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Date: 28.09.2012

Expertise

Examination of the Product

"AnaGain"

Lot 0845-001

Concentration: undiluted

by Human Photo Patch Test (Cosmetic Trial)

Sponsor
Mibelle AG Biochemistry
Bolimattstrasse 1
5033 Buchs
Switzerland

Performing Laboratory
Derma Consult GmbH
Brunnenstr. 61
53347 Alfter
Germany

Study Details

Type of study.....: Determination of irritating effects to the skin with an occlusive Photo patch test.
Study Period.....: September 2012
Study Director....: Dr. med. H. Prieur
Test subjects.....: 50 (20-66 years; sex distribution non-standardized)
28 normal healthy, 4 eczema, 4 allergy and 14 subjects with sensitive skin
Test site.....: Back
Concentration.....: Undiluted

Summary Results

All participants completed the study. None of the subjects showed any reaction to the test product. On the basis of the test results and under the test conditions, there was no evidence of a primary photo toxic reaction to the product

"AnaGain".

Signature:

Dr. med. H. Prieur
Dermatologist - Allergist

Signature:

Dr. J. Nissen
Pharmacist - M.D.R.A.

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Methodology

Introduction

The purpose of the photo patch test is to determine skin sensitivity to irradiated products. It allows to assess the photo toxic potential of cosmetic-finished products and raw materials.

Description

All the work described in this expertise was conducted 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). Because it was a study with humans, it was carried out in accordance with the Declaration of Helsinki (1964) and subsequent revisions.
Experiments were carried out on 50 volunteers (28 normal healthy subjects, 4 eczema patients, 4 allergy patients, 14 subjects with sensitive skin) between the ages of 20 to 66. Sex distribution was not standardized. 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 participating in the study.
Participants could withdraw from the study at any time without giving reason. During the test period, the subjects refrained from using other substances on the test areas.

Inclusion criteria

- informed volunteers
- age ≥ 18 years

Exclusion criteria

- pregnant or lactating women
- blemishes or marks (tattoos, sunburn) which interfere with scoring
- any skin disease that may interfere with the aim of the study

Procedure

The product was applied in a concentration as outlined above in square test-chambers (Haye`s Test Chambers - Haye's Service B.V., The Netherlands) to the backs of the panellists in duplicate as parallel series on either side of the back for 24 hours. Treatment sites were assessed for the presence of irritations 30 minutes after the removal of the occlusion. Then one of the two test areas was irradiated with UV-A light in a dose of 10J/cm².

The treatment sites were again assessed for the presence of irritation by a trained evaluator using a 5 point visual scoring scale at 24 and 48 hours after the irradiation.

Scoring scale

Reaction 0: no R., 1: slight R., 2: significant R., 3: pronounced R., 4: strong R.

Results

The test results outlining the data on a per subject base for the test product are attached in tabulated form.

Literature

Roy A. Palmer, Ian R. White:
"Photopatch Testing" in
P.J. Frosch, T. Menné & J.-P. Lepoittevin (eds.),
Contact Dermatitis 4th Edition
Springer-Verlag, Berlin Heidelberg, Germany (2006), pp. 433-440

Appendix: test protocol

28.09.2012
PROTOCOL

Product: AnaGain (Photo Patch)
Lot 0845-001

No.	Type	after 24 h		after 48 h		after 72 h	
		left	right	left	right*	left	right*
1	S	0	0	0	0	0	0
2		0	0	0	0	0	0
3	E	0	0	0	0	0	0
4		0	0	0	0	0	0
5	S	0	0	0	0	0	0
6		0	0	0	0	0	0
7		0	0	0	0	0	0
8	S	0	0	0	0	0	0
9		0	0	0	0	0	0
10		0	0	0	0	0	0
11		0	0	0	0	0	0
12	A	0	0	0	0	0	0
13		0	0	0	0	0	0
14	E	0	0	0	0	0	0
15		0	0	0	0	0	0
16		0	0	0	0	0	0
17		0	0	0	0	0	0
18		0	0	0	0	0	0
19	A	0	0	0	0	0	0
20	S	0	0	0	0	0	0
21	S	0	0	0	0	0	0
22		0	0	0	0	0	0
23	S	0	0	0	0	0	0
24		0	0	0	0	0	0
25	S	0	0	0	0	0	0
26	S	0	0	0	0	0	0
27		0	0	0	0	0	0
28	E	0	0	0	0	0	0
29		0	0	0	0	0	0
30		0	0	0	0	0	0
31	A	0	0	0	0	0	0
32		0	0	0	0	0	0
33	S	0	0	0	0	0	0
34		0	0	0	0	0	0
35	S	0	0	0	0	0	0
36		0	0	0	0	0	0
37	E	0	0	0	0	0	0
38		0	0	0	0	0	0
39		0	0	0	0	0	0
40		0	0	0	0	0	0
41		0	0	0	0	0	0
42	S	0	0	0	0	0	0
43		0	0	0	0	0	0
44		0	0	0	0	0	0
45	A	0	0	0	0	0	0
46	S	0	0	0	0	0	0
47	S	0	0	0	0	0	0
48		0	0	0	0	0	0
49		0	0	0	0	0	0
50	S	0	0	0	0	0	0
SUM		0,0	0,0	0,0	0,0	0,0	0,0

Reaction: no R.: 0, slight R.: 1, visible R.: 2, clearly visible R.: 3, heavy R.: 4.

*Radiation with UV-A (10 J/cm²)

S: subjects with sensitive skin
E: patients with eczema
A: patients with allergy