

Derma
Consult
GmbH

Gesellschaft zur Prüfung von
Dermatika

DC Brunnenstraße 61 53347 Alfter Germany

Phone: +49 - (0)2222 / 9108 - 10
Fax: +49 - (0)2222 / 9108 - 40
E-mail: info@dermaconsult.com
Web: www.dermaconsult.com
Date: 19.08.2022

Expertise

Examination of the Product

“Sansin Dishwashing Gel Sensitive”

14.06.2022.

Concentration: 1,0% in water

by Human Patch Test (Cosmetic Trial)

Sponsor

ChemCore Impex Kft.
Szemlőhegy street 6
1022 Budapest,
Hungary

Performing Laboratory

Derma Consult GmbH
Brunnenstr. 61
53347 Alfter
Germany

Study Details

Type of study.....: Determination of irritating effects to the skin with an occlusive patch test.
Study Period.....: August 2022
Study Director: Dr. med. H. Prieur
Test subjects: 50 (18-69 years; sex distribution non-standardized)
31 normal healthy, 3 eczema, 2 allergy and 14 subjects with sensitive skin
Test site.....: Back
Concentration.....: 1,0% in water
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 11 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

“Sansin Dishwashing Gel Sensitive“

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

Signature:

Dr. med. H. Prieur
Dermatologist - Allergist

Signature:

Dr. J. Nissen
Pharmacist - M.D.R.A.

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 considering 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; COSMETICS EUROPE: Product test guidelines for the assessment of human skin compatibility 1997).

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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. Drop-outs were replaced and their data discarded.

Inclusion criteria

- informed volunteers
- age \geq 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 (allergEAZE[®] clear Patch Test Chambers; SmartPractice[®], Phoenix, AZ) 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.

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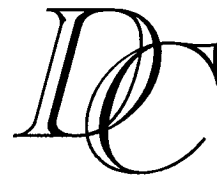
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2		0	0	0	0	0	0
3	S	0	0	0	0	0	0
4		0	0	0	0	0	0
5		0	0	0	0	0	0
6	S	0	0	0	0	0	0
7		0	0	0	0	0	0
8		0	0	0	0	0	0
9		0	0	0	0	0	0
10	S	0	0	0	0	0	0
11	S	0	0	0	0	0	0
12		0	0	0	0	0	0
13		0	0	0	0	0	0
14		0	0	0	0	0	0
15		0	0	0	0	0	0
16	S	0	0	0	0	0	0
17		0	0	0	0	0	0
18		0	0	0	0	0	0
19	S	0	0	0	0	0	0
20	S	0	0	0	0	0	0
21		0	0	0	0	0	0
22	A	0	0	0	0	0	0
23		0	0	0	0	0	0
24	S	0	0	0	0	0	0
25	A	0	0	0	0	0	0
26		0	0	0	0	0	0
27	S	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	S	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	E	0	0	0	0	0	0
38	E	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		0	0	0	0	0	0
43		0	0	0	0	0	0
44		0	0	0	0	0	0
45	E	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
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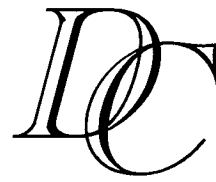
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4		0	0	0	0	0	0
5		0	0	0	0	0	0
6	S	0	0	0	0	0	0
7		0	0	0	0	0	0
8		0	0	0	0	0	0
9		0	0	0	0	0	0
10	S	0	0	0	0	0	0
11	S	0	0	0	0	0	0
12		0	0	0	0	0	0
13		0	0	0	0	0	0
14		0	0	0	0	0	0
15		0	0	0	0	0	0
16	S	0	0	0	0	0	0
17		0	0	0	0	0	0
18		0	0	0	0	0	0
19	S	0	0	0	0	0	0
20	S	0	0	0	0	0	0
21		0	0	0	0	0	0
22	A	0	0	0	0	0	0
23		0	0	0	0	0	0
24	S	0	0	0	0	0	0
25	A	0	0	0	0	0	0
26		0	0	0	0	0	0
27	S	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	S	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	E	0	0	0	0	0	0
38	E	0	0	0	0	0	0
39		0	0	0	0	0	0
40		0	0	0	0	0	0
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42		0	0	0	0	0	0
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7		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		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	S	0	0	0	0	0	0
17		0	0	0	0	0	0
18		0	0	0	0	0	0
19	S	0	0	0	0	0	0
20	S	0	0	0	0	0	0
21		0	0	0	0	0	0
22	A	0	0	0	0	0	0
23		0	0	0	0	0	0
24	S	0	0	0	0	0	0
25	A	0	0	0	0	0	0
26		0	0	0	0	0	0
27	S	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	S	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	E	0	0	0	0	0	0
38	E	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		0	0	0	0	0	0
43		0	0	0	0	0	0
44		0	0	0	0	0	0
45	E	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
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