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STUDY OF ACCEPTABILITY OF A COSMETIC

NON-COMEDOGENICITY TEST UNDER DERMATOLOGICAL CONTROL

CLINICAL TRIAL IN HEALTHY ADULT VOLUNTEERS FOR THE EVALUATION OF THE NON-COMEDOGENITY AND SKIN ACCEPTABILITY OF A COSMETIC PRODUCT.

Product:

Pantalla Solar & Ambiental SPF 60+ Color

Research promoter:

CELINDE COSMETICS, SL.

Jenaro Checa, 77 Local
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(ESPAÑA)

SUBJECT OF TEST	:	Pantalla Solar & Ambiental SPF 60+ Color
LIMSA REFERENCE CODE	:	21_000052
REPORT	:	21_000052 – TU
STARTING DATE	:	14th January 2021
ENDING DATE	:	11th February 2021

PROTOCOL

Aim of the test:

Verify skin acceptability and non-comedogenicity (increase of comedones as a consequence of the use of the product), applied under normal conditions of use.

Type of clinical study: Use test under dermatological control on facial skin.

Duration of the study: 4 weeks (28 days)

Methodology:

The dermatologist carried out 3 evaluations: initial visit during which a first reading of the skin was carried out as well as a count of comedones, using a plastic template (5 x 5 cm) with an opening that allows verification of the effect of the product on the exact area to be analised..

During the intermediate control, the dermatologist examined different parts of the face to evaluate possible undesirable effects and the comedone count was carried out in the area previously delimited for the study.

And finally, a final visit where, in addition to examining the area of application of the product, the questionnaire on the subjective qualities of the product was collected.

The product is considered non-comedogenic if the number of volunteers who increased the number of comedones does not exceed 35%.

INFORMATION ABOUT VOLUNTARIES:

Inclusion criteria:

GENERAL

- The volunteers sign an informed consent to participate in the study, which states the purpose of the study, how it is conducted and possible side effects.
- The site of product application shall be free from irritation and changes requiring pharmacological treatment (specialist evaluation).
- It should always be noted that the results may be affected by:
    1. Type and condition of the application area
    2. Inter-individual genetic characteristics
    3. Individual preferences of subjects

SPECIFIC

- Gender: Women
- Amount of subjects: 20
- Age: 18 – 70 years old
- All types of skin

The qualified subjects receive the investigational product, a specially developed questionnaire and were obliged to follow these guidelines :

- Regular use of the product according to the method of use.
- During the test any other products of similar effects must not be used.
- A detailed evaluation of the tested product using the questionnaire provided.
- In case of any side effects at application site they should immediately stop using the product and consult the dermatologist.

SUBJECTS CHARACTERISTICS

GENRE		AGE		SKIN TYPE	
Women	20	Maximum age	55	Dry	2
Men	0	Minimum age	18	Oily	2
		Average age	44	Normal	11
				Sensitive	5

INFORMATION ABOUT THE SAMPLE

Use frequency: Daily, once a day.

Application mode: Apply gently before exposure to the sun. Repeat application after sport or bathing, avoiding contact with the eyes.

Recommended quantity for its application: -

RESULTS

Confirmation of the declared effect for the cosmetic product

With regard to acceptability and effectiveness, a positive assessment and a favourable evaluation by the subjects, in particular of the following criteria:

	Respuestas satisfactorias
Do you find pleasant the appearance of the product?	80%
Is the odour of the product pleasant?	70%
Do you find the texture of the product pleasant?	75%
Do you find the product easy to apply?	75%
Does your skin tone feel more even?	75%
Does your skin feel protected after the application?	75%
Do you feel more comfortable with your skin even without make-up?	90%
Is the product suitable for daily use?	75%
Would you recommend this product?	75%
What is your final assessment of this product?	90%

**These percentage values were calculated by taking into account only the answers 'Very' and 'Fairly'.*

To verify the evolution of the comedone count, a statistical analysis was performed on the readings taken from all the volunteers before, during and at the end of the study. That is, at the beginning of the study (before applying the product), after 14 days and after 28 days of continuous use of the product.

On table 1, Individual results were expressed as absolute values for each time and as a percentage of variation.

Table 1: Comedones count for each volunteer at the start of product application, after 14 days and after 28 days of product use.

Subjets	READINGS				
	Absolute values			Percentage values (%)	
	D0	D14	D28	D14	D28
1	1	0	0	-100%	-100%
2	1	1	1	0%	0%
3	4	5	5	25%	25%
4	1	1	1	0%	0%
5	1	1	1	0%	0%
6	2	2	2	0%	0%
7	3	2	1	-33%	-67%
8	0	0	2	0%	200%
9	1	1	0	0%	-100%
10	0	1	1	100%	100%
11	2	2	1	0%	-50%
12	2	2	2	0%	0%
13	2	2	2	0%	0%
14	4	4	5	0%	25%
15	0	0	0	0%	0%
16	0	0	0	0%	0%
17	6	7	6	17%	0%
18	4	3	2	-25%	-50%
19	1	1	1	0%	0%
20	2	2	2	0%	0%
Mean	1.85	1.82	1.75	-0.01	-0.01
SD	1.631	1.785	1.713	0.345	0.652

As can be seen in the statistical data, in the count of comedones between the readings at day 0 and day 28, 20% of volunteers increased the number of comedones, 55% remained the same and 25% decreased.

COSMETIC PRODUCT EVALUATION

Based on the medical examinations and the volunteers' answers to the questionnaire, it is considered that the product **Pantalla Solar & Ambiental SPF 60+ Color** was very well tolerated at the site of application.

None of the volunteers (20 subjects) who completed the study found any abnormal clinical manifestations that might indicate an intolerance to any of the components of the product, such as irritation, burning sensation, redness or itching. The product also did not cause dryness at the application site in any of the subjects.

The results obtained in the use test allow us to conclude that the product, when used under normal or foreseeable conditions of use, is safe for the health of people, provided that no contraindications for its use are detected.

CONCLUSION

According to the results obtained in the use test, we can conclude that the skin acceptability of the product **Pantalla Solar & Ambiental SPF 60+ Color** can be considered **VERY GOOD**, after repeated applications under normal conditions of use, on a daily basis for 4 weeks, by 20 subjects.

Claims of the type **TOLERANCE TESTED UNDER DERMATOLOGICAL CONTROL and NON - COMEDOGENIC** may be justified.

Regarding the answers to the questionnaires, we can conclude that the subjects' perception of their sensory properties and cosmetic efficacy on the skin can be considered **GOOD.**

Evaluation	Score
VERY GOOD	90-100%
GOOD	70-80%
ACCEPTABLE	50-60%
NON ACCEPTABLE	<50%

L'Hospitalet de Llobregat (Barcelona), 03rd March 2021.

SIGNATURES :

Review of the report by:

Dr. Baldomero García Mir

Dermatologist, Coleg. Nº :14/06382

Reviewed and approved by:

Pilar Torrecilla

Technical Director

Electronically signed by:
LIMSA CORPO S.L.

Report Version	Modification Date	Reason for modification
V0	---	---

BIBLIOGRAPHY

1. Regulation (EC) nº 1223/2009 of the European Parliament and of the Council of November 30, 2009 of the cosmetic products.

2. Declaration of Helsinki - ethical principles for medical research involving human subjects adopted by the 18th wma general assembly, Helsinki, Finland, June 1964, and consecutive amendments (last amendment: 59th wma general assembly, Seoul, October 2508).

3. Guidelines for the evaluation of the efficacy of cosmetic products, revised version may 2008. Cosmetics Europe – the personal care association-.

ANNEX

PRODUCT ASSESMENT QUESTIONNARIE

EFFECTIVENESS AFTER USE					
	Very	Fairly	Neutral	Slightly	Not al all
Do you find pleasant the appearance of the product?	8	8	4	0	0
Is the odour of the product pleasant?	8	6	6	0	0
Do you find the texture of the product pleasant?	11	4	5	0	0
Do you find the product easy to apply?	10	5	5	0	0
Does your skin tone feel more even?	7	8	5	0	0
Does your skin feel protected after the application?	9	6	5	0	0
Do you feel more comfortable with your skin even without make-up?	8	10	2	0	0
Is the product suitable for daily use?	8	7	5	0	0
Would you recommend this product?	9	6	5	0	0
What is your final assessment of this product?	8	10	2	0	0