

**ASSESSMENT IN HUMAN HAIR OF THE SEBO-REGULATING EFFECT OF A COSMETIC TREATMENT-
ORGANIC HAIR COLOUR CREAM BASED**

CHECKING OF ITS ACCEPTABILITY AFTER APPLICATION UNDER

NORMAL CONDITIONS OF USE

SUBJECTIVE ASSESSMENT OF ITS COSMETIC QUALITIES AND EFFICACY

Use test with clinical control by a dermatologist and oncologist with instrumental evaluation

(Compiled by Neha Rana (Pharmacist) with inputs from Eric Favre Laboratoire, France)



ABSTRACT

AIM AND PRINCIPLE OF STUDY

This study intended to assess the sebo-regulating effect, as well as to check the acceptability and to assess the cosmetic qualities and efficacy.

1. Investigator centre

EVIC hispania

Centro experimental de evaluation Cutanea, S.L.

Travessera de Dalt, n^o, Entlo.4^a

08024 Barcelona (Spain)

Tel.(+34) 93.285.14.46

2. Technical staff

Investigator: Dr. Isabel DEL BUSTO (Dermatologist)

Technical Department Manager: Mireria LLOBET

Responsible Technician: Raquel MONTBLANCH

Quality Assurance Personnel: Jordi TIERRA

Relevance ofThe Study

- **ETHICS**

The study aiming at a better knowledge of the cutaneous tolerance and efficacy of the test treatment and the foreseeable risk incurred by the subjects who took part in the study being minor, there was a suitability between the aim of the study and its possible risks.

- **METHODOLOGICAL APPROACH**

The observance of the experimental conditions by the subjects who took part in the study was assessed by a questionnaire at the end of the study.

- **TYPE OF STUDY**

It was performed according to the general conditions of EVIC hispania, established for the performance (opinion n°CI-S41/12 of October 4th,2012).

SUBJECTS

- **Number**

The number of subjects whose data had to be exploited at the end of the study was 24,with a lower acceptable limit of 23.

The treatment consisted of 12 different tones. Each tone had to be tested by 2 subjects..

- **Specific inclusion criteria**

Age: 18-70 years old

Sex: female

Phototype (Fitzpatrick): I to V,

Regular or occasional users of the hair dye.

Results

- Checking of the acceptability

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

instrumental assessment of the sebo-regulating effect

Table-1

	Measurements of the sebum index		
	D0	D42	% Variation D42-D0
Mean	88.1	71.3	-6.7%
Standard deviation	54.0	43.3	53.9%

CONCLUSION

After 42 days of treatment there has not been observed an important variation in the sebum content of the scalp.

- Statistical analysis

Statistic value	P	Significance of the difference
1.34306	0.179251	NS

*s=significant if $p < 0.05$ NS=non significant

conclusion: The analysis of the results doesn't show statistical differences in the sebum index, after use of the treatment.

Patients And Methods

The experimental conditions, defined in the protocol, were as follows:

Experimental area	Treatment directions for use	Applications at home Frequency / duration
Hair	Application, by the subject himself/herself , according to the directions of use planned by the Sponsor	From D0 to D42 Application twice for 42+/-2 consecutive days (6 weeks)

The constraints imposed on the subjects were as follows:

- Full respect of the test treatment conditions of use,
- No change in hair hygiene and care habits
- Neither anti-allergic, anti-inflammatory treatment nor treatment with patients on medicines containing Vitamin A acid or its derivatives during the study
- Wash hair at home between 2.5 and 3.5 days before coming to the investigator centre,
- Neither initiation of a hormonal treatment nor change of the usual hormonal treatment during the study,

Control of the observance

The subjects were questioned at the end of the study about the way they used the test treatment.

The investigator checked the respect of the constraints.

A control of the product consumption was performed at the end of the study. The sample(s) given to each subject was(were)weighed before opening, at the beginning of the study and after the last application.

Instrumental assessment of the sebo-regulating effect

- Descriptive analysis:

The measurements of the sebum index were performed on D0 and D42.the individual data and the variation of D42 to D0 shown in the table above in table 1.

- Statistical analysis

The statistical analysis (Wilcoxon's signed-rank test) allowed to compare the variation of the sebum content before and after treatment.

Cosmetic qualities

For each item, the number and percentage of subjects according to the answer and the number and percentage of subjects are mentioned in the table below

Items (24 exploitable results)	Number of satisfied subjects	Percentage of satisfied subjects
1. The general application of the dye is easy/very easy	19	79%
2. The application of the different elements of the dye is easy/very easy .	20	83%

Cosmetic efficacy

Items	Number of satisfied subjects	Percentage of satisfied subjects
3. Grey hairs are covered (19 subjects concerned)	17	89%
5. Adequate colour durability	21	88%
6. Adequate intensity of the colour	22	92%
7. Provides vitality to hair	22	92%
8. Provides a healthy look to hair	22	92%
9. Ability to repair hair	16	67%
10. does not cause hair aggression	21	88%
11. Moisturizes hair and scalp	19	79%
12. Nourishes hair	20	83%
13. Does not irritate scalp	21	88%
14. Takes care of hair	20	83%
15. Takes care of scalp	18	75%
16. Regulates fat on scalp	16	67%
17. Does not itch during the dye application	22	92%
18. Does not itch during the whole treatment	23	96%
19. Provides shine to hair	21	88%
20. Provides silkiness to hair	20	83%
21. Provides volume to hair	18	75%

CONCLUSION

According to the experimental conditions adopted and taking into account the instrumental parameter, the grading scale established by the investigator centre, as well as the subjective auto-evaluation, the treatment **PERMANENT HAIR COLORANT WITHOUT PPD REF: PG01172(1.0) + PG01173(3.0) + PG01174(4.0)+PG01175(5.0)+PG01176(6.0)+PG01177(7.0)+PG01178(8.0)+PG01179(10.0)+PG01180(5.3) +PG01181(6.3)+PG01182(7.3) +PG01183(8.3) +DEVELOPER 20 VOL.(PG07200) +DEVELOPER 25 VOL.(PG07300) +DEVELOPER 30 VOL.(PG07400) +DEVELOPER 40 VOL.(PG07500) +BALSAM**

- **Has a very good acceptability.**

Its very good skin tolerance was thus confirmed.

The treatment can claim the mention “test under dermatological control”.

Moreover for a statistically significant percentage of subject the treatment was judged that it covers grey hairs, has an adequate colour provides vitality to hair, provides a healthy look to hair, does not cause hair aggression, moisturizes hair and scalp, nourishes hair, does not irritate scalp, takes care of hair and scalp, does not cause itching during the dye application and during the whole treatment and provides shine, silkiness and volume to hair.

Dates of performance of the study

Beginning on: October 10,2012

End on :November 21 ,2012



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