

EPICUTANEOUS TEST

DermaNova Active Skin Care Cream

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1. Expertise

Examination of product formula in concentration 100%
by human patch test

1.1 SUMMARY

Type of study:	Determination of irritating effects to the skin with an occlusive patch test
Tests subjects:	50 persons
Test site:	Back
Test concentration:	100%

2. Introduction

The epicutaneous test allows us to assess the primary skin irritation potential of cosmetic finished products and raw materials.

2.1 METHODS

All the work described in this expertise was conducted according to Good Clinical Practice (CPMP Working Party on Efficacy of Medicinal Products Note for Guidance: Good Clinical Practice for Trials on Medicinal Products in the European Community - 1990-CB-55-89-706-EN-C) and in accordance with the Skin Compatibility of Cosmetic Finished Products in Man.

Food and Chemical Toxicology 34, 1996, 651-660). Because it was a study in humans, it was carried out in accordance with the Declaration of Helsinki (1964) and subsequent revisions.

Experiments were carried out on 50 volunteers (24 normal healthy subjects, 9 eczema patients, 2 allergy patients, 15 subjects with sensitive skin) between ages of 18-64. Sex distribution was not standardised. The volunteers were clearly informed verbally and in writing, regarding the nature of the study, the timetable, constraints and possible risks. They gave their written informed consent before participation in the study.

Inclusion criteria:

- Informed volunteers
- Age > 18 years

Non-inclusion criteria:

- Pregnant or lactating women
- Blemish, marks (tatoos, sunburn) which interfere with scoring
- Any skin disease that may interfere with the aim of the study

Participants can withdraw from the study, if they no longer wish to participate in the study. During the test period, the subjects refrained from using other substances on the test areas.

2.2 METHODS

The product was applied undiluted in square test-chambers (Haye's Test Chambers; HAL Allergie GmbH, Düsseldorf) to the backs of the panellists for a period of 48 hours. Proper adherence of the test patches was assured by the inclusion of sodium dodecyl sulphate (SDS) in one concentration (1%) as positive control. Water was used as a negative control. Treatment sites were assessed for the presence of irritation by a trained evaluator using a 5 point visual scoring scale 48 h. (30 minutes after patch removal) and 72 h. after patch application.

SCORING SCALE:

Erythema:	0	no erythema
	1	slight erythema
	2	significant erythema
	3	pronounced erythema
	4	strong erythema
Fissures	0	no fissures
	1	minimal fissures
	2	significantly perceptible fissures
	3	pronounced fissures
	4	ulceration
Scaling	0	no scaling
	1	minimal scaling
	2	moderate perceptible scaling
	3	significant scaling
	4	closed scale crust

3. Results

All participants completed the study. The results showed that, under the test conditions SDS (1% water) caused positive reactions in 10 subjects. The negative control water showed no reactions. None of the subjects showed any reaction on the test product.

On the basis of the test results and under the test conditions, the product formula is to be classified as “harmless” as regards the possibility of skin irritation.

4. Literature

- 1 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.