DERMATOLOGICAL AND ALLERGOLOGICAL

EXPERT REPORT

COSMETIC - TEST - GMBH

Institute for Scientific Dermatological Research
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Dermatological and allergological expert report

PATCH TEST

(Test of allergic contact reactions)

Preparation:

SF00578

proWIN TEX N'CLEAN BOUTIQUE No. 1 ZERO

Client:

proWIN Winter GmbH

Zeppelinstr. 8 D-66557 Illingen

Test subjects:

50 subjects with healthy skin

Test concentration:

1% diluted with tap water

Test result:

The preparation was well tolerated by all subjects.

No case of adverse skin reactions occurred.

Physician responsible

for the study:

Dr. med. Tilman Ertle

Eislingen, Germany, September 27th, 2019

Cosmetic-Test-GmbH

Institute for Dermatological and Allergological Investigations

Dr. med. Tilman Ertle

App: Principle and methodology/Evaluation criteria/Test result

Cosmetic-Test-GmbH, HR Göppingen Nr. B 1762
Institute for Dermatological and Allergological Investigations
Manager: Jutta Ertle - Bernitt
Project manager: Dr. med. Tilman M. Ertle, Dermatologist - Allergologist
Environmental Medicine

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Test principle

The patch test is a model used to detect a primary irritant effect or contact allergy (due to provocation of allergic skin reactions in patients who are already sensitised) by epidermal, local and limited contact with the test preparation. This investigation is the proper instrument to investigate the above mentioned adverse reactions of a cosmetic product.

To promote absorption of the test substances, they are applied under occlusive conditions. The substances selected for testing are used in subtoxic (i.e. not irritant) concentration on the skin.

Test method

The test preparation is applied undiluted or in the necessary dilution onto the clinically healthy skin using a commercially available test plaster (e.g. Curatest F, manufactured by Lohmann, Art. No.:30062). The transfer of the test substance to the test plaster is conducted by a cotton tip (undiluted product) or by a needle out of a disposable syringe, which is used for the preparation of final dilution of test product. The amount of product on plaster is 0.03 ml.

Toxicological information about the test product

The producer has given his approval for toxicological harmlessness of product.

Test medium

If necessary test preparation is diluted with e.g. tap water.

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Test location and procedure

Test plasters are applied to the back or to the inner surface of the upper arm. They are removed after an exposure time of 48 hours and the skin is assessed for the first time. A second assessment occurs 72 hours after the start of test. Readings are always made by a dermatologist and specialist for allergology.

Test persons

Participants are exclusively volunteer adult persons of both sexes. Using anti inflammatory drugs is not allowed, pregnant or breast-feeding women do not take part in the investigations.

Evaluation criteria

0	no irritation, negative
-/+	weak or doubtful erythema
+	clear erythema
++	severe erythema or papulation
+++	densely dispersed papules and/or vesiculation
++++	blistering or necrosis

Aim of investigation

The actual investigation is presented to proof that the test product in normal use will not lead to contact dermatitis or to allergic reactions on human skin. The epicutaneous patch test is the appropriate kind of investigation to proof this. Predictions about an allergenic potency of test product are not given.

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	72h
1 A.D. m 0	
2 H.K. f 0 0	
3 M.S. f 0	
4 E.L. f 0 0	
5 T.E. m 0	
6 T.F. m 0	
7 R.S. m 0 0	
8 PT. f 0	
9 P.R. f 0 0	
10 E.W. f 0	
11 A.P. f 0	
12 S.W. f 0	
13 F.T. f 0	
14 A.S. f 0	
15 V.P. m 0 0	
16 M.T. m 0	
17 H.K. f 0	
18 E.C. f 0	
19 L.B. f 0	
20 E.B. m 0 0	
21 H.M. m 0 0	
22 W.W. f 0	
23 E.S. f 0 0	
24 R.Z. m 0 0	
25 Y.F. f 0 0	
26 E.A. m 0 0	
27 C.B. f 0 0	
28 D.E. f 0 0	
29 H.H. f 0 0	
30 F.H, m 0	

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Subject	Initials	Sex m/f	Reading 48h	Reading 72h
31	C.N.	\mathbf{f}	0	0
32	F.L.	${f f}$	0	0
33	B.Y.	f	0	0
34	M.K.	\mathbf{f}	0	0
35	M.F.	m	0	0
36	F.H.	f	0	0
37	M.K.	f	0	0
38	A.R	m	0	0
39	M.E.	m	0	0
40	H.S.	m	0	0
41	B.A.	f	0	0
42	B.G.	m	0	0
43	K.N.	f	0	0
44	J.B.	f	0	0
45	G.S.	m	0	0
46	E.B.	f	0	0
47	T.S.	f	0	0
48	P.B.	m	0	0
49	E.N.	m	0	0
50	G.P.	f	0	0

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