





Industriepark Höchst, Geb. C770  
65926 Frankfurt am Main

Susanne Scheid  
Dipl.-Übersetzerin  
Tel: 069-305 2807  
Fax: 069-30 47 32  
E-mail: scheid.s@sprachen-service.de

09.07.2004

To whom it may concern

---

**Re: English translation of**  
**Patch test for investigating the skin-irritant effect of cosmetic products in humans**  
from the German into the English language

The English translation of  
**Patch test for investigating the skin-irritant effect of cosmetic products in humans**  
from the German into the English language was made by Sprachen-Service GbR, the successor  
of the Central Translation Department of Hoechst AG, by a specialist translator with  
comprehensive experience in the medical/pharmaceutical sector.

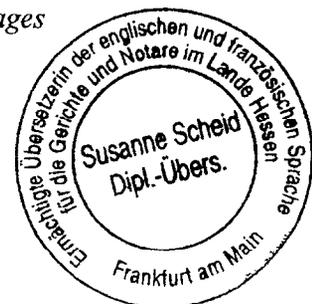
On behalf of Sprachen-Service GbR

*Susanne Scheid*

*Susanne Scheid*  
*(General Manager)*

*Sworn translator for the English and French languages*  
*for the courts and notaries public*  
*of the Federal State of Hesse, Germany*

*Frankfurt/Main, July 9, 2004*



Prof. Dr. med. Hagen Tronnier  
Institute for Experimental Dermatology  
University of Witten-Herdecke

D-5810 Witten-Annen  
Stockumer Strasse 10

17.06.1991

Hoechst AG  
Attn. Dr. Skrypzak  
Postfach 80 03 20

6230 Frankfurt/Main 80

## TEST REPORT

**Patch test for investigating the skin-irritant effect of cosmetic products in humans**

PROF. DR. MED. H. TRONNIER  
Page 2  
June 17, 1991

**Sponsor:**

**Hoechst AG**

**6230 Frankfurt/Main 80**

**Date of contract**

04.06.1991

**Research contract no.:**

57 / 6 / 91

**Scientific director:**

Prof. Dr. med. Hagen Tronnier

**Objective:**

Determination of the skin-irritant effect

**Test product:**

Ethanol / water formulations SI 77 / 3

**Test site:**

Back

**Test period:**

48-72 h

**Test subjects:**

50

**including allergic subjects  
and those with sensitive skin:**

19

**Sex:**

female: 31

male: 19

**Age:**

16-64

PROF. DR. MED. H. TRONNIER

Page 3

June 17, 1991

### **Principle**

The patch test is used to detect primary skin irritation or a contact allergy associated with the test substance and is limited in terms of area and time.

### **Test procedure**

A group of 50 female and male volunteers aged between 16 and 64 took part in the study (see enclosed list of volunteers in Appendix 1).

Using a commercial test plaster, the test substance is placed on the clinically healthy skin and secured. The test plaster is removed after 48 hours and the test site assessed. Further assessments are made after 72 hours.

### **Evaluation key:**

0	no irritation
±	slight or dubious erythema
+	pronounced erythema (also urticarial)
++	severe erythema and/or papulation
+++	dense papules and/or vesicles
++++	blistering or necrosis

### **Evaluation of the test results and conclusions in terms of subsequent use of the preparation:**

#### **Ethanol / water formulations SI 77 / 3**

No positive or dubious reactions were observed after either 48 h or 72 h, so this test gave no indication that the product has a primary irritant effect on the skin.

Also, in this test no sensitization possibly already present was triggered by the ingredients of the product.

### **INSTITUTE FOR EXPERIMENTAL DERMATOLOGY**

(signed)

Prof. Dr. med. Hagen Tronnier

ETHANOL / WATER FORMULATION

SI 77 / 3

Octopirox	0.3 g
<i>l.</i>	
Ethanol	50.0 g
Deionized water	49.7 g
Citric acid	pH 5.7

*l. Piroctone olamine*

Appendix 1 – Test product: Ethanol / water formulations SI 77 / 3

Serial no.	Test subject	Age	Sex	Diagnosis	Reaction	
					48h	72h
1	W.R.M.	48	f	allergic	0	0
2	W.J.	22	m	allergic	0	0
3	M.H.	37	m	healthy	0	0
4	M.A.	38	f	psoriasis	0	0
5	M.A.	18	m	sensitive skin	0	0
6	St.G.	58	m	allergic	0	0
7	K.K.	24	m	healthy	0	0
8	F.R.	54	f	allergic	0	0
9	F.G.	61	f	healthy	0	0
10	Sch.E.	39	f	allergic	0	0
11	Sch.H.	42	m	healthy	0	0
12	P.R.	63	m	allergic	0	0
13	P.R.	61	f	healthy	0	0
14	K.V.	34	f	healthy	0	0
15	H.E.	38	m	healthy	0	0
16	Sch.I.	41	f	healthy	0	0
17	Sch.H.	44	m	healthy	0	0
18	Sch.A.	24	f	allergic	0	0
19	Sch.K.	23	f	allergic	0	0
20	R.G.	62	f	healthy	0	0
21	R.P.	63	m	healthy	0	0
22	R.R.	34	m	allergic	0	0
23	M.B.	41	f	sensitive skin	0	0
24	B.U.	47	f	sensitive skin	0	0
25	B.A.	21	f	healthy	0	0
26	K.M.	47	f	allergic	0	0
27	K.S.	22	f	healthy	0	0
28	K.N.	47	m	healthy	0	0
29	K.M.	41	f	allergic	0	0
30	P.M.	34	f	healthy	0	0
31	K.M.	42	f	allergic	0	0
32	K.E.	17	f	healthy	0	0
33	M.M.	18	f	healthy	0	0
34	M.M.	51	f	allergic	0	0
35	M.H.	50	m	healthy	0	0
36	M.A.	16	f	healthy	0	0
37	B.M.	44	f	healthy	0	0
38	B.A.	48	f	sensitive skin	0	0
39	Sp.R.	42	f	healthy	0	0
40	Sp.Th.	20	m	healthy	0	0
41	H.U.	37	f	healthy	0	0
42	K.I.	52	f	healthy	0	0
43	W.S.	24	f	healthy	0	0
44	W.B.	25	f	healthy	0	0

45	M.K.	28	m	healthy	0	0
46	N.T.	21	m	healthy	0	0
47	Sch.R	64	f	healthy	0	0
48	Sch.H.	58	m	allergic	0	0
49	Sch.E.	35	m	healthy	0	0
50	N.O.	26	m	healthy	0	0