

ISPE

Institute of Skin and Product Evaluation

Report 178/07/01

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Milan, November 20th 2007

**INSTRUMENTAL and SUBJECTIVE EVALUATION of the EFFICACY of a
PRODUCT in INHIBITING THE HAIRS REGROWTH**

METHOD: Ref. S14C

CUSTOMER: **LIPOTEC S.A.**
Pol. Ind. Camì Ral
C/Isaac Peral, 17
08850 Gavà - BARCELONA
SPAIN

PRODUCT: **PRODUCT HGI, Code V16G1-07**
Ref. ISPE: 178/07/01 - 338/07

STARTING DATE OF THE STUDY: 03/09/'07

COMPLETION DATE: 19/11/'07

ETHICAL AND QUALITY CRITERIA

The current study was carried out in compliance with the quality assurance system requirements, according to the principles of good laboratory practice (GLP) and good clinical practice (GCP), as well as the principles established by the World Medical Association in the Declaration of Helsinki.

REFERENCES

The data given in this report are exclusively related to the tested sample.
This report can be only in full reproduced.

ISPE s.r.l.
Director of the Laboratory
Dr. Luigi Rigano

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1. SAMPLE DATA SHEET

SAMPLE REF: **PRODUCT HGI, Code V16G1-07**
Ref. ISPE: 178/07/01 - 338/07

SAMPLES ARRIVAL DATE: 23/07/'07

PRODUCT:

PHYSICAL FORM: fluid
COLOUR: white

QUALITATIVE FORMULA:

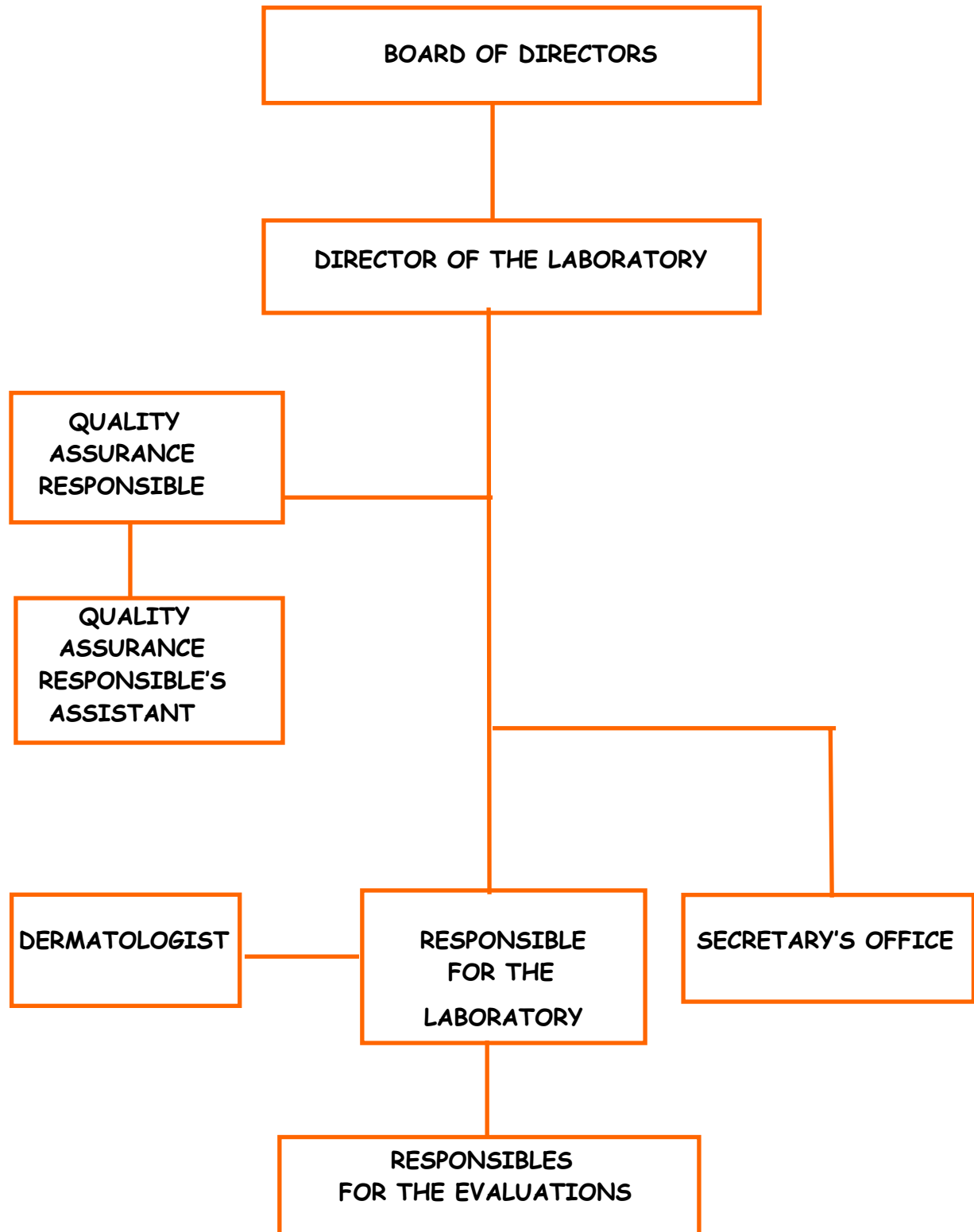
- KNOWN / X /
- OTHER INFORMATIONS / /

OTHER INFORMATION RELATED TO THE PRODUCTS SAFETY:

None.

FILE: 1 sample with the code number **Ref. ISPE: 178/07/01-338/07** and the study findings will be kept in our files for three years and ten years respectively. After these periods, the samples and the findings report will be discarded, unless otherwise required by the client.

2. ORGANIZATION CHART



INSTRUMENTAL and SUBJECTIVE EVALUATION of the EFFICACY of a PRODUCT in INHIBITING THE HAIRS REGROWTH

3. PRINCIPLE OF THE METHOD

Aim of the study is to evaluate the efficacy of a cosmetic product in inhibiting the hairs (beard) regrowth when applied to the face for 2 months.

Images of the skin surface covered by hairs are taken by FotoFinder Dermoscope and Thricoscan professional Ver. 2.0 at each check.

The controls take place at the beginning of the study and after 30 days and 60 days of treatment.

The variation of the hairs density, of the mean length of the hairs and the percentage of the length decrease in a 1 cm² area selected on the volunteers' face are evaluated from the analysis of the images recorded at the 3 control times

At the end of the test the volunteers fill in a specific questionnaire for the subjective evaluation of the performance of the product.

4. SELECTION OF THE VOLUNTEERS

4.a. Criteria for recruitment

At the beginning of the study each volunteer signed the informed consent drawn up by the technicians. 20 men (mean age 40) were included in this study according to the following criteria.

4.b. Inclusion criteria

- Race: Caucasian.
- Age: between 20 and 60 years.
- Sex: male.
- Health state: no pathological events both for the period immediately before and during the test.
- Contactability.

4.c. Exclusion criteria

- Subjects who are taking topical or systemic drugs that could affect the results of the test.
- Subjects affected by skin diseases.
- Subject with a history of intolerance to drugs and/or cosmetic products.

4.d. Drop-out

The following reasons were considered sufficient cause for interrupting the subject's participation in the study:

- Free choice of the subject.
- Medical reasons not correlated with the treatment (ex. onset of disease, surgical operation).
- Reasons correlated with the treatment (ex. irritant or allergic reactions).

4.e. Restrictions

For the whole duration of the study the subjects shall not use different products on the tested areas and must follow the directions of the testing engineer as regards the last shaving before each control.

5. INSTRUMENTS

5.a. Fotofinder Dermoscope and Trichoscan professional Ver. 2.0

Fotofinder Dermoscope is a powerful and versatile system that allow to carry out, memorize and process static and/or dynamic recorded images of any skin surface or mucous membrane.

The system consists in a high-definition colour videocamera which is able to magnify any surface on which it is placed by means of a series of magnifying lenses.

The digital images are shown on the screen in their real colours. This allows the observer to view the smallest details.

Thricoscan software can perform several functions on the recorded images: it can detect the number of hairs, the density, it can calculate length, diameter of surfaces, area of surfaces, etc.

The software can also compare the recorded images to references previously recorded by the user.

6. METHOD

6.a. Method of evaluation

20 volunteers of male sex, who usually shave off their beard were selected.

They were asked to shave off as they used to do and to come to the laboratory 48 hours later, having grown beard on their face. Moreover they were asked not to apply creams on the face the day of the test.

At the beginning of the study the testing engineer selected 1 area on the volunteers' face and took two images by means of Fotofinder Dermoscope and Trichoscan professional Ver. 2.0:

- the first image was a real-sized digital image showing one side of the face covered by the beard;
- the second image was a magnified (20x) digital image showing a 1 cm² selected area on the face.

The side of the face recorded by the instrument was randomized between the volunteers.

The product was then given the volunteers who applied it twice a day on their whole face 60 days.

The volunteers were also asked to shave off as they used to do.

After 30 days and at the end of the treatment, the volunteers came back to the laboratory for the intermediate and the final check, 48 hours after the last shaving, having beard growing on their face. Other images by means of Fotofinder Dermoscope and Trichoscan professional Ver. 2.0 were taken.

6.b. Reading of the questionnaires

For each question the partial score was determined by summarising the answers given for each level of intensity.

This score has been reported also as a percentage score in the tables.

6.c. Mathematical elaboration

The mean values and the standard deviations of the mean length of the hairs and of their density were calculated for the three times of reading (basal – intermediate - final control).

Furthermore it was calculated:

$$T_f - T_0 = \text{VARIATION OF THE PARAMETER}$$

Where:

T_f = mean value after 30 days or after 60 days of treatment

T_0 = mean value at the beginning of the treatment

This difference was reported as a percentage of variation, too.

The obtained data were statistically compared by means of the following non-parametric statistical tests:

- **Friedman test**: in order to find out statistically significant differences among the values recorded at the different control times;
- **Wilcoxon Matched Paired test**: in order to find out the groups of data different from one another.

The difference between the groups of analysed data was considered significant for a probability value $p \leq 0.05$.

7. RESULTS

TABLE 1: Mean value and standard deviation of the density of the hairs per cm².

	T ₀	T _{1month}	T _{2months}	% Variation	Wilcoxon T ₀ vs T _F
DENSITY/CM²	mean 50.7 <i>std. dev. 20.7</i>	mean 46.5 <i>std. dev. 18.5</i>	mean 42.7 <i>std. dev. 17.2</i>	- 8.3 % (T ₀ vs T ₁) - 15.8% (T ₀ vs T ₂)	p < 0.05 (T ₀ vs T ₁) p < 0.05 (T ₀ vs T ₂)

The statistical comparison made through the **Friedman test** and the **Wilcoxon Matched Paired test**, between T₀ and T₁ and between T₀ and T₂ showed a statistically significant decrease (**p<0.05**) in the density of the hairs per cm².

TABLE 2: Mean value and standard deviation of the mean length of the hairs and percentage of the length decrease.

	T ₀	T ₁	T _F	% Variation	Wilcoxon T ₀ vs T _F
LENGTH (mm)	mean 0.8610 <i>std. dev. 0.2006</i>	mean 0.7237 <i>std. dev. 0.1859</i>	mean 0.5985 <i>std. dev. 0.2220</i>	- 15.9 % (T ₀ vs T ₁) - 30.5% (T ₀ vs T ₂)	p < 0.01 (T ₀ vs T ₁) p < 0.001 (T ₀ vs T ₂)

The statistical comparison made through the **Friedman test** and the **Wilcoxon Matched Paired test**, between T₀ and T₁ and between T₀ and T₂ showed a highly statistically significant decrease (**p< 0.01 and p< 0.001**) in the mean length of the hairs.

PERCENTAGE OF LENGTH DECREASE:

The percentage of the length decrease is equal to **15.9 %** after 1 month of treatment and equal to **30.5 %** at the end of the treatment.

8. QUESTIONNAIRE'S RESULTS

The results concerning the volunteers' opinion on the product are reported below:

How do you judge the product as regards its capacity to decrease beard regrowth?

	Number of answers	Percentage
Very effective	5	25%
Fairly effective	10	50%
Not very effective	4	20%
Not effective at all	1	5%

How do you judge the product as regards its capacity to decrease beard hardness?

	Number of answers	Percentage
Very effective	2	10%
Fairly effective	12	60%
Not very effective	6	30%
Not effective at all	0	0%

How do you judge the product as regards its capacity to decrease beard density?

	Number of answers	Percentage
Very effective	2	10%
Fairly effective	10	50%
Not very effective	7	35%
Not effective at all	1	5%

How soft do you judge your skin after the product application?

	Number of answers	Percentage
Very soft	9	45%
Fairly soft	10	50%
Not very soft	1	5%
Not soft at all	0	0%

How do you judge the absorption of the product?

	Number of answers	Percentage
Very quick	7	35%
Fairly quick	7	35%
Not very quick	5	25%
Not quick at all	1	5%

Touching your skin after the product application, the residue makes your skin appear...

	Number of answers	Percentage
Greasy	1	5%
Oily	8	40%
Silky	6	30%
No residue is left	5	25%

Do you perceive a freshness sensation on the skin after the product application?

	Number of answers	Percentage
Very intense	5	25%
Fairly intense	8	40%
Not very intense	5	25%
Absent	2	10%

Did you perceive any side effects during and/or after the product application (erythema, burning sensation, etc.)?

	Number of answers	Percentage
Very intense	1	5%
Fairly intense	1	5%
Not very intense	4	20%
Absent	14	70%

6 volunteers perceived side effects due to the product use, **only when applied just after shaving**. 5% perceived very intense burning sensation after the product application, 5% perceived fairly intense burning sensation, 15% not very intense burning sensation and 5% not very intense itching.

9. CONCLUSIONS

In order to evaluate the efficacy of a cosmetic product in inhibiting the hairs (beard) regrowth when applied to the face, 20 volunteers applied **PRODUCT HGI, Code V16G1-07, Ref. ISPE: 178/07/01 - 338/07**, twice a day for 60 days on their face.

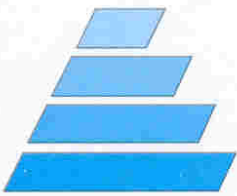
The data recorded at the basal, intermediate and final controls gave the following results:

- ❖ The statistical comparison made through the **Friedman test** and the **Wilcoxon Matched Paired test**, between T₀ and T₁ and between T₀ and T₂ showed a statistically significant decrease (p<0.05) in the density of the hairs per cm².
- ❖ The statistical comparison made through the **Friedman test** and the **Wilcoxon Matched Paired test**, between T₀ and T₁ and between T₀ and T₂ showed a highly statistically significant decrease (p< 0.01 and p< 0.001) in the mean length of the hairs.
- ❖ The percentage of the length decrease was equal to **15.9 %** after 1 month of treatment and equal to **30.5 %** at the end of the treatment.

We can therefore conclude that **PRODUCT HGI is efficient in inhibiting and slowing down the hairs regrowth.**

The subjective evaluation of the volunteers showed the following results:

- ✓ **95%** of the volunteers judged their skin *fairly soft or very soft* after the product application;
- ✓ **75%** of the volunteers thought the product was *fairly effective or very effective* in decreasing beard regrowth;
- ✓ **70%** of the volunteers believed the product *effective or very effective* in decreasing skin hardness;



- ✓ **70%** of the volunteers said that the absorption of the product was fairly quick or very quick;
- ✓ **65%** of the volunteers judged the freshness sensation perceived after the product application fairly intense or very intense;
- ✓ **60%** of the volunteers thought that the product *fairly effective* or *very effective* in decreasing beard density;
- ✓ The volunteers believed that the residue left by the product on the skin was greasy (**5%**), oily (**40%**), silky (**30%**) or that the product left no residue (**25%**);
- ✓ 6 volunteers perceived side effects due to the product use, **only when applied just after shaving**. **5%** perceived very intense burning sensation after the product application, **5%** perceived fairly intense burning sensation, **15%** not very intense burning sensation and **5%** not very intense itching.

Responsible for the laboratory
Dr. Adriana Bonfigli

Responsible for the evaluation
Dr. Valerie Pagani

Dermatologist
Dr. Fernanda Distante

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