



FINAL REPORT

STUDY OF PERCEIVED EFFICACY

REVITA® HIGH PERFORMANCE HAIR GROWTH STIMULATING SHAMPOO

SULAMERICANA COMERCIO E DISTRIBUIÇÃO LTDA

#10-2274-01-08-10-S01-V01

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(11/14/2011)
FORMULA MODIFICATION

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STUDY OF PERCEIVED EFFICACY

1. PRODUCT IDENTIFICATION

Official	Perception Code
REVITA® HIGH PERFORMANCE HAIR GROWTH STIMULATING SHAMPOO	10-2274- 01

2. ORGANIZATIONS RESPONSIBLE FOR THE STUDY

Study's Sponsor

SULAMERICANA COMERCIO E DISTRIBUIÇÃO LTDA

Address: Rua Visconde de Inhaúma, 64 sala 404 - Centro Rio de

Janeiro – RJ – Brazil

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

People in Charge of Study

Study Coordinator: Regina Lúcia F. de Noronha, Ph.D.

Technician in Charge: Cristiane N. C. Moreira

3. LENGTH OF STUDY

Duration: This report presents the results obtained after using the product for 56 days.

Study start date: 23/Aug/2010 (start of study)

Study end date: 18/Oct/2010 (end of study)

4. DIRECTIONS FOR USE

After gently massaging in the product, leave it on the scalp for 1-2 minutes before rinsing. Then repeat the procedure and let it act on the scalp for 3-5 minutes. If you like, use a high-quality conditioner. For best results, use the product at least 3 times a week.

5. OBJECTIVE

The objective of this study is to determine the efficacy of a topical hair product using sensory testing.

6. POPULATION

Evaluation of Perceived Efficacy by the Subject

Of the 28 subjects initially recruited, 25 were selected and 3 were rejected for not having the specific inclusion criteria.

Of the 25 subjects selected, 20 completed the study. Four subjects (003, 010, 016, 023) withdrew from the study for personal reasons unrelated to product use and one subject (002) was advised by his dermatologist to stop using the product. Therefore, his data were not disregarded [sic].

Inclusion Criteria

Either sex between the ages of 18 and 50 who complain about hair loss.

Exclusion Criteria

The exclusion criteria applied to this study were:

- Pregnancy/breast feeding;
- Use of anti-inflammatory/immunosuppressant drugs;
- History of adverse reactions to products in the same category as the one being tested;
- Active cutaneous illnesses/injuries (localized or disseminated) that might interfere in the study's outcome.

7. TYPE OF TEST

Single-blind monadic test

8. METHODOLOGY

Evaluation of Perceived Efficacy by Subjects: the subjects did evaluations at the following times:

- T0: On the first day of the study, before using the product (Subject Profile);
- T56: After 56 days of using the product (Perceived Efficacy).

9. STATISTICAL ANALYSIS

An exploratory analysis of the data was performed (frequencies, percentages, pie charts and bar graphs).

The number of subjects who completed the study was equal to 20 (HOUGH et. al., 2006 and STONE & SIDEL, 2004).

10. RESULTS

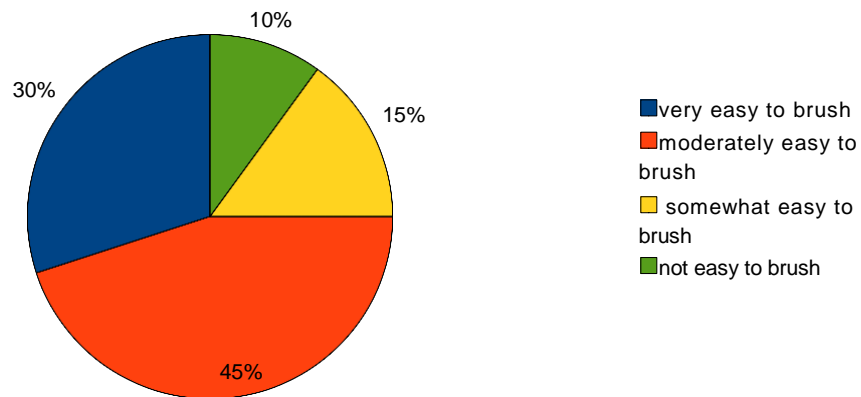
During the study, it was noted that:

On 30/Sept/2010 (38th day of using the product), subject 002 came to the Institute to report that as of the third application of the product, he had started experiencing moderate itching on his scalp and face (location where the product had dripped – forehead and nose), which lasted until his next washing. A test was run to determine skin sensitivity to lactic acid, and the result was positive. The clinical dermatological exam noted light biparietal flushing of the subject's own skin tone and the amount of his hair (which were thin and sparse on top of his head), with very fine flaking in the parietal region. The subject was advised to stop using the product, and the case was closed as being a sensitive scalp. The data from that subject were disregarded.

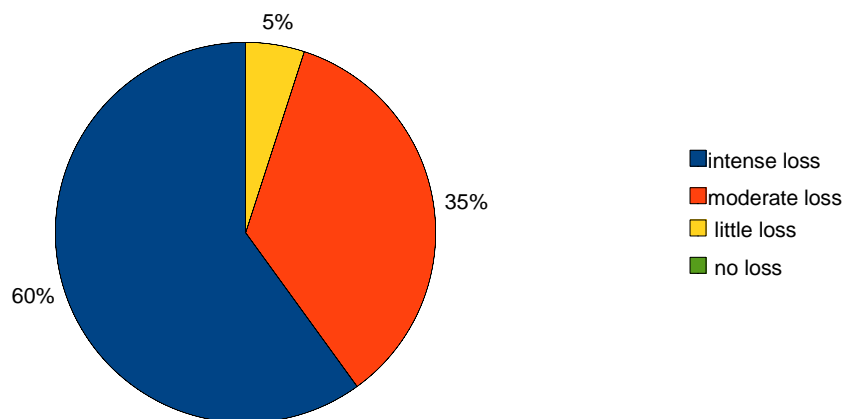
10.1. SUBJECT PROFILES

The figure below (pie chart) shows the subjects' evaluation before using the product.

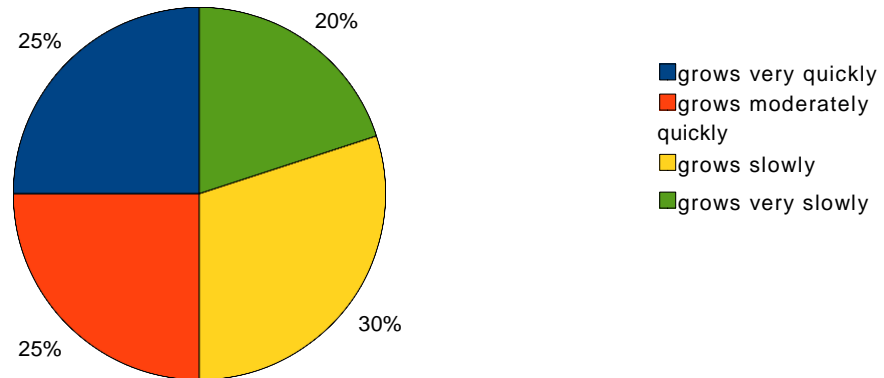
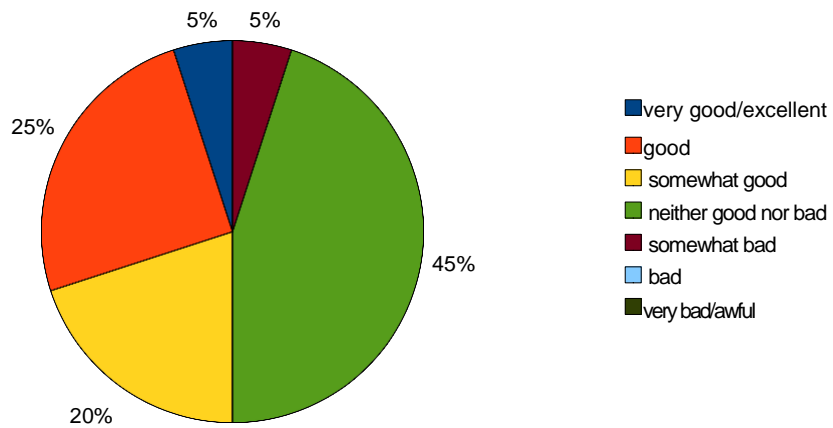
Brushability



Hair loss



SUBJECT PROFILES

Speed of Growth

Overall Appearance


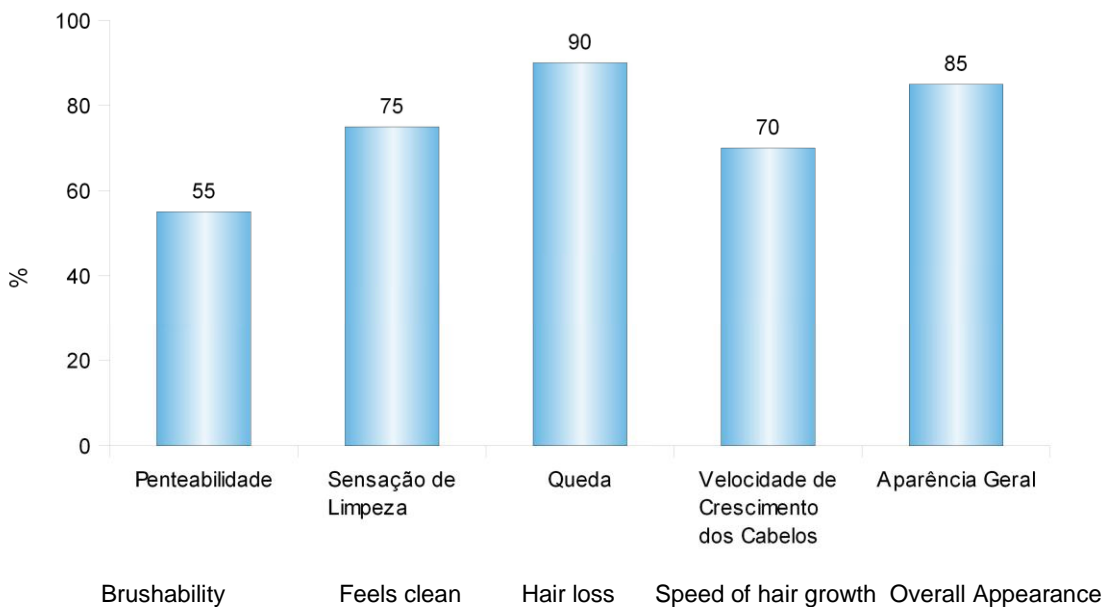
10.2. SUBJECTS' EVALUATION OF PERCEIVED EFFICACY

The Table below contains the subjects' evaluation after fifty-six days (T56) of using the product.

Attribut	T56 (%)
Brushability	55.
Feels Clean	75.
Hair Loss	90.
Speed of Hair Growth	70.
Overall Appearance	85.

Brushability, Feels Clean, and Speed of Hair Growth were based on the sum of: grew a lot, grew moderately, and grew a little. Overall Appearance was based on the sum of: improved a lot, improved moderately, and improved a little. Hair Loss was based on: decreased a lot, decreased moderately and decreased a little.

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



11. CONCLUSION

According to the methodology used to evaluate the product REVITA® HIGH PERFORMANCE HAIR GROWTH STIMULATING SHAMPOO, ordered by SULAMERICANA COMERCIO E DISTRIBUIÇÃO LTDA, one may conclude that:

Subjects' Evaluation of Perceived Efficacy

After 56 days of using the product (T56), the following results were obtained:

- 55.0% of subjects noticed an increase in their hair's Brushability;
- 75.0% of subjects noted an increase to their hair Feeling Clean;
- 90.0% of subjects noted a decrease in Hair Loss;
- 70.0% of subjects noted an increase in the Speed of Hair Growth;
- 85.0% of subjects noted an improvement to the Overall Appearance of their hair.



Regina Lúcia F. de Noronha, Ph.D.
In Charge of Study



Vivian Pessoto Rosa
Technician in Charge



Fátima Ap. Ortigoza de Lima
Quality Assurance

10/25/2010



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

12. REFERENCES

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- BARAN. R. & MAIBACH. H. I. Cosmetic Dermatology. Baltimore: Willians & Wilkins, 1994.
- COLIPA. Guidelines for the Evaluation of the Efficacy of Cosmetic Products. 3rd Edition, 2008; <http://www.colipa.com>.
- CONSELHO NACIONAL DE SAÚDE [NATIONAL HEALTH COUNCIL]- Resolution 196 of the Ministry of Health. Diário Oficial. 10/16/1996.
- MEILGARD, M.; CIVILLE, V. & CARR, B.T. Sensory Evaluation Techniques. Florida: CRC Press Inc. Boca Raton , 3rd Edition, 1999.
- MONTGOMERY, D. C. 1991. Design and analysis of experiments. New York : John Wiley and Sons pp 110-114.
- SAMPAIO, S.A.P. & COL. Dermatologia Básica. São Paulo: 2nd edition, Artes Médicas,1989.
- 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	Age	Sex	Statu
1	LGL	4	F	A
2	ICL	4	F	A
3	MSSA	3	F	A
4	DGSS	3	F	A
5	SDLS	4	F	A
6	MIL	3	F	A
7	KFS	2	F	A
8	HCRTS	3	F	A
9	MKP	4	F	A
1	MAP	2	F	A
1	M	4	F	FS
1	AJSA	4	F	A
1	ERP	5	F	FS
1	SHSC	3	F	A
1	AMRS	5	F	FS
1	V	2	F	A
1	NAF	4	F	A
1	EFA	3	F	A
1	RLP	4	F	A
2	DVG	2	F	A
2	DJS	2	F	A
2	NCS	3	F	A
2	ESSA	3	F	A
2	AGS	4	F	A
2	JOR	2	F	A
2	MCMA	3	F	A
2	MACB	4	F	A
2	ACSM	3	F	A

F: female; M: male; A: approved; FS: selection failure

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;

Evaluation of the perceived efficacy of hair-loss treatment product, under real conditions of use. The goal of this study is to evaluate the perceived efficacy before and after using a hair-loss treatment product, through questionnaires. You will be evaluated by a technician and will answer questionnaires before using the product and upon your return, T56. You will receive the product to be tested to use at home for 56 days, and a home product-use diary to be filled out regarding frequency of product use and any complaints about product use deemed necessary. By signing this consent form you will 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. Directions for use: After gently massaging in the product, you should leave it on the scalp for 1-2 minutes before rinsing. Then, repeat the procedure and let it act on the scalp for 3-5 minutes. If you like, use a high-quality conditioner. For best results, the product should be used at least 3 times a week.

You will be evaluated before beginning the study by a trained technician and monitored during the study. 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, and your transportation expenses will be partially reimbursed;

You may withdraw from the study at any time you so desire, or if necessary, at the researcher's discretion.

The study will be conducted on 25 volunteers;

The study's duration will be 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 that we may better interpret the results;

Do not use any type of product (deodorant or antiperspirant, talcum powder, bath oils, creams, lotions, perfumes, colognes, or topical medications) on the areas adjacent to 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.

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, and you will be notified of any other relevant information;

ATTACHMENT 2 – CONTINUED

All raw materials used in the product are approved for topical use and are non-toxic. However, like any product, it may cause unexpected reactions such as “reddening,” “swelling,” “itching,” and “burning” in the areas where product is applied;

Volunteers are duly insured by Mapfre Seguros, policy number 18/442/2001000095518.

All information collected from the volunteers will be kept confidential;

If you have any questions or problems, you may contact the medical team at 19 3789 8615 and at the address: Avenida Dr. Romeu Tórtima, 452 – Barão Geraldo, Campinas.

One copy of this form will remain on file at PERCEPTION, and another will be given to the volunteer.

All of the items were read aloud and explained to the volunteers.

I,

01 First and Last Names (*complete, no abbreviations*)

02 Date of Birth Telephone for Contact

03 Identification (R.G.) number

hereby agree to participate in the “**EVALUATION OF THE PERCEIVED EFFICACY OF A HAIR-LOSS TREATMENT PRODUCT UNDER REAL CONDITIONS OF USE**” and I declare that all of the items above have been explained.

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

Witness (complete first and last name, no abbreviations)

05 Identification (R.G.) number


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

Complete this section only if the volunteer is illiterate.



ATTACHMENT 3 – PRODUCT FORMULA

REVITA® HIGH PERFORMANCE HAIR GROWTH STIMULATING SHAMPOO




DS LABORATORIES

DS Laboratories, Inc.
1680 Meridian Avenue
Suite 301
Miami Beach FL 33139
Phone (305) 509-8333
Fax (646) 219-2572
E-mail raquel@dslaboratories.com
Web site <http://www.dslaboratories.com>

Revita® High performance hair growth stimulating shampoo

Ingredients	%
1 Acetyl Cysteine: skin-conditioning agent	1.4000
2 Aloe Barbadensis Leaf Juice (Spray Dried): skin-conditioning agent	2.5000
3 Pyrus Malus Extract	8.0000
4 Aspalathus Linearis Leaf Extract (rooibos): skin-conditioning agent.	6.0000
5 Beta-Carotene: color	0.1000
6 Biotin: active	0.8000
7 Caffeine: active	1.5000
8 Carnitine HCl: skin-conditioning agent	1.6000
9 Citric Acid: pH adjuster	0.2000
10 Cocamidopropyl Betaine: surfactant	12.0000
11 Coco-Glucoside: surfactant.	4.5000
12 Prezotide Copper Acetate: active	1.2000
13 Dimethyl Sulfone (MSM): skin-conditioning agent	1.3000
14 Emu Oil: essential oil	1.1000
15 EUK-134 (Ethylbisiminomethylguaiaicol /manganese chloride): skin-conditioning agent	1.0000
16 Glycereth -7: humectant	1.0000
17 Glycerin: humectant	0.8000



PERCEPTION

18	Glycol Stearic: viscosity increasing agent	0.5000
19	Hydrolyzed Wheat Protein: skin-conditioning agent	0.9000
20	*Ingredient Removed	
21	Menthol: skin-conditioning agent	10.1.
22	Menthol Lactate (Menthol Derivative): skin-conditioning agent	0.2000
23	Methylchloroisothiazolinone: preservative	0.00075
24	Methylisothiazolinone: preservative	0.00075
25	Oleanolic Acid: skin-conditioning agent	1.6000
26	Omitine 1-ICI: active	1.2000
27	PEG-150 Pentaerythrityl Tetrastearate: viscosity increasing agent	
28	PEG-6 Caprylic/Capric Glycerides: surfactant	0.2000
29	Polyquaternium 10: skin-conditioning agent.	1.1000
30	Riboflavin: color	0.1000
31	Sodium Chloride: viscosity increasing agent	0.1000
32	Taurine: surfactant	2.5000
33	Tetrasodium EDTA: chelating agent	0.1000
34	Water solvent	44.6985
35	Zinc PCA: humectant	1.4000

Primary Packing: plastic bottle

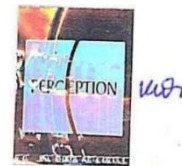
Secondary Packing: carton box

Product Validity: 2.5 years

Cautions with the preservation: keep product under 30°C

Application manual: after applying Revita® with a gentle massage, you should leave it on the scalp from 1-2 minutes before rinsing. Then repeat and leave on scalp for 3-5 minutes. If desired, follow with a high quality conditioner. For optimal results, Revita® should be used at least 5 times per week.

7



ATTACHMENT 4 – QUESTIONNAIRES FOR SUBJECTS’ EVALUATION**Subjects’ Profile Questionnaire
Classification of skin characteristics before using the product – T0**

01- With respect to BRUSHABILITY, your hair:

- is very easy to brush
- is moderately easy to brush
- is somewhat easy to brush
- is not easy to brush

02- With respect to hair LOSS, you have:

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

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

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

04- With respect to the OVERALL APPEARANCE of your hair, you consider it:

- very good/excellent
- good
- somewhat good
- not good or bad
- somewhat bad
- bad
- very bad/awful



ATTACHMENT 4 – CONTINUED

Perceived efficacy questionnaire
Comparison of skin characteristics after using the product – T56

01- After using the product, the BRUSHABILITY of your hair:

- increased a lot (easier to brush)
- increased moderately
- increased a little
- is the same, I didn't notice a change
- decreased a little
- decreased moderately
- decreased a lot (harder to brush)

02- After using the product, your FEELING OF CLEAN 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 of the product, the LOSS of your hair:

- 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

ATTACHMENT 4 – CONTINUED

04- 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

05- After using the product, the OVERALL APPEARANCE of your hair:

- improved a lot
- improved moderately
- improved a little
- is the same, I didn't notice a change
- worsened a little
- worsened moderately
- worsened a lot