

DERMATOLOGICAL AND ALLERGOLOGICAL

EXPERT OPINION

COSMETIC - TEST - GMBH

Institute for Scientific Dermatological Research

Danzigerstr. 13

D - 73054 Eislingen

Germany

Fax Eislingen office: 07161/814004

Expert medical, dermatological and allergological opinion

C L O S E D P A T C H T E S T

Designation of preparation: proWIN SOFTCLEAN (SF00437)

Client: proWIN Winter GmbH
Zeppelinstr. 8
D-665576 Illingen
Germany

Test subjects: 50 subjects with healthy skin

Test concentration: 1% diluted with tap water

Physician responsible for the study: Dr. med. Tilman M. Ertle

Test results: The preparation was well tolerated by all subject.

Eislingen, May, 2nd, 2008

Cosmetic-Test-GmbH

Institute for dermatological and allergological investigations

Dr. med. Tilman M. Ertle

Dermatologist and allergologist, environmental medicine

Appendices: Principle and Methods/Evaluation criteria/Test results



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Test principle

The patch test is a method of demonstrating primary irritation or contact allergy (by provoking allergic skin reactions in previously sensitised subjects) by epidermal, local and time delineated contact with the preparation to be investigated. Thus the method is suitable to examine the above mentioned adverse effects of the preparation to be tested.

In order to favour absorption, the procedure is carried out under occlusion conditions (closed patch test).

The substances to be tested are used in sub-toxic, i.e. non-irritant, concentrations on the skin.



Test method

The preparation to be tested is used undiluted or at the required dilution. It is applied and fixed to clinically healthy skin using a commercially available test plaster (e.g. Curatest F, Lohmann, Art.No. 30062).

The transfer of the product to the test plaster is performed by means of a cotton swap (undiluted test preparation) or by the needle of a graduated disposable syringe which is used to establish the dilution of test preparation.

Toxicological informations about test preparation

In his order of investigation the manufacturer has laid down the toxicological harmlessness of the test product.

Test vehicle

Tap water is used for dilution of the test preparation (rinse - off product).

Test area and conduct of test

Test plasters are applied to the back or the inner aspect of the upper arm.

Test plasters are removed after 48h and readings are done.

All evaluations are carried out by a **dermatologist and allergologist**.

Test persons

Only adult and volunteer persons of both sexes take part in the test.

Pregnant or lactating women are not allowed to participate.

Using anti-inflammatory drugs leads to exclusion from the investigation

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Evaluation criteria

- 0 no irritation
- + weak or dubious erythema
- + significant erythema
- ++ severe erythema or papule formation
- +++ thick papules and/or vesicles
- ++++ blistering or necrosis

Object of examination

The end of the investigation is to proof that the test preparation will neither lead to irritative alterations (contact dermatitis) nor to allergic contact reactions in human skin when used in practical use.

The closed patch test is the correct examination to answer this question.

Statements about the allergologic sensitisation potency of the product tested are not indicated.

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Test person	Initials	Sex	Reading 48h
1	B.B.	F	0
2	A.N.	F	0
3	R.U.	M	0
4	E.U.	F	0
5	T.O.	M	0
6	B.C.	F	0
7	R.R.	M	0
8	R.H.	M	0
9	R.I.	M	0
10	N.N.	F	0
11	F.E.	F	0
12	A.A.	F	0
13	A.R.	F	0
14	R.D.	F	0
15	O.A.	M	0
16	R.O.	M	0
17	R.A.	M	0
18	A.U.	F	0
19	O.L.	M	0
20	L.T.	F	0
21	E.E.	F	0
22	R.L.	F	0
23	A.E.	F	0
24	T.A.	F	0
25	E.N.	M	0
26	C.O.	F	0
27	R.N.	F	0
28	A.L.	M	0
29	L.E.	F	0
30	S.L.	F	0

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Test person	Initials	Sex	Reading 48h
31	W.N.	M	0
32	G.F.	M	0
33	B.D.	M	0
34	F.H.	M	0
35	W.P.	F	0
36	D.B.	F	0
37	F.G.	M	0
38	W.H.	F	0
39	R.B.	M	0
40	S.S.	M	0
41	B.H.	F	0
42	K.F.	F	0
43	J.B.	F	0
44	J.E.	M	0
45	C.K.	M	0
46	H.S.	M	0
47	F.T.	F	0
48	P.U.	F	0
49	E.C.	F	0
50	B.D.	F	0

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Evaluation and test results

In the closed patch test examination of the above mentioned cosmetic preparation in 50 volunteers we found no skin reactions in any subject after 48h.

From these results it can be concluded that the preparation tested will not lead to adverse skin reactions caused of skin irritation in practical and proper use.

Cosmetic-Test-GmbH
Danziger Str. 13
D - 73054 Eislingen
Tel./Fax Nr. ++49(0)7161/8170701
e-mail: cosmetic@dr-ertle.de