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

2nd PAGE - COPY
(11/14/2011)
FORMULA MODIFICATION

PERCEPTION Pesquisa em Análise Sensorial Ltda.
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CEP 13084-520. Campinas. São Paulo. Brazil
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STUDY OF PERCEIVED EFFICACY

1. PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>Official</th>
<th>Perception Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>REVITÀ® HIGH PERFORMANCE HAIR GROWTH</td>
<td>10-2274-01</td>
</tr>
<tr>
<td>STIMULATING SHAMPOO</td>
<td></td>
</tr>
</tbody>
</table>

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**

- Very easy to brush: 45%
- Moderately easy to brush: 30%
- Somewhat easy to brush: 15%
- Not easy to brush: 10%

**Hair loss**

- Intense loss: 35%
- Moderate loss: 60%
- Little loss: 5%
SUBJECT PROFILES

Speed of Growth

- 25% grows very quickly
- 25% grows moderately quickly
- 20% grows slowly
- 30% grows very slowly

Overall Appearance

- 45% very good/excellent
- 25% good
- 20% somewhat good
- 5% neither good nor bad
- 5% somewhat bad
- 5% bad
- 5% very bad/awful
10.2. SUBJECTS’ EVALUATION OF PERCEIVED EFFICACY

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

<table>
<thead>
<tr>
<th>Attribute</th>
<th>T56 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brushability</td>
<td>55.</td>
</tr>
<tr>
<td>Feels Clean</td>
<td>75.</td>
</tr>
<tr>
<td>Hair Loss</td>
<td>90.</td>
</tr>
<tr>
<td>Speed of Hair Growth</td>
<td>70.</td>
</tr>
<tr>
<td>Overall Appearance</td>
<td>85.</td>
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</tbody>
</table>

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

See the scope on ANVISA’s website:  
12. REFERENCES


## ATTACHMENT 1 – SUBJECTS WHO PARTICIPATED IN THE STUDY

<table>
<thead>
<tr>
<th>Subject</th>
<th>Initials</th>
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<td>F</td>
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<tr>
<td>4</td>
<td>DGSS</td>
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<td>4</td>
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<td>3</td>
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<td>7</td>
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<td>A</td>
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<td>8</td>
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<td>F</td>
<td>A</td>
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<td>F</td>
<td>A</td>
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<td>A</td>
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<td>26</td>
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<td>F</td>
<td>A</td>
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<td>28</td>
<td>ACSM</td>
<td>3</td>
<td>F</td>
<td>A</td>
</tr>
</tbody>
</table>

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 deserve, 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;
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, 

First and Last Names (complete, no abbreviations)

Date of Birth

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.

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

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**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetyl Cysteine</td>
<td>1.4000</td>
</tr>
<tr>
<td>Aloe Barbados Leaf Juice (F creeping Root)</td>
<td>2.5000</td>
</tr>
<tr>
<td>Pyrus Malus Extract</td>
<td>8.0000</td>
</tr>
<tr>
<td>Aloe Vera Leaf Extract (moisture)</td>
<td>6.0000</td>
</tr>
<tr>
<td>DMSO-Cosmetic color</td>
<td>0.1000</td>
</tr>
<tr>
<td>Biotin-activ</td>
<td>0.8000</td>
</tr>
<tr>
<td>Cellulose- active</td>
<td>1.5000</td>
</tr>
<tr>
<td>Cornstarch (LC)</td>
<td>1.6000</td>
</tr>
<tr>
<td>Citric Acid pH adjuster</td>
<td>0.2000</td>
</tr>
<tr>
<td>Cocamidopropyl Betaine</td>
<td>12.0000</td>
</tr>
<tr>
<td>Coco-Glucoside surfactant</td>
<td>4.5000</td>
</tr>
<tr>
<td>Ferrous Copper Anaerobic activite</td>
<td>1.2000</td>
</tr>
<tr>
<td>Diethyl Sulfoxane (MES)</td>
<td>1.3000</td>
</tr>
<tr>
<td>Emu Oil- essential oil</td>
<td>1.1000</td>
</tr>
<tr>
<td>EUG-134 (3,3'-bis[3-methoxy-4-hydroxyphenyl]-5-methoxy-4-hydroxyphenyl) skin-conditioning agent</td>
<td>1.0000</td>
</tr>
<tr>
<td>Glycerol-7% humectant</td>
<td>1.0000</td>
</tr>
<tr>
<td>Glycerol humectant</td>
<td>0.8000</td>
</tr>
</tbody>
</table>
18 Glycol Stearate: viscosity increasing agent 0.500%  
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 Methylchloroiodoacetone: preservative 0.00075  
24 Methylisothiazolinone: preservative 0.00075  
25 Oleic Acid: skin-conditioning agent 1.6000  
26 Omitine ICI active 1.2000  
27 PEG-150 PentarylUtryl Tetraester: viscosity increasing agent  
28 PEG-6 Caprylic/Capric Glycerides: surfactant 0.2000  
29 Polysodium 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 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 for 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.
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
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