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B. Braun Medical AG
Desinfektion und Hygiene
Seesatz

CH-6203 Sempach Station

Ihre Nachricht vom

Ihr Zeichen

Unser Zeichen

Datum

Münster, 19.07.2002

REPORT ON A

HUMAN PATCH TEST

Test on primary skin irritation and allergic hypersensitivity on human subjects

Responsible for the study: Dr.med.Werner Voss
Specialist for dermatology
and allergology

The following report is an accurate account of the test methods uses and results obtained during the course of the above study which was performed within the two weeks prior to the date of this report.

Product tested:

Meliseptol rapid (Tränklösung für Meliseptol HBV-Tücher, Chargen-Nr.:1225M10 (Haltbar bis: 05.2003)

Aussehen: Farblose, leicht bewegliche Flüssigkeit – Geruch: alkoholisch parfümiert

Customer: B. Braun Medical AG
Seesatz
CH-6203 Sempach Station

Test Panel: Thirty volunteers of either sex, with no visible skin diseases or known allergic hypersensitivities

Concentration of the product: undiluted

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Page: 2

OBJECTIVE

The objective of the study was to detect a primary skin irritation potency and/or an allergic hypersensitivity to the tested product.

Patch testing represents a sound, relatively safe and reasonable reliable method for identifying allergens.

A positive reaction to a correctly applied patch-test proves that the person has a contact sensitivity to the substance tested, but not necessarily that the substance is the cause of the clinical dermatitis.

In patch testing, the suspected topical allergen has to penetrate the stratum corneum to the viable (effector) cells of the skin to present a local challenge to the immune system.

METHODOLOGY

The product to be tested is applied on a patch of filter paper, placed on an impermeable sheet and fixed to the skin with adhesive tape (Leukotest (R), Fa. Hartmann). Test site: inner side of the forearm. The test patch is left in place for 24 hours then removed. The examination by the dermatologist follows. A second and third examination are performed after 48 and 72 hours by the dermatologist.

All assessments were performed under standard lighting conditions by the responsible dermatologist.

Panellists were instructed to keep the test sites dry over the application period.

DATA STORAGE AND PROTECTION

All raw data relating to this study will be stored under data protection for a period of 10 years. Then they will be destroyed.

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Page: 3

RESULTS

Concentration of the product: undiluted

Test-person No.:	Name	Sex	Age	Diagnosis	Reactions		
					24h	48h	72h
1.	D. H.	m	20	healthy skin	-	-	-
2.	M. V.	m	20	healthy skin	-	-	-
3.	In. H.	m	25	healthy skin	-	-	-
4.	S. St.	f	25	healthy skin	-	-	-
5.	Ul. R.	f	23	healthy skin	-	-	-
6.	Mi. Sch.	f	18	healthy skin	-	-	-
7.	Na. R.	f	19	healthy skin	-	-	-
8.	Ho. Sch.	m	26	healthy skin	-	-	-
9.	An. Ma.	m	19	healthy skin	-	-	-
10.	A. Bec.	m	21	healthy skin	-	-	-
11.	S. Ma.	f	28	healthy skin	-	-	-
12.	Si. La.	f	34	healthy skin	-	-	-
13.	Su. Ma.	f	18	healthy skin	-	-	-
14.	Da. N.	m	18	healthy skin	-	-	-
15.	St. Pr.	f	19	healthy skin	-	-	-
16.	Na. Kl.	f	21	healthy skin	-	-	-
17.	M. Gr.	f	32	healthy skin	-	-	-
18.	G. B.	f	43	healthy skin	-	-	-
19.	R. D.	f	47	healthy skin	-	-	-
20.	G. T.	f	50	healthy skin	-	-	-
21.	A. T.	f	24	healthy skin	-	-	-
22.	N. T.	f	22	healthy skin	-	-	-
23.	R. Z.	f	46	healthy skin	-	-	-
24.	G. R.	f	43	healthy skin	-	-	-
25.	R. W.	f	49	healthy skin	-	-	-
26.	Ch. K.	f	47	healthy skin	-	-	-
27.	C. D.	f	21	healthy skin	-	-	-
28.	A. U.	f	39	healthy skin	-	-	-
29.	K. Sch.	f	62	healthy skin	-	-	-
30.	M. Sp.	f	43	healthy skin	-	-	-

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Page: 4

RESULTS

RESULTS OF CONTROL

Concentration of the product: blanc patch-test

Test-person No.:	Name	Sex	Age	Diagnosis	Reactions		
					24h	48h	72h
1.	D. H.	m	20	healthy skin	-	-	-
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Page: 5

INTERPRETATION KEY:

-	negative, no reaction
-+	doubtful reaction
+	weak (non-vesicular) reaction
++	strong (oedematous or vesicular) reaction
+++	strong, infiltrated erythema and accompanying vesicae or superficial erosions
++++	bullae or extensive erosions
IR	irritant reaction

DERMATOLOGICAL CRITERIAS:

Positive reactions of an allergic nature are red and infiltrated, commonly with minute papula or vesicae, which, in severe reactions, coalesce to become bullae. They diffuse and extend beyond the margins of the patch. As with contact dermatitis, there is usually some itching.

Once developed, positive allergic reactions persist for several days. Reactions positive at 2 days and negative at 3 days are often of an irritant nature.

Choice of a suitable concentration is of fundamental importance. Too high concentrations result in false-positive reactions, because of their irritant effect and may even sensitize previously negative patients and too low concentrations produce false-negative reactions.

Well-known allergens are conventionally tested in such concentrations as that a 24-hours exposure period under an occlusive patch will ensure penetration of an amount sufficient to provoke a reaction in clinically sensitive persons.

Distinction between allergic and primary irritant reactions demands special experience on the part of the dermatologist, and is often impossible on clinical examination.

Clinical sensitivity may be related to the level of patch-test sensitivity, but with some substances the relationship is not clear-cut.

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Page: 6

CONCLUSIONS

Under the conditions of this test we found no evidence of primary irritation or allergic hypersensitivity.

None of the thirty patch-tests resulted in positive reactions after 24, 48 and after 72 hours.

The investigating specialist for dermatology and allergology considers this test-product safe for use.



Dr.med.Werner Voss
Investigating specialist
for dermatology , allergology
venerology and
environmental medicine

literature:

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4. Scientific Basis of Patch Testing – S. Iris Ale and Howard I. Maibach, Dermatol. Beruf Umwelt / Occup. Environ. Dermatol. 50, Nr. 2, 43-50 (2002)