



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: 28.08.2010

## Expertise

Examination of the Product

**“Dline BS Basic Shampoo”**

20053-5

Concentration: 10,0% in water

by Human Patch Test (Cosmetic Trial)

*Sponsor*

**dline AG**

Holzmoosrütistrasse 48  
CH-8820 Wädenswil  
Switzerland

*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 2010  
*Study Director* ....: Dr. med. H. Prieur  
*Test subjects* .....: 50 (23-62 years; sex distribution non-standardized)  
22 normal healthy, 7 eczema, 4 allergy and 17 subjects with sensitive skin  
*Test site*.....: Back  
*Concentration*.....: 10,0% 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 16 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

**“Dline BS Basic Shampoo“**

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

Signature:

Dr. med. H. Prieur  
Dermatologist - Allergist

Signature:

Dr. Hans-Peter Nissen  
Chemist – Ph.D.

manager: Dr. H. P. Nissen B. R. Nissen-Zoufal district court Bonn HRB 5272  
bank account: VR Bank Bonn account 6 106 665 018 BLZ 381 602 20  
IBAN: DE38 3816 0220 6106 6650 18 BIC: GENO DE D1 HBO

VAT-REG.No. DE 123369725  
Tax No. 222/5703/0374

Page 1 of 3

## **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 in accordance with 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). Because it was a study with humans, it was carried out in accordance with the Declaration of Helsinki (1964) and subsequent revisions.

Experiments were carried out on 50 volunteers (22 normal healthy subjects, 7 eczema patients, 4 allergy patients, 17 subjects with sensitive skin) between the ages of 23 to 62. Sex distribution was not standardized. 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 informed consent before participating in the study.

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.

### ***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 (Haye's Test Chambers - Haye's Service B.V., The Netherlands) 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***

<u>Erythema</u>	0: no E., 1: slight E., 2: significant E., 3: pronounced E., 4: strong E.
<u>Fissure</u>	0: no F., 1: minimal F., 2: significantly perceptible F., 3: pronounced F., 4: ulceration
<u>Scaling</u>	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.

### **Literature**

*Jan E. Wahlberg, Magnus Lindberg:*  
“Patch Testing” in  
P.J. Frosch, T. Menne & J.-P. Lepoittevin (eds.),  
Contact Dermatitis 4<sup>th</sup> Edition  
Springer-Verlag, Berlin Heidelberg, Germany (2006), pp. 365-390

***Appendix:*** test protocol

No.	Type	after 48 h			after 72 h		
		E	F	S	E	F	S
1	S	0	0	0	0	0	0
2	S	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	E	0	0	0	0	0	0
7		0	0	0	0	0	0
8	S	0	0	0	0	0	0
9		0	0	0	0	0	0
10	E	0	0	0	0	0	0
11	E	0	0	0	0	0	0
12		0	0	0	0	0	0
13	S	0	0	0	0	0	0
14	A	0	0	0	0	0	0
15		0	0	0	0	0	0
16		0	0	0	0	0	0
17	S	0	0	0	0	0	0
18		0	0	0	0	0	0
19	S	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	S	0	0	0	0	0	0
24	A	0	0	0	0	0	0
25		0	0	0	0	0	0
26	S	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	E	0	0	0	0	0	0
31	S	0	0	0	0	0	0
32		0	0	0	0	0	0
33	A	0	0	0	0	0	0
34	S	0	0	0	0	0	0
35	A	0	0	0	0	0	0
36		0	0	0	0	0	0
37	S	0	0	0	0	0	0
38		0	0	0	0	0	0
39	S	0	0	0	0	0	0
40	S	0	0	0	0	0	0
41	E	0	0	0	0	0	0
42		0	0	0	0	0	0
43		0	0	0	0	0	0
44	E	0	0	0	0	0	0
45		0	0	0	0	0	0
46	S	0	0	0	0	0	0
47	S	0	0	0	0	0	0
48		0	0	0	0	0	0
49	E	0	0	0	0	0	0
50		0	0	0	0	0	0
SUM		0,0	0,0	0,0	0,0	0,0	0,0

Erythema (E): no E.: 0, slight E.: 1, clear E.: 2, severe E.: 3, very severe E.: 4  
 Fissures (F): no F.: 0, minimal F.: 1, clearly visible F.: 2, distinct F.: 3, ulceration: 4  
 Scales (S): no S.: 0, minimal S.: 1, clearly visible S.: 2, moderate S.: 3, distinct S.: 4

S: subjects with sensitive skin  
 E: patients with eczema  
 A: patients with allergy