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STUDY/PRODUCT REFERENCES: 21-0125/0 / 21.0102

CHECKING IN HUMAN OF THE ACCEPTABILITY OF A PRODUCT AFTER APPLICATION UNDER NORMAL CONDITIONS OF USE

Use test with clinical control by a dermatologist

SPONSOR: PAYMSA

TEST PRODUCT: AROMATIZANTE DE MASCARILLAS REF: PL CARIN4MASK FRESA

Study report
version 1

Barcelona, March 17th, 2021

8 pages in this report

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I. AIM AND PRINCIPLE OF THE STUDY

This study intended to check the skin acceptability of the product **AROMATIZANTE DE MASCARILLAS REF: PL CARIN4MASK FRESA,** after application under the normal conditions of use planned by the Sponsor.

The acceptability was:

- checked every day, by the subjects themselves at home,
- controlled after visual examination of the experimental area, by a dermatologist or the responsible technician, and after questioning of the subjects.

II. TYPE OF THE STUDY

This monocentric study was performed in open.

The subject was used as own control.

It was performed according to the general conditions of Eurofins Cosmetics & Personal Care Spain, established for the performance of Human test project.

III. INVESTIGATOR CENTRE AND TECHNICAL STAFF

III.1. Investigator centre

EUROFINS PRODUCT TESTING, COSMETICS & PERSONAL CARE SPAIN, S.L.U.
Ausiàs March, 148-150
08013 Barcelona (Spain)

tel: (+34) 93.285.14.46

III.2. Technical staff

Investigator: Isabel DEL BUSTO, MD (Dermatologist)

Responsible technician: Maria RUIZ

IV. DATES OF PERFORMANCE OF THE STUDY

Beginning on: February 19th, 2021

End on: March 5th, 2021

V. TEST PRODUCT

V.1. Identification of the test product

Denomination	AROMATIZANTE DE MASCARILLAS
Reference	PL CARIN4MASK FRESA
Batch number	210128C01
Reference Eurofins	21.0102
Galenic form and organoleptic characteristics	Transparent solution
Number and type of samples	25 transparent spray plastic flasks
Content of samples	20mL

V.2. Information concerning the test product

The documents relating to the test product supplied with the samples were the qualitative and quantitative formula and the Sponsor's letter of agreement particularly concerning the conformity of the formula to the regulations in force and its safety.

VI. SUBJECTS

VI.1. Number

The number of subjects whose data had to be exploitable at the end of the study was 20, with a lower acceptable limit of 19, in accordance with the corresponding procedure.

22 subjects were included in the study.
1 withdrawal (subject ref. 10) was noted due to personal reasons not related with the study and no exclusion was decided by the investigator.

The acceptability of the test product was therefore assessed in 21 subjects.

VI.2. Specific inclusion criteria

The specific inclusion criteria were the following ones:

- age: 18-70 years old,
- sex: female and/or male,
- phototype (Fitzpatrick): I to V,
- all type of skin on face,
- users of FFP2 face masks (50% of the panel) and surgical face mask (50% of the panel).

All the subjects corresponded to these specific inclusion criteria.

VI.3. Specific non inclusion criteria

The specific non inclusion criteria were the following ones:

- cutaneous marks on the experimental area which could interfere with the assessment of skin reactions,
- personal history of adverse reactions to the same type of product as the one tested,
- atopy,
- forecast of intensive sun or UVA exposure (U.V. lamps) during the test period,
- treatment with Vitamin A acid or its derivatives stopped less than 3 months before the beginning of the study.

All the subjects corresponded to these specific non inclusion criteria.

VII. METHODOLOGY

The experimental conditions were the following ones:

Experimental area	Product directions for use	Applications at the investigator centre	Applications at home Frequency/duration
Face	Keeping the spray and the mask upright, spray 8-10 cm from the inside of the mask*. Allow to dry for 1 minute before putting on the mask. Use 1 mask a day.	None	From **D0 to D14** Apply **once every 2 hours** for 14 +/- 1 consecutive days **(2 weeks)**

**the sponsor supplied 400 face masks to be used with the test product*

All the experimental conditions of use at home were respected by the subjects.

All the constraints of the study were respected by the subjects.

VII.1. Checking of the acceptability

The subjects were requested to note every day any reaction observed and sensation of discomfort felt on the **individual observation sheet** they were given at the beginning of the study.

A skin examination of the experimental area had to be performed by the dermatologist or responsible technician.

This examination had to be performed visually under standard “daylight” source, before then after 14 +/- 1 consecutive days of use.

Concurrently with the clinical examination performed after use of the product, each subject had to be questioned about the possible sensations of discomfort he felt.

All the examinations were performed in accordance with the conditions defined in the protocol.

VIII. RESULTS / DISCUSSION

Characteristics of the panel

Number of subjects included in the study	22
Withdrawal	1 (ref. 10) for personal reasons
Exclusion	None
Valid cases	Skin acceptability
	21

Age (years)	Valid cases	
Minimum age	21	
Maximum age	66	
Mean	53	
Criteria	Valid cases	
	Nb	%
Phototype		
I	0	0%
II	4	19%
III	12	57%
IV	5	24%
V	0	0%
Sex		
Female	12	57%
Male	9	43%
Type of skin on face		
Dry skin	4	19%
Normal skin	10	48%
Combination skin	6	29%
Oily skin	1	5%
User of FFP2 face mask	10	48%
User of surgical face mask	11	52%

VIII.1. Checking of the acceptability

Types of skin reactions ascribable to the test product	% of subjects exhibiting clinical signs ascribable to the test product	Types of sensations of discomfort ascribable to the test product	% of subjects exhibiting sensations of discomfort ascribable to the test product
None	0%	None	0%

It should be noted that some subjects felt sensations of discomfort that were not taken into account in the conclusion about the cutaneous tolerance of the test product since they did not relate to skin sensations, as follows:

SENSATIONS OF DISCOMFORT					
Ref. Subject	Nature	Location	Intensity	Duration	Time of apparition after product application
11	Itching	Throat	Mild	10-15min (on D4 and D8 at home)	Immediately
12	Stinging	Left eye	Very mild	5min (D0 and D1 at home)	Immediately

Discussion:

Taking into account that no subject felt any sensations of discomfort of dermatological origin and that no subject showed clinical signs ascribable to the test product, the dermatologist classed the product in relation to the grading scale and judged it very well tolerated by the skin.

IX. CONCLUSION

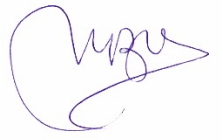
According to the experimental conditions adopted and taking into account the grading scale established by the investigator centre, the product **AROMATIZANTE DE MASCARILLAS REF: PL CARIN4MASK FRESA has a very good cutaneous acceptability.**
Its very good skin tolerance was thus confirmed.

The product can claim the mention "tested under dermatological control".

Signatures and dates

Investigator: Isabel DEL BUSTO, MD (Dermatologist)

I the undersigned, Isabel DEL BUSTO, declare that the overall conduct of the study was carried out under my responsibility and in the spirit of the Good Clinical Practices (International recommendations ICH topic E6, CPMP/ICH/135/95 of 1/5/1996, Directive of the European Parliament and Council 2001/20/EC – OJ/EC of 1/5/2001).



Quality Assurance Personnel: Marta RIVERA

I the undersigned, Marta RIVERA, declare that:
- this final report was examined on 18th of March 2021,
- the results reported accurately and completely reflect the raw data of the study.