

Version 01



FINAL REPORT

PERCEIVED EFFICACY EVALUATION UNDER REAL CONDITIONS OF USE

SPECTRAL.RS®

DS LABORATORIES

Per-E-EP-28257-01-10-11

PERCEPTION Pesquisa em Análise Sensorial Ltda.
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1.IDENTIFICATION

Research Sponsor

DS LABORATORIES

Address: Rua Visconde de Inhaúma, 64 sala 404

Centro- Rio de Janeiro - RJ

Telephone: (21) 3546 2943

Institution / Execution

PERCEPTION PESQUISA EM ANÁLISE SENSORIAL LTDA.

Address: Avenida Dr. Romeu Tórtima, 739

Campinas - SP - Brazil

Telephone: (19) 3749 8300

In Charge of Study

In Charge of Study: Vivian Pessoto Rosa

Product Tested

Official	Perception Code
SPECTRAL.RS	11-28257-01

A sample of the product under study was stored at the research institute as a retention sample for 1 year after the issuance of the final report.



2. OBJECTIVE

The objective of this study was to verify the efficacy of a hair cosmetic product through the subjects' subjective perception using Perceived Efficacy evaluations under real conditions of use of the product **SPECTRAL.RS®** based upon guidelines described in the "Guidelines for the Evaluation of the Efficacy of Cosmetic Products" (COLIPA, 2008) under conditions of real use [sic].

3. LENGTH OF STUDY

This report presents the results obtained after using the product 56 +/- 2 days.

Study start date: 14/Oct/2011

Study end date: 09/Dec/2011

4. STUDY CONDITIONS

The judges were explained and instructed concerning the research objectives and methods. They also received instructions about the study and signed a Free and Clear Consent Form.

After the explanations were given, the subjects evaluated the perceived efficacy by using the questionnaires at the beginning of the study and at the end of the study, after using the product fifty-six days (T56).

The approved subjects were instructed to use the product for 56 +/- 2 days based upon the instructions provided by the company. During this period of time, they were instructed to immediately seek out the person in charge of the study if any sign and/or symptom appeared.

**Direction for use**

Spray the scalp where hair loss is most intense, 10 times (10 sprays), taking care to spray the scalp as directly as possible (avoiding product loss by spraying the strands). After product application, massage the entire area. This process should be done in the morning and before going to bed at night.

Application time

56 +/- 2 days

Application site

Scalp

Amount of Product Applied

Apply the amount deemed necessary according to directions for use.

5. STUDY POPULATION

Of the 29 subjects initially recruited, 28 were selected and one subject (005) was not included in the study because he/she possessed some exclusion criteria and/or did not possess some inclusion criteria - NI. The study began with 28 subjects approved, in order to complete it with at least 20 subjects.

Of the 28 subjects selected, 24 subjects completed the study after using the product 56 +/- 2 days (T56). Four subjects (subject numbers 002, 004, 013 and 019) withdrew from the study for personal reasons unrelated to product use.

Inclusion Criteria

1. Both sexes (with at least 51% of them female);
2. Between the ages of 18 and 60;
3. Possessing fine and delicate hair, complaining of hair loss.

Exclusion Criteria

1. Pregnancy.
2. Breastfeeding.
3. Use of anti-inflammatory/immunosuppressant drugs;
4. Active cutaneous illnesses/injuries (localized or disseminated) that might interfere in the study's outcome.
5. History of adverse reactions to products in the same category as the one being tested;
6. Medicated or cosmetic treatments for hair loss

6. METHODOLOGY

6.1. Evaluation of Perceived Efficacy

The methodology used for Evaluation of Perceived Efficacy was based on the "Guidelines for the Evaluation of the Efficacy of Cosmetic Products" (COLIPA, 2008) and "Standard Guide for Sensory Claim Substantiation" (ASTM E 1958-06, 2006).

The subjects were asked to evaluate the scalp using the Perceived Efficacy Questionnaire (Attachment 4) at the following times:

- T0: On the first day of the study, before applying the test-product (Subject Profiles);
- T56: After using the product 56 +/-2 days (Perceived Efficacy).

6.2. Type of Test

The test of Perceived Efficacy was performed by the Subject under a single-blind monadic test.

7. ETHICAL ASPECTS

The subjects were given explanations and instructed concerning the research objectives and methods. They also received instructions about the study and signed a Free and Clear Consent Form (Attachment 2) prepared on the basis of the Helsinki declaration and Resolution 196/96.

Each subject was informed that he/she could withdraw from the study at any time, with no reasons given.

8. STATISTICAL ANALYSES

An exploratory analysis of the data was performed (percentages and bar graphs).

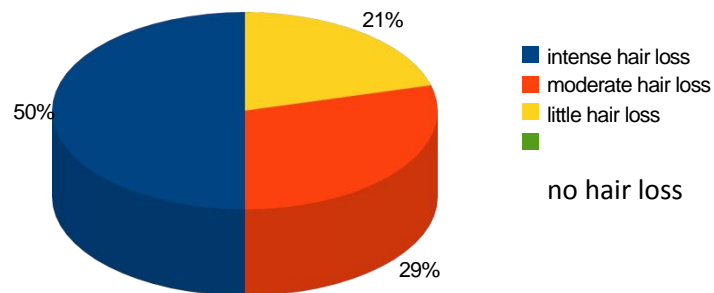
The number of subjects who completed the study was equal to 24 (HOUGH et. al., 2006 and STONE & SIDEL, 2004).

9. RESULTS

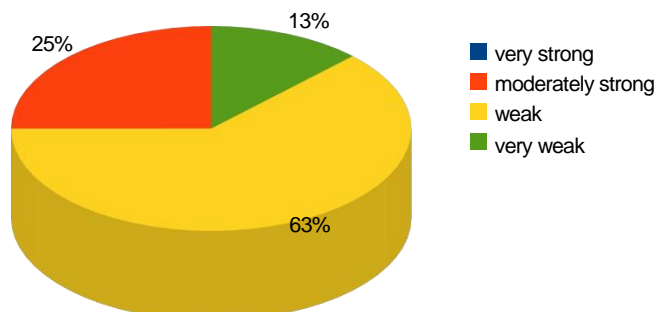
9.1. Subject Profiles

The Figures below (pie chart) show the subjects' evaluation before using the product (Subject Profiles).

Hair Loss

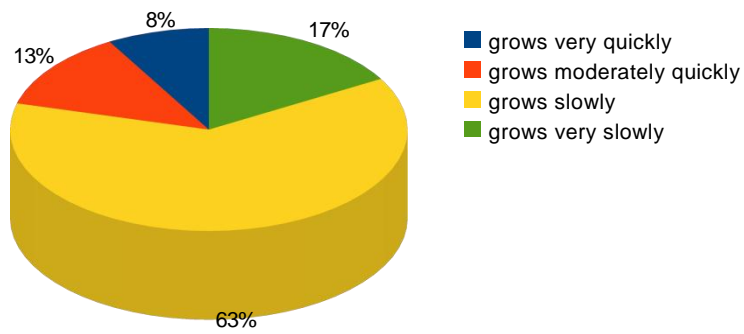


Strength



PROFILE OF THE JUDGES

Speed of Growth



1.2. Subjects' Evaluation of Perceived Efficacy

The following Table presents the subjects' percentage with respect to the perceived improvement of their hair after using the product 56 +/- days (T56).

Attribut	T56 (%)
Hair Loss	83.
Strength	70.
Speed of Growth	70.

The table shows the subjects' percentages that refer to improvements to the scalp after product use. Hair loss was considered the sum of the categories: *decreased a lot*, *decreased moderately* and *decreased a little*.

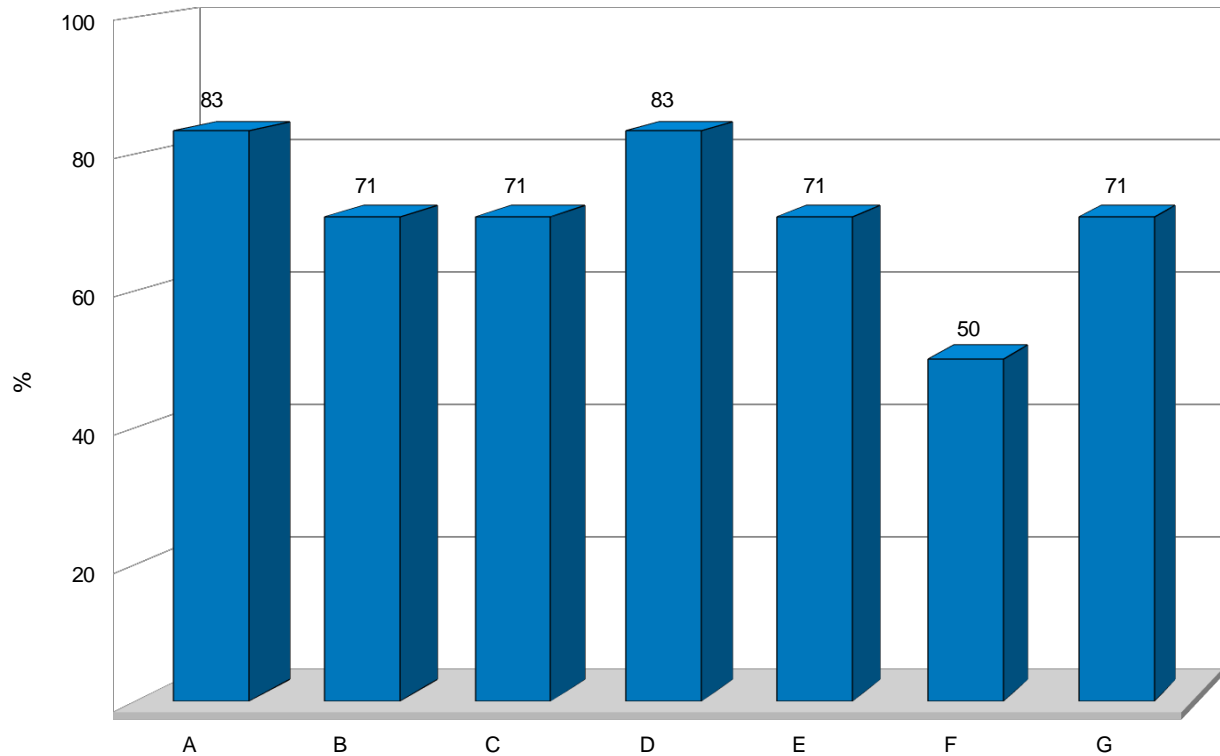
Strength and Speed of Growth were the sum of the categories: *increased a lot*, *increased moderately* and *increased a little*.

Affirmatio	T56 (%)
"Using the product led to less hair loss"	83. 3
"Using the product left my hair stronger"	70.
"Using the product thickened my hair"	50. 0
"After using the product, I noticed an increase in hair growth"	70. 8

The table shows the subjects' percentages that refer to improvements to the scalp after product use. The statements made above were considered to be the sum of the categories *I fully agree* and *I agree*.

SUBJECTS' EVALUATION OF PERCEIVED EFFICACY

The figure below contains a summary of the percentage of acceptance of the Perceived Efficacy attributes evaluated on T56.

**Attributes**

A: Hair Loss

B: Strength

C: Speed of Growth

Statements

D: "Using the product led to less hair loss";

E: "Using the product made my hair stronger";

F: "Using the product thickened my hair";

G: "After using the product, I noticed an increase in hair growth"

10. CONCLUSION

According to the methodology used to evaluate **SPECTRAL.RS®**, ordered by the company **DS LABORATORIES**, one may conclude that:

Subjects' Evaluation of Perceived Efficacy

After using the product 56 +/- 2 days, the following results were obtained:

- 83.3% of subjects noticed less *hair* loss;
- 70.8% of subjects noticed increased *hair* strength;
- 70.8% of subjects noticed increased *hair* growth;
- 83.3% of subjects fully agreed or agreed with the statement "Using the product led to less hair loss";
- 70.8% of subjects fully agreed or agreed with the statement "Using the product left my hair stronger";
- 50.0% of subjects fully agreed or agreed with the statement "Using the product thickened my hair";
- 70.8% of subjects fully agreed or agreed with the statement "After using the product, I noticed an increase in hair growth."



Vivian Pessoto Rosa

In Charge of Study

Fátima Ap. Ortigoza de Lima

Quality Assurance

12/19/2011



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See the scope on ANVISA's
website:
<http://www.anvisa.gov.br/reblas/bio/anali/index.htm>

11 REFERENCES

ASTM E 1958-06. Standard Guide for Sensory Claim Substantiation. 2006.

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MONTGOMERY, D.C. 1991. Design and analysis of experiments. New York : John Wiley and Sons pp 110-114.

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STONE, H & SIDEL, J.L. Sensory Evaluation Practices. Redwood City: 3rd Edition, Elsevier Academic, 2004. p.247-272.

ATTACHMENT 1 – SUBJECTS WHO PARTICIPATED IN THE STUDY

Subject	Initials (name)	Age (years)	Sex	Status
00	AP	5	F	I
00	MS	3	F	I
00	CA	4	F	I
00	V	2	F	I
00	CA	3	F	N
00	JF	5	M	I
00	CP	4	F	I
00	M	5	F	I
00	SR	3	F	I
01	LC	3	F	I
01	S	3	F	I
01	EPF	3	F	I
01	AB	4	F	I
01	MCA	5	F	I
01	W	5	F	I
01	MS	4	F	I
01	IAC	5	F	I
01	LD	2	F	I
01	LR	2	F	I
02	MN	4	F	I
02	AMGPP	4	F	I
02	L	4	F	I
02	OR	3	M	I
02	ACJ	3	F	I
02	LN	5	F	I
02	JA	3	M	I
02	GA	5	F	I
02	A	6	F	I
02	CR	2	M	I

I: Included

NI: Not Included



ATTACHMENT 2 – FREE AND CLEAR CONSENT FORM

- You have been invited to participate in a study. We ask that you thoroughly understand all stages, and if you agree, sign this consent form;
- The purpose of the study is to verify the efficacy of a hair cosmetic product through the subjects' subjective perception by evaluating Efficacy under real conditions of use.
- The study will be carried out at ALLERGISA pesquisa dermatocósmica Ltda, located at Av. Dr. Romeu Tórtima, 452/466 – Barão Geraldo – Campinas – SP;
- You should use the product for up to 56 +/- 2 days based upon the recommended use explained by the technician in charge and/or indicated in the Daily Home Product Use;
- If you agree to participate in the study, you will complete questionnaires before using the product and at the end of testing. You will receive the product to be tested to use at home, and a home product-use diary to be filled out regarding the frequency of product use and any complaints about its use deemed necessary. By signing this consent form you guarantee the veracity of the information reported, and at the end of the study, you will bring the test products and the duly completed diary;
- Attendance will be required twice, and you will have to stay 3 1/2 hours at the start (T0) and 3 hours at the end of the research (T56);
- The expected outcome is to prove the efficacy of the hair cosmetic product, through subjects' perception, under recommended conditions of use.
- You should be the only one using the product;
- Applications, as well as any adverse events, should be recorded in the Mini-Diary you will receive;
- You may be dismissed by the dermatologist after you sign the free and clear consent form if you present any criteria that could exclude you from the research, and also if the existing vacancies have already been filled.
- If you are a woman, you must state that you are not pregnant or breastfeeding and that you commit to refrain from getting pregnant during the study period;
- Your consent does not exempt the organizers of the research center from their obligations;
- You are aware of the fact that on occasion a representative of the sponsor company may be present to observe the study;
- You accept that, within the context of the study, your data will be collected and may be subject to electronic processing. If any changes are made to your registration data (telephone number, address, etc...), please ask the study organizers to update them;
- You will be evaluated prior to the study by a trained technician and monitored during the study by a dermatologist.

ATTACHMENT 2 – FREE AND CLEAR CONSENT FORM CONTINUED

- If you present with any clinical signs in the area where the study product is applied, the affected area will be photographed for recording purposes, but your identity will be kept confidential;
- Any questions that arise during and after the study will be promptly answered;
- Your contribution will ensure a safe and effective product for the community;
- According to current legislation, you will receive no cash payment;
- You will be reimbursed for travel expenses at each visit. At the end of the study you will be reimbursed for your participation in the form of Carrefour vouchers in the amount of R\$ 30.00;
- You may withdraw from the study at any time, but you must inform the institute of your withdrawal.
- You can be removed from the study if you do not fulfill your obligations, based upon the study protocol, at the researcher's discretion
- The study will be conducted on 28 volunteers;
- You will participate in the study for 56 days / 8 weeks;
- Your voluntary collaboration will be of great importance to our work; therefore, we ask that you arrive on time and on the dates listed throughout the course of the study.
- If there is any change to your habits, we ask that you please tell us so we may better interpret the results;
- Do not use any type of product (for example: deodorant or antiperspirant, talcum powder, bath oils, creams, lotions, perfumes, colognes, or topical medications) on the areas around the test area. If you use any of these products or take systemic medication, please let us know;
- In the event of intense itching or other strong signs of irritation, immediately report it and come to the test-application location, or call us at 19-3789-8615 (business hours) or 19-9778-0204 (24h);
- We guarantee that any adverse reaction caused by the tested product will be monitored by the dermatologist and/or specialist in charge of the project, and if necessary, proper medication will be provided.
- Potential indemnifications are insured.
- We guarantee that any new relevant information that may interfere with your consent will be reported;
- All raw materials used in the product are approved for topical use and are not toxic. However, like any product, it may cause unexpected reactions such as "reddening", "swelling", "itching" and "burning" in the areas where the product is applied.

**ATTACHMENT 2 – FREE AND CLEAR CONSENT FORM
CONTINUED**

- All information collected from volunteers will be kept confidential. However, when you sign this form, you allow the sponsor and regulatory authorities to audit all documents and research data;
- If you have any questions or problems, you may contact the medical team at 19-3789-8615.
- One copy of this form will remain on file at Allergisa and another will be given to the volunteer.

I agree to participate in the study **“EVALUATION OF PERCEIVED EFFICACY UNDER REAL CONDITIONS OF USE”** and I declare that all of the aforementioned items have been explained to me.

Volunteer's Signature *(same as the R.G. or Driver's License C.N.H.)*

Date

Witness *(complete first and last name, no abbreviations)*

Identification (R.G.) number

Area Code

Telephone number

Witness' Signature *(same as the R.G. or Driver's License C.N.H.)*

Date

Only complete this section if the volunteer is illiterate.

Signature of the Person In Charge of applying the TCLE

Date



ATTACHMENT 3 – PRODUCT FORMULA

SPECTRAL.RS®

ATTACHMENT 4 – QUESTIONNAIRES FOR THE SUBJECTS’ EVALUATION

Subjects’ Profile Questionnaire

Classification of hair characteristics before using the product (T0)

01 - With respect to **hair LOSS**, you have:

- intense loss
- moderate loss
- little loss
- no hair loss

02 - With respect to **STRENGTH**, your hair is:

- very strong
- moderately strong
- weak
- very weak

03 - With respect to **SPEED OF GROWTH**, your hair:

- grows very quickly
- grows moderately quickly
- grows slowly
- grows very slowly



**ATTACHMENT 4 – QUESTIONNAIRES FOR THE SUBJECTS’
EVALUATION
CONTINUED**

Perceived efficacy questionnaire

Comparison of skin characteristics after using the product – T56

01 - After using the product, your **hair** loss:

- decreased a lot
- decreased moderately
- decreased a little
- is the same, I didn't notice a change
- increased a little
- increased moderately
- increased a lot

02 - After using the product, the **STRENGTH** of your hair:

- increased a lot
- increased moderately
- increased a little
- is the same, I didn't notice a change
- decreased a little
- decreased moderately
- decreased a lot

03 - After using the product, the **SPEED OF GROWTH** of your hair:

- increased a lot
- increased moderately
- increased a little
- is the same, I didn't notice a change
- decreased a little
- decreased moderately
- decreased a lot



**ATTACHMENT 4 – QUESTIONNAIRE TO EVALUATE JUDGES
CONTINUED**

04 - Regarding the phrase **"Using the product led to less hair loss,"** you:

- fully agree
- agree
- neither agree nor disagree
- disagree
- completely disagree

05 - Regarding the phrase **"Using the product left my hair stronger,"** you:

- fully agree
- agree
- neither agree nor disagree
- disagree
- completely disagree

06 - Regarding the phrase **"Using the product thickened my hair,"** you: fully agree

- agree
- neither agree nor disagree
- disagree
- completely disagree

07 - Regarding the phrase **"After using the product, I noticed an increase in hair growth,"** you:

- fully agree
- agree
- neither agree nor disagree
- disagree
- completely disagree