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REPORT ON A HUMAN PATCH TEST

013729 PRELINE - RAPID BRONZ
259612

Testing of the skin irritation potency of a cosmetic product.

RAPID BRONZ

CLINICAL STUDY DESIGNS

Title
Testing of the skin irritation potency of a cosmetic product.

Objective
Determination of the side effects (skin erythema and edema) on skin is useful in the assessment and evaluation of the safety of the tested cosmetic product which exposure by the dermal rout is likely.

Sample size
25 healthy and well-informed on the test purpose volunteers.

Dose level
A dose of 20µL of liquid or 20 µg of solid or semisolid is applied to the test side.

Preparation of the products
The tested product is applied to the skin surface according to its final use as suggested by customer. 013729 PRELINE RAPID BRONZ 259612 is applied as it is by using the Finn Chamber.

Preparation of test site
Only volunteers with healthy intact skin are selected for the test. The test skin area (dorsal skin) has been cleaned with a 70% alcoholic solution to make it sensible to the product action.

Application of the test substance.
The cosmetic product is applied to all volunteers by using the Finn Chamber, a 8 mm diameter aluminium disk, containing disks in filter paper supporting a fixed quantity of the sample which is being analysed. Finn Chambers are supported on a tape already tested for its safe of use.

Ethical Principles for Medical Research
All of the study procedures are carried out in compliance with the ethical principles for medical research: Helsinky declaration (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975, 35th WMA General Assembly, Venice, Italy, October 1983, 41st WMA General Assembly, Hong Kong, September 1989, 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996, 52nd WMA General Assembly, Edinburgh, Scotland, October 2000, by the General Assembly, Washington, 2002 (note of clarification on paragraph 29), by the 53th WMA General Assembly, Tokyo, 2004 (note of clarification on paragraph 30) and by the 59a WMA General Assembly, Seoul, October 2008).

Product informations
Name: 013729 RAPID BRONZ 259612

Information provided by the customer:
The tested cosmetic products do not contain any substance which is forbidden by the EEC legislation as far as the use of cosmetic and personal hygiene products is concerned, the preservatives in the product formula are in the list of accepted components published by the EEC and are used in a concentration provided for by the law and moreover limits and instructions, published in the Enclosures of the 76/768 EEC regulation, are mentioned for those substances for which there is a concentration limit.

MATERIALS AND METHODS

Inclusion criteria
25 people both men and women only with an age between 18 and 60 years are selected for the test , following the undermentioned inclusion criteria :

a) good state of general health
b) no dermatological disease that might interfere with the evaluation of test site reaction
c) no pharmacological treatment in progress
d) promise not to change the usual daily routine
e) no atopy
f) no pregnant women

Preparations of the products
013729 RAPID BRONZ 259612 is applied as it is by using the Finn Chamber.

Execution of the test
The involved skin area (skin surface of the back) has been cleaned with a 70% alcoholic solution The cosmetic product has been applied and left in contact with the skin surface for 48 hours. Finn chamber assures an occlusive application of the product. The cutaneous reactions are analysed 15 minutes, one hour and 24 hours after Finn Chamber removal

Clinical examination and scoring
After removal of the patch, volunteers are examined for signs of erythematic and oedema and the responses scored within 15 minutes, 1 hour and 24 hours after patch removal. Dermal reactions are scored and recorded following the grades reported in table no. 1 . Erythematic and oedema reaction are summarized in tabular form and graphically represented. The results of the irritating powers are obtained by calculating the medium values of both eritema and oedema. The product is classified following table no. 2.

Table number. 1 - Clinical score of skin reactions

Eritema	**Erythema**	
Assenza di eritema	No erythema	**0**
Eritema leggero (appena visibile)	Light erythema (hardly visible)	**1**
Eritema ben visibile	Clearly visible erythema	**2**
Eritema moderato	Moderate erythema	**3**
Eritema grave (rosso barbabietola con eventuale formazione di lievi escare)	Serious erythema (dark red with possible formation of light eschars).	**4**
Edema	**Edema**	
Assenza di edema	No edema	**0**
Edema molto leggero (appena visibile)	Very light edema (hardly visible)	**1**
Edema leggero	Light edema	**2**
Edema moderato (bordi sollevati di circa 1 mm)	Moderate edema (about 1mm raised skin)	**3**
Edema forte (tumefazione estesa oltre l'area di applicazione)	Strong edema (extended swelling even beyond the application area)	**4**

Table number. 2 - Classification of the medium irritation index (following the amended Draize classification)

Indice	Index	Classificazione	Classification
0,5	0,5	non irritante	non irritating
da 0,5 0 2,0	from 0,5 to 2,0	leggermente irritante	slightly irritating
da 2,0 a 5,0	from 2,0 to 5,0	moderatamente irritante	moderately irritating
da 5,0 a 8,0	from 5,0 to 8,0	fortemente irritante	highly irritating

RESULTS

Summery of the data found out from the test carried out on the volunteers and evaluation of the possible irritating potency of the tested product.

Edema and Erythema reaction found out

(Clinical score see table no. 1)

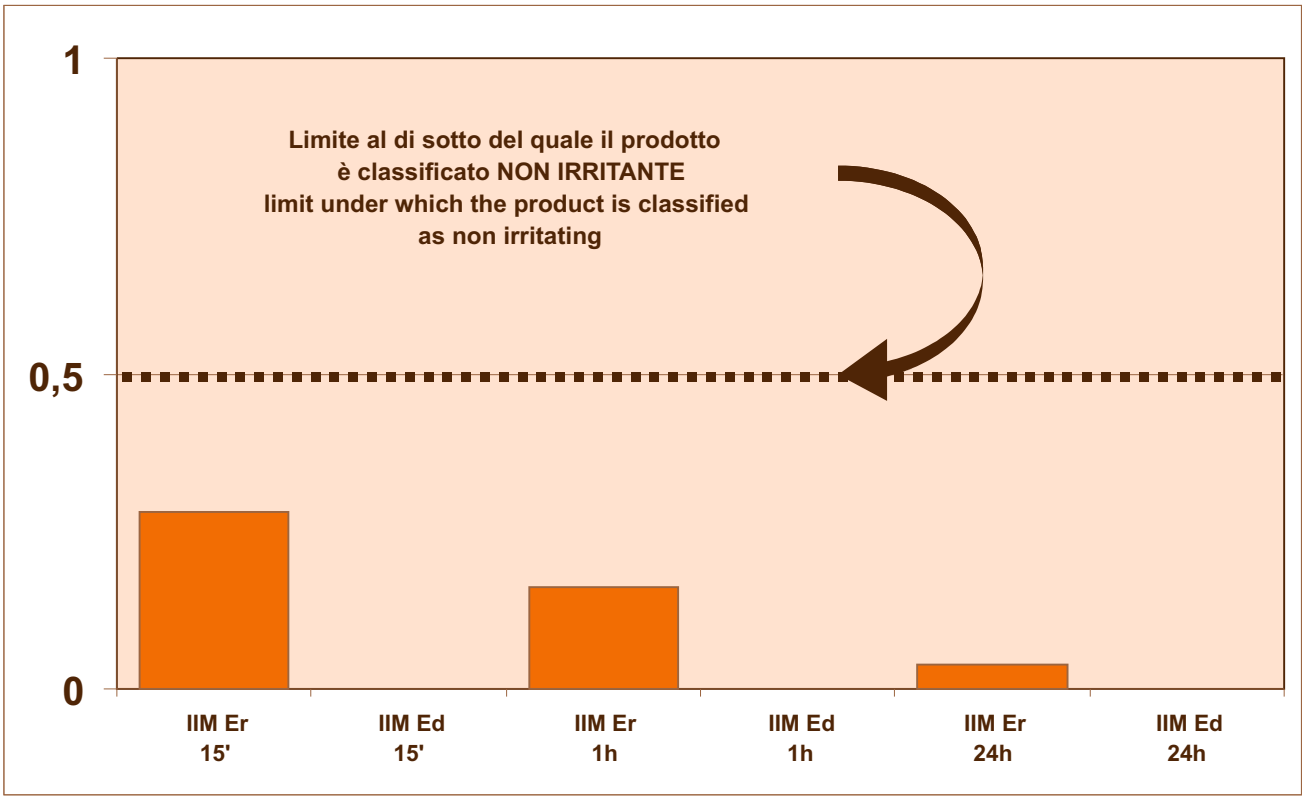
Riferimento dei volontari Panellist name	SESSO	ERITEMA Erytema 15'	EDEMA Edema 15'	ERITEMA Erytema 1h	EDEMA Edema 1h	ERITEMA Erytema 24h	EDEMA Edema 24h
01MA	F	0	0	0	0	0	0
02TG	F	0	0	0	0	0	0
03DM	F	0	0	0	0	0	0
04NP	M	0	0	0	0	0	0
05VN	M	0	0	0	0	0	0
06CP	F	1	0	1	0	0	0
07GF	F	1	0	0	0	0	0
08SI	F	0	0	0	0	0	0
09BL	F	0	0	0	0	0	0
10SG	F	0	0	0	0	0	0
11SC	F	1	0	1	0	0	0
12ES	F	0	0	0	0	0	0
13PD	F	0	0	0	0	0	0
14MG	F	0	0	0	0	0	0
15BR	F	0	0	0	0	0	0
16FM	M	0	0	0	0	0	0
17CM	F	1	0	1	0	0	0
18FA	F	0	0	0	0	0	0
19FA	F	0	0	0	0	0	0
20FE	F	0	0	0	0	0	0
21LT	F	1	0	0	0	0	0
22AC	F	1	0	0	0	0	0
23IS	F	0	0	0	0	0	0
24VC	F	0	0	0	0	0	0
25SR	F	1	0	1	0	1	0

EDEMA AND ERYTHEMA MEDIUM VALUES FOUND OUT

IIM Er 15'	IIM Ed 15'	IIM Er 1h	IIM Ed 1h	IIM Er 24h	IIM Ed 24h
0,28	0,00	0,16	0,00	0,04	0,00

Medium irritation indexes Values

(See table no. 2)



CONCLUSIONS

The table and the charts listed above contain the values of the erythema and edema indexes found out for each volunteer. Skin irritating potency of the product has been assessed according to the amended Draize classification.

On the basis of the data obtained we asses that the product:

013729 RAPID BRONZ 259612

NON IRRITATING