“RANDOMIZED PLACEBO-CONTROLLED CLINICAL-TRIAL FOR THE ASSESSMENT ON THE EFFICACY OF A FOOD SUPPLEMENT IN IMPROVING HAIR APPEARANCE”

BIOS LINE S.P.A

Principium Hair Beauty

KEY PERSONNEL

Customer

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STUDY DESIGN

1.1. Title

Randomized placebo-controlled clinical-trial for the assessment on the efficacy of a food supplement in improving hair appearance.

1.2. Aim of the study

The study aims to assess the efficacy of a food supplement (tested in different concentrations) in improving hair conditions, in particular improving hair strength and radiance and reducing hair breakage compared to a placebo product.

In order to reach this goal a randomized, placebo controlled, parallel group (3 arms), clinical trial* is carried out on 60 (66 included**) healthy female subjects enrolled according to specific inclusion and non-inclusion criteria (see section 1.5). In particular, female subjects aged between 18 and 60 (+ 2) years old, with thin, brittle hair that breaks easily.

According to a predisposed randomization list, the enrolled subjects were divided into 3 groups as follows:

- **GROUP 1 (G1)**: 22 subjects took 2 cpr/die of the active food supplement and 2 cpr/die of placebo food supplement (for a total of 4 cpr/die),
- **GROUP 2 (G2)**: 22 subjects took 4 cpr/die of the active food supplement,
- **GROUP 3 (G3)**: 22 subjects took 4 cpr/die of the placebo food supplement.

**The study was carried out under dermatological control in accordance with the ethical principles applicable to medical research, based on the following protocol; the study protocol and informed consent were submitted to the approval of an Independent Ethical Committee.*

***6 more subjects were included for a total of 66 subjects, considering a 10% drop-out.*

1.2.1. Primary objectives/endpoints

The primary objective of the study is to assess the efficacy of the active product (taken in different concentration) in comparison with a placebo as evaluated through the following endpoints:

- hair elasticity (hair elongation) by means dynamometer and hair radiance by means of spectrophotometer/colorimeter,
- hair breakage by means of the count of the broken hair after a standardized brushing procedure,
- overall hair appearance by means clinical internal scale.

1.2.2. Secondary objectives/endpoints

The secondary objectives of the study are to assess:

- subject's satisfaction of the tested product (self-evaluation questionnaire);
- incidence and nature of Adverse Event (AE) and Serious Adverse Event (SAE).

1.3. Tested product

1.3.1. Information provided by the Customer

☒ Products name: **Active product - Principium Hair Beauty**
Placebo product

☒ Products dosage and way of use :

- **G1**: 22 subjects took 2 cpr/die of the active food supplement and 2 cpr/die of placebo food supplement (for a total of 4 cpr/die),
- **G2**: 22 subjects took 4 cpr/die of the active food supplement,
- **G3:** 22 subjects took 4 cpr/die of the placebo food supplement.

☒ The products submitted to study are food supplements produced in accordance with the guidelines and regulations applicable in the field (food regulation) and the cosmetic products conforms to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) and to its annexes.

☒ Qualitative INCI formulas:

ACTIVE PRODUCT - Principium Hair Beauty

L-CISTINA, AGENTE DI CARICA: MICROCELLULOSA CRITALLINA, MALTODESTRINE, VITAMINA C (ACIDO L-ASCORBICO), INULINA DA CICORIA (CICHHORIUM INTYBUS L.) RADICE, SCOTANO (COTINUS COGGYGRIA SCOP.) CORTECCIA ESTRATTO TITOLATO SECCO AL 20% IN FISETINA, SPIRULINA (SPIRULINA PLATENIS (GOMONT) GAITLER) TALLO POLVERE, AGENTE ANTIAGGLOMERANTE: BIOSSIDO DI SILICIO, STABILIZZANTE: IDROSSIPROPILMETILCELLULOSA, AGENTE ANTIAGGLOMERANTE: SALI DI MAGNESIO DEGLI ACIDI GRASSI, SOLFATO DI ZINCO, GRANO (TRITICUM SATIVUM LAM.)

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FRUTTO ESTRATTO SECCO TITOLATO AL 50% IN CERAMIDI, ACIDO FOLICO (ACIDO PTEROILMONOGLUTAMMICO), VITAMINA B12 (METILCOBALAMINA).
The product does not contain allergens; the product is gluten-free.

PLACEBO PRODUCT
SORBITOLO, CELLULOSA MICROCRISTALLINA, ESTRATTO DI CARTAMO, SPIRULINA BIOSSIDO DI SILICIO, MAGNESIO STEARATO, OSSIDO DI FERRO NERO.
The product does not contain allergens.

☒ Product labeling

Figure 1. Tested **PRODUCT 1** label

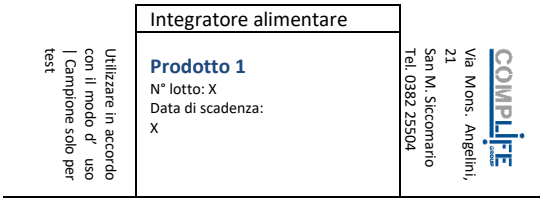


Figure 2. Tested **PRODUCT 2** label

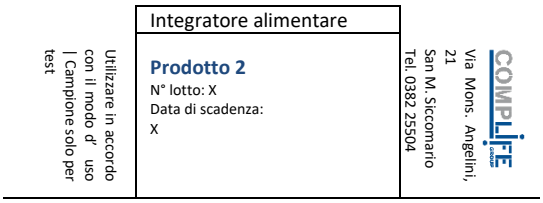
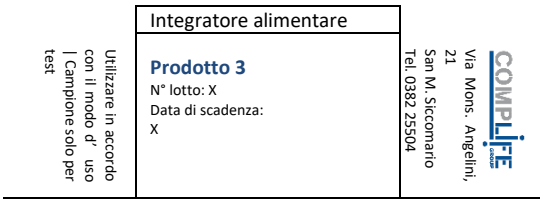


Figure 3. Tested **PRODUCT 3** label



AVVERTENZE:

Legend. Product 1 and 2 - Active product
Product 3 - Placebo product.

1.3.2. Storage

All products are stored at room temperature (between 15 and 25°C) at COMPLIFE ITALIA srl, protected from direct light, heat and source of water safe place with restricted access.

1.3.3. Accountability

The principal investigator and his collaborators maintain a record of the products delivered to the subjects at the study starting and received by the subjects at the study ending.
The returned product at the end of the study are destroyed according to the current internal procedures.

1.3.4. Compliance to treatment

At the beginning of the study (T0) subjects received one bottle containing product samples sufficient for all the study duration. The compliance to treatment was assessed by the principal investigator by counting and recording the remaining pills in the bottle after 28 days and 84 days of treatment.
The principal investigator may withdraw the subject in case of suspicion and/or if he has the evidence that the subject was not compliant to the treatment regimen.
Compliance to treatment will be calculated by product accountability, as follows:

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$$\text{Compliace to treatment} = \frac{\text{number of intake product}}{\text{number of product to intake}} \text{x100}$$

The average of overall compliance shall be ≥ 80%.

1.3.5. Randomization

A restricted randomization lists are generated by the in-site Study Director using an appropriate statistic algorithm ("Wey's urn"). For each subject participating in the study, an envelope containing the information on the product tested is prepared. Both the randomization list and the subjects' envelopes are stored by the in-site Study Director under appropriate safety conditions in a place that is not accessible neither to volunteers nor to the experimenter.

1.4. Ethical requirements

The study is carried out according to the ethical requirements listed here below.

I. All participants in the study are healthy volunteers, aged over 18 years old.
II. All participants in the study are screened and enrolled under the supervision of a dermatologist according to specific inclusion/non-inclusion criteria.
III. Volunteers' participation in the study is free.
IV. All participants in the study are informed of the aim and the nature of the study.
V. All participants in the study are informed of the possible risks involved in the study.
VI. All participants in the study sign a written consent form before the study begins.
VII. Before volunteers are exposed to the tested product, all safety information regarding the product and its individual ingredients are assessed.
VIII. All the study procedures are carried out in compliance with the ethical principles for medical research (Ethical Principles for Medical Research Involving Human Subjects, Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and its amendment).
IX. All the precautions are taken in order to avoid adverse reactions occurrence.
X. In case of non-expected/adverse reaction occurrence the medical investigating specialist evaluate the severity of the reaction (reporting it in the data collecting sheet of the volunteer) and as a consequence start the appropriate therapy.

1.5. Subjects participating in the study

A total of 66 female subjects will be enrolled. Withdrawn/lost to follow-up/drop-out subjects will not be replaced.
All inclusion and non-inclusion criteria will be checked by the principal investigator or delegate (co-investigator), through a questionnaire during the screening visit.

1.5.1. Inclusion criteria

- ✓ Good general health
- ✓ Caucasian ethnicity
- ✓ Female sex
- ✓ Age between 18 and 60 (+ 2) years old
- ✓ Subjects with thin, brittle hair that breaks easily
- ✓ Subjects agreeing not to take any treatment (oral or topic) able to interfere with the hair strength during the whole study duration
- ✓ Willingness not to dye/blench hair during the 2 weeks preceding each visit
- ✓ Willingness not to cut hair for all the study length
- ✓ Subjects registered with health social security or health social insurance
- ✓ Subjects having signed their written Informed Consent form (ICF) and Privacy Policy for their participation in the study and a photograph authorization
- ✓ Subjects able to understand the language used in the investigation centre and the information given
- ✓ Subjects able to comply with the protocol and follow protocol constraints and specific requirements
- ✓ Willingness to take during all the study period only the product to be tested
- ✓ Willingness not to use/take similar products/food supplement that could interfere with the product to be tested
- ✓ Willingness to not vary the normal daily routine (i.e. lifestyle, physical activity, diet etc.)
- ✓ Subjects under effective contraception (oral/not oral) if women of childbearing potential; not

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expected to be changed during the trial

1.5.2. Non-inclusion criteria

☒ Subjects who do not meet the inclusion criteria
☒ Subject is taking part or planning to participate to another clinical study in the same or in another investigation centre
☒ Subject who is deprived of freedom by administrative or legal decision or under guardianship
☒ Subject admitted in a sanitary or social facilities
☒ Subject who is planning a hospitalization during the study
☒ Subjects under treatment with food supplements which could interfere with the functionality of the product under study
☒ Subject has participated in another clinical study with anti-hair loss product or treatment within the last 24 weeks before the inclusion visit
☒ Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (if women of childbearing potential)
☒ Subject has started or changed oestrogen-progesterone contraception or hormonal treatment, within the 3 months prior to the study or foreseeing it for the duration of the study
☒ Subject having an acute, chronic or progressive illness liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
☒ Subjects under radiotherapy, chemotherapy at any time
☒ Subjects under locally pharmacological/non-pharmacological treatment applied on the area of interest monitored during the test
☒ Subject having food disorders
☒ Subject who has any other hair disorder or hair disease (female pattern hair loss, any type of alopecia…)
☒ Subject having excessive and/or fluctuating hair shedding for more than 6 months
☒ History or clinical signs of hyperandrogenaemia
☒ Any hair care product applied on the scalp between the last shampoo and the inclusion visit (e.g. gel, hairspray, wax, foam…)
☒ Scalp surgery (hair transplants, laser) at any time.

1.5.3. Withdrawal of subjects

In compliance with the Helsinki Declaration (1964) and its successive, subjects have the right to exit from the study at any time and for any reason. In all cases, the Investigator should attempt to contact the subject as soon as possible for a final assessment in order to: i) have the subject's decision written on the consent form, ii) obtain the reason(s) of their withdrawal so they can be recorded, iii) evaluate the subject's clinical condition, iv) if necessary, take appropriate therapeutic measures (management of an AE or concomitant disease), v) recover the investigation product given to the subject. The Investigator can also interrupt the subject participation in the study prematurely in the case of a disease occurrence, a pregnancy or the occurrence of adverse reactions or a serious adverse event, particularly if it is considered by the Investigator liable to threaten the health of the subject or if necessitates the prescription of a medication incompatible with the pursuit of the study. In this case, the Sponsor is informed by phone or fax and a letter or report explaining the withdrawal is forwarded to him as soon as possible. Any premature discontinuation linked to an AE or a SAE have to be followed-up (until final outcome). The Sponsor can demand that any subject be excluded from the study for major infringements to the protocol, for administrative reasons or any other motive. Nevertheless, premature removal of a high percentage of subjects from the study can make it difficult or impossible to interpret. Consequently, any premature exit without valid reasons should be avoided as much as possible and is carefully documented in the case report form, the final report and, if necessary, in the AE form. Every premature exit must be classified as follows: i) presence of a non-inclusion criteria, ii) AE occurrence, iii) SAE occurrence, iv) withdrawal of consent, v) lost to follow-up, vi) appearance of non-inclusion criteria, vii) non-adherence to the protocol, viii) other reason (to be clearly specified).

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1.5.4. Subject discontinuation

The subjects are entitled to discontinue the study for any reason at any time if they desire. Should this occur, the Investigator or designee determines the reasons in order to know if it is linked to the study or not and the primary reason will be recorded in the data collection sheet. If the subject has withdrawn due to Serious Adverse Event (SAE), the subject will be followed until Serious Adverse Event (SAE) resolution.

In the case where subject does not present for a visit, the investigator or designee must attempt to contact the subject by telephone on two consecutive occasions. The subject will be considered as lost to follow-up if the investigator or designee fails to reach him/her. These attempts and the result must be recorded on source document.

1.5.5. Study completion

The study completion is achieved by a subject when she completes the entire treatment and she is undergone all the check visits.

1.5.6. Subjects risk and benefit

Risks associated with the products intake are considered from low to very low, in absence of allergy/intolerances to product ingredients; other ingredients in the product formula are commonly used in dietary supplement.

The potential benefits associated with the use of the product are related to an improvement of hair conditions in particular improving hair length, improving hair density and reducing hair breakage.

1.6. Study development

The duration of the study will be 84±2 days. Clinical visits are planned at baseline days (T0±2), after 28 days (T28±2) and 84 days (T84±2) days of products intake.

1.6.1. Study schedule

Study schedule is as follows:

Study phases	Initial visit (T0±2)	Follow-up visit (T28±2)	Final visit (T84±2)
Signed Informed Consent and Privacy Policy	X	--	--
Subject eligibility*	X	X	X
Products distribution	X	--	--
Recording the subject demographic data and medical history	X	--	--
Product collection and counting	X	X	X
Hair elongation	X	X	X
Hair radiance	X	X	X
Assessment of the number of broken hair	X	X	X
Digital macrophotography	X	X	X
Clinical evaluation	X	X	X
Digital macrophotography	X	X	X
Self-assessment questionnaire supplying and collection	--	--	X
AE and local tolerance assessment	--	X	X

**The experimenter checks at each visit the compliance of the subjects with all inclusion/exclusion criteria.*

1.6.2. Screening – Initial visit (T0±2)

Subjects are screened as follows:

- screening in the Complife volunteers' database*. The subjects identified by Complife volunteers management database screened by appropriate personnel (authorized by the investigator, pursuant to and for the effects of the legislation on protection of personal data). Screened subjects are then invited to participate to the study and the date for the screening visit is planned.
  ** The database is used only for screening purposes, without storing additional data that can allow the identification of the subject as a potential participant in the clinical study.*

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During the screening visit (T0) the principal investigator or her designee evaluates if the subject is eligible to participate in the study. The following procedures are carried out:

- signature of the Informed Consent Form and the Privacy Policy
- recording of the subject demographic data
- checking of the current and previous subject's medical history and concomitant therapies
- checking of subject eligibility
- in order to check the compliance to the product use, the products are previously counted
- supplying of the product/placebo in accordance with the randomization list
- supplying of the brush and subjects are asked to brush their hair according to a standard procedure and indicate the number of broken hair found during hair brushing
- instrumental evaluation: hair elongation, hair radiance, assessment of number of broken hair
- digital macrophotography
- fixing the date of the follow-up visit after 28 days of treatment.

1.6.3. Intermediate visit (T28±2)

The following procedures are carried out:

- checking of subject eligibility
- product collection and count to check the compliance to the treatment
- instrumental evaluation: hair elongation, hair radiance, assessment of number of broken hair
- digital macrophotography
- clinical evaluation of the overall hair appearance
- recording reactions (AE, SAE) and assessment of product tolerability
- fixing the date of the final visit after 84 days of treatment.

1.6.4. Final visit (T84±2)

The following procedures are carried out:

- checking of subject eligibility
- product collection and count to check the compliance to the treatment
- instrumental evaluation: hair elongation, hair radiance, assessment of number of broken hair
- digital macrophotography
- clinical evaluation of the overall hair appearance
- supplying and collecting of the self-assessment questionnaire

1.7. Materials and methods

In the sections here below are reported the materials and methods employed in the study for the evaluation of product efficacy. All the study procedures are carried out under controlled ambient conditions (T = 18-26°C and RH = 40-60%). Subjects are left to acclimatize to ambient condition for 15-20 minutes before the check visit.

1.7.1. 60-seconds hair count

The subjects are issued identical combs (having the teeth separated by 1 mm on one half of the comb and by 2 mm on the other half) to be used throughout the study. The subjects used their usual shampoo (without any claim related to hair repairing). Two days after the shampoo, they are instructed to comb their hair for 60 seconds before in the morning, starting at the vertex, and combing forward. The hair is combed over a towel or pillowcase of contrasting color so that any broken hair could be adequately visualized. The subjects then collected the broken hairs and recorded their number.

1.7.2. Hair elongation

Hair elasticity is measured using a dynamometer (C610 Autotensile Tester, Labthink.) in accordance with UNI EN ISO 5079:1998 standard procedure. Hair elasticity is calculated as the maximum elongation before hair breakage.

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1.7.3. Hair radiance

Hair radiance (ability to reflect the light) is measured using a spectrophotometer/colorimeter CM 700D (Konica Minolta) by means of the 8° gloss value (Fig. 1).

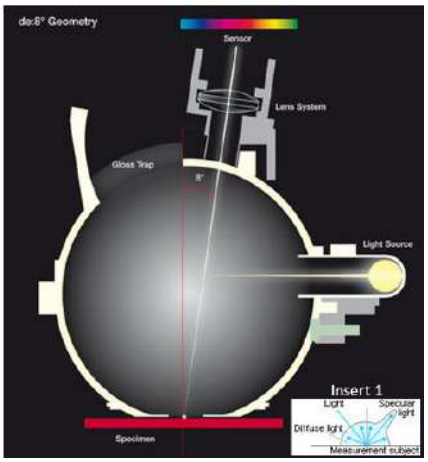

Figure 1 Skin radiance (8° gloss value).
When light reach a surface it is reflected at the equal but opposite angle from the light source; this is called specularly reflected light. This specular component is reflected as if reflected by a mirror. The light that is not specularly reflected, but scattered in many directions, is called diffuse reflectance (insert 1). The sum of the specular reflectance plus the diffuse reflectance is called the total reflectance. For objects with shiny surfaces, the specularly reflected light is relatively strong and the diffused light is weaker. On rough surfaces with a low gloss, the specular component is weak and the diffused light is stronger. The measuring geometry d:8° features an optical device which provides diffuse illumination (Ulbricht sphere). The light (Xenon lamp) is projected into a sphere. The interior of the sphere is coated with a white highly reflecting substance (barium sulphate, ceramic, special plastic) which reflects the light manifold. A shutter, an optical element inside the sphere, prevents the directional rays from reaching the measuring sample directly. The sample is positioned at an opening of the sphere and is illuminated from all directions with a close to perfect diffuse light. Through an opening at the top of the sphere the sensor is viewing the surface being measured with an angle of 8° to the vertical. In order to prevent reflection of specular light from the sample surface, the instrument feature a gloss trap. When the trap which is arranged with an angle of -8° to the viewing opening, is open, the light which would otherwise be reflected from the interior wall of the sphere, will be eliminated and can therefore not illuminate the sample. The relation between directional and diffuse reflection allows calculating the gloss component. The measuring system including gloss is named di:8° whilst the measuring system excluding gloss is described as de:8°.

1.7.4. Expert scoring

The experimenter evaluated according to an internal clinical scale (on digital pictures) the following parameter:

- **OVERALL HAIR ASPECT**

Box 1. Clinical classification of overall hair aspect at T28 and T84	Score
No variation	1
Slight improved	2
Moderately improved	3
Remarkably improved	4

1.7.5. Digital macrophotography

Digital pictures are taken, under standard lighting conditions, using a professional digital reflex camera. Two images per subject are taken: one frontal view and one image at vertex level. Images are taken under standard reproducible lighting conditions.
The best 3 cases (for each active treatment) are reported in Annex I.

1.7.6. Self-assessment questionnaire

At the end of the study (T84) subjects are asked to express their opinion on the tested treatment by answering to a questionnaire about products acceptability and effects.

1.8. ASSESSMENT OF PRODUCT SAFETY

1.8.1. Adverse Events (AE) and Serious Adverse Events (SAE)

1.8.1.1. Definition of Adverse Event (AE)

An Adverse Event is any untoward medical occurrence in a clinical investigation subject administered a test product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a test product, whether related to the test product.

1.8.1.2. Definition of Serious Adverse Event (SAE)

A Serious Adverse Event is any untoward medical occurrence that: i) results in death, ii) is life-threatening, iii) requires inpatient hospitalization or prolongation of existing hospitalization, iv) results in persistent or significant disability/incapacity, or v) is a congenital anomaly/birth defect.

1.8.1.3. Documentation of AE and SAE

All concomitant treatments are reported in the data collecting sheet and the study report. All Adverse Events likely to be related to the studied product (adverse reactions) are reported in the data collecting sheet and the study report. All Serious Adverse Events are reported in the data collecting sheet and the study report.

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1.8.1.4. Notification to the Sponsor

AEs occurring during the study or after the study must be reported to the Sponsor's vigilance officer by email (Cristiano Meggiato - cmeggiato@biosline.com) with a copy to the project manager. SAE must be sent within 24 hours after the observation. Reactions related to the product must be reported as soon as possible. If pictures of the reactions are available, they should be enclosed with the notification.

1.8.1.5. Follow-up

SAE and reactions related to the product must be followed up until resolution or stabilization. To inform Sponsor's vigilance officer of any new information the investigator must use the appropriate forms filled in with results collected from the examination carried out. Reports of hospitalization must be enclosed with the notification form.

1.8.2 Tolerability

Tolerability of the treatment are closely followed by the study principal investigator during the course of the study. Subjects have access to the investigators in case of intolerance reactions via a contact phone number provided with the informed consent form (contact at Complife: Gloria Roveda T: +39 0382 25504). If a subject reports a reaction, the principal investigator has to decide if it is related to the investigational product use. If yes, she reports it as an adverse event.

Any unexpected, related side effect judged as severe by the principal investigator is reported to the Sponsor. Upon investigator judgment, the subject may be withdrawn from the study and the side effect is followed until resolution (maximum until the end of the study).

1.8.2.1. Tolerance assessment

For each sign, intensity, location, duration (hours, minutes), and frequency is recorded. Moreover, the investigator collects all discomfort or reactions reported by the subjects. Each time a sign (physical or functional) appears (new sign or worsened compared to the baseline evaluation i.e evaluation at day 1), a reaction must be recorded. All the reactions observed by the dermatologist and reported by the subject are recorded. The following information is recorded: i) subject characteristics, ii) details about study product (product code or name, date of first application, way of use), iii) description of the reaction (functional and physical signs, intensity of the signs, location, date/time of onset, timeframe between product application and onset of the reaction, date/time of end or duration (hours, minutes), frequency, diagnosis/nature of the reaction), iv) significant medical history , v) concomitant events: cutaneous diseases (atopic dermatitis flare), medical treatments, sunscreen product application, food, external factors (weather conditions), other diseases, vi) outcome and actions taken (application modalities modification, temporary interruption, definitively discontinuation, medical treatment, care), and viii) relationship to the product (study product and/or associated product) (causality assessment): analysis of the probability that the reaction is attributable to the product(s) used in the study. This assessment must be done in conjunction with clinical expertise, knowledge of the product (type of product, conditions of use…), identification of concomitant events.

1.8.2.2. Causality assessment of local tolerance

Five levels of causality can be described.

1.8.2.2.1. Very likely

Clinical signs suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product use and rechallenge is positive.

1.8.2.2.2. Likely

Clinical signs suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product application and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or Clinical signs suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product application and rechallenge is positive. Or Clinical signs only partially suggest or do not suggest a link with the product, the reaction follows a definite reasonable temporal sequence from the time of the product application and rechallenge is positive.

1.8.2.2.3. Not clearly attributable

Clinical signs suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product application and rechallenge is negative. Or clinical signs suggest a link with the product; the reaction follows a partially reasonable or unknown temporal

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sequence from the time of the product application and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product application and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product application and rechallenge is positive.

1.8.2.2.4. Unlikely

Clinical signs suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product application and rechallenge is negative. Or: clinical signs only partially suggest or do not suggest a link with the product; the time sequence between use of the product and occurrence of the symptoms is compatible; and rechallenge is negative. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product application and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product application and rechallenge is negative.

1.8.2.2.5. Excluded

Causality can only be excluded if another aetiology has been medically validated or when time sequence between exposure and signs occurrence is incompatible. If necessary, in case of adverse events, subjects can also contact the Study Manager. If required, they would be assessed by the Dermatologist who would perform the clinical assessment and decide the appropriate measures to take (i.e. medical treatment, withdrawal …).

1.9. Results and statistic

1.9.1. Study population for analysis

A total of 66 subjects are enrolled in the study. Efficacy analysis is based on the Per Protocol Population (for subjects with a compliance ≥80%). The per-protocol (PP) population is defined as all subjects who complete the study without any major protocol violations. Subjects are excluded from the per-protocol population if: they miss the one or more evaluation visit; or they do not used the product properly during the study period (as referred by the subject itself). Analysis of safety is based on the Intent to Treat Population (IT) that is defined as all subjects that have been assigned a subject number and received at least one study treatment.

1.9.2. Descriptive analysis

Demographic variables (age) and randomization list are showed in a Microsoft® Excel sheet. The quantitative demographic variable (age) are described with i) the mean value, ii) the minimum value, iii) the maximum value, iv) the standard deviation.

Sample data of the endpoints are reported for the PP population and are described, represented, and summarised using common descriptive statistical techniques. They are reported in a Microsoft® Excel sheet and will be described with i) the mean value and/or the median value, ii) the standard error and/or interquartile range, iii) the individual variation or percentage variation (vs. basal value) if applicable, iv) the minimum variation or percentage variation (vs. basal value) if applicable, v) the maximum variation or percentage variation (vs. basal value) if applicable, vi) the mean variation or percentage variation (vs. basal value) if applicable.

The data on the self-evaluation questionnaire are described with the frequency percentages of subjects that assigned a judgment (among those proposed).

1.9.3. Statistical analysis

To assess the efficacy of the product, inferential statistical analyses are performed on the endpoints.

For each quantitative and qualitative endpoints (except self-evaluation questionnaire), an appropriate statistical model (parametric or not-parametric) is applied based on data distribution.

- Time effect (intra-group analysis): repeated measures ANOVA for normally distributed data (or Friedman test otherwise) followed by post-hoc test for multiple comparisons to the control (T0); for

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endpoints assessed at only two time points, a paired t-test will be used for normally distributed data (or the Wilcoxon signed-rank test otherwise).

- Treatment effect (inter-group analysis): performed on the variation versus T0 using one-way ANOVA for normally distributed data (or Kruskal-Wallis test otherwise) followed by post-hoc test for multiple pairwise comparisons (G1 vs G2 vs G3, at each time point).

Statistical analysis is performed using NCSS 10 software.
p values < 0.05 is considered as statistically significant.

1.9.4. Interpretation of results

The study here above reported was designed to demonstrate the test product claim(s) in the current framework proposed by Commission Regulation (EU) No 655/2013. Endpoints are measured using techniques currently accepted in the cosmetic field while biases are minimized by procedure(s) standardization according to ISO 9001 Quality Management System. Data are analyzed and interpreted by skilled technician according to both descriptive and inferential statistical analysis procedures. Due to the lack of reference values in the cosmetic field, statistical significance (for instrumental analysis) and percentage of subjects showing an effect (for clinical/sensorial endpoints) are the primary criterion to evaluate the correspondence between the proposed claim(s) and the study output(s). In particular intragroup (vs. T0) or intergroup (e.g. active vs. placebo, treated vs non treated) statistical analysis criterion to reject the null hypothesis (no product effect) is set at $p<0.05$. For clinical evaluations, the positive effect of the product on the evaluated parameter is confirmed if more than 50% of the subjects register an improvement. Finally, for the self-assessment questionnaires, the performance and the pleasantness of the product must be perceived by at least 60% of the subjects. Whenever reference values or threshold values exists, those values are used to validate product claim(s).

1.10. Start/end date of study

The table here below shows date of beginning and end of the study.

Start date	End date
14/01/2026	19/06/2026

1.11. Report change record

The table here below reports the change log of all approved changes made to the document that make up the course after initial approval.

Rev. no	Date	Description
00	07/07/2026	Release of the first report.

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PANEL CHARACTERISTICS

TABLES A, B, C. The tables below summarize the ages of each enrolled subject.

GROUP 1

no.	Vol. ID	Age
01	P6046R	52
05	G6798C	46
10	M10490S	53
12	D7720D	51
16	B7589E	51
17	S6884S	36
18	C1498S	53
25	F02697N	21
29	C01075E	22
31	O02511V	22
33	C00644A	24
42	M7619F	49
43	C3813C	40
44	M8432V	39
45	M3875A	50
48	IN00322C	37
50	IS00078C	62
51	IH00309I	53
54	IO00163S	48
56	IG00037M	33
57	IA00339S	42
66	IB00620M	45
	Mean	42,2
	SE	2,5
	Min	21
	Max	62

GROUP 2

no.	Vol. ID	Age
03	V8958G	60
04	A6245L	62
06	D5573N	25
11	S5086M	53
13	C5641B	55
15	A9126V	30
19	M1104S	52
22	N7929N	51
23	T8446S	42
30	M01450D	31
32	L01135S	56
34	L02298C	22
35	B7550S	50
36	Z8240D	33
37	M4022P	59
39	M4330E	58
47	IV00644P	22
52	IO00262M	52
55	IC00363Ú	31
59	IS00414N	56
63	IP00594S	51
65	IV00558M	57
	Mean	45,8
	SE	2,9
	Min	22
	Max	62

GROUP 3

no.	Vol. ID	Age
02	C1167R	61
07	C7666M	47
08	P6021A	58
09	D9000V	58
14	S6976M	60
20	F1334T	57
21	G8171T	44
24	S02220R	23
26	A01240G	48
27	T02077C	26
28	D02447V	27
38	C7361K	52
40	B1020S	27
41	B6712D	54
46	V3902A	60
49	IG00609M	45
53	IM00493S	62
58	IA00500C	44
60	IB00169E	19
61	IS00156S	58
62	ID00067G	49
64	IV00531J	24
	Mean	45,6
	SE	3,1
	Min	19
	Max	62

Legend: SE= Standard error.

NOTE.

Subject 48 (IN00322C) in Group 1 reported moderate headache and abdominal bloating following the initial doses of the supplements. Initially, she attributed these symptoms to premenstrual syndrome and continued supplementation. However, by the end of the cycle, the discomfort persisted, and she reported ongoing symptoms which, although less severe than at onset, prevented her from continuing the trial.
In agreement with the specialist, the subject was withdrawn from the study.
Moreover, two subjects (N=32) dropped out from the study for reasons unrelated to product use.
As per protocol, all data presented refers to the 63 subjects (21 subjects each group) who completed the study and remained compliant with the study protocol throughout the 84-days duration.

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SUBJECTS COMPLIANCE TO TREATMENT

TABLES E, F, G. The table report subject compliance to treatment. Compliance to treatment is calculated by product accountability and shall be ≥ 80%.

GROUP 1

		Active product		Placebo product	
no.	Vol. ID	T28	T84	T28	T84
01	P6046R	104%	104%	104%	104%
05	G6798C	100%	100%	102%	100%
10	M10490S	107%	89%	107%	89%
12	D7720D	107%	92%	100%	92%
16	B7589E	104%	99%	96%	96%
17	S6884S	107%	101%	93%	101%
18	C1498S	100%	99%	102%	99%
25	F02697N	96%	105%	96%	105%
29	C01075E	93%	99%	93%	99%
31	O02511V	93%	103%	93%	102%
33	C00644A	89%	91%	89%	89%
42	M7619F	98%	98%	98%	98%
43	C3813C	109%	99%	109%	99%
44	M8432V	100%	102%	100%	101%
45	M3875A	100%	100%	100%	100%
48	IN00322C	[DO]	[DO]	[DO]	[DO]
50	IS00078C	91%	99%	102%	99%
51	IH00309I	89%	96%	88%	95%
54	IO00163S	86%	100%	88%	101%
56	IG00037M	107%	98%	107%	101%
57	IA00339S	104%	93%	104%	95%
66	IB00620M	109%	104%	111%	105%

Legend: DO: Drop out.

GROUP 2

		Active product	
no.	Vol. ID	T28	T84
03	V8958G	100%	106%
04	A6245L	93%	93%
06	D5573N	103%	96%
11	S5086M	107%	95%
13	C5641B	105%	94%
15	A9126V	102%	101%
19	M1104S	84%	96%
22	N7929N	111%	96%
23	T8446S	[DO]	[DO]
30	M01450D	139%	90%
32	L01135S	96%	96%
34	L02298C	101%	100%
35	B7550S	100%	100%
36	Z8240D	100%	99%
37	M4022P	104%	99%
39	M4330E	100%	98%
47	IV00644P	106%	103%
52	IO00262M	96%	101%
55	IC00363Ú	98%	99%
59	IS00414N	100%	100%
63	IP00594S	98%	102%
65	IV00558M	96%	95%

Legend: DO: Drop out.

GROUP 3

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		Placebo product	
no.	Vol. ID	T28	T84
02	C1167R	93%	106%
07	C7666M	102%	94%
08	P6021A	100%	95%
09	D9000V	104%	91%
14	S6976M	111%	100%
20	F1334T	102%	99%
21	G8171T	93%	85%
24	S02220R	104%	102%
26	A01240G	88%	96%
27	T02077C	100%	102%
28	D02447V	102%	102%
38	C7361K	93%	101%
40	B1020S	99%	99%
41	B6712D	105%	99%
46	V3902A	94%	98%
49	IG00609M	107%	103%
53	IM00493S	98%	98%
58	IA00500C	102%	101%
60	IB00169E	[DO]	[DO]
61	IS00156S	100%	106%
62	ID00067G	105%	101%
64	IV00531J	100%	101%

Legend: DO: Drop out.

COMMENT: products accountability is ≥ 80% for each enrolled subject. All the subjects participating in the study are considered compliant with the study schedule.

RESULTS

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60-SECONDS HAIR COUNT

TABLES 1a, b, c. The tables report the data obtained for each subject participating in the study for the analyzed parameter. Data are reported as number of broken hairs.

GROUP 1

no.	Vol. ID	T0	T28	T84	Variation vs. T0	T28	T84	% variation vs. T0	T28	T84
01	P6046R	37	19	16		-18	-21		-48,6%	-56,8%
05	G6798C	38	22	21		-16	-17		-42,1%	-44,7%
10	M10490S	26	13	8		-13	-18		-50,0%	-69,2%
12	D7720D	45	52	12		7	-33		15,6%	-73,3%
16	B7589E	40	27	15		-13	-25		-32,5%	-62,5%
17	S6884S	55	39	15		-16	-40		-29,1%	-72,7%
18	C1498S	28	23	15		-5	-13		-17,9%	-46,4%
25	F02697N	39	23	12		-16	-27		-41,0%	-69,2%
29	C01075E	33	19	25		-14	-8		-42,4%	-24,2%
31	O02511V	33	20	13		-13	-20		-39,4%	-60,6%
33	C00644A	53	45	42		-8	-11		-15,1%	-20,8%
42	M7619F	22	18	10		-4	-12		-18,2%	-54,5%
43	C3813C	33	21	8		-12	-25		-36,4%	-75,8%
44	M8432V	41	28	16		-13	-25		-31,7%	-61,0%
45	M3875A	34	23	8		-11	-26		-32,4%	-76,5%
48	IN00322C	[128]	[DO]	[DO]		[DO]	[DO]		[DO]	[DO]
50	IS00078C	130	70	81		-60	-49		-46,2%	-37,7%
51	IH00309I	31	28	13		-3	-18		-9,7%	-58,1%
54	IO00163S	40	11	6		-29	-34		-72,5%	-85,0%
56	IG00037M	39	29	18		-10	-21		-25,6%	-53,8%
57	IA00339S	87	59	69		-28	-18		-32,2%	-20,7%
66	IB00620M	55	25	31		-30	-24		-54,5%	-43,6%
	Mean	**44,7**	**29,2**	**21,6**		**-15,5**	**-23,1**		**-33,4%**	**-55,6%**
	SE	5,2	3,3	4,3	Max	-60	-49	Max	-72,5%	-85,0%
	Friedman vs. T0	---	0,000	0,000	Min	7	-8	Min	15,6%	-20,7%

Legend: SE: standard error; **DO:** Drop out.

GROUP 2

no.	Vol. ID	T0	T28	T84	Variation vs. T0	T28	T84	% variation vs. T0	T28	T84
03	V8958G	41	24	15		-17	-26		-41,5%	-63,4%
04	A6245L	34	27	19		-7	-15		-20,6%	-44,1%
06	D5573N	23	8	11		-15	-12		-65,2%	-52,2%
11	S5086M	47	15	22		-32	-25		-68,1%	-53,2%
13	C5641B	37	35	10		-2	-27		-5,4%	-73,0%
15	A9126V	32	19	14		-13	-18		-40,6%	-56,3%
19	M1104S	36	30	25		-6	-11		-16,7%	-30,6%
22	N7929N	39	30	15		-9	-24		-23,1%	-61,5%
23	T8446S	[32]	[27]	[DO]		[-5]	[DO]		[-15,6%]	[DO]
30	M01450D	60	55	40		-5	-20		-8,3%	-33,3%
32	L01135S	26	22	10		-4	-16		-15,4%	-61,5%
34	L02298C	42	36	29		-6	-13		-14,3%	-31,0%
35	B7550S	34	20	7		-14	-27		-41,2%	-79,4%
36	Z8240D	35	25	2		-10	-33		-28,6%	-94,3%
37	M4022P	26	23	10		-3	-16		-11,5%	-61,5%
39	M4330E	32	30	7		-2	-25		-6,3%	-78,1%
47	IV00644P	77	16	19		-61	-58		-79,2%	-75,3%
52	IO00262M	110	93	100		-17	-10		-15,5%	-9,1%
55	IC00363Ú	35	18	31		-17	-4		-48,6%	-11,4%
59	IS00414N	138	74	39		-64	-99		-46,4%	-71,7%
63	IP00594S	88	20	5		-68	-83		-77,3%	-94,3%
65	IV00558M	47	11	13		-36	-34		-76,6%	-72,3%
	Mean	**49,5**	**30,0**	**21,1**		**-19,4**	**-28,4**		**-35,7%**	**-57,5%**
	SE	6,5	4,5	4,6	Max	-68	-99	Max	-79,2%	-94,3%
	Friedman vs. T0	---	0,000	0,000	Min	-2	-4	Min	-5,4%	-9,1%

Legend: SE: standard error; **DO:** Drop out.

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no.	Vol. ID	T0	T28	T84		T28	T84		T6	T7
02	C1167R	63	51	64		-12	1		-19,0%	1,6%
07	C7666M	29	57	15		28	-14		96,6%	-48,3%
08	P6021A	105	112	96		7	-9		6,7%	-8,6%
09	D9000V	52	27	30		-25	-22		-48,1%	-42,3%
14	S6976M	25	30	29		5	4		20,0%	16,0%
20	F1334T	34	40	35		6	1		17,6%	2,9%
21	G8171T	42	40	35		-2	-7		-4,8%	-16,7%
24	S02220R	33	30	17		-3	-16		-9,1%	-48,5%
26	A01240G	19	21	13		2	-6		10,5%	-31,6%
27	T02077C	22	19	28		-3	6		-13,6%	27,3%
28	D02447V	23	30	21		7	-2		30,4%	-8,7%
38	C7361K	24	32	30		8	6		33,3%	25,0%
40	B1020S	21	27	26		6	5		28,6%	23,8%
41	B6712D	17	12	8		-5	-9		-29,4%	-52,9%
46	V3902A	22	25	17		3	-5		13,6%	-22,7%
49	IG00609M	25	25	27		0	2		0,0%	8,0%
53	IM00493S	80	42	35		-38	-45		-47,5%	-56,3%
58	IA00500C	81	61	49		-20	-32		-24,7%	-39,5%
60	IB00169E	[90]	[45]	[DO]		[-45]	[DO]		[-50,0%]	[DO]
61	IS00156S	123	124	118		1	-5		0,8%	-4,1%
62	ID00067G	133	110	87		-23	-46		-17,3%	-34,6%
64	IV00531J	23	15	13		-8	-10		-34,8%	-43,5%
	Mean	**47,4**	**44,3**	**37,8**		**-3,1**	**-9,7**		**0,5%**	**-16,8%**
	SE	7,9	7,1	6,4	Max	-38	-46	Max	-48,1%	-56,3%
	Friedman vs. T0	---	0,337	0,000	Min	28	6	Min	96,6%	27,3%

Variation vs. T0

% variation vs. T0

Legend: SE: standard error; **DO:** Drop out.

GRAPH 1. The graphs show the mean data obtained at each experimental time for the analyzed parameter. Data are expressed as mean ± SE. Above the error bar the intragroup (vs. T0) statistical analysis is reported as follows: *p<0.05; **p<0.01; ***p<0.001.

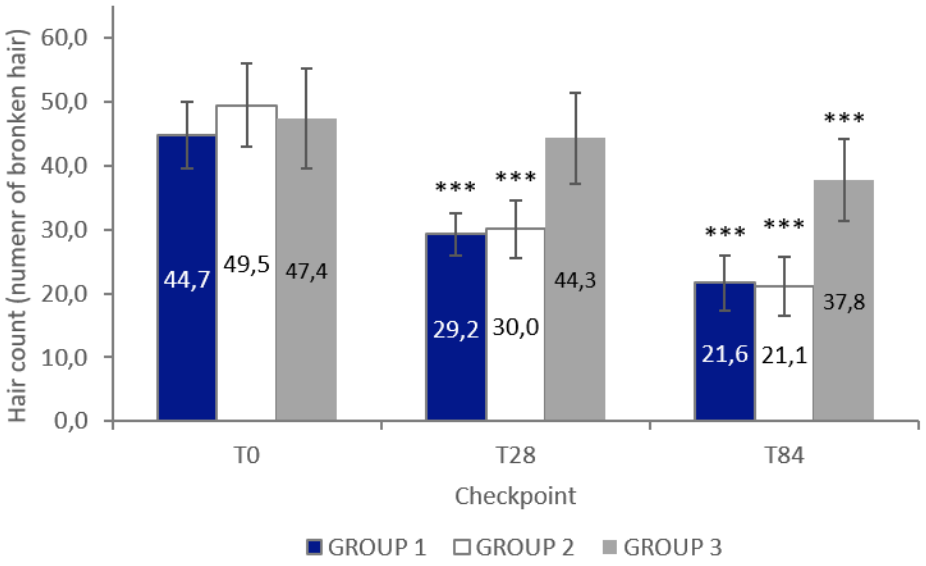

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TABLE 1d. The table reports the inter-group statistical analysis (p-values) carried out by means of Kruskal-Wallis test (one-way ANOVA) measures on % variations. p-values highlighted in bold indicate a statistically significant difference between groups.

Intergroup statistical analysis (p-value)		
	T28	**T84**
Group 1 vs Group 2	0,956	0,963
Group 1 vs Group 3	**0,000**	**0,000**
Group 2 vs Group 3	**0,000**	**0,000**

COMMENT

As it is possible to notice, a statistically significant reduction in broken hair was observed in both *Groups 1* and *2*.

In particular, *Group 2* showed a reduction by 35.7% (19.4 hair) at T28 and 57.5% (28.4 hair) at T84, while *Group 1* showed a reduction by 33.4% (15.5 hair) and 55.6% (23.1 hair) at T28 and T84, respectively. Although *Group 2* showed a greater improvement at both timepoints, no statistically significant differences were detected between *Groups 1* and *2*.

Finally, a statistically significant reduction was also observed in *Group 3* at T84 by 9.7 (16.8%), the reductions were consistently smaller compared to *Groups 1* and *2*, with statistically significant intergroup differences at all monitored time points.

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HAIR ELONGATION (ELASTICITY)

TABLES 2a, b, c. The tables report the data obtained for each subject participating in the study for the analyzed parameter. Data are reported as average elasticity and expressed in percentage (%).

GROUP 1

no.	Vol. ID	T0	T84		T84		T84
01	P6046R	41,4	46,1		4,7		11,4%
05	G6798C	35,9	39,9		4,0		11,1%
10	M10490S	42,4	46,9		4,5		10,6%
12	D7720D	43,4	43,9		0,5		1,2%
16	B7589E	42,0	43,8		1,8		4,3%
17	S6884S	43,6	44,9		1,3		3,0%
18	C1498S	45,3	46,1		0,8		1,8%
25	F02697N	40,3	44,8		4,5		11,2%
29	C01075E	43,1	47,4		4,3		10,0%
31	O02511V	41,4	47,1		5,7		13,8%
33	C00644A	40,9	41,6		0,7		1,7%
42	M7619F	44,5	46,5		2,0		4,5%
43	C3813C	37,2	43,3		6,1		16,4%
44	M8432V	39,6	44,8		5,2		13,1%
45	M3875A	40,5	43,4		2,9		7,2%
48	IN00322C	[33,3]	[DO]		[DO]		[DO]
50	IS00078C	35,8	41,4		5,6		15,6%
51	IH00309I	35,3	42,1		6,8		19,3%
54	IO00163S	40,6	45,6		5,0		12,3%
56	IG00037M	32,8	39,5		6,7		20,4%
57	IA00339S	37,5	43,3		5,8		15,5%
66	IB00620M	40,1	46,2		6,1		15,2%
	Mean	**40,2**	**44,2**		**4,0**		**10,4%**
	SE	0,72	0,51	Min	0,5	Min	1,2%
	t test vs. T0	---	0,000	Max	6,8	Max	20,4%

Variation vs. T0 | % variation vs. T0

Legend: SE: standard error; **DO:** Drop out.

GROUP 2

no.	Vol. ID	T0	T84		T84		T84
03	V8958G	31,4	36,9		5,5		17,5%
04	A6245L	40,1	46,5		6,4		16,0%
06	D5573N	41,6	41,8		0,2		0,5%
11	S5086M	45,7	48,4		2,7		5,9%
13	C5641B	36,0	37,0		1,0		2,8%
15	A9126V	38,7	42,7		4,0		10,3%
19	M1104S	36,3	41,5		5,2		14,3%
22	N7929N	35,5	44,5		9,0		25,4%
23	T8446S	[35,7]	[DO]		[DO]		[DO]
30	M01450D	42,8	43,1		0,3		0,7%
32	L01135S	38,4	40,6		2,2		5,7%
34	L02298C	37,8	41,7		3,9		10,3%
35	B7550S	38,5	45,0		6,5		16,9%
36	Z8240D	38,1	42,7		4,6		12,1%
37	M4022P	44,3	47,2		2,9		6,5%
39	M4330E	29,9	37,7		7,8		26,1%
47	IV00644P	43,8	44,9		1,1		2,5%
52	IO00262M	42,9	48,8		5,9		13,8%
55	IC00363Ú	36,1	46,6		10,5		29,1%
59	IS00414N	38,7	41,0		2,3		5,9%
63	IP00594S	36,9	41,3		4,4		11,9%
65	IV00558M	36,1	40,3		4,2		11,6%
	Mean	**38,6**	**42,9**		**4,3**		**11,7%**
	SE	0,9	0,8	Min	0,2	Min	0,5%
	t test vs. T0	---	0,000	Max	10,5	Max	29,1%

Variation vs. T0 | % variation vs. T0

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Legend: SE: standard error; **DO:** Drop out.

GROUP 3

no.	Vol. ID	T0	T84	Variation vs. T0	T84	% variation vs. T0	T7
02	C1167R	37,6	38,8		1,2		3,2%
07	C7666M	39,9	41,1		1,2		3,0%
08	P6021A	41,2	43,3		2,1		5,1%
09	D9000V	42,7	42,7		0,0		0,0%
14	S6976M	38,6	41,1		2,5		6,5%
20	F1334T	43,6	44,3		0,7		1,6%
21	G8171T	40,9	43,9		3,0		7,3%
24	S02220R	42,2	40,8		-1,4		-3,3%
26	A01240G	38,8	38,1		-0,7		-1,8%
27	T02077C	40,0	43,9		3,9		9,8%
28	D02447V	42,7	38,8		-3,9		-9,1%
38	C7361K	43,0	42,2		-0,8		-1,9%
40	B1020S	42,5	40,6		-1,9		-4,5%
41	B6712D	38,7	41,1		2,4		6,2%
46	V3902A	41,7	38,3		-3,4		-8,2%
49	IG00609M	40,1	39,9		-0,2		-0,5%
53	IM00493S	42,9	45,6		2,7		6,3%
58	IA00500C	41,9	36,9		-5,0		-11,9%
60	IB00169E	[43,2]	[DO]		[DO]		[DO]
61	IS00156S	42,3	41,3		-1,0		-2,4%
62	ID00067G	37,5	35,0		-2,5		-6,7%
64	IV00531J	38,9	42,4		3,5		9,0%
	Mean	**40,8**	**41,0**		**0,1**		**0,4%**
	SE	0,4	0,6	Min	-5,0	Min	-11,9%
	t test vs. T0	---	0,839	Max	3,9	Max	9,8%

Legend: SE: standard error; **DO: Drop out**

GRAPH 2. The graphs show the mean data obtained at each experimental time for the analyzed parameter. Data are expressed as mean ± SE. Above the error bar the intragroup (vs. T0) statistical analysis is reported as follows: *p<0.05; **p<0.01; ***p<0.001.

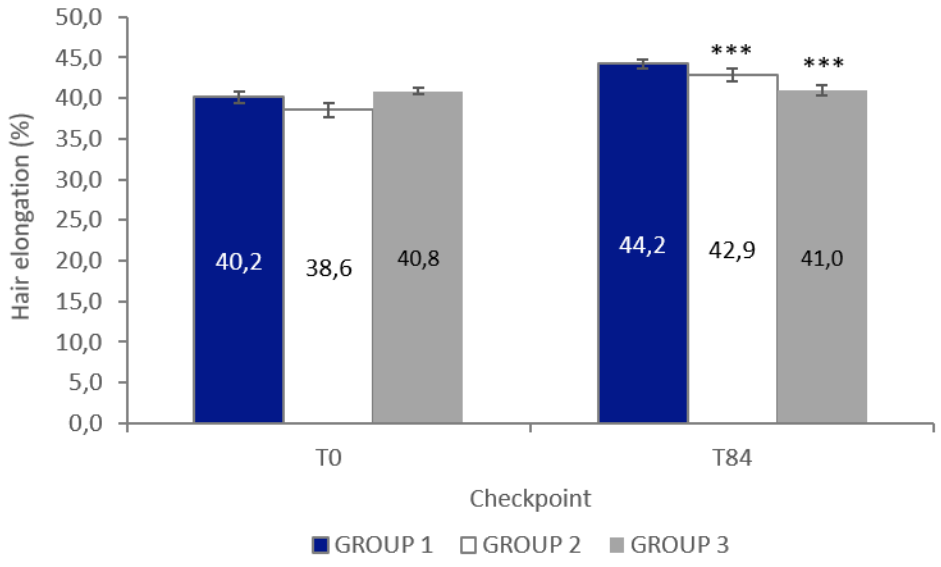

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TABLE 2d. The table reports the inter-group statistical analysis (p-values) carried out by means of one-way ANOVA test measures on % variations. p-values highlighted in bold indicate a statistically significant difference between groups.

Intergroup statistical analysis (p-value)	
	T84
Group 1 vs Group 2	0,825
Group 1 vs Group 3	**0,000**
Group 2 vs Group 3	**0,000**

COMMENT

As it is possible to notice, a statistically significant increase of hair elasticity was observed in both *Groups 1* and *2*.

In particular, *Group 2* showed an increase by 11.7% (4.3 percentage points) at T84, while *Group 1* showed an increase by 10.4% (4.0 percentage points) T84. Although *Group 2* showed a greater improvement, no statistically significant differences were detected between *Groups 1* and *2*.

No statistically significant variation in the monitored parameter was observed in *Group 3* at T84.

Finally, the intergroup statistical analysis highlights that the results obtained in *Groups 1* and *2*, are significantly greater compared to those obtained in *Group 3* at T84.

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HAIR RADIANCE - GLOSS PARAMETER

TABLES 3a, b, c. The tables report the data obtained for each subject participating in the study for the analyzed parameter. Data are expressed in arbitrary units (a.u.).

GROUP 1

no.	Vol. ID	T0	T28	T84	% variation vs. T0	T28	T84
01	P6046R	3,87	4,75	5,26		22,7%	35,9%
05	G6798C	5,60	7,00	7,20		25,0%	28,6%
10	M10490S	7,30	8,20	6,96		12,3%	-4,7%
12	D7720D	11,00	13,30	12,50		20,9%	13,6%
16	B7589E	7,61	8,63	8,65		13,4%	13,7%
17	S6884S	3,48	4,22	4,52		21,3%	29,9%
18	C1498S	4,26	4,46	5,98		4,7%	40,4%
25	F02697N	4,40	5,79	7,13		31,6%	62,0%
29	C01075E	5,18	7,42	6,98		43,2%	34,7%
31	O02511V	5,97	6,10	6,04		2,2%	1,2%
33	C00644A	5,26	5,97	8,60		13,5%	63,5%
42	M7619F	5,20	6,20	6,80		19,2%	30,8%
43	C3813C	4,10	4,60	5,20		12,2%	26,8%
44	M8432V	3,96	5,76	5,80		45,5%	46,5%
45	M3875A	3,98	4,80	4,90		20,6%	23,1%
48	IN00322C	[3,64]	[DO]	[DO]		[DO]	[DO]
50	IS00078C	9,57	10,41	10,23		8,8%	6,9%
51	IH00309I	12,68	9,57	12,35		-24,5%	-2,6%
54	IO00163S	7,40	9,18	8,54		24,1%	15,4%
56	IG00037M	9,18	9,73	7,09		6,0%	-22,8%
57	IA00339S	4,39	5,24	4,52		19,3%	2,9%
66	IB00620M	4,53	5,74	4,48		26,7%	-1,1%
	Mean	**6,14**	**7,00**	**7,13**		**17,6%**	**21,2%**
	SE	0,56	0,52	0,51	Min	-24,5%	-22,8%
	Friedman vs. T0	---	0,004	0,001	Max	45,5%	63,5%

Legend: SE: standard error; **DO:** Drop out.

GROUP 2

no.	Vol. ID	T0	T28	T84	% variation vs. T0	T28	T84
03	V8958G	8,14	10,14	10,88		24,6%	33,7%
04	A6245L	6,47	7,12	7,39		10,0%	14,2%
06	D5573N	7,00	8,00	8,34		14,3%	19,1%
11	S5086M	7,80	11,22	11,00		43,8%	41,0%
13	C5641B	2,40	4,30	3,80		79,2%	58,3%
15	A9126V	5,11	5,22	6,15		2,2%	20,4%
19	M1104S	7,30	8,10	8,23		11,0%	12,7%
22	N7929N	5,60	6,20	6,12		10,7%	9,3%
23	T8446S	[4,91]	[6,33]	[DO]		[28,9%]	[DO]
30	M01450D	4,12	4,85	5,97		17,7%	44,9%
32	L01135S	5,72	6,70	5,37		17,1%	-6,1%
34	L02298C	5,57	6,46	6,68		16,0%	19,9%
35	B7550S	6,22	7,70	7,70		23,8%	23,8%
36	Z8240D	5,40	6,80	7,00		25,9%	29,6%
37	M4022P	4,10	5,60	5,70		36,6%	39,0%
39	M4330E	5,70	6,20	6,40		8,8%	12,3%
47	IV00644P	3,80	3,95	5,98		3,9%	57,4%
52	IO00262M	10,59	9,74	8,38		-8,0%	-20,9%
55	IC00363Ú	7,52	5,71	7,17		-24,1%	-4,7%
59	IS00414N	10,02	16,18	12,13		61,5%	21,1%
63	IP00594S	12,97	15,47	16,61		19,3%	28,1%
65	IV00558M	5,87	6,33	7,75		7,8%	32,0%
	Mean	**6,54**	**7,71**	**7,85**		**19,1%**	**23,1%**
	SE	0,53	0,71	0,62	Min	-24,1%	-20,9%
	RM Anova vs. T0	---	0,001	0,000	Max	79,2%	58,3%

Legend: SE: standard error; **DO:** Drop out.

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GROUP 3

no.	Vol. ID	T0	T28	T84		T28	T84
02	C1167R	6,95	6,75	7,63		-2,9%	9,8%
07	C7666M	7,30	8,00	7,80		9,6%	6,8%
08	P6021A	8,50	9,30	6,50		9,4%	-23,5%
09	D9000V	5,20	6,50	5,70		25,0%	9,6%
14	S6976M	4,41	4,20	5,20		-4,8%	17,9%
20	F1334T	5,70	6,68	7,10		17,2%	24,6%
21	G8171T	7,20	7,60	8,12		5,6%	12,8%
24	S02220R	6,24	5,62	5,62		-9,9%	-9,9%
26	A01240G	5,57	5,10	4,46		-8,4%	-19,9%
27	T02077C	6,20	6,09	5,64		-1,8%	-9,0%
28	D02447V	3,98	3,90	4,26		-2,0%	7,0%
38	C7361K	4,42	4,40	5,60		-0,5%	26,7%
40	B1020S	6,20	6,30	6,50		1,6%	4,8%
41	B6712D	6,40	5,60	7,94		-12,5%	24,1%
46	V3902A	5,20	5,75	6,84		10,6%	31,5%
49	IG00609M	8,02	10,30	9,63		28,4%	20,1%
53	IM00493S	5,67	6,40	5,59		12,9%	-1,4%
58	IA00500C	9,97	9,10	7,93		-8,7%	-20,5%
60	IB00169E	[8,58]	[10,08]	[DO]		[17,5%]	[DO]
61	IS00156S	6,36	7,07	8,20		11,2%	28,9%
62	ID00067G	12,97	14,08	13,00		8,6%	0,2%
64	IV00531J	9,45	10,33	8,54		9,3%	-9,6%
	Mean	**6,76**	**7,10**	**7,04**		**4,7%**	**6,2%**
	SE	0,46	0,53	0,43	Min	-12,5%	-23,5%
	Friedman vs. T0	---	0,309	0,448	Max	28,4%	31,5%

% variation vs. T0

Legend: SE: standard error; **DO:** Drop out.

GRAPH 3. The graphs show the mean data obtained at each experimental time for the analyzed parameter. Data are expressed as mean ± SE. Above the error bar the intragroup (vs. T0) statistical analysis is reported as follows: *p<0.05; **p<0.01; ***p<0.001.

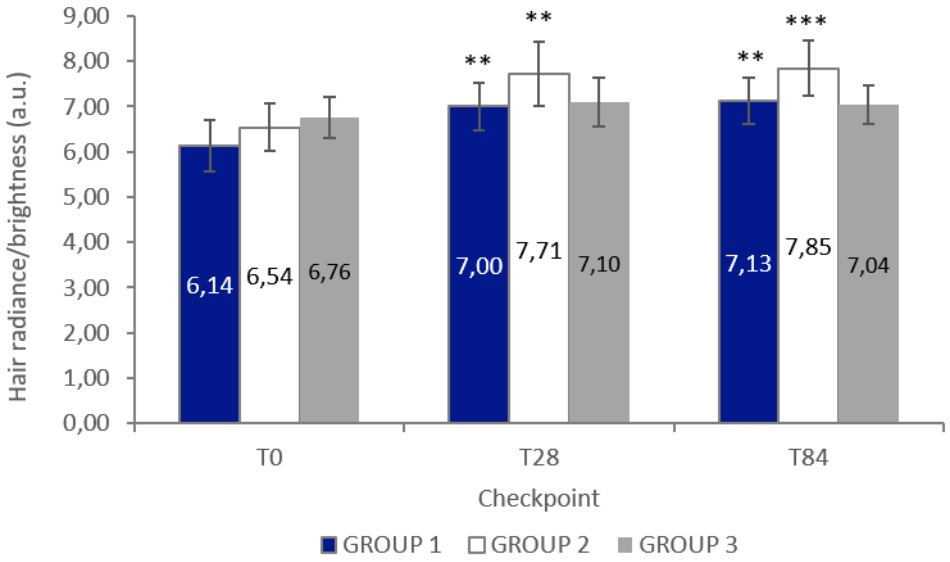

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TABLE 3d. The table reports the inter-group statistical analysis (p-values) carried out by means of Kruskal-Wallis test (one-way ANOVA) measures on % variations. p-values highlighted in bold indicate a statistically significant difference between groups.

Intergroup statistical analysis (p-value)		
	T28	**T84**
Group 1 vs Group 2	0,949	0,947
Group 1 vs Group 3	**0,041**	**0,045**
Group 2 vs Group 3	**0,019**	**0,020**

COMMENT

As it is possible to notice, a statistically significant increase of gloss parameter was observed in both *Groups 1* and *2*. In particular, *Group 2* showed an increase by 19.1% at T28 and 23.1% at T84, while *Group 1* showed an increase by 17.6% and 21.2% at T28 and T84, respectively. Although *Group 2* showed a greater improvement at both timepoints, no statistically significant differences were detected between *Groups 1* and *2*.

No statistically significant variation in the monitored parameter was observed in *Group 3* at each timepoint.

Finally, the intergroup statistical analysis highlights that the results obtained in *Groups 1* and *2*, are significantly greater compared to those obtained in *Group 3* at all monitored time points.

An increase of gloss parameter indicates an improvement of hair radiance/brightness.

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EXPERT SCORING: OVERALL HAIR ASPECT

TABLES 4a, b, c. The tables report the clinical scores recorded for each subject participating in the study for the analysed parameter. Data are scored as reported in the legend below.

GROUP 1

no.	Vol. ID	T28	T84
01	P6046R	2	2
05	G6798C	2	2
10	M10490S	2	3
12	D7720D	2	2
16	B7589E	2	2
17	S6884S	1	1
18	C1498S	1	1
25	F02697N	2	2
29	C01075E	2	2
31	O02511V	2	2
33	C00644A	1	2
42	M7619F	1	2
43	C3813C	1	2
44	M8432V	2	2
45	M3875A	3	3
48	IN00322C	[DO]	[DO]
50	IS00078C	1	1
51	IH00309I	2	2
54	IO00163S	2	2
56	IG00037M	2	2
57	IA00339S	1	2
66	IB00620M	1	2
	Mean	**1,7**	**2,0**
	SE	0,1	0,1

Legend: SE: standard error**; DO:** Drop out.
Clinical classification of overall hair aspect at T28 and T84: 1. No variation; **2.** Slight improvement; **3.** Moderately improved; **4.** Remarkable improved.

GROUP 2

no.	Vol. ID	T28	T84
03	V8958G	2	2
04	A6245L	2	2
06	D5573N	2	3
11	S5086M	2	2
13	C5641B	2	3
15	A9126V	2	3
19	M1104S	1	2
22	N7929N	2	2
23	T8446S	[2]	[DO]
30	M01450D	2	2
32	L01135S	2	2
34	L02298C	1	2
35	B7550S	2	2
36	Z8240D	1	2
37	M4022P	1	2
39	M4330E	1	2
47	IV00644P	2	2
52	IO00262M	1	1
55	IC00363Ú	2	3
59	IS00414N	1	2
63	IP00594S	2	2
65	IV00558M	2	2
	Mean	**1,7**	**2,1**
	SE	0,1	0,1

Legend: SE: standard error**; DO:** Drop out.
Clinical classification of overall hair aspect at T28 and T84: 1. No variation; **2.** Slight improvement; **3.** Moderately improved; **4.** Remarkable improved.

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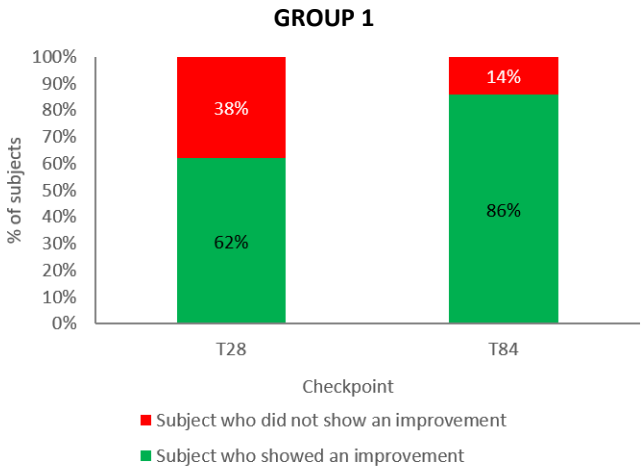
GROUP 3

no.	Vol. ID	T28	T84
02	C1167R	1	1
07	C7666M	1	2
08	P6021A	2	2
09	D9000V	1	1
14	S6976M	1	1
20	F1334T	1	1
21	G8171T	2	2
24	S02220R	1	2
26	A01240G	1	1
27	T02077C	2	2
28	D02447V	1	1
38	C7361K	1	1
40	B1020S	1	1
41	B6712D	1	2
46	V3902A	2	3
49	IG00609M	2	2
53	IM00493S	2	2
58	IA00500C	1	1
60	IB00169E	[2]	[DO]
61	IS00156S	1	1
62	ID00067G	1	2
64	IV00531J	1	1
	Mean	**1,3**	**1,5**
	SE	0,1	0,1

Legend: SE: standard error**; DO:** Drop out.
Clinical classification of overall hair aspect at T28 and T84: 1. No variation; **2.** Slight improvement; **3.** Moderately improved; **4.** Remarkable improved.

GRAPHS 4a/b/c. The graphs report the percentage (%) of subjects related to the effect.



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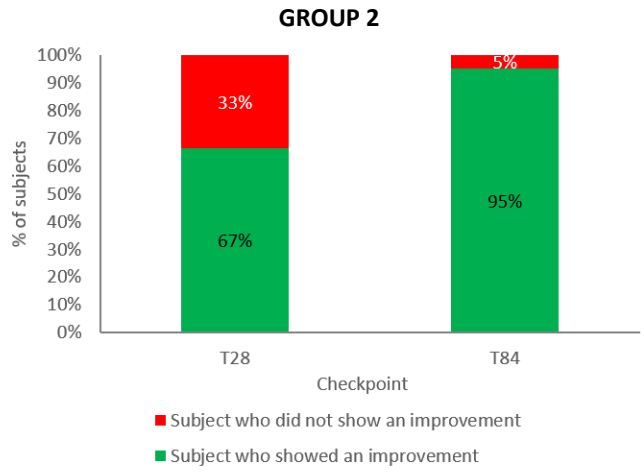

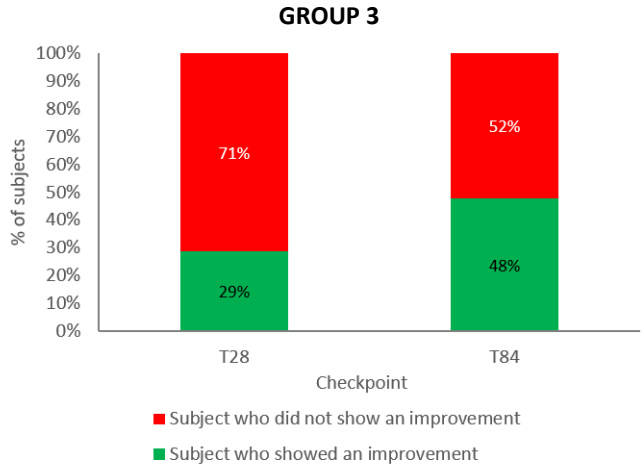

TABLE 4d. The table below reports the results (p-values) of the inter-group statistical analysis performed by means of Kruskal-Wallis test (Group 1 vs Group 2 vs Group 3). Statistically significant p-values (<0.05) are highlighted in bold.

Intergroup statistical analysis (p-value)		
	T28	**T84**
Group 1 vs Group 2	1,000	0,479
Group 1 vs Group 3	**0,049**	**0,029**
Group 2 vs Group 3	**0,049**	**0,001**

COMMENT

As it is possible to notice, a clinically relevant improvement in the overall hair aspect was observed in both *Groups 1* and *2*. In particular, *Group 2* showed an improvement in 67% and 95% of the enrolled subjects at T28 and T84, respectively, while *Group 1* showed an improvement in 62% and 86% of them at T28 and T84, respectively. Although *Group 2* showed a greater improvement at both timepoints, no statistically significant differences were detected between *Groups 1* and *2*.

No clinically relevant variation in the monitored parameter was observed in *Group 3* at each timepoint.

Finally, the intergroup statistical analysis highlights that the results obtained in *Groups 1* and *2*, are significantly greater compared to those obtained in *Group 3* at all monitored time points.

For expert scoring evaluations, the positive effect of the product on the evaluated parameter is confirmed if more than 50% of the subjects register an improvement.

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SELF-ASSESSMENT QUESTIONNAIRES

TABLES 5a, b, c. The tables summarize the results of the self-assessment questionnaire after **84 days** of products intake. Results are calculated as percentage of subjects who assigned a judgment among those proposed.

GROUP 1

Data refer to 21 out 22 enrolled subjects for *Group 1*, who completed the study as per protocol.

No.	Items	Completely agree	Agree	Disagree	Completely disagree	Positive answers
01	My hair looks healhier	42,9%	42,9%	14,3%	0,0%	85,7%
02	My hair has a natural bounce and is fuller	28,6%	66,7%	4,8%	0,0%	95,2%
03	My hair looks shinier	42,9%	42,9%	14,3%	0,0%	85,7%
04	My hair feels stronger and revitalized	38,1%	52,4%	9,5%	0,0%	90,5%
05	My hair seems repaired	38,1%	47,6%	14,3%	0,0%	85,7%
06	My hair seems thicker	38,1%	52,4%	9,5%	0,0%	90,5%
07	My hair feels more flexible and less brittle	38,1%	57,1%	4,8%	0,0%	95,2%
08	My hair feels silky and smooth	28,6%	57,1%	14,3%	0,0%	85,7%
09	My hair looks sleek and frizz-free	38,1%	42,9%	19,0%	0,0%	81,0%

No.	Items	Very satisfied	Satisfied	Unsatisfied	Very unsatisfied	Positive answers
10	Are you satisfied with the product?	42,9%	42,9%	14,3%	0,0%	85,7%

No.	Items	Yes	No	Positive answers
11	Was the product well tolerated?	100,0%	0,0%	100,0%
12	Would you buy the product?	81,0%	19,0%	81,0%

Legend: positive answers → % of subjects who gave positive judgement (completely agree/Completely/Very satisfied/Satisfied/Yes).
The percentages are rounded off, this is why the sum of these percentages may be different from 100%.

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GROUP 2

Data refer to 21 out 22 enrolled subjects for *Group 2*, who completed the study as per protocol.

No.	Items	Completely agree	Agree	Disagree	Completely disagree	Positive answers
01	My hair looks healhier	9,5%	81,0%	4,8%	4,8%	90,5%
02	My hair has a natural bounce and is fuller	19,0%	66,7%	9,5%	4,8%	85,7%
03	My hair looks shinier	9,5%	76,2%	14,3%	0,0%	85,7%
04	My hair feels stronger and revitalized	23,8%	61,9%	9,5%	4,8%	85,7%
05	My hair seems repaired	19,0%	57,1%	19,0%	4,8%	76,2%
06	My hair seems thicker	23,8%	47,6%	19,0%	9,5%	71,4%
07	My hair feels more flexible and less brittle	23,8%	66,7%	9,5%	0,0%	90,5%
08	My hair feels silky and smooth	19,0%	71,4%	9,5%	0,0%	90,5%
09	My hair looks sleek and frizz-free	14,3%	57,1%	23,8%	4,8%	71,4%

No.	Items	Very satisfied	Satisfied	Unsatisfied	Very unsatisfied	Positive answers
10	Are you satisfied with the product?	28,6%	47,6%	19,0%	4,8%	76,2%

No.	Items	Yes	No	Positive answers
11	Was the product well tolerated?	100,0%	0,0%	100,0%
12	Would you buy the product?	76,2%	23,8%	76,2%

Legend: positive answers → % of subjects who gave positive judgement (completely agree/Completely/Very satisfied/Satisfied/Yes).
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GROUP 3

Data refer to 21 out 22 enrolled subjects for *Group 3*, who completed the study as per protocol.

No.	Items	Completely agree	Agree	Disagree	Completely disagree	Positive answers
01	My hair looks healhier	9,5%	71,4%	19,0%	0,0%	81,0%
02	My hair has a natural bounce and is fuller	19,0%	61,9%	19,0%	0,0%	81,0%
03	My hair looks shinier	14,3%	57,1%	28,6%	0,0%	71,4%
04	My hair feels stronger and revitalized	14,3%	61,9%	23,8%	0,0%	76,2%
05	My hair seems repaired	14,3%	57,1%	28,6%	0,0%	71,4%
06	My hair seems thicker	23,8%	42,9%	33,3%	0,0%	66,7%
07	My hair feels more flexible and less brittle	19,0%	47,6%	33,3%	0,0%	66,7%
08	My hair feels silky and smooth	19,0%	47,6%	33,3%	0,0%	66,7%
09	My hair looks sleek and frizz-free	14,3%	42,9%	42,9%	0,0%	57,1%

No.	Items	Very satisfied	Satisfied	Unsatisfied	Very unsatisfied	Positive answers
10	Are you satisfied with the product?	19,0%	52,4%	28,6%	0,0%	71,4%

No.	Items	Yes	No	Positive answers
11	Was the product well tolerated?	100,0%	0,0%	100,0%
12	Would you buy the product?	71,4%	23,8%	71,4%

Legend: positive answers → % of subjects who gave positive judgement (completely agree/Completely/Very satisfied/Satisfied/Yes).
The percentages are rounded off, this is why the sum of these percentages may be different from 100%.

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CONCLUSIONS

According to the obtained results:

BIOS LINE S.P.A

Group 1:

Principium Hair Beauty + Placebo product

intakes determined:

- a statistically significant (vs. T0) reduction in broken hair by 33.4% (15.5 hair) and 55.6% (23.1 hair) at T28 and T84, respectively,
- a statistically significant increase of hair elasticity by 10.4% (4.0 percentage points) at T84,
- a statistically significant (v. T0) of gloss parameter by 17.6% and 21.2% at T28 and T84, respectively. *An increase of gloss parameter indicates an improvement of hair radiance/brightness,*
- a clinically relevant improvement in the overall hair aspect in 62% and 86% of enrolled subjects at T28 and T84, respectively.
  For expert scoring evaluations, the positive effect of the product on the evaluated parameter is confirmed if more than 50% of the subjects register an improvement.

  All results obtained are significantly greater compared to those obtained in Group 3 at all monitored time points.

  Moreover, most of the enrolled volunteers positively judged the product for all the monitored aspects at T84.

Group 2:

Principium Hair Beauty

intakes determined:

- a statistically significant (vs. T0) reduction in broken hair by 35.7% (19.4 hair) and 57.5% (28.4 hair) at T28 and T84, respectively,
- a statistically significant increase of hair elasticity by 11.7% (4.3 percentage points) at T84,
- a statistically significant (v. T0) of gloss parameter by 19.1% and 13.1% at T28 and T84, respectively. *An increase of gloss parameter indicates an improvement of hair radiance/brightness,*
- a clinically relevant improvement in the overall hair aspect in 67% and 95% of the enrolled subjects at T28 and T84, respectively.
  For expert scoring evaluations, the positive effect of the product on the evaluated parameter is confirmed if more than 50% of the subjects register an improvement.

  All results obtained are significantly greater compared to those obtained in Group 3 at all monitored time points.

  Moreover, most of the enrolled volunteers positively judged the product for all the monitored aspects at T84.

Principal investigator	Data analysis and report	Quality control
Dr Gloria Roveda	Dr Sabrina Ghirlanda	Dr Francesca De Gennaro

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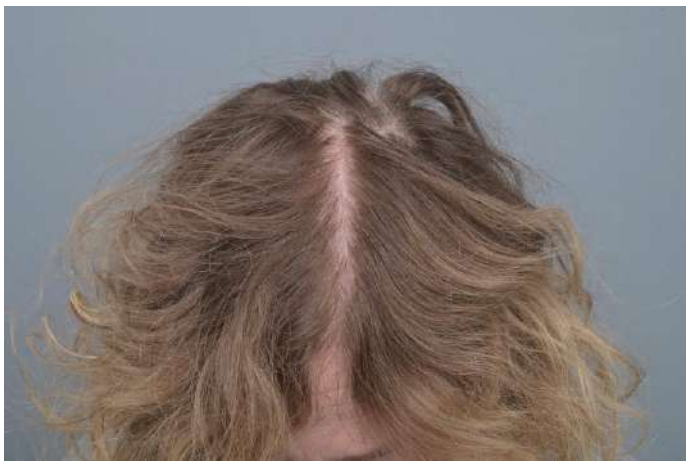
ANNEX I_*Digital pictures*

VOL. 10 – GROUP 1	
T0_frontal	**T0_vertex**
	
T28_frontal	**T28_vertex**
	
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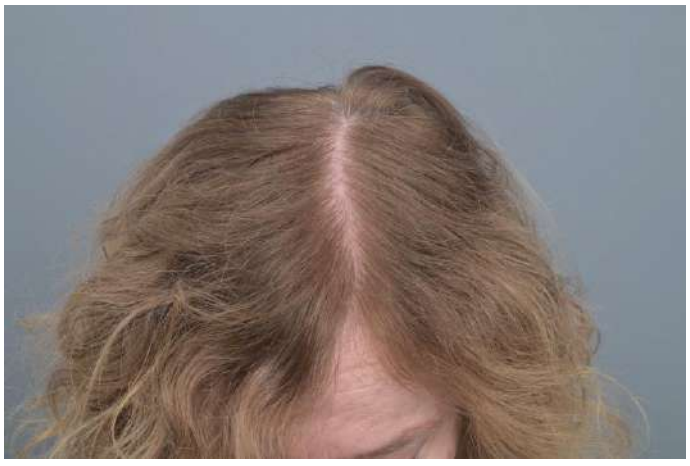	

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VOL. 45 – GROUP 1	
T0_frontal	**T0_vertex**
	
T28_frontal	**T28_vertex**
	
T84_frontal	**T84_vertex**
	

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VOL. 06 – GROUP 2	
T0_frontal	**T0_vertex**
	
T28_frontal	**T28_vertex**
	
T84_frontal	**T84_vertex**
	

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VOL. 13 – GROUP 2	
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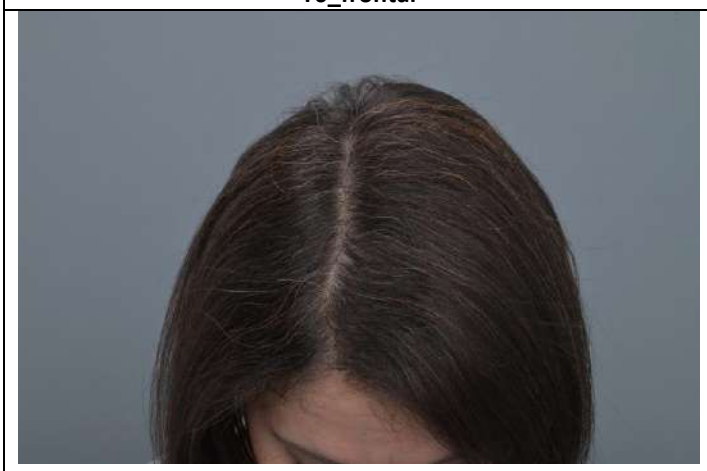
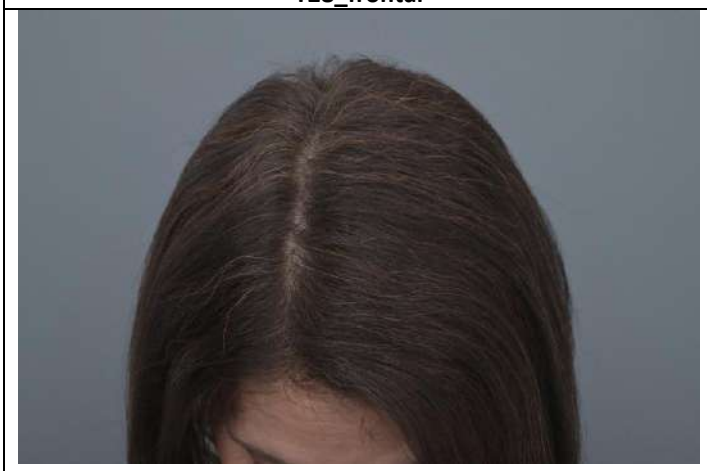
	
T28_frontal	**T28_vertex**
	
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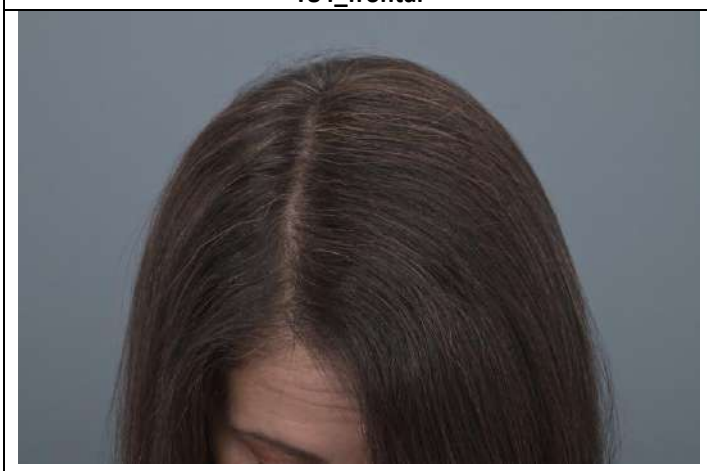	

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