

Test report 504771 24.11.2005

- 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 : 09.11.2005

Date of test report : 24.11.2005

Order no. : 504771

Test period : November 2005

Products : leather

Sample no.	Sample designation
010/5375022	Natural leather; ecopell chianti 622 Lot: 3861 KW 39 Co 90, (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 15 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

Natural leather; ecopell chianti 622
Lot: 3861 KW 39 Co 90, (Nappa side and suede-backside)

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. A. Inga Mickley

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 to 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	Eczema
2	-
3	Eczema
4	Eczema
5	-
6	-
7	Sensitive skin
8	Sensitive skin
9	-
10	Sensitive skin
11	Sensitive skin
12	-
13	Eczema
14	-
15	-
16	Eczema
17	Sensitive skin
18	Sensitive skin
19	Eczema
20	-
21	-
22	Eczema
23	Sensitive skin
24	-
25	-

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Demographic data of test persons

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

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Naturleder pflanzlich gegerbt naturbelassen
Stärke: ca. 1,4 – 1,6 mm, ecopell chianti 622
Partie: 3861 KW 39 Co 90, (Nappaseite und Velour-Rückseite)

(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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Stärke: ca. 1,4 – 1,6 mm, ecopell chianti 622
Partie: 3861 KW 39 Co 90, (Nappaseite und Velour-Rückseite)

(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	1	0	0	0	0	0
3	0	0	0	0	0	0
4	1	0	1	1	0	0
5	0	0	0	0	0	0
6	0	0	0	0	0	0
7	0	0	0	0	0	0
8	1	0	0	1	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	0	0	0	0	0	0
15	0	0	0	0	0	0
16	1	0	0	0	0	0
17	0	0	0	0	0	0
18	1	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	1	1	0	0
24	0	0	0	0	0	0
25	1	0	0	1	0	1

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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	1	0	0	0	0	0
28	0	0	0	0	0	0
29	0	0	0	0	0	0
30	1	0	1	1	0	1
31	0	0	0	0	0	0
32	1	0	0	1	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	1	0	1	1	0	1
40	0	0	0	0	0	0
41	0	0	0	0	0	0
42	0	0	0	0	0	0
43	1	0	0	0	0	0
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	0,3	0,0	0,08	0,14	0,0	0,06

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