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date:

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**REPORT ON A
HUMAN PATCH TEST
ON SCARIFIED SKIN**

Test on primary skin irritation and allergic hypersensitivity on human subjects

Grau

Customer: MediUm – TECH Medizingeräte GmbH
Gustav-Krone-str. 3
D-14167 Berlin

Test Panel: Thirty volunteers of either sex,
without visible skin diseases or known allergic hypersensitivities

Concentration
of the product: undiluted

Patch test on scratched skin
Test Product: Grau

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 irritant products.

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

To increase the possibility for the tested product to produce irritant reaction, the skin is scarified before application.

The absorption of the test substances is advantaged by application under occlusive conditions.

A positive reaction to a correctly applied patch-test proves that the person has a suffered an irritant reaction to the substance tested or is suffering from a proves that the person has a pre-existing contact sensitivity to the substance tested or a component of it.

The suitability for daily use without irritation is documented in applying the preparation to previously scarified skin.

METHODOLOGY

The test substance is applied to a skin area that has previously been scarified linearly without bleeding using a lancet.

The product to be tested is undiluted applied on a patch of filter paper, placed on an impermeable sheet.

The test substance is 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 follows after 48 and 72 hours by the dermatologist.

All assessments were accomplished 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 5 years. Then they will be destroyed.

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SUBJECTS

30 panellists with healthy skin are included in the study.
The test conditions are explained in detail to the participants and the anamnesis is recorded.
All participants give written informed consent afterwards.
Information about possible and expected reaction is given to the test persons.
The subjects are allowed to withdraw at any time without reason. Also the responsible physician is able to interrupt the testing if medical reasons contradict further treatment.

No.	Name	Gender	Age
1.	D.S.	f	38
2.	W.B.	f	47
3.	W.C.	f	20
4.	U.J.	m	66
5.	U.T.	m	37
6.	W.J.	f	25
7.	M.B.	f	46
8.	D.S.	m	17
9.	G.K.	f	32
10.	G.N.	f	28
11.	G.F.	m	56
12.	C.M.	f	36
13.	S.U.	f	48
14.	G.G.	f	52
15.	K.H.	f	41
16.	K.A.	m	41
17.	D. N.,	f	32
18.	D.M.	m	41
19.	U.S.	f	34
20.	H.F.	m	20
21.	D.B.	m	73
22.	D. U.	m	40
23.	D.G.	f	73
24.	W.D.	m	22
25.	G.E.	f	67
26.	U. M.	f	60
27.	P.M.	f	55
28.	S.B.	m	41
29.	U. F.	m	65
30.	F.F.	f	19

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RESULTS (I)

Test substance is applied to scarified skin

No.	Name	Gender	Age	Diagnosis	24 h	48 h	72 h
1.	D.S.	f	38	healthy skin	-	-	-
2.	W.B.	f	47	healthy skin	-	-	-
3.	W.C.	f	20	healthy skin	-	-	-
4.	U.J.	m	66	healthy skin	-	-	-
5.	U.T.	m	37	healthy skin	-	-	-
6.	W.J.	f	25	healthy skin	-	-	-
7.	M.B.	f	46	healthy skin	-	-	-
8.	D.S.	m	17	healthy skin	-	-	-
9.	G.K.	f	32	healthy skin	-	-	-
10.	G.N.	f	28	healthy skin	-	-	-
11.	G.F.	m	56	healthy skin	-	-	-
12.	C.M.	f	36	healthy skin	-	-	-
13.	S.U.	f	48	healthy skin	-	-	-
14.	G.G.	f	52	healthy skin	-	-	-
15.	K.H.	f	41	healthy skin	-	-	-
16.	K.A.	m	41	healthy skin	-	-	-
17.	D. N..	f	32	healthy skin	-	-	-
18.	D.M.	m	41	healthy skin	-	-	-
19.	U.S.	f	34	healthy skin	-	-	-
20.	H.F.	m	20	healthy skin	-	-	-
21.	D.B.	m	73	healthy skin	-	-	-
22.	D. U.	m	40	healthy skin	-	-	-
23.	D.G.	f	73	healthy skin	-	-	-
24.	W.D.	m	22	healthy skin	-	-	-
25.	G.E.	f	67	healthy skin	-	-	-
26.	U. M.	f	60	healthy skin	-	-	-
27.	P.M.	f	55	healthy skin	-	-	-
28.	S.B.	m	41	healthy skin	-	-	-
29.	U. F.	m	65	healthy skin	-	-	-
30.	F.F.	f	19	healthy skin	-	-	-

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RESULTS (II)

Product control applied to healthy skin

No.	Name	Gender	Age	Diagnosis	24 h	48 h	72 h
1.	D.S.	f	38	healthy skin	-	-	-
2.	W.B.	f	47	healthy skin	-	-	-
3.	W.C.	f	20	healthy skin	-	-	-
4.	U.J.	m	66	healthy skin	-	-	-
5.	U.T.	m	37	healthy skin	-	-	-
6.	W.J.	f	25	healthy skin	-	-	-
7.	M.B.	f	46	healthy skin	-	-	-
8.	D.S.	m	17	healthy skin	-	-	-
9.	G.K.	f	32	healthy skin	-	-	-
10.	G.N.	f	28	healthy skin	-	-	-
11.	G.F.	m	56	healthy skin	-	-	-
12.	C.M.	f	36	healthy skin	-	-	-
13.	S.U.	f	48	healthy skin	-	-	-
14.	G.G.	f	52	healthy skin	-	-	-
15.	K.H.	f	41	healthy skin	-	-	-
16.	K.A.	m	41	healthy skin	-	-	-
17.	D. N..	f	32	healthy skin	-	-	-
18.	D.M.	m	41	healthy skin	-	-	-
19.	U.S.	f	34	healthy skin	-	-	-
20.	H.F.	m	20	healthy skin	-	-	-
21.	D.B.	m	73	healthy skin	-	-	-
22.	D. U.	m	40	healthy skin	-	-	-
23.	D.G.	f	73	healthy skin	-	-	-
24.	W.D.	m	22	healthy skin	-	-	-
25.	G.E.	f	67	healthy skin	-	-	-
26.	U. M.	f	60	healthy skin	-	-	-
27.	P.M.	f	55	healthy skin	-	-	-
28.	S.B.	m	41	healthy skin	-	-	-
29.	U. F.	m	65	healthy skin	-	-	-
30.	F.F.	f	19	healthy skin	-	-	-

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RESULTS (III)

blanc patch-test on scarified skin

No.	Name	Gender	Age	Diagnosis	24 h	48 h	72 h
1	D.S.	f	38	healthy skin	-	-	-
2	W.B.	f	47	healthy skin	-	-	-
3	W.C.	f	20	healthy skin	-	-	-
4	U.J.	m	66	healthy skin	-	-	-
5	U.T.	m	37	healthy skin	-	-	-
6	W.J.	f	25	healthy skin	-	-	-
7	M.B.	f	46	healthy skin	-	-	-
8	D.S.	m	17	healthy skin	-	-	-
9	G.K.	f	32	healthy skin	-	-	-
10	G.N.	f	28	healthy skin	-	-	-
11	G.F.	m	56	healthy skin	-	-	-
12	C.M.	f	36	healthy skin	-	-	-
13	S.U.	f	48	healthy skin	-	-	-
14	G.G.	f	52	healthy skin	-	-	-
15	K.H.	f	41	healthy skin	-	-	-
16	K.A.	m	41	healthy skin	-	-	-
17	D. N..	f	32	healthy skin	-	-	-
18	D.M.	m	41	healthy skin	-	-	-
19	U.S.	f	34	healthy skin	-	-	-
20	H.F.	m	20	healthy skin	-	-	-
21	D.B.	m	73	healthy skin	-	-	-
22	D. U.	m	40	healthy skin	-	-	-
23	D.G.	f	73	healthy skin	-	-	-
24	W.D.	m	22	healthy skin	-	-	-
25	G.E.	f	67	healthy skin	-	-	-
26	U. M.	f	60	healthy skin	-	-	-
27	P.M.	f	55	healthy skin	-	-	-
28	S.B.	m	41	healthy skin	-	-	-
29	U. F.	m	65	healthy skin	-	-	-
30	F.F.	f	19	healthy skin	-	-	-

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RESULTS (IV)

blanc patch-test on healthy skin

No.	Name	Gender	Age	Diagnosis	24 h	48 h	72 h
1	D.S.	f	38	healthy skin	-	-	-
2	W.B.	f	47	healthy skin	-	-	-
3	W.C.	f	20	healthy skin	-	-	-
4	U.J.	m	66	healthy skin	-	-	-
5	U.T.	m	37	healthy skin	-	-	-
6	W.J.	f	25	healthy skin	-	-	-
7	M.B.	f	46	healthy skin	-	-	-
8	D.S.	m	17	healthy skin	-	-	-
9	G.K.	f	32	healthy skin	-	-	-
10	G.N.	f	28	healthy skin	-	-	-
11	G.F.	m	56	healthy skin	-	-	-
12	C.M.	f	36	healthy skin	-	-	-
13	S.U.	f	48	healthy skin	-	-	-
14	G.G.	f	52	healthy skin	-	-	-
15	K.H.	f	41	healthy skin	-	-	-
16	K.A.	m	41	healthy skin	-	-	-
17	D. N..	f	32	healthy skin	-	-	-
18	D.M.	m	41	healthy skin	-	-	-
19	U.S.	f	34	healthy skin	-	-	-
20	H.F.	m	20	healthy skin	-	-	-
21	D.B.	m	73	healthy skin	-	-	-
22	D. U.	m	40	healthy skin	-	-	-
23	D.G.	f	73	healthy skin	-	-	-
24	W.D.	m	22	healthy skin	-	-	-
25	G.E.	f	67	healthy skin	-	-	-
26	U. M.	f	60	healthy skin	-	-	-
27	P.M.	f	55	healthy skin	-	-	-
28	S.B.	m	41	healthy skin	-	-	-
29	U. F.	m	65	healthy skin	-	-	-
30	F.F.	f	19	healthy skin	-	-	-

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INTERPRETATION KEY:

Symbol	Morphology	meaning
-	No reaction	negative
?	Only erythema, no infiltration	doubtful
+	Erythema, infiltration, possibly discrete papules	simple-positive reaction
++	Erythema, infiltration, papules, vesicules	Double- positive reaction
+++	Erythema, infiltration, papules, confluent vesicules	3-positive reaction
ir	Different changes (soap effect, vesicules, bulla, necrosis)	Irritative
nt		Not tested

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.

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.

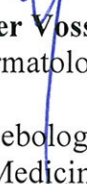
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CONCLUSIONS


Under the conditions of this test we found no evidence of primary irritation or allergic hypersensitivity. The substance was tested on scarified skin and under occlusion, to get a maximum safety for the application on sensitive skin.

None of the 30 patch-tests resulted in positive reactions after 24, 48 and after 72 hours.

The investigating specialists for dermatology and allergology considers this test-product safe in daily use.


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