	0	0	0	0	0	0
20	0	0	0	0	0	0
21	0	0	0	0	0	0
22	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

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Product leather (results)

Test person No.	after 48 hours			after 72 hours		
	Erythema	Fissure	Scaling	Erythema	Fissure	Scaling
26	0	0	0	0	0	0
27	0	0	0	0	0	0
28	0	0	0	0	0	0
29	0	0	0	0	0	0
30	0	0	0	0	0	0
31	0	0	0	0	0	0
32	0	0	0	0	0	0
33	0	0	0	0	0	0
34	0	0	0	0	0	0
35	0	0	0	0	0	0
36	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	0	0	0	0	0	0
42	0	0	0	0	0	0
43	0	0	0	0	0	0
44	0	0	0	0	0	0
45	0	0	0	0	0	0
46	0	0	0	0	0	0
47	0	0	0	0	0	0
48	0	0	0	0	0	0
49	0	0	0	0	0	0
50	0	0	0	0	0	0
Average	0,0	0,0	0,0	0,0	0,0	0,0

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Negative control water (results)

Test person No.	after 48 hours			after 72 hours		
	Erythema	Fissure	Scaling	Erythema	Fissure	Scaling
1	0	0	0	0	0	0
2	0	0	0	0	0	0
3	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	0	0	0	0	0	0
9	0	0	0	0	0	0
10	0	0	0	0	0	0
11	0	0	0	0	0	0
12	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	0	0	0	0	0	0
18	0	0	0	0	0	0
19	0	0	0	0	0	0
20	0	0	0	0	0	0
21	0	0	0	0	0	0
22	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

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Negative control water (results)

Test person No.	after 48 hours			after 72 hours		
	Erythema	Fissure	Scaling	Erythema	Fissure	Scaling
26	0	0	0	0	0	0
27	0	0	0	0	0	0
28	0	0	0	0	0	0
29	0	0	0	0	0	0
30	0	0	0	0	0	0
31	0	0	0	0	0	0
32	0	0	0	0	0	0
33	0	0	0	0	0	0
34	0	0	0	0	0	0
35	0	0	0	0	0	0
36	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	0	0	0	0	0	0
42	0	0	0	0	0	0
43	0	0	0	0	0	0
44	0	0	0	0	0	0
45	0	0	0	0	0	0
46	0	0	0	0	0	0
47	0	0	0	0	0	0
48	0	0	0	0	0	0
49	0	0	0	0	0	0
50	0	0	0	0	0	0
Average	0,0	0,0	0,0	0,0	0,0	0,0

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Positive control NLS 1%ig (results)

Test person No.	after 48 hours			after 72 hours		
	Erythema	Fissure	Scaling	Erythema	Fissure	Scaling
1	1	0	0	0	0	0
2	0	0	0	0	0	0
3	1	0	0	1	0	0
4	0	0	0	0	0	0
5	0	0	0	0	0	0
6	0	0	0	0	0	0
7	1	0	1	1	0	0
8	0	0	0	0	0	0
9	0	0	0	0	0	0
10	0	0	0	0	0	0
11	1	0	0	0	0	0
12	0	0	0	0	0	0
13	1	0	0	1	0	0
14	0	0	0	0	0	0
15	0	0	0	0	0	0
16	1	0	1	1	0	1
17	0	0	0	0	0	0
18	0	0	0	0	0	0
19	0	0	0	0	0	0
20	0	0	0	0	0	0
21	0	0	0	0	0	0
22	0	0	0	0	0	0
23	1	0	0	0	0	0
24	0	0	0	0	0	0
25	0	0	0	0	0	0

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Positive control NLS 1%ig (results)

Test person No.	after 48 hours			after 72 hours		
	Erythema	Fissure	Scaling	Erythema	Fissure	Scaling
26	0	0	0	0	0	0
27	0	0	0	0	0	0
28	0	0	0	0	0	0
29	1	0	0	1	0	0
30	0	0	0	0	0	0
31	0	0	0	0	0	0
32	1	0	0	0	0	0
33	0	0	0	0	0	0
34	0	0	0	0	0	0
35	1	0	0	1	0	0
36	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	0	0	0	0	0	0
42	1	0	0	0	0	0
43	0	0	0	0	0	0
44	1	0	0	0	0	0
45	0	0	0	0	0	0
46	0	0	0	0	0	0
47	0	0	0	0	0	0
48	0	0	0	0	0	0
49	0	0	0	0	0	0
50	1	0	0	0	0	0
Average	0,26	0,0	0,04	0,12	0,0	0,02

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