

**Test report 1089746-02  
10.03.2008****- Human Patch Test -****Client:****Ecopell GmbH  
Heinrich-Nicolaus-Str. 31  
D-87480 Weitnau-Seltmans**

# Test report

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

**Client** : Ecopell GmbH  
Heinrich-Nicolaus-Str. 31  
D-87480 Weitnau-Seltmans  
Germany

**Reference** : Mr. J.-P. Schomisch

**Order date** : February 19, 2008

**Date of test report** : March 10, 2008

**Order no.** : 1089746

**Test period** : February/ March 2008

**Products** : **Natural Leather**

Sample no.	Sample designation
010/8083747	<b>Chromfreies Naturleder (natural leather, chromium free) Pflanzlich gegerbt, naturbelassen Stärke: 1,4 – 1,6 mm, ecopell enzian 700 Partie: 0097 SL, KW 3/08</b>

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**Number of test persons** : number : 50  
including : 24 normal healthy subjects  
5 eczema patients  
20 subjects with sensitive skin  
1 allergy patients

age : 23 – 61  
sexus : male and female

**Test product** : **natural leather**

**Number of application** : singular

**Test area** : back

**Product quantity per test area** : small pieces (25 Persons Velour side)  
(25 Persons Nappa side)

**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 72 h after patch application

### 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 12 panelists. The negative control water showed no reactions. None of the test persons showed any reaction on the test product.

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

**Chromfreies Naturleder**  
**Pflanzlich gegerbt, naturbelassen**  
**Stärke: 1,4 – 1,6 mm, ecopell enzian 700**  
**Partie: 0097 SL, KW 3/08**

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

Best regards

**SGS INSTITUT FRESENIUS GmbH**

i. V. Gabriele Götsch

i. V. Inga Mickley

### Enclosure:

Method	(2 pages)
Demographic Data	(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 dodecyl sulphate (SLS 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.

<b>Erythema</b>	0	=	none Erythema
	1	=	slight Erythema
	2	=	significant Erythema
	3	=	pronounced Erythema
	4	=	strong Erythema
<b>Fissure</b>	0	=	none Fissure
	1	=	minimal Fissure
	2	=	significantly perceptible Fissure
	3	=	pronounced Fissure
	4	=	Ulceration
<b>Scaling</b>	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	Eczema
5	-
6	sensitive skin
7	sensitive skin
8	-
9	-
10	sensitive skin
11	Allergy
12	-
13	sensitive skin
14	sensitive skin
15	-
16	Eczema
17	-
18	sensitive skin
19	-
20	-
21	sensitive skin
22	sensitive skin
23	sensitive skin
24	-
25	-

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**Demographic data of test persons**

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



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700, Partie: 0097 SL, KW 3/08**

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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700, Partie: 0097 SL, KW 3/08**

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
<b>Average</b>	<b>0,0</b>	<b>0,0</b>	<b>0,0</b>	<b>0,0</b>	<b>0,0</b>	<b>0,0</b>

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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	0	0	0	0	0	0
2	0	0	0	0	0	0
3	0	0	0	0	0	0
4	1	0	1	1	0	1
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	1	0	1	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	1	0	1	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	1	0	1	1	0	1
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	1	0	1	1	0	0
28	0	0	0	0	0	0
29	0	0	0	0	0	0
30	1	0	0	1	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	0	0	0	0	0	0
38	0	0	0	0	0	0
39	0	0	0	0	0	0
40	0	0	0	1	0	1
41	0	0	0	0	0	0
42	0	0	0	0	0	0
43	0	0	0	0	0	0
44	1	0	1	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	1	0	1	1	0	0
49	0	0	0	0	0	0
50	0	0	0	0	0	0
<b>Average</b>	<b>0,22</b>	<b>0,0</b>	<b>0,14</b>	<b>0,12</b>	<b>0,0</b>	<b>0,06</b>

**SGS INSTITUT FRESENIUS GmbH**

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