

CLINICAL STUDY PROTOCOL

STUDY TITLE

CLINICAL INSTRUMENTAL EVALUATION OF THE EFFICACY OF A FOOD SUPPLEMENT FOR HAIR CARE: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

PROTOCOL REFERENCES

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GENERAL INFORMATION

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Authorized Signatory:

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External partners for blood analyses

External partner for hair image acquisition by Scanning Electron Microscopy (SEM)

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Headquarters: Via Guido Rossa, 1 - 20024 Garbagnate Milanese (MI), Italy



PROTOCOL APPROVAL

The undersigned acknowledge having read and understood the Clinical Study Protocol EC_P0000363/25 Ver.01 of 03/11/2025. They hereby agree with its content and commit to conduct or oversee the study in full compliance with this Protocol, the Declaration of Helsinki, Good Clinical Practice (GCP), and applicable regulatory requirements.

AUTHORIZED SIGNATORY OF THE SPONSOR

Date and Signature:

11/11/2025 *Albue*

PRINCIPAL INVESTIGATOR

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PROTOCOL AMENDMENTS

All protocol amendments must be jointly approved and signed by the Sponsor, the Principal Investigator, and the Project Manager of the study.

Deviations during the study will be reviewed to determine whether they require a formal amendment or justify study termination.

Updates to the list of investigators and study sites will not be formally updated through protocol amendments but will be managed by the project manager (or delegate) and included in the final report.

AMENDMENTS HISTORY

Clinical Study Protocol Version and Date of issue:

00, 26/09/2025

Description:

First release

Clinical Study Protocol Version and Date of issue:

01, 03/11/2025

Description:

Minor changes



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1. PROTOCOL SUMMARY

The primary aim of this study is to evaluate the efficacy of a food supplement in improving overall hair condition, including structure, shine, and growth. In addition, the study will assess the efficacy and pleasantness of the product as perceived by the subjects, improvements in overall scalp condition, and the safety of use.

To achieve this objective, a randomized, double-blind, placebo-controlled, parallel-group clinical trial will be conducted under the supervision of a board-certified dermatologist. A total of 132 healthy volunteers with mild to moderate hair damage and hair shine ranging from luster-less to lustrous will be enrolled.

The investigational product will be tested at two dosage levels: 44 subjects will receive the active product at a lower dose, 44 subjects will receive the active product at a higher dose, and 44 subjects will receive a placebo. The products will be administered for 168 days according to the instructions for use. Assessments will be performed at baseline and after 56, 112, and 168 days of supplementation.

The occurrence of adverse events will also be monitored throughout the study.

2. BACKGROUND AND RATIONALE

EVRA S.r.L., the Sponsor of the study, is interested in investigating the efficacy of the food supplement in enhancing overall hair condition, with benefits on structure, radiance, and growth.

The extract of *Malus pumila* Mill. cv *Annurca* (Annurtrofil) is used in the nutricosmetic sector to support hair and skin health. A growing body of preclinical and clinical evidence has demonstrated its efficacy in promoting hair growth and quality, counteracting oxidative stress, and contributing to overall aesthetic well-being [1–3].

Annurtrofil is distinguished from other apple-derived extracts by a unique phytochemical profile, characterized by a specific complex of polyphenols and defined marker compounds, including vitamin B2 $\geq 90 \mu\text{g/g}$, chlorogenic acid $\geq 200 \mu\text{g/g}$, and total polyphenols $\geq 3000 \mu\text{g/g}$. This composition of bioactive molecules is closely linked to the traditional post-harvest ripening process of Annurca apples, during which the fruits are matured in straw beds, a method that optimizes the concentration of active constituents [4].

The polyphenols and other key components of the extract exert their activity through multiple biological mechanisms, including antioxidant protection with a consequent reduction in cellular oxidative stress [1, 2, 6], stimulation of keratin biosynthesis as demonstrated in in vitro studies [3], documented benefits on cutaneous microcirculation and protection of cells from oxidative damage [1, 4], as well as complementary metabolic activity with potential positive effects on general well-being and lipid profile [5].

Several studies also support the favorable safety profile of the Annurca apple extract. In vitro studies have shown protective effects on dermal follicular cells and erythrocytes without evidence of cytotoxicity [1], while a clinical trial involving the daily consumption of Annurca apples by hypercholesterolemic subjects over a four-month period reported no significant adverse events, confirming the tolerability of long-term intake [5, 7].

Collectively, these findings indicate that Annurtrofil combines a well-established safety profile with clinically relevant functional benefits.

Previous clinical investigations have demonstrated the efficacy and safety of Annurtrofil at a daily dose of 800 mg; however, to broaden its potential applications and support the development of new nutricosmetic claims, it is important to evaluate efficacy and safety at a lower dosage (400 mg/day). This strategy is consistent with current market needs, including improved consumer accessibility and compliance, greater flexibility in formulation development (such as potential synergistic combinations with other bioactives), and the generation of additional clinical evidence to support claims specifically related to hair, skin, and oxidative stress management.

The present study is therefore designed to further characterize the safety profile of Annurtrofil at a reduced dosage and to evaluate its efficacy on clinically relevant endpoints related to the well-being and aesthetic quality of hair. To provide robust and comparative evidence, the study will include three parallel arms: Annurtrofil at the reference dose of 800 mg/day, Annurtrofil at the reduced dose of 400 mg/day, and placebo. This design will allow a direct assessment of the dose–response relationship, while also confirming the reproducibility of the efficacy previously documented at 800 mg/day [3]. The comparison with placebo will ensure the validity of the findings and highlight the specific contribution of the active product. The results are expected to generate clinical evidence, addressing both scientific and regulatory needs, while also strengthening the commercial positioning of Annurtrofil in the nutricosmetic field.

1. Benedetto N, Mangieri C, De Biasio F, Carvalho RF, Milella L, Russo D. *Malus pumila* Mill. cv *Annurca* apple extract might be therapeutically useful against oxidative stress and patterned hair loss. *FEBS Open Bio*. 2024.



2. Tenore GC, et al. Annurca Apple Nutraceutical Formulation Enhances Keratin Expression in a Human Model of Skin and Promotes Hair Growth and Tropism in a Randomized Clinical Trial. *Int J Mol Sci.* 2018;19(1):108.
3. De Biasio F, Ielpo A, Santarsiere L, Ivaldi L, Salamone R, Gorgoglione D. A randomized double-blind placebo-controlled clinical trial to evaluate the effect of an Annurca apple supplement formula in androgenic alopecia. *Journal of Applied Cosmetology.* 2023;41(2):28–46.
4. Tenore GC, Campiglia P, Stiuso P, Ritieni A and Novellino E (2013) Nutraceutical potential of polyphenolic fractions from Annurca apple (*M. pumila* Miller cv Annurca). *Food Chem* 140, 614–622. *J Med Food.* 2014.
5. Tenore GC, Caruso D, Buonomo G, et al. A Healthy Balance of Plasma Cholesterol by a Novel Annurca Apple-Based Nutraceutical Formulation: Results of a Randomized Trial. *J Med Food.* 2017 Mar 1;20(3):288–300.
6. Lee YI, Ham S, Lee SG, Jung I, Suk J, Yoo J, Choi SY, Lee JH. An Exploratory In Vivo Study on the Effect of Annurca Apple Extract on Hair Growth in Mice. *Curr Issues Mol Biol.* 2022;44:6280–6289.
7. D'Angelo S, et al. Protective Effect of Annurca Apple Extract Against Oxidative Damage in Human Erythrocytes. *Current Nutrition & Food Science.* 2015;11(3). doi:10.2174/1573401311666150610210529.

3. OBJECTIVES

3.1. Primary objective

The primary objective of this study is to evaluate the efficacy of the product in improving hair structure, shine, and growth.

Primary end-points:

- Hair gloss (A.U.)
- Phototricogram parameters:
 - Hair density (number/cm²)
 - Anagen hair density (number/cm²)
 - Telogen hair density (number/cm²)
 - Anagen hair (%)
 - Telogen hair (%)
 - Anagen/Telogen ratio
 - Hair vellus density (number/cm²)
 - Terminal hair density (number/cm²)
 - Hair thickness (µm)
- Hair elasticity (%)
- Hair shine (score from 1 to 5)
- Hair structure (score from 1 to 12)
- Keratin content (µg/mL)

3.2. Secondary objectives

The secondary objective of this study is to evaluate the efficacy and pleasantness of the product as perceived by the subjects, improvements in overall scalp condition, and the safety of use.

Secondary end-points:

- Self-evaluation questionnaire (multiple choice questions / numerical rating scale from 1 to 10)
- Overall scalp condition (score from -3 to +3)
- Blood analysis:
 - Complete blood count (Red Blood Cells, Leukocyte Count, Hemoglobin, Hematocrit, Platelets)
 - Lactate dehydrogenase (LDH)
 - GOT transaminase (AST)
 - GPT transaminase (ALT)
 - Alkaline phosphatase
 - Creatinine
 - Total cholesterol
 - HDL cholesterol
 - LDL cholesterol



- Triglycerides
- Fasting glucose
- TSH Reflex
- Prothrombin time (PT)
- Activated partial thromboplastin time (APTT)

4. STUDY DESIGN

The study will be a randomized, double-blind, placebo-controlled, parallel-group trial.

Participants will be randomly assigned, in equal proportions (1:1:1), to one of three treatment groups.

One third of the subjects (Group 1) will receive the active product at the higher dose (two capsules of 400 mg each, for a total daily dose of 800 mg/day). Another third (Group 2) will receive the active product at the lower dose (one 400 mg active capsule and one placebo capsule, for a total daily dose of 400 mg/day). The remaining third (Group 3) will receive two placebo capsules per day. All participants will take the assigned treatment once daily, for a total duration of 168 consecutive days, following the directions for use.

4.1. Randomization

A restricted randomization list will be generated by an independent technician using the appropriate algorithm ("Wei's urn") of the PASS 11 software (PASS, LLC. Kaysville, UT, USA) and stored in a secure location. In order to ensure a balanced allocation by sex, the randomization will be stratified so that male and female participants are equally distributed among the low-dose active group, the high-dose active group, and the placebo group. The Principal Investigator or designated personnel will dispense the products according to the generated randomization list.

4.2. Blinding

The study will be double-blind, meaning that subjects, Principal Investigator and collaborators are kept masked to products assignment. The products will be supplied in the same packaging with no obvious differences between the products (see Annex 1).

5. INVESTIGATIONAL PRODUCTS

5.1. Composition

Active product

Annurtrofil[®]*, magnesium stearate, silicon dioxide;

White size 0 capsule (hydroxypropyl methylcellulose, purified water, and zinc oxide).

*Annurca apple fruit dry extract

Allergens

Not present

Placebo

Cellulose, maltodextrin, magnesium stearate, silicon dioxide;

White size 0 capsule (hydroxypropyl methylcellulose, purified water, and zinc oxide).

Allergens

Not present

The food supplements are compliant to the current national and international legislation (The sponsor is responsible for providing a statement to this regard).

5.2. Dosage and direction of use

Group 1: subjects will take two capsules of the active product once daily, in the morning on an empty stomach.

Group 2: subjects will take one capsule of the active product and one capsule of the placebo once daily, in the morning on an empty stomach.

Group 3: subjects will take two capsules of the placebo once daily, in the morning on an empty stomach.

In addition, all subjects will be provided with a neutral shampoo to be used throughout the study with the following composition:



INGREDIENTS: AQUA (WATER), SODIUM LAURETH SULFATE, COCAMIDOPROPYL BETAINE, DECYL GLUCOSIDE, COCO GLUCOSIDE, SODIUM CHLORIDE, CITRIC ACID, GOSSYPIUM HIRSUTUM (COTTON) SEED OIL, GLYCERIN, GUAR HYDROXYPROPYLTRIMONIUM CHLORIDE, GLYCERYL OLEATE, GLYCOL DISTEARATE, DICAPRYLYL ETHER, HYDROGENATED CASTOR OIL, SODIUM BENZOATE, BENZOIC ACID, PARFUM (FRAGRANCE).

5.3. Supply and storage

The products will be supplied by the Sponsor.

If shipped without a pallet, the delivery address is: Complife S.r.l., Via Monsignor Angelini, 21 - 27028, S. Martino Siccomario (PV), Italy.

If shipped on a pallet, the delivery address is: Complife S.r.l., Via Guido Rossa, 1, 20024 - Garbagnate Milanese (MI), Italy.

The contact person is Sabrina Martinazzo (@: segreteriapavia@complifegroup.com; T: +39 0382 25504).

The product will be stored in a cool, dry place, protected from direct light, heat, and moisture, in a secure area with restricted access.

6. STUDY POPULATION

6.1. Sample size

The study will be performed on 132 (120 + 12, considering a 10% drop-out) subjects.

6.1. Subjects' enrolment

Subjects are enrolled according to specific inclusion and exclusion criteria listed in the sections below.

All inclusion and exclusion criteria are checked by the Principal Investigator or designated personnel. The Principal Investigator maintains a record of all subjects who are enrolled and who are considered screen-failed (i.e., subject who signs the informed consent form and is not enrolled) and for each subject, the primary reason for not enrolling is recorded. Subjects enrolled are identified by a unique code that remains personal and cannot be associated to another subject during the study.

6.1.1. Inclusion criteria

1. Healthy female and male subjects (50% per gender in each group)
2. Subjects of Caucasian ethnicity
3. Subjects aged between 18 and 60 years (extremes included)
4. Subjects with mild to moderate damaged hair (Total hair damage score based on exposure to risk factors <18)*
5. Subjects with hair shine ranging from luster-less to lustrous (scores 1–3 on the 5-point Visual Shine Scale)**
6. Subjects who commit to refraining from the use of any specialized hair products or topical depilatory agents throughout the study
7. Subjects who commit to not manipulating their hair, while maintaining their usual hairstyle during the study
8. Subjects who commit to using a neutral shampoo during the 2-week washout period prior to the experimental phase and throughout the entire study
9. Subjects registered with National Health Service (NHS)
10. Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel
11. Subjects able to understand the language used in the investigation centre and the information given by the Principal Investigator or designated personnel
12. Subjects able to respect the instructions given by the Principal Investigator or designated personnel as well as able to respect the study constraints and specific requirements
13. Subjects who commit not to change the daily routine and lifestyle during the study
14. Stable pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) for at least one month without any changes expected or planned during the study
15. Subjects informed about the test procedures who have signed a consent form and privacy agreement

*Hair damage is evaluated using a scoring system based on the frequency of exposure to specific damaging practices and environmental factors. Each behaviour is assigned a point value according to its frequency of occurrence (see table below). The total score is then used to classify the extent of hair damage.

BEHAVIOR / TREATMENT	1 OR MORE TIMES / 6 WEEKS	1 TIME / 6 WEEKS TO 3 MONTHS	LESS THAN ONCE / 3 MONTHS
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Bleaching	+10 points	+5 points	+1 point
Perming	+10 points	+5 points	+1 point
Coloring	+10 points	+5 points	+1 point
Hair cut	-3 points	-2 points	-1 point
BEHAVIOR / TREATMENT	5 OR MORE TIMES / WEEK	1-5 TIMES / WEEK	LESS THAN ONCE / WEEK
Flat iron	+5 points	+3 points	+1 point
Blow dry	+3 points	+2 points	+1 point
Combing / brushing	+3 points	+2 points	+1 point
Washing	+3 points	+2 points	+1 point
Deep conditioning treatment	-5 points	-3 points	-1 point
Rinse-off conditioner	-3 points	-2 points	-1 point
Heat protection spray	-3 points	-2 points	-1 point
BEHAVIOR / TREATMENT	5+ HOURS / DAY	1-5 HOURS / DAY	LESS THAN 1 HOUR / DAY
Sun exposure	+5 points	+3 points	+1 point

Total score interpretation: Less than 7: Mild damage; 7 to 18: Moderate damage; 18 or more: Severe damage.

****Visual evaluation is performed by the Principal Investigator or designated qualified personnel using a 5-point scale, as follows:**

- 1 = Luster-less (little to no shine)
- 2 = Somewhat luster-less (slightly lacking shine)
- 3 = In-between (normal shine)
- 4 = Somewhat lustrous (slightly shiny)
- 5 = Lustrous (very shiny)

6.1.2. Exclusion criteria

1. Subjects who do not meet the inclusion criteria
2. Subjects with scalp or hair diseases (e.g.: scalp psoriasis, eczema, and seborrheic dermatitis) or other causes of hair loss, including androgenetic alopecia, alopecia areata, or other clinically significant alopecia conditions
3. Subjects who are taking oral contraceptives
4. Subjects with any acute, chronic, or progressive disease or condition that may interfere with the study data or that the Principal Investigator considers dangerous to the subject or incompatible with the requirements of the study ***
5. Subjects participating or planning to participate in other clinical trials
6. Subjects who participated in a similar study without respecting an adequate washout period (at least three month)
7. Subjects that have food intolerances or food allergies to ingredients of the study product
8. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the Principal Investigator ****
9. Subjects who are currently using food supplement(s) and/or products with the same activity as the study product, or who haven't observed an adequate washout period (at least three month)
10. Subjects admitted to a health or social facility
11. Subjects planning a hospitalization during the study
12. Subjects not able to be contacted in case of emergency
13. Subjects deprived of freedom by administrative or legal decision or under guardianship
14. Subjects who have or have had a history of alcohol or drug addiction
15. Subjects with eating disorders (i.e. bulimia, psychogenic eating disorders, etc.)
16. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential).



***AST or ALT > 2 × UNL (Upper Normal Limit);
hepatitis, liver cirrhosis, fatty liver requiring treatment;
serum creatinine > 2 × unL, chronic renal failure, kidney disease requiring dialysis;
hypertension;
diabetes mellitus;
known malignancy within the past 5 years;
clinically relevant psychiatric conditions;
infectious skin conditions;
autoimmune diseases.

**** use of topical hair growth agents within the past month;
Application of steroid preparations to the scalp within the past month;
use of any of the following drugs within the past month: steroids, cytostatics, vasodilators, antihypertensives, anticonvulsants, beta-receptor blockers, bronchodilators, diuretics, spironolactone, cimetidine, diazoxide, cyclosporine, ketoconazole, or other agents known to affect hair growth;
use of oral antiandrogens (e.g., dutasteride, finasteride) within the last 6 months;
use of any medication known to interfere with hair growth within the past 3 months;
use of chemotherapeutic;
use of biologic medicines.

6.2. Subject withdrawal and discontinuation

In compliance with the Declaration of Helsinki, subjects have the right to withdraw from the study at any time and for any reason. In all cases, the Principal Investigator or designated personnel should try to contact the subject as soon as possible for a final assessment to: i) document the subject's decision on the informed consent form, ii) record the reason(s) for withdrawal on the data collection sheet, iii) evaluate the subject's clinical condition, if relevant iv) provide appropriate therapeutic measures if necessary (e.g., management of adverse events or concomitant conditions), v) collect any investigational product provided to the subject.

If a subject misses a scheduled visit, the Principal Investigator or designated personnel will attempt to contact the subject by phone on two separate occasions. If the subject cannot be reached after these attempts, they will be considered lost to follow-up. These contact attempts and their outcomes will be documented in the source document. The Principal Investigator may also decide to withdraw a participant from the trial early if the subject no longer meets the eligibility criteria, fails to comply with the protocol, or is deemed unsuitable to continue the study. This may occur, for example, in the event of illness, pregnancy, or the occurrence of an Adverse Event (AE) or Serious Adverse Event (SAE), particularly if the Principal Investigator considers that the subject's health may be at risk or if concomitant treatments required are incompatible with the continuation of the trial. In such cases, the Sponsor will be notified immediately, and a detailed report explaining the reason for withdrawal will be forwarded as soon as possible. Any early termination related to an AE or SAE will be monitored until its resolution.

The sponsor has the right to exclude any subject from the trial for major protocol violations, administrative reasons, or other justifiable reasons.

However, a high dropout rate may compromise or invalidate the interpretability of the study. Therefore, premature exits without valid reasons should be minimized and carefully documented in the case report form, the final report, and, if applicable, in the AE form. Each premature exit will be categorized as follows: i) violation of inclusion and exclusion criteria, ii) occurrence of an AE, iii) occurrence of an SAE, iv) withdrawal of consent, v) lost to follow-up, vi) non-adherence to the protocol, vii) other reason (to be clearly specified).

Withdrawn/lost to follow-up/drop-out subjects will not be replaced.

Further details regarding safety reporting and management are provided in Paragraph 10.

6.3. Subject full participation

Study completion is achieved when a subject has completed all treatment and has attended all scheduled visits.

7. ETHICAL CONSIDERATIONS

7.1. Risk and benefit

The food supplement administered in this study is in compliance with current food legislation and is composed of ingredients with a well-established history of safe use in humans.



No adverse effects are expected under the indication of use. However, as with any food product, the possibility of individual reactions cannot be completely excluded. If applicable, information regarding the presence of any substances that may cause hypersensitivity will be provided prior to participation.

The potential benefits associated with the use of the product are related to improvement in overall hair condition, including structure, shine, and growth.

7.2. Compliance with the Declaration of Helsinki

The study will be conducted in accordance with the ethical principles for the medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amendments).

7.3. Informed Consent

During the recruitment phase, the Principal Investigator or designated personnel will explain to each subject the nature, purpose, potential benefits, and possible risks of participation in the study. The investigator must ensure that the subject has understood all relevant aspects of the study. Sufficient time will be provided to allow questions to be asked and answered.

After this discussion, subjects will be asked to carefully read and sign the study information sheet, the informed consent form, and the privacy agreement pursuant to art. 13 of EU Regulation 2016/679.

The informed consent form, approved by the Sponsor, will be prepared in two versions: a version in English and a version in the local language, written in terms readily understandable to the subject. Only the version in the local language will be presented to and signed by study participants.

The informed consent form, approved by the Sponsor, will contain all required elements in language that is readily understandable to the subject. Each original consent form, personally signed and dated by both the subject and the investigator conducting the consent discussion, will be retained by the investigator. A copy will be provided to the subject. Subjects will be informed that they have the right to withdraw their consent.

The consent form may need to be revised during the study, either because important new information has become available that may be relevant to the safety of the subjects, or because of protocol amendments. It is the investigator's responsibility to ensure that the amended form is signed by all subjects who are subsequently entered into the study, as well as by those who are already in it. This is documented in the same way as previously described.

7.4. Confidentiality and Data Protection

All information, data, and results of the study are strictly confidential, and all individuals with access to such data are informed of this obligation.

In accordance with the applicable law on data protection (EU Regulation 679/2016), the personal data, which may be special, including date of birth, sex, race, etc., the information resulting from clinical studies and on health status are processed in confidence, only for research purposes in relation with this study. If the results arising from the clinical study should be published or disseminated in scientific journals or conferences, this is done in a manner that preserves confidentiality. For this purpose, relevant subject data may be forwarded to the Sponsor or its partners abroad. In each case, subject data will be pseudonymised and identified only by a code number and initials. The Principal Investigator will be responsible for maintaining the list of codes that links each subject's number with their identity.

In all cases, nominative information shall not be transmitted to the Sponsor. If a subject's name appears on a document required by the Sponsor (e.g., photographs), the name will be permanently blacked out by the site personnel, leaving only the initials visible and annotating the subject number for identification.

The data will remain strictly confidential and will not be made public. However, at any time during or after the study, health authorities may be granted direct access to the records to verify the accuracy of the collected information. In such cases, subject identity may be disclosed. All individuals granted access to these records are bound by professional secrecy.

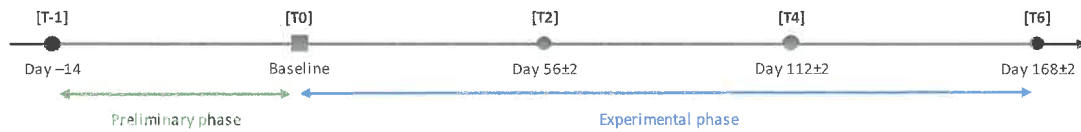
8. STUDY SCHEDULE AND PROCEDURES

The study will last 168 ± 2 days. Clinical visits are planned at T-1 (initial visit), T0 (baseline visit), T2 (follow-up visit, after 56 ± 2 days of treatment), T4 (follow-up visit, after 112 ± 2 days of treatment) and at T6 (final visit, after 168 ± 2 days of treatment).



8.1 Timeline diagram

A schematic flow diagram is provided below:



8.2. Summary of study visits and procedures

The following table summarizes the planned visits and procedures:

Procedures	T-1	T0	T2	T4	T6
Verification of subject eligibility	X	X	X	X	X
Signature of informed consent and privacy statement	X	-	-	-	-
Collection of subjects' demographic data and variables relevant to eligibility assessment	X	-	-	-	-
Distribution of neutral shampoo	X	-	-	-	-
Randomization to treatment	-	X	-	-	-
Distribution of products	-	X	X	X	-
Measurement of hair gloss	-	X	X	X	X
Execution of phototrichogram	-	X*	X*	X*	X*
Measurements of hair elasticity	-	X	X	X	X
Assessment of hair shine	-	X	X	X	X
Assessment of hair structure	-	X	X	X	X
Measurement of keratin content	-	X	X	X	X
Assessment of overall scalp condition	-	X	X	X	X
Completion of the self-assessment questionnaire by subjects	-	-	X	X	X
Blood analysis	-	X**	-	-	X**
Collection and counting of products	-	-	X	X	X
Monitoring of Tolerability	-				

*A follow-up visit is scheduled 48 hours after the visit for the assessment of phototrichogram parameters (for details see paragraph 10.2).

**Blood analyses are performed in the morning following the visit.

8.3. Preliminary phase: T-1 (Initial visit)

Subjects to be enrolled will be screened in the volunteer's database by appropriate personnel (authorized by the investigator, pursuant to and for the effects of the legislation on protection of personal data) and invited to participate in the study.

At the first visit, the Principal Investigator or designated personnel will assess whether each participant meets all inclusion and exclusion criteria and collect the subject's demographic data together with the variables relevant to eligibility assessment. Subjects will be informed of the study procedure and will be asked to sign an informed consent form and an authorization for the personal data treatment.

Subjects will be provided with a neutral shampoo to be used during the subsequent two-week washout period and throughout the entire experimental phase.

The Principal Investigator or designated personnel will set the date of the baseline visit.

8.4. Experimental phase: T0 (Baseline visit)

Following two weeks of washout, the Principal Investigator or designated personnel will assess whether each participant still meets all inclusion and exclusion criteria.

Measurement of hair gloss and phototrichogram analysis procedures will be performed.



Assessment of hair shine and overall scalp condition and will be performed.

Hair will be collected for measurement of hair elasticity, assessment of hair structure and measurement of keratin content assay.

According to the previously defined randomization list, 44 subjects assigned to Group 1 will receive a sufficient quantity of products to take the active product at the higher dose (two capsules per day) for at least 56 days of treatment. 44 subjects assigned to Group 2 will receive a sufficient quantity of products to take the active product at the lower dose (one active capsule and one placebo capsule per day) for at least 56 days of treatment. Finally, 44 subjects assigned to the placebo group will receive a sufficient quantity of products to take two placebo capsules per day for at least 56 days of treatment.

Each participant will take one capsule from each of two separate containers per day, for a total of 168 consecutive days. Participants in Group 1 will take capsules from two containers both containing the active product; participants in Group 2 will take capsules from one container containing the active product and one containing the placebo; and participants in Group 3 will take capsules from two containers both containing the placebo. (See Annex 1 for details).

Subjects will be advised to bring back the advanced products at the next follow-up visit.

The Principal Investigator or designated personnel will set the date of the follow-up visit.

On the following morning, while fasting and prior to product intake, subjects will undergo blood tests at an external partner facility.

After 48 hours, the volunteers will return to the study centre for assessments related to the phototrichogram procedures.

8.5. Experimental phase: T2 (follow-up visit - after 56 ± 2 days)

After 56 days (± 2 days) of product intake subjects will be visited by the Principal Investigator or designated personnel. The Principal Investigator or designated personnel will assess whether each participant still meets all inclusion and exclusion criteria.

Measurement of hair gloss and phototrichogram analysis procedures will be performed.

Assessment of hair shine and overall scalp condition and will be performed.

Hair will be collected for measurement of hair elasticity, assessment of hair structure and measurement of keratin content assay.

Recruited subjects will complete the self-assessment questionnaire.

To assess the compliance, unused products will be collected and counted. Subjects will receive enough amount of the same products for at least other 56 days of treatment, and they will be advised to bring back the advanced products at the next visit.

The Principal Investigator or designated personnel will set the date of the next follow-up visit.

After 48 hours, the volunteers will return to the study centre for assessments related to the phototrichogram procedures.

8.6. Experimental phase: T4 (follow-up visit - after 112 ± 2 days)

After 112 days (± 2 days) of product intake subjects will be visited by the Principal Investigator or designated personnel. The Principal Investigator or designated personnel will assess whether each participant still meets all inclusion and exclusion criteria.

Measurement of hair gloss and phototrichogram analysis procedures will be performed.

Assessment of hair shine and overall scalp condition and will be performed.

Hair will be collected for measurement of hair elasticity, assessment of hair structure and measurement of keratin content assay.

Recruited subjects will complete the self-assessment questionnaire.

To assess the compliance, unused products will be collected and counted. Subjects will receive enough amount of the same products for at least other 56 days of treatment, and they will be advised to bring back the advanced products at the next visit.

The Principal Investigator or designated personnel will set the date of the next follow-up visit.

After 48 hours, the volunteers will return to the study centre for assessments related to the phototrichogram procedures.



8.7. Experimental phase: T6 (follow-up visit - after 168 ± 2 days)

After 168 days (± 2 days) of product intake subjects will be visited by the Principal Investigator or designated personnel. The Principal Investigator or designated personnel will assess whether each participant still meets all inclusion and exclusion criteria.

Measurement of hair gloss and phototrichogram analysis procedures will be performed.

Assessment of hair shine and overall scalp condition and will be performed.

Hair will be collected for measurement of hair elasticity, assessment of hair structure and measurement of keratin content assay.

Recruited subjects will complete the self-assessment questionnaire.

To assess the compliance, unused product samples will be collected and counted.

On the following morning, while fasting, subjects will undergo blood tests at an external partner facility.

After 48 hours, the volunteers will return to the study centre for assessments related to the phototrichogram procedures.

NOTES:

The tolerability of the product will be monitored through the reporting of adverse events throughout the entire duration of the study (see paragraph 11).

9. TREATMENT COMPLIANCE

The Principal Investigator and designated personnel will keep a record of products given to subjects and unused products received by subjects during the visits.

Any returned product will be destroyed according to current internal procedures.

Compliance will be calculated as follows:

$$\text{Compliance to treatment} = \frac{\text{number of intake product}}{\text{number of product to intake}} \times 100$$

Subjects will be defined as compliant if they use 80 –120% of the treatment regimen over the 168-day period.

10. ENDPOINTS

10.1. Hair gloss

Hair gloss (radiance) is assessed using a spectrophotometer/colorimeter CM 700D (Konica Minolta). The 8° gloss parameter is measured, representing light reflection at an 8° angle, and expressed in arbitrary units (A.U.).

10.2. Phototrichogram

The procedure consists of the following steps:

1. Clipping: A scalp area located approximately two finger widths away from the parting line on the parietal-occipital region is clipped using a trimmer. A template (Ø 1.8 cm) is used to standardize the area.
2. Hair removal: The clipped hair are removed with adhesive tape.
3. Imaging: A dermatoscopic photograph of the clipped area is taken 48 hours after hair clipping.

The following hair cycle related parameters are measured using the TrichoScan® software:

- Hair density (number/cm²)
- Anagen hair density (number/cm²)
- Telogen hair density (number/cm²)
- Anagen hair (%)
- Telogen hair (%)
- Anagen/Telogen ratio
- Hair vellus density (number/cm²)
- Terminal hair density (number/cm²)
- Hair thickness (µm)



10.3. Hair elasticity

Hair elasticity is measured using a dynamometer (C610 Autotensile Tester, LabThink) as the maximum elongation before hair breakage. The dynamometer reading is done on a single hair, setting the instruments as follows: elongation velocity: 50 mm/min; pre-tension: 5 Cn.

Ten hair are collected and measured and the average elasticity is calculated. Data are expressed in % of elongation.

10.4. Hair shine

Visual evaluation is performed by the Principal Investigator and/or designated qualified personnel using a 5-point as follows:

- 1 = Luster-less (little to no shine)
- 2 = Somewhat luster-less (slightly lacking shine)
- 3 = In-between (normal shine)
- 4 = Somewhat lustrous (slightly shiny)
- 5 = Lustrous (very shiny)

10.5. Hair structure

Hair morphology is assessed using Scanning Electron Microscopy (SEM), focusing on the first few centimetres of newly grown hair from the bulb. The evaluation is conducted by the Principal Investigator or designated qualified personnel. It is a qualitative assessment based on the condition of the cuticle, the outermost layer of the hair shaft, composed of overlapping scales: a uniform cuticle with closed scales indicates healthy hair, whereas lifted or opened scales indicate damage. Hair structure is assessed by the investigator using the following 12-point scale

1. Intact hair
2. Irregular overlay only
3. Very gentle lifting up on the edge
4. Crevices due to visibly lifting up on the edge
5. Overall lifting up of cuticle layers and slightly crack or hole form
6. Severe lifting up, crack and hole form
7. Began to slightly desquamation process of severe lifting up of cuticle layers
8. Partially visible desquamation form
9. Overall severe desquamation form
10. Began to exposure the cortex and rest the one-third of cuticle layers
11. Partially exposing of the cortex and rest the half of cuticle layers
12. Exposing of the cortex without cuticle layers

10.6. Keratin content

Collected hair samples undergo an *in vitro* analysis. They are solubilised overnight in a 37% HCl solution, a process that breaks down the hair structure and releases keratin into solution for subsequent quantification. The acid hair solutions are then evaluated for their keratin content using the Lowry et al. (1951) colorimetric assay. This method is based on the principle that, under alkaline conditions, Cu⁺ ions form complexes with proteins and catalyze the oxidation of tyrosine and tryptophan residues. The resulting reaction reduces the Folin–Ciocalteu reagent, causing a colour change from yellow to blue. The intensity of the colour is proportional to the protein content and is quantified by interpolation against a standard curve prepared with known keratin concentrations. Results are expressed as µg/mL.

10.7. Self-assessment

The self-evaluation questionnaire consists of 15 questions designed to assess the perceived efficacy and pleasantness of the product. Seven questions are answered using a 1–10 rating scale, while eight questions are multiple-choice, with the option to add a free-text comment (see Annex 2).

10.8. Overall scalp condition

By observing scalp images captured with a dermatoscope, the Principal Investigator or designated qualified personnel evaluates both the mildness of the product and its efficacy on scalp discomfort reported at baseline. Global efficacy is rated using a 7-point Likert scale, with changes from baseline defined as: -3 = greatly worsened, -2 = moderately



worsened, -1 = slightly worsened, 0 = no change, +1 = slightly improved, +2 = moderately improved, +3 = greatly improved.

10.9. Tolerability assessment endpoints

Blood samples will be collected in the fasting state to monitor product tolerability and to evaluate key clinical safety parameters, including hematological profile, liver and kidney function, metabolic status, coagulation, and endocrine balance.

Hematological profile

- Complete Blood Count (CBC):
 - Red blood cells
 - Leukocyte count
 - Hemoglobin
 - Hematocrit
 - Platelets

Liver function

- Alanine aminotransferase (ALT)
- Aspartate aminotransferase (AST)
- Alkaline phosphatase (ALP)
- Lactate dehydrogenase (LDH)

Kidney function

- Creatinine

Carbohydrate metabolism

- Fasting glucose

Lipid metabolism

- Total cholesterol
- LDL-C
- HDL-C
- Triglycerides (TG)

Coagulation function

- Prothrombin time (PT)
- Activated partial thromboplastin time (APTT)

Endocrine function

- Thyroid-stimulating hormone (TSH reflex)

11. SAFETY ASSESSMENT

The tolerability of the product will be closely followed by the study Principal Investigator during the study. Subjects will have access to the investigator via a contact phone number provided with the study information sheet in case of intolerance reactions. If a subject reports an event, the Principal Investigator will establish whether it is product-related. If so, report it as an adverse reaction. Any unexpected side effects related to the product will be reported to the sponsor. At the investigator's discretion, the subject may be withdrawn from the study, in which case the side effect will be monitored until it is resolved.

11.1. Causality assessment

There are five levels of causality that can be used to determine whether the event is related to the product.

- Very likely

Clinical signs suggest a link with the product. The reaction follows a clear temporal sequence in relation to the time of product use and rechallenge is positive.

- Likely

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

- 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 intake and rechallenge is negative. 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 intake 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 intake 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 intake and rechallenge is positive.

- 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 intake 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 intake 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 intake and rechallenge is negative.

- Excluded

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

11.2. Recording and evaluation of adverse reactions

For each sign, intensity, location, duration (hours, minutes), and frequency are 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 on the first day of the study), a reaction is recorded. All the reactions observed by the specialist and reported by the subject are recorded. The following information are recorded: i) subject characteristics, ii) details about study product (product code or name, date of first use, way of use), iii) description of the reaction (functional and physical signs, intensity of the signs, location, date/time of onset, timeframe between product use 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, medical treatments, products application, food, external factors (weather conditions), other diseases, vi) outcome and actions taken (way of use modification, temporary interruption, definitively discontinuation, medical treatment, care), and viii) relationship to the product (causality assessment). This assessment is done in conjunction with clinical expertise, and knowledge of the product (type of product, conditions of use...).

11.3. Documentation of Adverse Event and Serious Adverse Event

All Adverse Events considered likely to be related to the study product, as well as all Serious Adverse Events, will be documented in the data collection sheet and included in the report of the study. If no Adverse Events occur, the report will explicitly state that no side effects were observed during the study.

11.4. Notification to the Sponsor

Any adverse events occurring during the study or after the study will be reported to the Sponsor's vigilance officer by e-mail (Dr. Arianna Vanelli: Arianna.Vanelli@evra-ingredients.com) with a copy to the project manager, using the appropriate notification forms. Serious adverse events will be reported within 24 hours of observation, and adverse events related to the product will be reported as soon as possible. If pictures of the reactions are available, these will be included in the notification.



11.5. Follow-up procedures

Any adverse events or serious adverse events related to the product will be followed up until they are resolved or stabilised. To inform the sponsor's vigilance officer of any new information, the investigator will use the appropriate forms, which will be filled in with the results collected from the examination carried out. Reports of hospitalisation will be enclosed with the notification form.

11.6. Definitions

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.

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.

12. DATA HANDLING AND RECORD KEEPING**12.1. Data collection**

Data will be recorded in paper and/or electronic data collection sheets. The Principal Investigator, or appropriately qualified staff authorized by the Investigator, will be responsible for completing the data collection sheets. Paper forms will be completed in blue ballpoint pen, while electronic data capture will be performed using Microsoft® Office 365. The Principal Investigator will review the data collection sheets and all adverse event reporting forms, attesting to the accuracy and completeness of the information. Any corrections made to the data collection sheets or source documents must be performed by the responsible staff member or an authorized delegate in a manner that does not obscure the original entry. For paper forms, all corrections must be dated and initialled by study site personnel. For electronic data capture, all modifications will be automatically tracked. Where the reason for a correction is not self-evident, an explanatory note must be provided.

Data entry and quality control will be performed by two different persons. The Principal Investigator remains ultimately responsible for all recorded data.

In line with Good Clinical Practice, the following definitions apply to clarify the nature and origin of recorded information:

- **Source Data:** all original records and certified copies of original records of clinical findings, observations, or other activities necessary for the reconstruction and evaluation of the trial. Source data are contained within source documents (i.e., original records or certified copies).
- **Source Documents:** original documents, data, and records, such as subject files, data collection sheets, notes, or evaluation checklists.

12.2. Quality assurance

All study-related files (including data collection sheets, the protocol, results, the final report, and other study documents) are subject to quality assurance procedures in compliance with regulatory requirements. Investigating sites authorize inspections by Regulatory Authorities and audits or controls by the Sponsor, granting access to raw data as needed.

12.3. Archiving and Retention

An original copy of all study documentation (signed protocol, Sponsor's safety assessment letter, case report forms, raw data, administrative file including all correspondence, etc.) will be retained in the records of Complife Srl for 10 years. The archives will only be destroyed after receipt of written and signed authorization from the Sponsor. However, documents will be kept for a longer period if required by applicable regulatory requirements or by agreement with the Sponsor. The Investigator must take appropriate measures to prevent accidental or premature destruction of these documents. Archiving arrangements will be defined at site close-out. The Sponsor will inform Complife Srl in writing when the documents are no longer required to be kept.

13. STATISTIC**13.1. Study population for analysis**

The analysis will be conducted on the Per Protocol population. The per-protocol (PP) population is defined as all subjects who will complete the study without any major protocol violations. Subjects will be 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 reported by the subject itself).

Any drop-outs and the reason for each drop-out will be reported in the final report.

13.2. Descriptive analysis

Demographic data and eligibility variables will be collected and reported in a Microsoft® Excel spreadsheet together with the randomization list and will be summarized using: i) mean value and/or median value; ii) standard error and/or interquartile range; iii) minimum value; iv) maximum value.

Endpoint variables will be recorded in a Microsoft® Excel spreadsheet, graphically represented, and analysed using: i) mean value and/or median value; ii) standard error and/or interquartile range; iii) minimum value; iv) maximum value; v) individual variation or percentage variation versus baseline; vi) mean and/or median variation versus baseline.

The data from the self-evaluation questionnaire will be reported as follows: i) the median value for questions with a 1–10 scoring scale; ii) the frequency distribution (percentage of subjects) for questions with multiple-choice answers.

13.3. Inferential statistical analysis

To assess the efficacy of the product, inferential statistical analyses will be performed on the endpoints, with the exception of the self-evaluation questionnaires.

For each endpoint, depending on the data distribution, appropriate parametric (e.g., two-way mixed ANOVA) or non-parametric (e.g. Friedman test, Wilcoxon signed-rank test, Mann–Whitney U test,) methods will be applied to compare active placebo groups and to evaluate their effect over time.

No inferential analysis by subgroup (e.g., sex, age) will be performed.

The significance level (α) will be set at 0.05 (two-sided). Where applicable, adjustments for multiple comparisons (e.g., Bonferroni correction) may be applied.

Statistical analysis will be performed using NCSS 10 data analysis (Copyright © 1983-2015, NCSS, LLC.) or RStudio (Copyright © 2009-2025 Posit Software, PBC).

14. ADMINISTRATIVE ASPECTS

14.1. Publication policy

The results of the study as well as any other data disclosed or generated in the context of the study are confidential. Any publication in relation to the study shall be subject to Sponsor's prior written approval and authorization of the Principal Investigator of the study.

14.2. Contractual and financial agreements

The Principal Investigator and the Sponsor sign a clinical study agreement prior to the start of the study, outlining overall sponsor and investigator responsibilities in relation to the study. Financial remuneration covers the cost per included subject, based on the calculated costs of performing the study assessments in accordance with the protocol, and the terms of payment are described in the contract.

14.3. Insurance

Product liability insurance may be provided by the Sponsor.



ANNEX 1- Labelling

Complife SrL will affix on each product the following labels:

GROUP 1:

Integratore alimentare	
Prodotto A1 N° lotto: IT25003A Data di scadenza: 07/2027 IT0005615-25 Modo d'uso: assumere una capsula al giorno, insieme a una capsula di Prodotto A2, al mattino a stomaco vuoto	Complife SrL Compilife S.r.l., Via Monsignor Angelini, 21 - 27028, S. Martino Siccomario (PV), Italy
Utilizzare in accordo con il modo d'uso Campione solo per test	
AVVERTENZE: -	

Integratore alimentare	
Prodotto A2 N° lotto: IT25003A Data di scadenza: 07/2027 IT0005615-25 Modo d'uso: assumere una capsula al giorno, insieme a una capsula di Prodotto A1, al mattino a stomaco vuoto	Complife SrL Compilife S.r.l., Via Monsignor Angelini, 21 - 27028, S. Martino Siccomario (PV), Italy
Utilizzare in accordo con il modo d'uso Campione solo per test	
AVVERTENZE: -	

GROUP 2:

Integratore alimentare	
Prodotto B1 N° lotto: IT25003 Data di scadenza: 07/2027 IT0005615-25 Modo d'uso: assumere una capsula al giorno, insieme a una capsula di Prodotto B2, al mattino a stomaco vuoto	Complife SrL Compilife S.r.l., Via Monsignor Angelini, 21 - 27028, S. Martino Siccomario (PV), Italy
Utilizzare in accordo con il modo d'uso Campione solo per test	
AVVERTENZE: -	

Integratore alimentare	
Prodotto B2 N° lotto: Data di scadenza: IT0005615-25 Modo d'uso: assumere una capsula al giorno, insieme a una capsula di Prodotto B1, al mattino a stomaco vuoto	Complife SrL Compilife S.r.l., Via Monsignor Angelini, 21 - 27028, S. Martino Siccomario (PV), Italy
Utilizzare in accordo con il modo d'uso Campione solo per test	
AVVERTENZE: -	

GROUP 3:

Integratore alimentare	
Prodotto C1 N° lotto: IT25002 Data di scadenza: 07/2027 IT0005615-25 Modo d'uso: assumere una capsula al giorno, insieme a una capsula di Prodotto C2, al mattino a stomaco vuoto	Complife SrL Compilife S.r.l., Via Monsignor Angelini, 21 - 27028, S. Martino Siccomario (PV), Italy
Utilizzare in accordo con il modo d'uso Campione solo per test	
AVVERTENZE: -	

Integratore alimentare	
Prodotto C2 N° lotto: Data di scadenza: IT0005615-25 Modo d'uso: assumere una capsula al giorno, insieme a una capsula di Prodotto C1, al mattino a stomaco vuoto	Complife SrL Compilife S.r.l., Via Monsignor Angelini, 21 - 27028, S. Martino Siccomario (PV), Italy
Utilizzare in accordo con il modo d'uso Campione solo per test	
AVVERTENZE: -	



ANNEX 2 - Self-Evaluation Questionnaire

N°	Domanda	1	2	3	4	5	6	7	8	9	10
01	Pensi che i tuoi capelli siano danneggiati?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
02	Quando pettini i capelli asciutti, senti resistenza e difficoltà nel pettinarli?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
03	Pensi che i tuoi capelli siano privi di lucentezza?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
04	Pensi che i tuoi capelli si spezzino facilmente?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
05	Pensi che i tuoi capelli siano secchi?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
06	Pensi che i tuoi capelli non siano elastici?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
07	Ritieni che la struttura dei tuoi capelli sia ruvida?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
N°	Domanda	Completamente d'accordo		D'accordo		Neutrale		In disaccordo		Completamente in disaccordo	
08	Il mio cuoio capelluto è lenito	☐		☐		☐		☐		☐	
09	Il mio cuoio capelluto è rinnovato	☐		☐		☐		☐		☐	
N°	Domanda	Completamente d'accordo		D'accordo		Neutrale		In disaccordo		Completamente in disaccordo	
10	Il mio cuoio capelluto è nutrito	☐		☐		☐		☐		☐	
11	Il mio cuoio capelluto è più sano	☐		☐		☐		☐		☐	
N°	Domanda	Molto soddisfatt a/o		Soddisfatta/o		Insoddisfatta/o		Molto insoddisfatta/o			
12	Sei soddisfatta/o del prodotto?	☐		☐		☐		☐			
N°	Domanda	Sì					No				
13	Il prodotto è ben tollerato?	☐					☐				
14	Raccomanderesti il prodotto ad un amico?	☐					☐				
15*	Compreresti il prodotto, indipendentemente dal prezzo?	☐					☐				

15* Se no, perché?



Self-Evaluation Questionnaire – English version

N°	Item	1	2	3	4	5	6	7	8	9	10
01	Do you think your hair is damaged?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
02	When combing your dry hair, do you feel resistance and difficulty in combing it?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
03	Do you think your hair lacks shine?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
04	Do you think your hair breaks easily?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
05	Do you think your hair is dry?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
06	Do you think your hair is not elastic?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
07	Do you think your hair texture is rough?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
N°	Item	Completely agree	Agree	Neutral	Disagree	Completely disagree					
08	My scalp is soothed	☐	☐	☐	☐	☐					
09	My scalp is renewed	☐	☐	☐	☐	☐					
N°	Item	Completely agree	Agree	Neutral	Disagree	Completely disagree					
10	My scalp is nourished	☐	☐	☐	☐	☐					
11	My scalp is healthier	☐	☐	☐	☐	☐					
N°	Item	Very satisfied	Satisfied	Unsatisfied	Very Unsatisfied						
12	Are you satisfied with the product?	☐	☐	☐	☐						
N°	Item	Si	No								
13	Is the product well tolerated?	☐	☐								
14	Would you recommend the product to a friend?	☐	☐								
15*	Would you purchase the product, regardless of the price?	☐	☐								

15* If not, why?

