Test report 704805-02
14.09.2006

– Human Patch Test -

Client:

Schomisch GmbH
Heinrich-Nicolausstr. 31
87480 Weitnau-Seltmans

Test report

Test parameter	**:**	**singular, occlusive human patch test - 48 h**
Client	**:**	Schomisch GmbH Heinrich-Nicolausstr. 31 87480 Weitnau-Seltmans
Reference	**:**	Mr. Schomisch
Order date		28.08.2006
Date of test report	**:**	14.09.2006
Order no.	**:**	704805
Test period	**:**	September 2006
Products	**:**	leather

Sample no.	Sample designation
010/6323712	Natural leather; ecopell black 100 ca. 1,4 – 1,6 mm, Lot: 5514 SL KW 16/2006 (Nappa side and suede – back side)

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Number of test persons	**:**	number	:	50 (2 x 25 persons)
		including	:	23 normal healthy subjects 10 eczema patients 17 subjects with sensitive skin 0 allergy patients
		age	:	23 – 59
		sexus	:	male and female
Test product	**:**	Leather (nature)		
Number of application	**:**	singular		
Test area	**:**	back		
Product quantity per test area	**:**	small pieces (~0.7 x 0.7) (25 persons nappa site and 25 persons velour site)		
Contact time	**:**	48 h under occlusion		
Controls	**:**	1. positive control: sodium dodecyl sulphate (SDS) 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 product.

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

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

Best regards

SGS INSTITUT FRESENIUS GmbH

i. V. Uwe Aßmus i. V. Inga Mickley

Enclosure:

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

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 dodecyl sulphate (SDS 1%ig) was used as a positive control.

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Scoring scale:

The treatment site was 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	Eczema
3	-
4	-
5	Sensitive skin
6	-
7	-
8	Allergy
9	-
10	Sensitive skin
11	Sensitive skin
12	Sensitive skin
13	Sensitive skin
14	Sensitive skin
15	-
16	-
17	Eczema
18	Sensitive skin
19	Sensitive skin
20	Sensitive skin
21	-
22	Sensitive skin
23	-
24	Eczema
25	-

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Demographic data of test persons

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

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(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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(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 SDS 1%ig (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	1	0	1	1	0	0
4	0	0	0	0	0	0
5	0	0	0	0	0	0
6	1	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	1	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	1	0	0	1	0	1
15	0	0	0	0	0	0
16	0	0	1	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	1	0	1	1	0	1
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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Positive control SDS 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	1	0	0	0	0	0
29	0	0	0	0	0	0
30	0	0	0	0	0	0
31	1	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	1	0	0	1	0	0
38	0	0	0	0	0	0
39	0	0	0	0	0	0
40	0	0	0	0	0	0
41	1	0	1	1	0	1
42	0	0	0	0	0	0
43	1	0	1	1	0	1
44	0	0	0	0	0	0
45	0	0	0	0	0	0
46	1	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	0,24	0,0	0,1	0,12	0,0	0,08

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i. V. Uwe Aßmus i. V. Inga Mickley