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EXPERTISE
Examination of the Product "BioVersal QF" (6%) by Human Patch Test

The purpose of the patch-test is to determine skin sensitivity to the product. The test was conducted in June 1997.

The human patch test allows us to assess the skin irritation potential of new dermatological and cosmetic products.

Material and Methods

All the work described in this expertise was conducted according to Good Laboratory Practice and 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).

Experiments were carried out on 30 volunteers (16 normal healthy subjects, 4 eczema patients, 2 allergy patients, 8 subjects with sensitive skin) between the ages of 18 - 70. Sex distribution was not standardized.

During the test period, the subjects refrained from using other substances on the test areas. All procedures were described in detail to all panellists who signed consent forms.

Procedure

The product (50 µl) was applied in square finn-chambers (1 cm side length, manufactured by Van der Bend) in a concentration of 6 % in distilled water to the backs of the panellists for 24 hours. Proper adherence of the test patches was assured by the inclusion of sodium lauryl sulphate (SDS) in two concentrations (2 % and 1 %) as a positive control. Water was used as a negative control.
Treatment sites were assessed for the presence of irritation using a 5 point visual ranking scale at 24 h, 48 h and 72 h after patch application.

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 results showed that, under the test conditions the SDS (2 %) caused positive reactions in 30 subjects. SDS (1 %) showed less response than the higher SDS-concentration with 28 panellists reacting. The negative control water showed no reactions.

The test results outlining the data for erythema, scaling and fissure formation are attached.

On the basis of the test results and under the test conditions, the product

" BioVersal QF"
(6%)

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

Literature

J.E. Wahlberg:
"Patch Testing" in
R.J.G. Rycroft, T. Menné, P.J. Frosch und C. Benezra (eds.),
Textbook of Contact Dermatitis
Springer-Verlag, Berlin (1992), p. 241-265

Appendix: test results

Signature:

Priv. Doz. Dr. med. Holger Biltz
Hautarzt – Allergologe

26.06.97

PRÜFPROTOKOLL

Produkt: BioVersal QF 6%

Nr.	Initialen	nach 24 h			nach 48 h			nach 72 h		
		E	F	S	E	F	S	E	F	S
1	AK	0	0	0	0	0	0	0	0	0
2	RG	0	0	0	0	0	0	0	0	0
3	FR	0	0	0	0	0	0	0	0	0
4	FN	0	0	0	0	0	0	0	0	0
5	KA	0	0	0	0	0	0	0	0	0
6	PK	0	0	0	0	0	0	0	0	0
7	PL	0	0	0	0	0	0	0	0	0
8	TZ	0	0	0	0	0	0	0	0	0
9	RT	0	0	0	0	0	0	0	0	0
10	UH	0	0	0	0	0	0	0	0	0
11	RT	0	0	0	0	0	0	0	0	0
12	HS	0	0	0	0	0	0	0	0	0
13	EW	0	0	0	0	0	0	0	0	0
14	HU	0	0	0	0	0	0	0	0	0
15	RP	0	0	0	0	0	0	0	0	0
16	TR	0	0	0	0	0	0	0	0	0
17	IN	0	0	0	0	0	0	0	0	0
18	WF	0	0	0	0	0	0	0	0	0
19	TU	0	0	0	0	0	0	0	0	0
20	BD	0	0	0	0	0	0	0	0	0
21	RD	0	0	0	0	0	0	0	0	0
22	MK	0	0	0	0	0	0	0	0	0
23	UB	0	0	0	0	0	0	0	0	0
24	DB	0	0	0	0	0	0	0	0	0
25	WZ	0	0	0	0	0	0	0	0	0
26	KI	0	0	0	0	0	0	0	0	0
27	TO	0	0	0	0	0	0	0	0	0
28	EN	0	0	0	0	0	0	0	0	0
29	OA	0	0	0	0	0	0	0	0	0
30	JA	0	0	0	0	0	0	0	0	0
	Summe	0	0	0	0	0	0	0	0	0

Erythem: kein E.: 0, leichtes E.: 1, deutliches E.: 2, ausgeprägtes E.: 3, starkes E.: 4

Fissur: keine F.: 0, minimale F.: 1, deutlich wahrnehmbare F.: 2, ausgeprägte F.: 3, Ulceration: 4

Schuppung: keine S.: 0, minimale S.: 1, mäßige S.: 2, deutliche S.: 3, geschlossene Schuppenkruste S.: 4