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Patch Test

Evaluation of the possible irritant power of a cosmetic product according to the amended Draize classification (on volunteers with sensitive skin)

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RMC_50_25_11_19_MED.01

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Title

Patch Test.
Evaluation of the possible irritant powers of a cosmetic product according to amended Draize classification.

Aim

To evaluate the tolerability of a cosmetic product through the individualization and the classification of its potential irritant power.

Legal information

In accordance with the current legislation and the declaration of Helsinki, all volunteers must be adequately informed of the aims, methods, clinical trial details, anticipated benefits and potential undesirable effects of the study. Each panellist must sign an informed consent form, which is managed and archived by applying the internal procedure of the Quality Management System of Bio Basic Europe S.r.l.

Contract information

Technical report performed by BIO BASIC EUROPE s.r.l. and Università degli Studi di Pavia.

Final technical report written by BIO BASIC EUROPE s.r.l. on behalf of DERMCOS GMBH

Experimentation performed at CDC - Dermo-clinic Research Institute

Materials and methods

The test will be carried out on 30 volunteers with sensitive skin* recruited according to the following inclusion and exclusion criteria: a) good state of health/absence of psychological and/or cognitive disorders; b) no dermatopathies and allergic pathologies (to cosmetics or other specific excipient), or other pathologies (as unknown irritant responses); c) no ongoing pharmacological treatments that could affect the result of the test; d) no participations in other clinical trial during the previous 30 days; e) signature of the informed consent form.

**The test is monitored by a dermatologist and it will be performed on volunteers with sensitive skin.*
This evaluation will be clinically performed by our MD and will take into consideration different factors such as the capillary fragility, the tendency of skin to get red, irritated and to flake easily.

Applications of the samples

The products have been applied following their usual use: as they are (leave-on products) or with a 10% standard concentration (rinse-off products). Liquid products are applied on the skin in a dose of 20 µl. Solid and semisolid products are applied in a dose of 20 µg.
Finn Chamber (a plaster containing a 7 mm aluminium disk and disks of blotting paper) is a patch test device which provides good occlusion.
For liquid products the Finn Chamber contains disks of blotting paper soaked with a certain quantity (20 µl) of the sample to be tested, for solid products the products to be tested are directly applied on skin (20 µg).

Execution of the test

- The involved skin area (surface of the back) has been cleaned with a 70% alcoholic solution
- The cosmetic product has been applied in a quantity of 0,02 mg or ml/ cm^2 of skin.
- The involved skin area is occluded with the Finn Chamber
- The cosmetic product has been left in contact with the skin surface for 48 hours.
- The Finn chamber is removed
- The cutaneous reactions have been analysed 15 minutes, 1 hour , 24 hours after Finn Chamber removal.
- Negative control with physiological water

PATCH TEST

<table>
<tr><td>No of volunteers</td><td colspan="4">30</td></tr>
<tr><td>SEX</td><td colspan="2">M (X)</td><td colspan="2">F (X)</td></tr>
<tr><td>AGE</td><td colspan="4">18-70</td></tr>
<tr><td rowspan="3">TIMES for TEST EXECUTION:
- product application
- evaluation of cutaneous reaction (ERYTHEMA and EDEMA) after the Finn Chamber removal</td><td>1st DAY</td><td colspan="3">Product application with the Finn Chamber and skin contact for 48 hours</td></tr>
<tr><td rowspan="2">2nd DAY</td><td colspan="3">Finn Chamber removal and evaluation of the cutaneous reaction</td></tr>
<tr><td>15 min [X]</td><td>1 hour
[X]</td><td>24 hours
[X]</td></tr>
<tr><td>Product use</td><td colspan="2">as it is (X)</td><td colspan="2">with a 10% dilution (…)</td></tr>
</table>

Inci name:

Aqua, C12-15 Alkyl Benzoate, Butyl Methoxydibenzoylmethane, Glycerin, Ethylhexyl Salicylate, Dicaprylyl Ether, Ethylhexyl Triazone, Cetyl Alcohol, Glyceryl Stearate, Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine, Diethylhexyl Butamido Triazone, Sodium Stearoyl Glutamate, Butyrospermum Parkii Butter, Phenylbenzimidazole Sulfonic Acid, 1,2-Hexanediol, Tocopheryl Acetate, Xanthan Gum, Caprylyl Glycol, Decylene Glycol, Ethylhexylglycerin, Sodium Hydroxide, Piroctone Olamine, Titanium Dioxide, Silver Chloride, Tocopherol, Diethylhexyl Sodium Sulfosuccinate, Propylene Glycol

Evaluation and calculation of the results

The reactions are evaluated according the arbitrary scale reported in table no. 1 .
Erythema and edema are evaluated after the Finn Chamber removal.
The index of total skin irritation (IIM tot) comes out by calculating the average of the irritation indexes for erythemas (IIM Er) and edemas (IIM Ed) at24 hours.
The product is classified according to table no. 2.

Table no. 1
Scale of evaluation

Erythema	
No erythema	**0**
Light erythema (hardly visible)	**1**
Clearly visible erythema	**2**
Moderate erythema	**3**
Serious erythema (dark red with possible formation of light eschars).	**4**
Edema	
No edema	**0**
Very light edema (hardly visible)	**1**
Light edema	**2**
Moderate edema (about 1mm raised skin)	**3**
Strong edema (extended swelling even beyond the application area)	**4**

Table no. 2
Classification of the index of average irritation (according to the amended Draize classification)

Index	Class
0,5	non irritant
from 0,5 to 2,0	slightly irritant
from 2,0 to 5,0	moderately irritant
from 5,0 to 8,0	highly irritant

Results

Values of edema and/or erythema

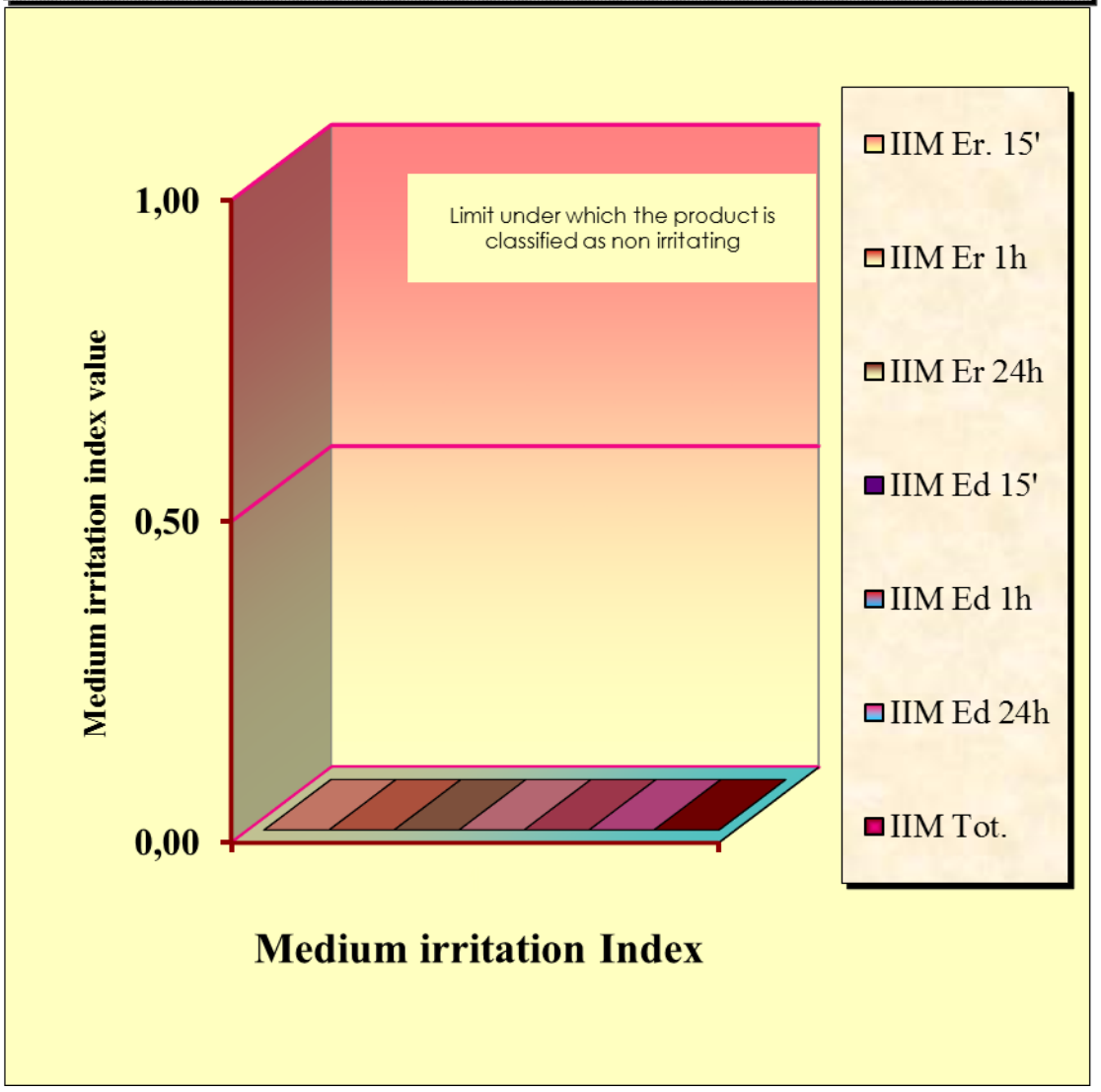
(scale of evaluation: see table no. 1)

Volunteers' references	SEX	Reaction after 15'		Reaction after 1 h		Reaction after 24 h	
		Erythema	Edema	Erythema	Edema	Erythema	Edema
1	F	0	0	0	0	0	0
2	F	0	0	0	0	0	0
3	F	0	0	0	0	0	0
4	F	0	0	0	0	0	0
5	F	0	0	0	0	0	0
6	F	0	0	0	0	0	0
7	F	0	0	0	0	0	0
8	F	0	0	0	0	0	0
9	F	0	0	0	0	0	0
10	F	0	0	0	0	0	0
11	F	0	0	0	0	0	0
12	F	0	0	0	0	0	0
13	F	0	0	0	0	0	0
14	F	0	0	0	0	0	0
15	F	0	0	0	0	0	0
16	F	0	0	0	0	0	0
17	M	0	0	0	0	0	0
18	M	0	0	0	0	0	0
19	M	0	0	0	0	0	0
20	M	0	0	0	0	0	0
21	F	0	0	0	0	0	0
22	F	0	0	0	0	0	0
23	F	0	0	0	0	0	0
24	F	0	0	0	0	0	0
25	F	0	0	0	0	0	0
26	F	0	0	0	0	0	0
27	F	0	0	0	0	0	0
28	M	0	0	0	0	0	0
29	M	0	0	0	0	0	0
30	F	0	0	0	0	0	0

Values and classification of the average irritation indexes

(See table no. 2)

IIM after		IIM after 1		IIM aft. 24		IIM
Erythem	Edema	Erythem	Edema	Erythem	Edema	TOT.
0,00	0,00	0,00	0,00	0,00	0,00	0,00



Conclusions

The table and the graphs listed above summarize the values of the indexes of erythema and edema found out for each volunteer. We can state that product named:

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has been dermatologically tested and it can be classified according to amended Draize classification :

NOT IRRITANT

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This document has been digitally signed, in compliance with any applicable law, ensuring the effective validation by all the subjects.

Bibliography

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