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ROPIMEX R. OPEL GmbH
Bildstocker Straße 12 – 14
66538 Neunkirchen – GERMANY

Muenster, 20.05.2019

Dermatological report on human Open Patch Test
Test for primary skin irritation and hypersensitivity of human subjects
after single application

GreenClean
BioReiniger

Customer: ROPIMEX R. OPEL GmbH
Bildstocker Straße 12 – 14
66538 Neunkirchen – GERMANY

Test Panel: 30 panellists of either sex,
without visible skin diseases or known hypersensitivity

Concentration of the product: undiluted

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PRINCIPLE AND METHODS

The objective of the study is to detect primary skin irritation potential and/or existing allergic sensitisation to the test substance.

The test substance is applied to the skin of the panellist.

The skin contact of the panellists to the test substance is limited locally and temporally.

The occlusion eases the absorption of the suspected topical allergen allowing it to penetrate the stratum corneum to the viable (effector) cells of the skin and thus presenting a local challenge to the immune system.

If the threshold level of sensitivity is reached, a positive reaction could potentially be induced.

A positive reaction to a correctly applied patch provides evidence of primary irritation to the substance tested, but is not necessarily evidence of sensitisation.

Patch testing provokes allergic skin reactions in already sensitised panellists.

PROCEDURES

Prospective panellists receive a complete explanation of study procedures. If they wish to participate and agree to the conditions of the study, panellists sign a written, informed consent and provide a medical history.

About 1 g/1 ml of the test product is applied to an area of 5x5 cm to clinically healthy skin on the inner forearm. Lotions are applied once, fluids several times.

If dilution is needed in fluids, the adequate liquid is aqua dest. Afterwards the solution is layed on the skin using a piece of linen. If creams, ointments or powder are tested, then vaseline is used to dilute.

A specialist of dermatology and allergology assesses the skin reaction in the test area after 20 min of exposition. Another assessment follows after 30 and 60 min. after the first exposition. Later assessments are performed by reactions.

All assessments are performed under standard lighting conditions.

Lower risk of toxic irritative skin reactions is the advantage of the open patch test, when unknown substances are examined firstly, due to shorter exposition and lack of occlusion. In case of existing sensitization, the allergic skin reaction is diminished as well as bullae or necrosis are not estimated.

Further, the real product utilization is imitated more likely, because of the application of cosmetics generally without occlusive condition. (Exception: intertriginous use).

The skin contact of so-called “rinse-off” products is even shorter as they are washed away immediately.

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PANELLISTS

The test panel includes 30 adult male and female panellists.

INCLUSION CRITERIA

- Standard design: Panellists aged 18 years and above with healthy skin in the test area
- Extra designs: Special inclusion of age, gender, skin type etc. according to claim of the study

EXCLUSION CRITERIA

- Acute diseases
- Pregnancy and lactation period
- Sensitisation to ingredients of the test plaster
- Severe illnesses
- Application of pharmaceutical products and skin care products with active ingredients until 4 weeks before testing
- Intake of drugs that possibly can interfere with skin reactions (steroids, antiallergics, topical immuno modulator, etc.)
- Extremely tanned skin

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RESULTS

Open epicutaneous test
Concentration of the product: undiluted

No.	Name	Gender	Age	Diagnosis	20 m	30 m	60 m
1.	DeRo	f	37	healthy skin	-	-	-
2.	FaEs	f	39	healthy skin	-	-	-
3.	FeAl	f	22	healthy skin	-	-	-
4.	FrAn	f	53	healthy skin	-	-	-
5.	GaJo	f	43	healthy skin	-	-	-
6.	HuBe	f	40	healthy skin	-	-	-
7.	JaLa	f	24	healthy skin	-	-	-
8.	JaMo	f	42	healthy skin	-	-	-
9.	JaVi	f	42	healthy skin	-	-	-
10.	KnDo	f	43	healthy skin	-	-	-
11.	KnJa	m	50	healthy skin	-	-	-
12.	KoAn	m	53	healthy skin	-	-	-
13.	KoDi	f	39	healthy skin	-	-	-
14.	KrSi	f	30	healthy skin	-	-	-
15.	NeEl	f	59	healthy skin	-	-	-
16.	NeEu	m	31	healthy skin	-	-	-
17.	NeNe	f	68	healthy skin	-	-	-
18.	NeWa	m	62	healthy skin	-	-	-
19.	PlGi	f	54	healthy skin	-	-	-
20.	RoSe	m	22	healthy skin	-	-	-
21.	RoTa	f	42	healthy skin	-	-	-
22.	ScAl	f	40	healthy skin	-	-	-
23.	ScAn	f	39	healthy skin	-	-	-
24.	SkEu	m	38	healthy skin	-	-	-
25.	SkLi	f	38	healthy skin	-	-	-
26.	TbSa	f	33	healthy skin	-	-	-
27.	TeHe	m	37	healthy skin	-	-	-
28.	TeMa	m	72	healthy skin	-	-	-
29.	WeJu	f	42	healthy skin	-	-	-
30.	WiRe	m	40	healthy skin	-	-	-

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INTERPRETATION CRITERIA

The assessment is based on the morphologic changes detailed in the modified guidelines of

ICDRG (Fregert S (1981/2nd edition) Manual of Contact Dermatitis. On behalf of the International Contact Dermatitis Research Group and the North American Contact Dermatitis Group, Munksgaard Publishers,Copenhagen)

Table 3. Grading of the patch test reactions

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

GENERAL DERMATOLOGICAL INTERPRETATION CRITERIA:

The discrimination between irritation and allergy is of importance. As a general rule, a positive reaction is said to be „allergic“ if it has been graded as “+” to “+++ “ up to 72 hours or beyond.

Understanding the dynamics of the reaction may aid the assessment.

Allergic test reactions could persis t("Plateau-type”) or even worsen ("Crescendo-type") on the day after the plaster has been removed). A “Decrescendo”-type (decrease of reaction after removal of plaster) on the other hand, indicates irritation.

If delayed reactions only develop 10-14 days after application, (“iatrogenic”) sensitisation should be considered.

Irritative and allergic reactions present erythema and could also cause infiltration.

Papules, vesicles and bullae could demonstrate irritation as well as allergy, whereas pustules and necrosis point to severe irritation reactions.

Both reactions could spread beyond the original application site.

Moreover the individual expression of a reaction lies within a wide range.

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CONCLUSION

No evidence of any skin disorder was detected in the test area of any of the 30 panellists after conducting open patch testing for 20, 30 and 60 minutes according to the internationally recognised guidelines of ICDRG (International Contact Dermatitis Research Group).

It can be concluded that the use of the product will not cause any unwanted skin reactions due to an irritating effect.

Dr. med. Gerrit Schlippe
Investigating specialist
for dermatology, venereology

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