

**CLINICAL AND INSTRUMENTAL EVALUATION OF THE  
ANTI-AGEING EFFICACY OF A COSMETIC PRODUCT  
Use test under ophthalmological control**

**RIVOLI COSMÉTIQUES SA**

**L'EAU DE JOUR N'02  
Formula code lab-01414.22**

**COMPLIFE Italia S.r.l.**

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

Sedi principali:  
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 | +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 | +39.0382.25504



## KEY PERSONNEL

### Customer

**RIVOLI COSMÉTIQUES SA**  
14 Rue de L'arquebuse  
1204 Genève  
Switzerland

### Dermatologist

**Dr Enza CESTONE**  
Degree in Medicine and Surgery, Specialist in Dermatology and Venereology  
Consultant to Complife Italia S.r.l.

### Ophthalmologist

**Dr Francesco SANDOLO**  
Degree in Medicine and Surgery, Specialist in Ophthalmology  
Consultant Complife Italia S.r.l.

### In vivo data analysis and report

**Dr Ludovica GERMANI**  
Pharmacist  
Complife Italia S.r.l.

### Quality control

**Dr Beatrice TENCONI**  
Biologist  
Complife Italia S.r.l.

### Complife Italia S.r.l.

Complife Italia S.r.l.  
Location  
Via Angelini, 21  
27028 San Martino Siccomario (PV)  
Italy  
tel. +39-0382 25504 fax. +39-0382 536006  
Mail: [info@complifegroup.com](mailto:info@complifegroup.com)



## INDEX

|  |    |
|--|----|
| STUDY DESIGN .....   | 4  |
| 1.1. Title .....   | 4  |
| 1.2. Aim of the study .....                                      | 4  |
| 1.3. Test product.....   | 4  |
| 1.3.1. Information provided by the Customer .....                | 4  |
| 1.4. Ethical requirements .....                                  | 4  |
| 1.5. Subjects participating in the study .....                   | 5  |
| 1.5.1. Subjects' enrolment .....                                 | 5  |
| 1.5.1.1. Inclusion criteria .....                                | 5  |
| 1.5.1.2. Non-inclusion criteria .....                            | 5  |
| 1.5.1.3. Withdrawal of subjects.....                             | 5  |
| 1.6. Study development .....                                     | 6  |
| 1.7. Materials and methods .....                                 | 6  |
| 1.7.1. Skin profilometry .....                                   | 6  |
| 1.7.2 Skin elasticity .....                                      | 7  |
| 1.7.3. Skin moisturization .....                                 | 8  |
| 1.7.4. Skin pH.....  | 8  |
| 1.7.5. Ophthalmological evaluation of product tolerability ..... | 8  |
| 1.7.5.1. Overall evaluation of product tolerability .....        | 8  |
| 1.7.6 Digital pictures.....                                      | 9  |
| 1.7.7. Self-assessment.....                                      | 9  |
| 1.8. Results and statistic .....                                 | 9  |
| 1.8.1. Results .....   | 9  |
| 1.8.2. Statistical analysis.....                                 | 9  |
| 1.8.3. Interpretation of results .....                           | 9  |
| 1.9. Start/end date of study .....                               | 10 |
| 1.10. Report change record.....                                  | 10 |
| PANEL DEMOGRAPHY.....  | 11 |
| RESULTS: .....   | 12 |
| SKIN MOISTURIZATION - SHORT TERM .....                           | 12 |
| SKIN MOISTURIZATION - LONG TERM .....                            | 14 |
| R2 PARAMETER - SKIN ELASTICITY.....                              | 16 |
| R0 PARAMETER – SKIN FIRMNESS .....                               | 18 |
| SKIN PROFILOMETRY – WRINKLE DEPTH.....                           | 20 |
| SKIN PROFILOMETRY – WRINKLE VOLUME .....                         | 22 |
| SKIN PROFILOMETRY - Ra PARAMETER .....                           | 24 |
| SKIN pH – SHORT TERM .....                                       | 26 |
| OPHTHALMOLOGICAL EVALUATION OF PRODUCT TOLERABILITY.....         | 28 |
| SELF-ASSESSMENT QUESTIONNAIRE .....                              | 29 |
| CONCLUSIONS .....  | 31 |
| ANNEX I.....   | 32 |



## STUDY DESIGN

### 1.1. Title

Clinical and instrumental evaluation of the anti-ageing efficacy of a cosmetic product. Use test under ophthalmological control.

### 1.2. Aim of the study

The study is aimed to evaluate the anti-aging activity of a cosmetic product (spray water). End points of the trial are the evaluation of product smoothing, filling, firming and hydrating efficacy. In order to reach this goal, a clinical/instrumental study is carried out on 20 healthy female subjects (22 enrolled), aged between 40 and 60 years old, with all skin type showing visible crow's feet wrinkles. The study foresees both a short and a long term test; instrumental evaluations are carried out at baseline (T0) 15 minutes and 1hour after the first product application and after 14 (T14) and 28 days (T28) days of product use. Moreover, after the first product application and at the end of the study, volunteers are asked to express their opinion about the tested product filling in a self-assessment questionnaire.

### 1.3. Test product

#### 1.3.1. Information provided by the Customer

- Product identification: **L'EAU DE JOUR N'02 Formula code lab-01414.22**  
See the statement on report results extension in the Annex I.
  - Way of use: The product is sprayed on the face 3 times a day (in the morning, at midday and in the late afternoon). Close the eyes and spray on face. Pat with fingertips palms for maximum absorption. In the morning and in the evening after product dry, subjects will apply a base cream\*, without any cosmetic efficacy claim, provided by Complife. For the short term test the product is applied in the test facility by the experimenter in a standardized quantity on the volar surface of the forearms following a predefined randomization scheme and on the face.
  - The cosmetic product to be tested 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.
  - The cosmetic product to be tested are safe under normal or reasonably foreseeable conditions of use.
  - INCI formula:  
**L'EAU DE JOUR N'02 Formula code lab-01414.22:** AQUA (WATER), PROPANEDIOL, NIACINAMIDE, 1,2-HEXANEDIOL, GLYCERIN, PROPYLENE GLYCOL, CAPRYLOYL/CAPROYL ANHYDRO METHYL GLUCAMIDE, PARFUM (FRAGRANCE), FUMARIC ACID, POLYDATIN GLUCOSIDE, CITRIC ACID, SODIUM CITRATE, METHYLGLUCOSIDE PHOSPHATE, COPPER LYSINATE/PROLINATE, CITRUS LIMON (LEMON) FRUIT EXTRACT, FUMARIA OFFICINALIS FLOWER/LEAF/STEM EXTRACT, DISODIUM ACETYL GLUCOSAMINE PHOSPHATE, CI 14700 (RED 4).
- \*Aqua, Helianthus Annuus Seed Oil, Isononyl Isononanoate, Polyglyceryl-3 Methylglucose Distearate, Glyceryl Stearate, Cetearyl Alcohol, Disodium Edta, Chlorphenesin, O-Cymen-5-OL, Fragrance/Parfum.

### 1.4. Ethical requirements

The study is carried out in accordance with the following ethical requirements:

- All the subjects participating in the study are healthy volunteers of at least 18 years old.
- All of the subjects participating in the study are selected with the supervision of a dermatologist according to inclusion/not inclusion criteria.
- Volunteers' participation in the study was totally free.
- All of the subjects participating in the study are informed of the aim and the design of the study.
- All of the subjects participating in the study are informed of the possible risk involved in the study execution.
- All of the subjects participating in the study give their informed consent signed at the beginning of the study.
- Before volunteer exposure to the tested product, all relevant safety information about the product itself and each ingredient were collected and evaluated.
- All of the study procedures are carried out in compliance 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).



- All of the precautions are taken in consideration in order to avoid excessive skin reactions.
- If any unexpected/adverse skin reaction occurs, medical investigating specialist evaluates the severity of the reaction (reporting it in the volunteer's data collecting sheet) and proceeds with appropriate therapy.

## 1.5. Subjects participating in the study

### 1.5.1. Subjects' enrolment

The subjects participating in the study are selected under the supervision of a board-certified dermatologist in accordance with the following inclusion and non-inclusion criteria.

#### 1.5.1.1. Inclusion criteria

- ✓ Healthy female subjects
- ✓ Age between 40 and 60
- ✓ All skin types
- ✓ Showing visible crow's feet wrinkles
- ✓ Willingness to not expose to sun/solar lamps during all the study period
- ✓ Subjects registered with National Health Service (NHS)
- ✓ Subjects certifying the truthfulness of the personal data disclosed to the investigator
- ✓ Subjects able to understand the language used in the investigation center and the information given by the investigator
- ✓ Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
- ✓ The pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) should be stable for at least one month without any changes expected or planned during the study
- ✓ Willingness to not use products likely to interfere with the product to be tested
- ✓ Commitment not to change the daily routine or lifestyle
- ✓ Subjects having signed an informed consent form.

#### 1.5.1.2. Non-inclusion criteria

- ✗ Subject does not meet the inclusion criteria above reported
- ✗ Sunburn, suntan, scars, or active dermal lesions on the test area
- ✗ Subjects accustomed to use tanning beds
- ✗ Subjects deprived of freedom by administrative or legal decision or under guardianship
- ✗ Subjects not able to be contacted in case of emergency
- ✗ Subjects admitted to a health or social facility
- ✗ Subjects planning a hospitalisation during the study
- ✗ Subjects who participated in a similar study without respecting an adequate washout period
- ✗ Subjects 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 pharmacological treatments that are considered incompatible with the study requirement by the investigator
- ✗ Subjects having a skin disease or condition liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
- ✗ Subjects that have shown allergies or sensitivity to cosmetic products, drugs, patch or medical devices
- ✗ Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential).

#### 1.5.1.3. Withdrawal of subjects

A subject enrolled in the study can be withdrawn and considered as a drop-out when: (i) no longer want to participate in the study, (ii) adverse reactions, judged severe and attributable to the tested product, occur, (iii) the subject is no longer eligible to participate in the study, (iv) the subject develops a pathological condition, not related to the study, but appearing during the study period, (v) it is required the prescription of a concomitant treatment, (vi) the study requirements are not satisfied (significant deviation from the protocol), (vii) significant non-compliance with respect to product use or to the study protocol.



## 1.6. Study development

The study is carried out as follow:

- ✓ **T0:** enrolment of 22 subjects according to inclusion/non-inclusion criteria. Ophthalmological assessment and instrumental evaluation of the parameter under study before product application.
- ✓ **First product application (face):** the product is applied (2 mg/cm<sup>2</sup>) under the experimenter supervision on the face.
- ✓ **First product application (forearm):** the product is applied (2 mg/cm<sup>2</sup>) under the experimenter supervision on one area of the volar surface of the forearm, while an area of the contralateral forearm remains untreated acting as control according to a predefined randomization scheme.
- ✓ **T15\*(short term evaluation-face):**
  - instrumental evaluation of skin pH 15 minutes after single product application
  - volunteers are asked to express their opinion on tested products by answering to a questionnaire.
- ✓ **T15\*, T1h\* (short term evaluation-forearms):**
  - instrumental evaluation of skin moisturization both in the treated and untreated areas 15 minutes and 1 hour after single product application.
- ✓ **T0-T28:** products use at home according to provided instructions.
- ✓ **T14, T28 (long term evaluation):**
  - ophthalmological assessment and instrumental evaluation of the parameter under study (skin moisturization, skin elasticity and firmness, skin profilometry) on the face after 14 and 28 days of product application.
  - volunteers are asked to express their opinion on tested products by answering to a questionnaire.

\*During the short term study volunteers remain in laboratory in controlled conditions of humidity and temperature. Moreover, subjects are asked not to wash the tested skin sites and not to apply any product until the end of the study.

## 1.7. Materials and methods

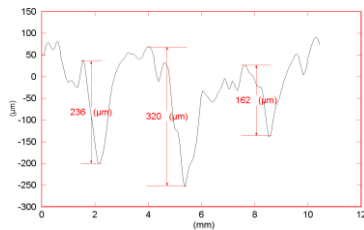
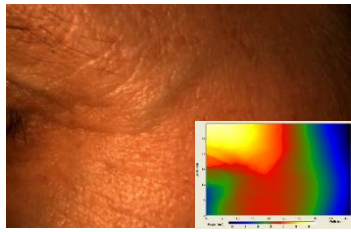
Here below are reported the parameters monitored during the study. The study evaluations are carried out in a temperature and humidity-controlled environment (respectively T= 18-26°C and RH= 50±10%).

### 1.7.1. Skin profilometry

Skin surface is quantitatively assessed by Primos 3D (GF Messtechnik GmbH). Primos 3D is a non-contact in vivo skin measurement device based on structured light projection. In conjunction with a comprehensive 3-D measurement and evaluation software, the sensor allows to evaluate skin surface properties (i.e., wrinkle depth, volume, roughness etc.). In this study wrinkle depth, wrinkle volume and skin roughness are evaluated in the periorcular area. For further information see box 1.



## Box 1 - Skin profilometry by means of Primos 3D analysis



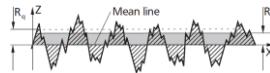
**The technique.** Primos 3D is a 3D scanner that create a point cloud (set of vertices in a three-dimensional coordinate system) of geometric samples on the surface of the subject. These points are then used to extrapolate the shape of the subject (a process called reconstruction). Like cameras, 3D-scanner has a cone-like field of view, and like cameras, they can only collect information about surfaces that are not obscured. While a camera collects color information about surfaces within its field of view, 3D scanners collect distance information about surfaces within its field of view. The “picture” produced by a 3D scanner describes the distance to a surface at each point in the picture (see the image in the insert).

**Calculation of wrinkle depth.** It is calculated the height of wrinkles in the sampling lengths: this calculation is done on the sectional picture (wrinkle depth vs. section).

**Calculation of wrinkle volume.** The software allows to select an area of which the volume of cavities is then calculated.

### Calculation of skin smoothness (Ra parameter)

For the calculation of a star roughness, intersections are arranged in a star shape by the program. The calculation of the parameter occurs accordingly to the determination of the line roughness (separate for every star shape arranged intersection). In this study skin smoothness is calculated through the Ra parameter. Ra parameter is the arithmetic average of the absolute values of the roughness profile ordinates. A decrease of this parameter indicates an improvement of skin smoothness.



Ra is mathematically calculated as:

$$R_a = \frac{1}{l} \int_0^l |Z(x)| dx$$

## 1.7.2 Skin elasticity

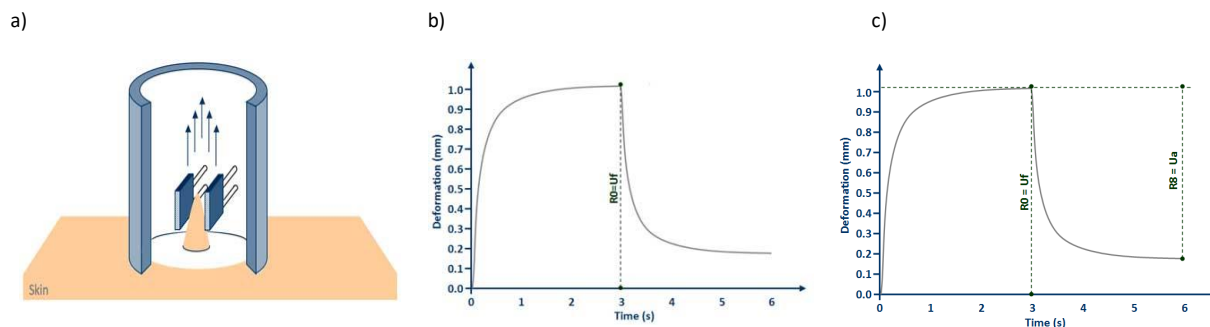
Skin elasticity measurement is based on the suction/elongation method and the subsequent release of the skin inside the opening of the instrument (Cutometer®MPA 580, Courage+Khazaka, electronic GmbH). During the suction/elongation phase the instrument generates, in fact, a constant negative pressure (450 mbar) able to aspirate the skin inside the measurement probe. The suction phase is followed by the release phase, in which the pressure inside the probe is switched to 0 mbar allowing the skin recovery after the elongation phase. An optical measurement system evaluates the depth of the skin inside the probe in the two phases of the measurement, the obtained data are then elaborated and showed graphically and numerically in order to calculate the viscoelastic properties of the skin. For further information see box 2.

- **R2 parameter** (gross elasticity or overall elasticity): it is the ratio between the residual deformation and the maximum elongation of the skin (Ua/Uf) and it indicates the ability of the skin to return to its original state of recovery after a stressing event. Closer the value is to 1, more elastic is the skin.
- **R0 parameter** (skin distensibility): it is the first max amplitude of the curve (Uf) and it represents the passive behavior of the skin to a force (i.e. gravity). A reduction of R0 parameter indicates an improvement of the skin ability to oppose to the deformation imposed by the probe during the suction phase, than can be expressed as an improvement of skin firmness.





**Box 2** (a) Skin elasticity measurement process. (b) R0 parameter. (c) R2 parameter.



### 1.7.3. Skin moisturization

Skin moisturizing is evaluated by means of Corneometer® measurement. This measurement is based on the completely different dielectric constant of water (81) and other substances (mostly < 7). The measuring capacitor shows changes of capacitance according to the moisture content of the skin. A metallic lamina separates the metallic tracks (gold) in the probe head from the skin in order to prevent current conduction in the measured area. An electric field between the tracks with alternating attraction develops. One track builds up a surplus of electrons (minus charge) the other a lack of electrons (plus charge). The scatterfield penetrates the very first layer of the skin (10-20 μm) during the measurement and the capacitance is determined.

### 1.7.4. Skin pH

The used instrument is the SKIN pH-METER 905®, Courage + Khazaka GmbH. The measure is based on a combined electrode of high quality, in which both the glass electrode sensitive to H+ and the additional reference electrode are placed in the same site. It is connected to a handle probe containing the measurement electronics. Before the measurements, the SKIN pH-meter® 905 (Courage + Khazaka electronic GmbH) is calibrated using two buffer solutions with known pH (pH 4.01 and 1.7) as reference.

Measurement range: 0 to 12; accuracy: ± 0.1 pH.

### 1.7.5. Ophthalmological evaluation of product tolerability

The ophthalmologist assesses, with the collaboration of the enrolled subject, both physical signs (lacrimation, vasodilatation, periocular swelling) and functional signs (foreign body sensation, itching/stinging sensation, burning sensation, other) according to scores reported in box 3a/3b.

| 3a. Physical signs | Score | 3b. Functional signs | Score |
|--------------------|-------|----------------------|-------|
| No/None            | 0     | No/None              | 0     |
| Very mild          | 1     | Very mild            | 1     |
| Mild               | 2     | Mild                 | 2     |
| Moderate           | 3     | Moderate             | 3     |
| Severe             | 4     | Severe               | 4     |

#### 1.7.5.1. Overall evaluation of product tolerability

Both the occurrence of new clinical signs and the worsening of pre-existing conditions are evaluated. The intensity, location, duration and frequency of each event are recorded, in order to define a relationship to the study product and (if needed) the subject would be asked to stop the product use as long as the symptomatology resolves and then to try to use it again.

The product is ultimately classified as:

- Tested under ophthalmological control and safe for its use if none or at most 15% of subjects show a clinical sign, related to the application of the product which causes their drop out from the clinical study.
- Not tolerated during its use, if more than 15% of the subjects show a clinical sign related to the application of the product which causes their drop out from the clinical study.





### 1.7.6 Digital pictures

Digital images are taken using Visioface (Courage+Khazaka, electronic GmbH) under standard lighting conditions. *The best digital pictures (3 cases) are sent to the sponsor in jpg format.*

### 1.7.7. Self-assessment

Both after the first product application and after 28 days of use, volunteers are asked to express their opinion about tested product by answering to a specific questionnaire.

## 1.8. Results and statistic

### 1.8.1. Results

- 1) Results are reported in tables in their respective units.
- 2) Mean values are calculated as follows:

$$m = \frac{\sum_{i=1}^n p}{n}$$

Where: p is the value of the parameter under analysis; n is the number of subjects participating in the study

- 3) Percentages are calculated as follows:

$$\%var.\text{vs.}T0 = \left( \frac{\sum_{i=1}^n p_i - p_0}{p_0} \right) \times 100$$

or

$$\% \text{ of subjects} = \left( \frac{\sum_{i=1}^n \text{answers}}{n} \right) \times 100$$

Where: p<sub>i</sub> is the value of the parameter under analysis after product use; p<sub>0</sub> is the value of the parameter under analysis before product application; n is the number of subjects participating in the study

- 4) The standard error of data is calculated as:

$$SE = \frac{\sqrt{\frac{\sum_{i=1}^n (p_i^2) - \frac{(\sum_{i=1}^n p_i)^2}{n}}{n-1}}}{\sqrt{n}}$$

where: p is the value of the parameter under analysis; n is the number of subjects participating in the study

All the calculations are done using a Microsoft® Excel file.

Final self-assessment data are reported in a Microsoft® Excel sheet. The percentages of subjects that attribute a given score to a given question is calculated. Results are calculated as percentage (%) of subjects who assigned a particular judgment (among those proposed). For each question, the number of subjects related to each judgment is counted → (number of subjects) and this number is then divided by the total number of subjects → % of answers.

### 1.8.2. Statistical analysis

The instrumental data are submitted to the 2-way Student's test t for paired data. Variations are considered statistically significant when p value is < 0,05.

### 1.8.3. 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 measured 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



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|-----------|--|
| Customer  | RIVOLI COSMÉTIQUES SA                  |
| Record no | H.E.HU.MP.NAA02.020.10.00_IT0003762/22 |
| Date      | 14/10/2022                             |

product must be perceived by at least 60% of the subjects. Whenever reference values or threshold values exist, those values are used to validate product claim(s).

### 1.9. Start/end date of study

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

| Start date | End date   |
|------------|------------|
| 27/07/2022 | 07/10/2022 |

### 1.10. 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      | 14/10/2022 | First release |
|         |            |               |
|         |            |               |
|         |            |               |

- The results of the study reported in this document are only referred to the tested samples and the specific experimental conditions.
- Any part of this report can only be reproduced with the consent of Complife Italia S.r.l.
- A copy of this report is kept on file at Complife Italia S.r.l.
- Both the informed consent and the information forms are kept on file at Complife Italia S.r.l. for 10 years after the date of issue of the report.

### COMPLIFE Italia S.r.l.

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

Sedi principali:  
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 | +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 | +39.0382.25504



## PANEL DEMOGRAPHY

**Table A.** The following table reports the characteristics of the enrolled subjects.

| no. | Vol. ID | Age  | Skin type   |
|-----|---------|------|-------------|
| 01  | S4252R  | 50   | NORMAL      |
| 02  | M0476P  | 53   | DRY         |
| 03  | P7029A  | 56   | COMBINATION |
| 04  | L1086A  | 59   | COMBINATION |
| 05  | I4588E  | 53   | COMBINATION |
| 06  | C5001G  | 55   | COMBINATION |
| 07  | P4280M  | 58   | NORMAL      |
| 08  | C1227F  | 44   | NORMAL      |
| 09  | S1741G  | 53   | NORMAL      |
| 10  | P4545D  | 50   | DRY         |
| 11  | C1267R  | 58   | OILY        |
| 12  | D5365P  | 58   | OILY        |
| 13  | B5498S  | 47   | NORMAL      |
| 14  | C4970G  | 56   | DRY         |
| 15  | P5128O  | 52   | DRY         |
| 16  | N5078M  | 48   | NORMAL      |
| 17  | F5103R  | 51   | NORMAL      |
| 18  | I5978L  | 58   | COMBINATION |
| 19  | S6370P  | 55   | COMBINATION |
| 20  | P5231S  | 45   | NORMAL      |
| 21  | C5228R  | 54   | OILY        |
| 22  | M5192P  | 42   | DRY         |
|     | Mean    | 52,5 |             |
|     | Min     | 42,0 |             |
|     | Max     | 59,0 |             |



**RESULTS:  
SKIN MOISTURIZATION - SHORT TERM**

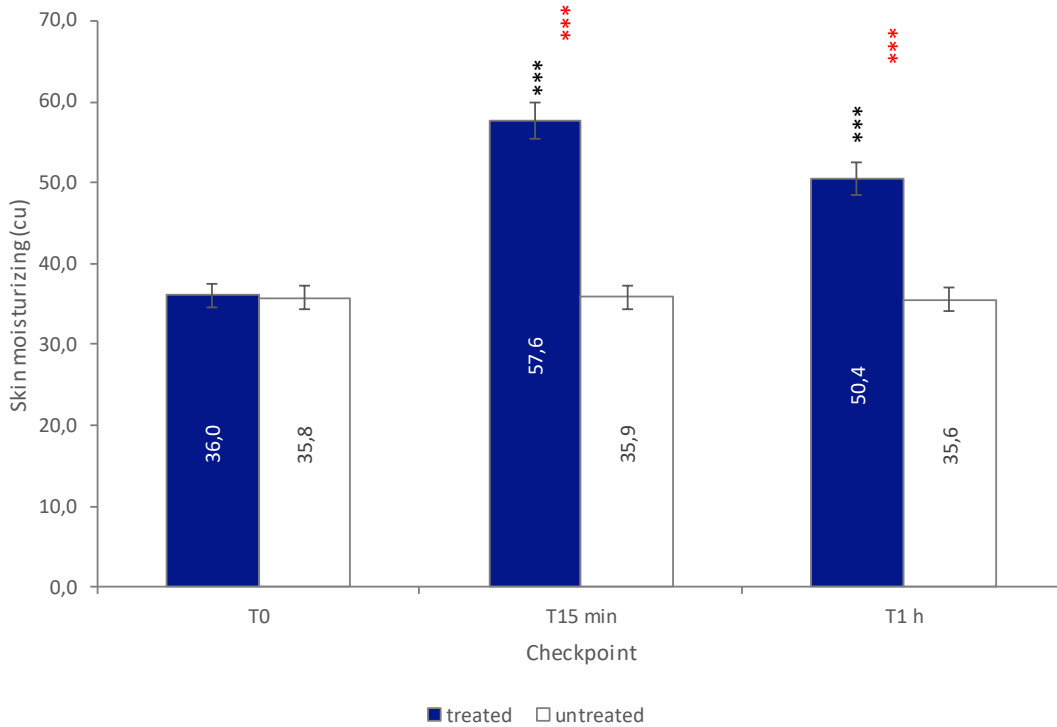
**TABLES 1a/b** - The tables report the obtained data for each volunteer at each experimental time. Data are expressed as corneometric units (c.u.).

| TREATED                        |         |             |             |             |     |       |
|--------------------------------|---------|-------------|-------------|-------------|-----|-------|
| no.                            | Vol. ID | T0          | T15 min     | T1 h        |     |       |
| 01                             | S4252R  | 37,7        | 62,2        | 54,8        |     |       |
| 02                             | M0476P  | 28,4        | 40          | 37,7        |     |       |
| 03                             | P7029A  | 30,5        | 42,7        | 34,2        |     |       |
| 04                             | L1086A  | 33,3        | 58,3        | 47,3        |     |       |
| 05                             | I4588E  | 40,6        | 67,4        | 50,3        |     |       |
| 06                             | C5001G  | 35,3        | 54,2        | 44,9        |     |       |
| 07                             | P4280M  | 40,5        | 51,3        | 48,6        |     |       |
| 08                             | C1227F  | 33,8        | 55,8        | 44,7        |     |       |
| 09                             | S1741G  | 34,3        | 59,2        | 50,2        |     |       |
| 10                             | P4545D  | 35,7        | 64,4        | 58,1        |     |       |
| 11                             | C1267R  | 43,6        | 55,1        | 51,1        |     |       |
| 12                             | D5365P  | 31,1        | 58,9        | 47,7        |     |       |
| 13                             | B5498S  | 32,7        | 62,5        | 54,7        |     |       |
| 14                             | C4970G  | 31,3        | 57,8        | 47,3        |     |       |
| 15                             | P5128O  | 27,1        | 45,7        | 45          |     |       |
| 16                             | N5078M  | 34,5        | 47,1        | 47,9        |     |       |
| 17                             | F5103R  | 29,8        | 49,7        | 42,4        |     |       |
| 18                             | I5978L  | 32,4        | 50          | 46          |     |       |
| 19                             | S6370P  | 48,5        | 83,1        | 72,5        |     |       |
| 20                             | P5231S  | 42,1        | 73,2        | 69,5        |     |       |
| 21                             | C5228R  | 56,3        | 75,3        | 68          |     |       |
| 22                             | M5192P  | 33,4        | 53,2        | 45,8        |     |       |
| Mean                           |         | <b>36,0</b> | <b>57,6</b> | <b>50,4</b> |     |       |
| SE                             |         | 1,5         | 2,3         | 2,0         | Min | 26,4% |
| t test vs. T0                  |         | ---         | 0,000       | 0,000       | Max | 91,1% |
| t test treated. vs. Untreated. |         | 0,317       | 0,000       | 0,000       |     | 67,3% |

| UNTREATED     |         |             |             |             |     |       |
|---------------|---------|-------------|-------------|-------------|-----|-------|
| no.           | Vol. ID | T0          | T15 min     | T1 h        |     |       |
| 01            | S4252R  | 36,8        | 36,2        | 36,3        |     |       |
| 02            | M0476P  | 31,2        | 31,3        | 31,5        |     |       |
| 03            | P7029A  | 30,8        | 30,8        | 29,9        |     |       |
| 04            | L1086A  | 34,4        | 34,6        | 34,3        |     |       |
| 05            | I4588E  | 41,1        | 40,8        | 40,7        |     |       |
| 06            | C5001G  | 34,2        | 34          | 33,6        |     |       |
| 07            | P4280M  | 41,8        | 41,2        | 40,8        |     |       |
| 08            | C1227F  | 33,3        | 33,6        | 30,3        |     |       |
| 09            | S1741G  | 33,1        | 32,3        | 32,5        |     |       |
| 10            | P4545D  | 32,4        | 32,5        | 33,2        |     |       |
| 11            | C1267R  | 43,7        | 43,3        | 43,7        |     |       |
| 12            | D5365P  | 30,6        | 31,5        | 29,5        |     |       |
| 13            | B5498S  | 33,6        | 34,2        | 33,9        |     |       |
| 14            | C4970G  | 31,7        | 32,2        | 32,4        |     |       |
| 15            | P5128O  | 26,3        | 26,4        | 26,1        |     |       |
| 16            | N5078M  | 34,8        | 34,2        | 34,6        |     |       |
| 17            | F5103R  | 29,5        | 30,3        | 30,4        |     |       |
| 18            | I5978L  | 31,2        | 31,6        | 30,9        |     |       |
| 19            | S6370P  | 47,9        | 48,2        | 47,6        |     |       |
| 20            | P5231S  | 40,9        | 41,6        | 42,2        |     |       |
| 21            | C5228R  | 55,6        | 56,2        | 55,4        |     |       |
| 22            | M5192P  | 32,1        | 32,7        | 32,4        |     |       |
| Mean          |         | <b>35,8</b> | <b>35,9</b> | <b>35,6</b> |     |       |
| SE            |         | 1,5         | 1,5         | 1,5         | Min | -2,4% |
| t test vs. T0 |         | ---         | 0,267       | 0,259       | Max | 2,9%  |



**GRAPH 1** - The graph shows the mean data obtained at each experimental time for the analysed parameter. Data are expressed as mean ± SE. Above the error bar the statistical analysis is reported as follow: \*\*\* p<0.001 vs T0; \*\* p<0.01 vs T0; \* p<0.05 vs T0 and \*\*\* p<0.001 vs Untreated Area; \*\* p<0.01 vs Untreated Area; \* p<0.05 vs Untreated Area.



**COMMENT**

After its single application, the tested product determines a statistically significant increase (both vs T0 and vs untreated area) of skin moisturization basal mean values respectively by +61.0% at T15min and +40.7% at T1h. No statistically significant variation has been observed in the untreated control area.

**COMPLIFE Italia S.r.l.**

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

Sedi principali:  
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504



### SKIN MOISTURIZATION - LONG TERM

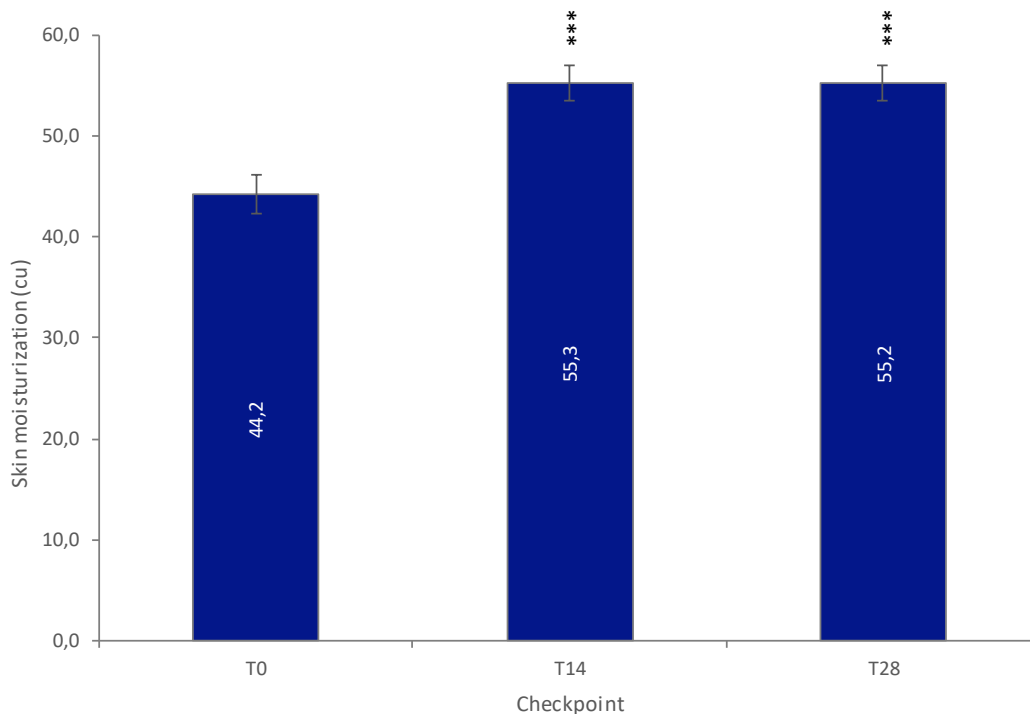
**TABLE 2** - The table reports the obtained data for each volunteer at each experimental time. Data are expressed as corneometric units (c.u.).

| no. | Vol. ID       | T0          | T14         | T28         |                  | T14          | T28          |
|-----|---------------|-------------|-------------|-------------|------------------|--------------|--------------|
| 01  | S4252R        | 42,2        | 48,4        | 50,2        | Variation vs. T0 | 14,7%        | 19,0%        |
| 02  | M0476P        | 41,6        | 59,3        | 59,4        |                  | 42,5%        | 42,8%        |
| 03  | P7029A        | 38,6        | 47,6        | 50          |                  | 23,3%        | 29,5%        |
| 04  | L1086A        | 43,3        | 55,3        | 55,8        |                  | 27,7%        | 28,9%        |
| 05  | I4588E        | 40,7        | 47,1        | 50,6        |                  | 15,7%        | 24,3%        |
| 06  | C5001G        | 30,5        | 44          | 47,1        |                  | 44,3%        | 54,4%        |
| 07  | P4280M        | 40,3        | 49,1        | 48,3        |                  | 21,8%        | 19,9%        |
| 08  | C1227F        | 42,2        | 57,7        | 55,5        |                  | 36,7%        | 31,5%        |
| 09  | S1741G        | 48,6        | 53,7        | 55,6        |                  | 10,5%        | 14,4%        |
| 10  | P4545D        | 33,9        | 53,1        | 48,8        |                  | 56,6%        | 44,0%        |
| 11  | C1267R        | 54,7        | 56,6        | 56          |                  | 3,5%         | 2,4%         |
| 12  | D5365P        | 59,1        | 71,1        | 73,5        |                  | 20,3%        | 24,4%        |
| 13  | B5498S        | 44,9        | 54,5        | 49,6        |                  | 21,4%        | 10,5%        |
| 14  | C4970G        | 32,6        | 41,2        | 38,7        |                  | 26,4%        | 18,7%        |
| 15  | P5128O        | 32,1        | 48          | 50          |                  | 49,5%        | 55,8%        |
| 16  | N5078M        | 52,1        | 69,1        | 66,4        |                  | 32,6%        | 27,4%        |
| 17  | F5103R        | 49,2        | 68          | 63,9        |                  | 38,2%        | 29,9%        |
| 18  | I5978L        | 45,8        | 59,6        | 58,8        |                  | 30,1%        | 28,4%        |
| 19  | S6370P        | 58,5        | 59,8        | 58,9        |                  | 2,2%         | 0,7%         |
| 20  | P5231S        | 41,4        | 61,6        | 61,2        |                  | 48,8%        | 47,8%        |
| 21  | C5228R        | 63,8        | 65,7        | 68,5        |                  | 3,0%         | 7,4%         |
| 22  | M5192P        | 36,7        | 45,6        | 48,1        |                  | 24,3%        | 31,1%        |
|     | Mean          | <b>44,2</b> | <b>55,3</b> | <b>55,2</b> |                  | <b>27,0%</b> | <b>27,0%</b> |
|     | SE            | 1,9         | 1,8         | 1,7         | Min              | 2,2%         | 0,7%         |
|     | t test vs. T0 | ---         | 0,000       | 0,000       | Max              | 56,6%        | 55,8%        |





**GRAPH 2** - The graph shows the mean data obtained at each experimental time for the analysed parameter. Data are expressed as mean  $\pm$  SE. Above the error bar the statistical analysis is reported as follow: \*\*\*  $p < 0.001$  vs T0; \*\*  $p < 0.01$  vs T0; \*  $p < 0.05$  vs T0.



**COMMENT**

Both after 14 and 28 days of application, the tested product determines a statistically significant increase (vs T0) of skin moisturization basal mean values by +27.0%.

**COMPLIFE Italia S.r.l.**

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

Sedi principali:  
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 | +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 | +39.0382.25504



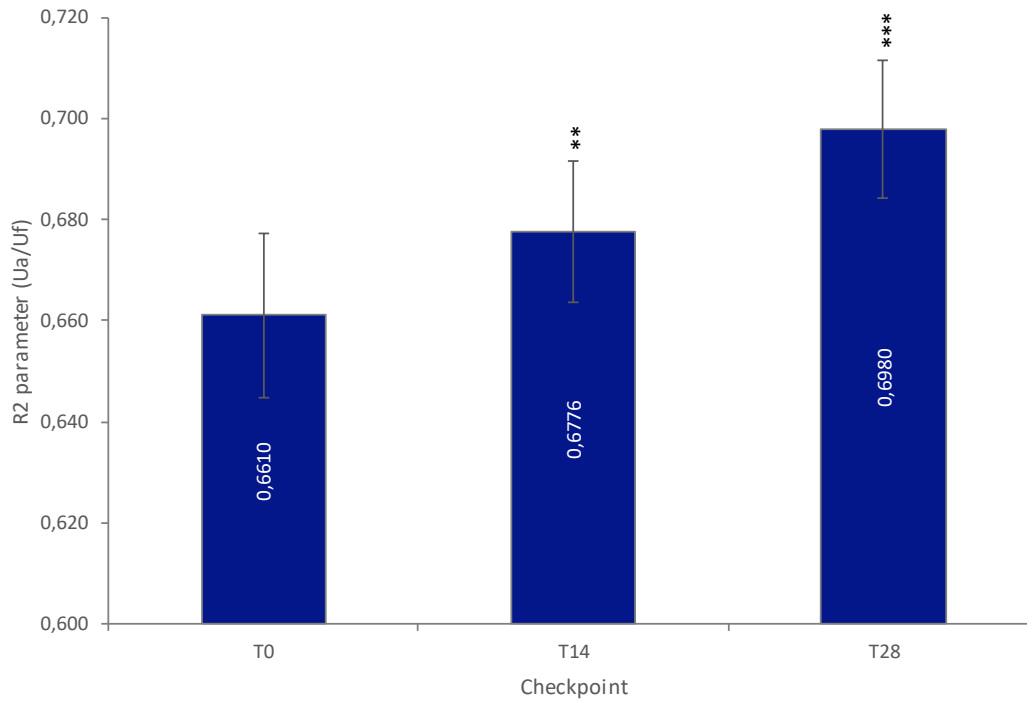
**R2 PARAMETER - SKIN ELASTICITY**

**TABLE 3** - The table reports the obtained data for each volunteer at each experimental time. Data are expressed as Ua/Uf.

| no. | Vol. ID       | T0            | T14           | T28           |                  | T14         | T28         |
|-----|---------------|---------------|---------------|---------------|------------------|-------------|-------------|
| 01  | S4252R        | 0,7289        | 0,7308        | 0,7501        | Variation vs. T0 | 0,3%        | 2,9%        |
| 02  | M0476P        | 0,7432        | 0,7531        | 0,7904        |                  | 1,3%        | 6,4%        |
| 03  | P7029A        | 0,7029        | 0,7130        | 0,7216        |                  | 1,4%        | 2,7%        |
| 04  | L1086A        | 0,7099        | 0,7556        | 0,7536        |                  | 6,4%        | 6,2%        |
| 05  | I4588E        | 0,6884        | 0,7026        | 0,7316        |                  | 2,1%        | 6,3%        |
| 06  | C5001G        | 0,6882        | 0,6703        | 0,6836        |                  | -2,6%       | -0,7%       |
| 07  | P4280M        | 0,6772        | 0,6849        | 0,7039        |                  | 1,1%        | 3,9%        |
| 08  | C1227F        | 0,7878        | 0,7963        | 0,7853        |                  | 1,1%        | -0,3%       |
| 09  | S1741G        | 0,6439        | 0,6600        | 0,7114        |                  | 2,5%        | 10,5%       |
| 10  | P4545D        | 0,6644        | 0,6677        | 0,6698        |                  | 0,5%        | 0,8%        |
| 11  | C1267R        | 0,7109        | 0,7266        | 0,7092        |                  | 2,2%        | -0,2%       |
| 12  | D5365P        | 0,4820        | 0,5020        | 0,5710        |                  | 4,1%        | 18,5%       |
| 13  | B5498S        | 0,6170        | 0,6280        | 0,6640        |                  | 1,8%        | 7,6%        |
| 14  | C4970G        | 0,5610        | 0,5640        | 0,5860        |                  | 0,5%        | 4,5%        |
| 15  | P5128O        | 0,5140        | 0,6150        | 0,5730        |                  | 19,6%       | 11,5%       |
| 16  | N5078M        | 0,6150        | 0,6230        | 0,6250        |                  | 1,3%        | 1,6%        |
| 17  | F5103R        | 0,5670        | 0,6380        | 0,6890        |                  | 12,5%       | 21,5%       |
| 18  | I5978L        | 0,6730        | 0,6890        | 0,7420        |                  | 2,4%        | 10,3%       |
| 19  | S6370P        | 0,6670        | 0,6840        | 0,6870        |                  | 2,5%        | 3,0%        |
| 20  | P5231S        | 0,7160        | 0,7090        | 0,7250        |                  | -1,0%       | 1,3%        |
| 21  | C5228R        | 0,7350        | 0,7160        | 0,7880        |                  | -2,6%       | 7,2%        |
| 22  | M5192P        | 0,6500        | 0,6790        | 0,6960        |                  | 4,5%        | 7,1%        |
|     | Mean          | <b>0,6610</b> | <b>0,6776</b> | <b>0,6980</b> |                  | <b>2,8%</b> | <b>6,0%</b> |
|     | SE            | 0,0162        | 0,0140        | 0,0137        | Min              | -2,6%       | -0,7%       |
|     | t test vs. T0 | ---           | 0,008         | 0,000         | Max              | 19,6%       | 21,5%       |



**GRAPH 3** - The graph shows the mean data obtained at each experimental time for the analysed parameter. Data are expressed as mean  $\pm$  SE. Above the error bar the statistical analysis is reported as follow: \*\*\*  $p < 0.001$  vs T0; \*\*  $p < 0.01$  vs T0; \*  $p < 0.05$  vs T0.



**COMMENT**

Both after 14 and 28 days of application, the tested product determines a statistically significant increase (vs T0) of R2 parameter basal mean values respectively by +2.8% at T14 and +6.0% at T28.

R2 parameter values are directly proportional to the degree of skin elasticity. An increase of this parameter is indicative of an improvement of skin elasticity.



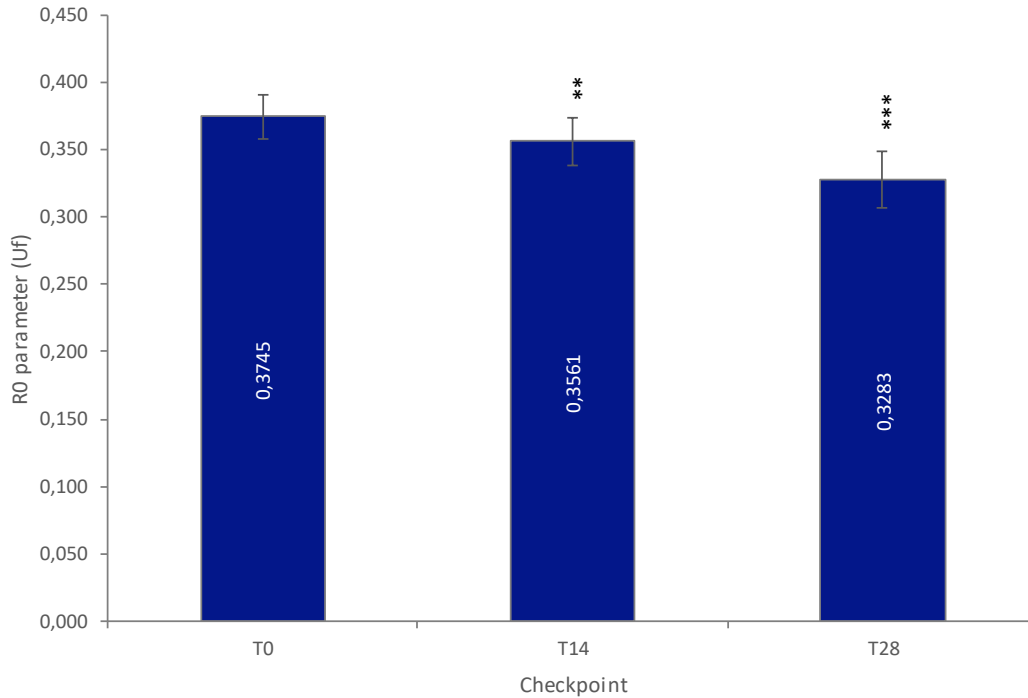
**RO PARAMETER – SKIN FIRMNESS**

**TABLE 4** - The table below reports the obtained data for each volunteer participating in the study. Data are expressed as Uf.

| no. | Vol. ID       | T0            | T14           | T28           |                  | T14          | T28           |
|-----|---------------|---------------|---------------|---------------|------------------|--------------|---------------|
| 01  | S4252R        | 0,4500        | 0,4480        | 0,4320        | Variation vs. T0 | -0,4%        | -4,0%         |
| 02  | M0476P        | 0,4230        | 0,4080        | 0,3740        |                  | -3,5%        | -11,6%        |
| 03  | P7029A        | 0,4890        | 0,4730        | 0,4520        |                  | -3,3%        | -7,6%         |
| 04  | L1086A        | 0,4620        | 0,4560        | 0,4590        |                  | -1,3%        | -0,6%         |
| 05  | I4588E        | 0,4110        | 0,4070        | 0,4000        |                  | -1,0%        | -2,7%         |
| 06  | C5001G        | 0,4420        | 0,4840        | 0,4670        |                  | 9,5%         | 5,7%          |
| 07  | P4280M        | 0,4390        | 0,3860        | 0,3520        |                  | -12,1%       | -19,8%        |
| 08  | C1227F        | 0,4140        | 0,4040        | 0,4100        |                  | -2,4%        | -1,0%         |
| 09  | S1741G        | 0,4370        | 0,4030        | 0,3930        |                  | -7,8%        | -10,1%        |
| 10  | P4545D        | 0,4440        | 0,4400        | 0,4310        |                  | -0,9%        | -2,9%         |
| 11  | C1267R        | 0,3840        | 0,3800        | 0,4120        |                  | -1,0%        | 7,3%          |
| 12  | D5365P        | 0,4020        | 0,4000        | 0,2840        |                  | -0,5%        | -29,4%        |
| 13  | B5498S        | 0,2710        | 0,2690        | 0,2160        |                  | -0,7%        | -20,3%        |
| 14  | C4970G        | 0,3440        | 0,3120        | 0,2980        |                  | -9,3%        | -13,4%        |
| 15  | P5128O        | 0,3890        | 0,2920        | 0,2520        |                  | -24,9%       | -35,2%        |
| 16  | N5078M        | 0,2520        | 0,2490        | 0,1980        |                  | -1,2%        | -21,4%        |
| 17  | F5103R        | 0,3670        | 0,3490        | 0,3060        |                  | -4,9%        | -16,6%        |
| 18  | I5978L        | 0,2750        | 0,2800        | 0,1810        |                  | 1,8%         | -34,2%        |
| 19  | S6370P        | 0,2800        | 0,2260        | 0,1950        |                  | -19,3%       | -30,4%        |
| 20  | P5231S        | 0,3300        | 0,2940        | 0,2240        |                  | -10,9%       | -32,1%        |
| 21  | C5228R        | 0,3050        | 0,2810        | 0,2670        |                  | -7,9%        | -12,5%        |
| 22  | M5192P        | 0,2280        | 0,1930        | 0,2200        |                  | -15,4%       | -3,5%         |
|     | Mean          | <b>0,3745</b> | <b>0,3561</b> | <b>0,3283</b> |                  | <b>-5,3%</b> | <b>-13,5%</b> |
|     | SE            | 0,0164        | 0,0182        | 0,0210        | Max              | -24,9%       | -35,2%        |
|     | t test vs. T0 | ---           | 0,005         | 0,000         | Min              | 9,5%         | 7,3%          |



**GRAPH 4** - The graph shows the mean data obtained at each experimental time for the analysed parameter. Data are expressed as mean ± SE. Above the error bar the statistical analysis is reported as follow: \*\*\* p<0.001 vs T0; \*\* p<0.01 vs T0; \* p<0.05 vs T0.



**COMMENT**

Both after 14 and 28 days of application, the tested product determines a statistically significant decrease (vs T0) of RO parameter basal mean values respectively by -5.3% at T14 and -13.5% at T28.

A reduction of RO parameter is indicative of an improvement of skin firmness; for marketing purposes this value can be expressed in absolute value as improvement of skin firmness.



**SKIN PROFILOMETRY – WRINKLE DEPTH**

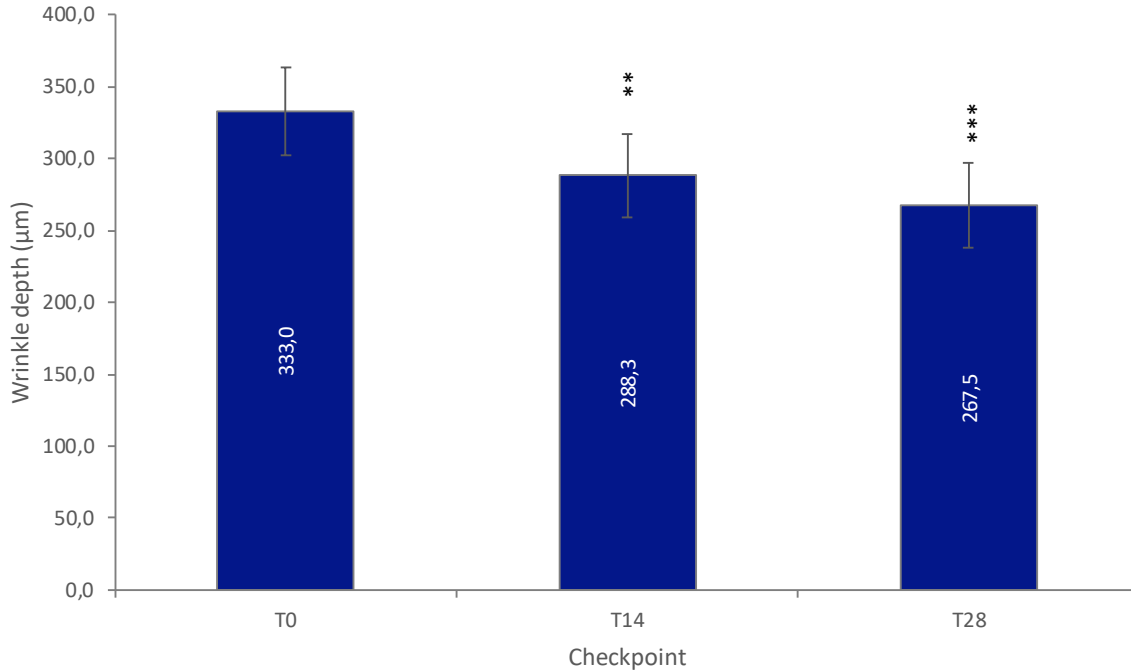
**TABLE 5** - The table below shows the data obtained for each subject participating in the study. Data are expressed as  $\mu\text{m}$ .

| no. | Vol. ID       | T0           | T14          | T28          |                  | T14           | T28           |
|-----|---------------|--------------|--------------|--------------|------------------|---------------|---------------|
| 01  | S4252R        | 312          | 297,6        | 187,5        | Variation vs. T0 | -4,6%         | -39,9%        |
| 02  | M0476P        | 299,1        | 334,9        | 314,5        |                  | 12,0%         | 5,1%          |
| 03  | P7029A        | 125,5        | 132,1        | 137,9        |                  | 5,3%          | 9,9%          |
| 04  | L1086A        | 358,1        | 332,5        | 259,5        |                  | -7,1%         | -27,5%        |
| 05  | I4588E        | 615,3        | 514,4        | 574          |                  | -16,4%        | -6,7%         |
| 06  | C5001G        | 376,1        | 218,5        | 156,8        |                  | -41,9%        | -58,3%        |
| 07  | P4280M        | 332,8        | 223,4        | 238,3        |                  | -32,9%        | -28,4%        |
| 08  | C1227F        | 278          | 295,9        | 185,5        |                  | 6,4%          | -33,3%        |
| 09  | S1741G        | 225,5        | 146,4        | 78,2         |                  | -35,1%        | -65,3%        |
| 10  | P4545D        | 258,7        | 251,9        | 250,2        |                  | -2,6%         | -3,3%         |
| 11  | C1267R        | 448,1        | 308,5        | 339          |                  | -31,2%        | -24,3%        |
| 12  | D5365P        | 380,7        | 284          | 308,6        |                  | -25,4%        | -18,9%        |
| 13  | B5498S        | 26,976       | 28,926       | 29,346       |                  | 7,2%          | 8,8%          |
| 14  | C4970G        | 362,8        | 298,5        | 316,6        |                  | -17,7%        | -12,7%        |
| 15  | P5128O        | 252          | 263,7        | 247          |                  | 4,6%          | -2,0%         |
| 16  | N5078M        | 241          | 163          | 196,9        |                  | -32,4%        | -18,3%        |
| 17  | F5103R        | 403          | 394,2        | 403,1        |                  | -2,2%         | 0,0%          |
| 18  | I5978L        | 287,6        | 242,6        | 242,4        |                  | -15,6%        | -15,7%        |
| 19  | S6370P        | 581,4        | 592,1        | 392,1        |                  | 1,8%          | -32,6%        |
| 20  | P5231S        | 262,6        | 230          | 216          |                  | -12,4%        | -17,7%        |
| 21  | C5228R        | 610,6        | 563,4        | 608,2        |                  | -7,7%         | -0,4%         |
| 22  | M5192P        | 289          | 226,2        | 202,7        |                  | -21,7%        | -29,9%        |
|     | Mean          | <b>333,0</b> | <b>288,3</b> | <b>267,5</b> |                  | <b>-12,3%</b> | <b>-18,7%</b> |
|     | SE            | 30,3         | 28,8         | 29,6         | Max              | -41,9%        | -65,3%        |
|     | t test vs. T0 | ---          | 0,001        | 0,000        | Min              | 12,0%         | 9,9%          |





**GRAPH 5** - The graph shows the mean data obtained at each experimental time for the analysed parameter. Data are expressed as mean  $\pm$  SE. Above the error bar the statistical analysis is reported as follow: \*\*\*  $p < 0.001$  vs T0; \*\*  $p < 0.01$  vs T0; \*  $p < 0.05$  vs T0.



**COMMENT**

Both after 14 and 28 days of application, the tested product determines a statistically significant decrease (vs T0) of wrinkle depth basal mean values respectively by -12.3% at T14 and -18.7% at T28.



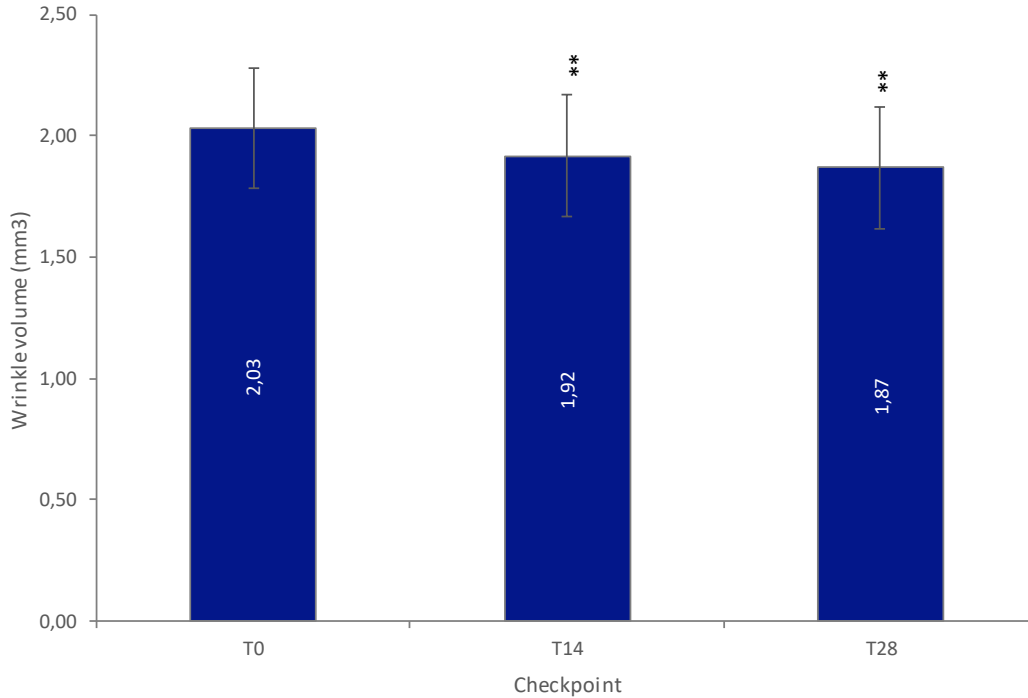
**SKIN PROFILOMETRY – WRINKLE VOLUME**

**TABLE 6** - The table below shows the data obtained for each subject participating in the study. Data are expressed as mm<sup>3</sup>.

| no. | Vol. ID       | T0          | T14         | T28         |                  | T14          | T28          |
|-----|---------------|-------------|-------------|-------------|------------------|--------------|--------------|
| 01  | S4252R        | 1,22        | 1,12        | 0,98        | Variation vs. T0 | -8,3%        | -19,3%       |
| 02  | M0476P        | 1,36        | 1,24        | 1,41        |                  | -8,6%        | 4,3%         |
| 03  | P7029A        | 0,21        | 0,20        | 0,21        |                  | -5,7%        | -2,3%        |
| 04  | L1086A        | 3,27        | 3,63        | 3,09        |                  | 11,2%        | -5,4%        |
| 05  | I4588E        | 3,93        | 4,11        | 4,17        |                  | 4,6%         | 6,3%         |
| 06  | C5001G        | 2,13        | 1,91        | 1,88        |                  | -10,2%       | -11,7%       |
| 07  | P4280M        | 3,76        | 3,65        | 4,05        |                  | -3,0%        | 7,5%         |
| 08  | C1227F        | 1,82        | 1,76        | 1,44        |                  | -3,2%        | -21,1%       |
| 09  | S1741G        | 1,20        | 0,80        | 0,70        |                  | -32,8%       | -41,3%       |
| 10  | P4545D        | 2,70        | 2,24        | 2,31        |                  | -17,1%       | -14,3%       |
| 11  | C1267R        | 2,87        | 2,59        | 2,93        |                  | -9,8%        | 2,1%         |
| 12  | D5365P        | 1,32        | 1,13        | 1,10        |                  | -14,4%       | -16,7%       |
| 13  | B5498S        | 0,68        | 0,68        | 0,69        |                  | 1,1%         | 1,8%         |
| 14  | C4970G        | 1,63        | 1,62        | 1,61        |                  | -0,6%        | -1,2%        |
| 15  | P5128O        | 1,65        | 1,56        | 1,62        |                  | -5,3%        | -1,9%        |
| 16  | N5078M        | 1,16        | 0,95        | 0,97        |                  | -17,9%       | -16,1%       |
| 17  | F5103R        | 2,03        | 1,89        | 1,72        |                  | -7,0%        | -15,6%       |
| 18  | I5978L        | 1,77        | 1,77        | 1,54        |                  | -0,2%        | -13,1%       |
| 19  | S6370P        | 4,77        | 4,49        | 4,01        |                  | -5,8%        | -16,0%       |
| 20  | P5231S        | 0,71        | 0,63        | 0,56        |                  | -11,5%       | -20,1%       |
| 21  | C5228R        | 3,06        | 2,91        | 2,97        |                  | -4,8%        | -3,0%        |
| 22  | M5192P        | 1,43        | 1,35        | 1,16        |                  | -6,1%        | -18,9%       |
|     | Mean          | <b>2,03</b> | <b>1,92</b> | <b>1,87</b> |                  | <b>-7,1%</b> | <b>-9,8%</b> |
|     | SE            | 0,25        | 0,25        | 0,25        | Max              | -32,8%       | -41,3%       |
|     | t test vs. T0 | ---         | 0,008       | 0,005       | Min              | 11,2%        | 7,5%         |



**GRAPH 6** - The graph shows the mean data obtained at each experimental time for the analysed parameter. Data are expressed as mean  $\pm$  SE. Above the error bar the statistical analysis is reported as follow: \*\*\*  $p < 0.001$  vs T0; \*\*  $p < 0.01$  vs T0; \*  $p < 0.05$  vs T0.



**COMMENT**

Both after 14 and 28 days of application, the tested product determines a statistically significant decrease (vs T0) of wrinkle volume basal mean values respectively by -7.1% at T14 and -9.8% at T28.



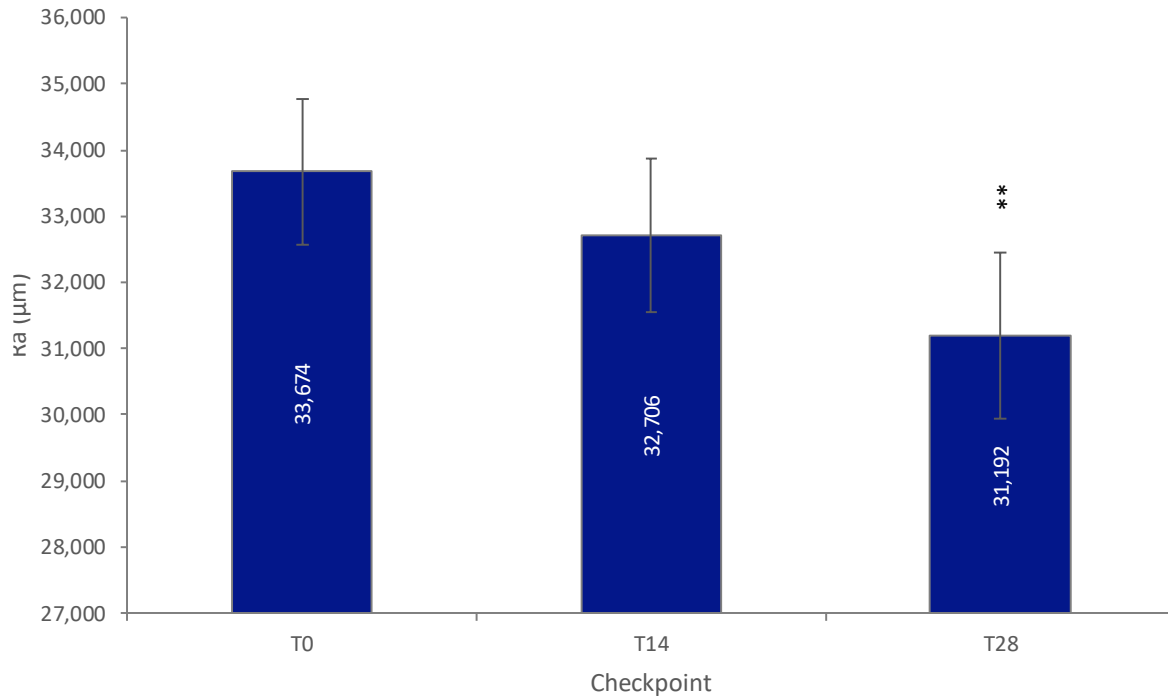
**SKIN PROFILOMETRY - Ra PARAMETER**

**TABLE 7** - The table below shows the data obtained for each subject participating in the study. Data are expressed in  $\mu\text{m}$ .

| no. | Vol. ID       | T0            | T14           | T28           |                  | T14          | T28          |
|-----|---------------|---------------|---------------|---------------|------------------|--------------|--------------|
| 01  | S4252R        | 35,376        | 35,126        | 32,061        | Variation vs. T0 | -0,7%        | -9,4%        |
| 02  | M0476P        | 34,122        | 36,195        | 32,782        |                  | 6,1%         | -3,9%        |
| 03  | P7029A        | 34,341        | 33,130        | 33,477        |                  | -3,5%        | -2,5%        |
| 04  | L1086A        | 30,013        | 30,190        | 31,171        |                  | 0,6%         | 3,9%         |
| 05  | I4588E        | 40,834        | 42,471        | 43,061        |                  | 4,0%         | 5,5%         |
| 06  | C5001G        | 28,302        | 30,226        | 29,980        |                  | 6,8%         | 5,9%         |
| 07  | P4280M        | 42,289        | 45,401        | 43,623        |                  | 7,4%         | 3,2%         |
| 08  | C1227F        | 29,713        | 30,675        | 23,734        |                  | 3,2%         | -20,1%       |
| 09  | S1741G        | 36,718        | 30,013        | 23,816        |                  | -18,3%       | -35,1%       |
| 10  | P4545D        | 29,231        | 28,435        | 27,671        |                  | -2,7%        | -5,3%        |
| 11  | C1267R        | 37,033        | 25,984        | 29,328        |                  | -29,8%       | -20,8%       |
| 12  | D5365P        | 30,072        | 29,259        | 29,492        |                  | -2,7%        | -1,9%        |
| 13  | B5498S        | 23,796        | 26,162        | 25,809        |                  | 9,9%         | 8,5%         |
| 14  | C4970G        | 34,401        | 32,241        | 32,427        |                  | -6,3%        | -5,7%        |
| 15  | P5128O        | 35,464        | 38,216        | 36,391        |                  | 7,8%         | 2,6%         |
| 16  | N5078M        | 25,859        | 24,211        | 24,883        |                  | -6,4%        | -3,8%        |
| 17  | F5103R        | 43,180        | 39,396        | 41,983        |                  | -8,8%        | -2,8%        |
| 18  | I5978L        | 31,114        | 31,782        | 26,170        |                  | 2,1%         | -15,9%       |
| 19  | S6370P        | 36,763        | 35,935        | 31,981        |                  | -2,3%        | -13,0%       |
| 20  | P5231S        | 37,906        | 35,802        | 30,543        |                  | -5,6%        | -19,4%       |
| 21  | C5228R        | 35,737        | 31,490        | 32,445        |                  | -11,9%       | -9,2%        |
| 22  | M5192P        | 28,556        | 27,185        | 23,387        |                  | -4,8%        | -18,1%       |
|     | Mean          | <b>33,674</b> | <b>32,706</b> | <b>31,192</b> |                  | <b>-2,5%</b> | <b>-7,2%</b> |
|     | SE            | 1,098         | 1,156         | 1,263         | Max              | -29,8%       | -35,1%       |
|     | t test vs. T0 | ---           | 0,185         | 0,006         | Min              | 9,9%         | 8,5%         |



**GRAPH 7** - The graph shows the mean data obtained at each experimental time for the analysed parameter. Data are expressed as mean  $\pm$  SE. Above the error bar the statistical analysis is reported as follow: \*\*\*  $p < 0.001$  vs T0; \*\*  $p < 0.01$  vs T0; \*  $p < 0.05$  vs T0.



**COMMENT**

After 28 days of application, the tested product determines a statistically significant decrease (vs T0) of Ra basal mean values by -7.2%. A decrease of this parameter indicates an improvement of skin smoothness.



**SKIN pH – SHORT TERM**

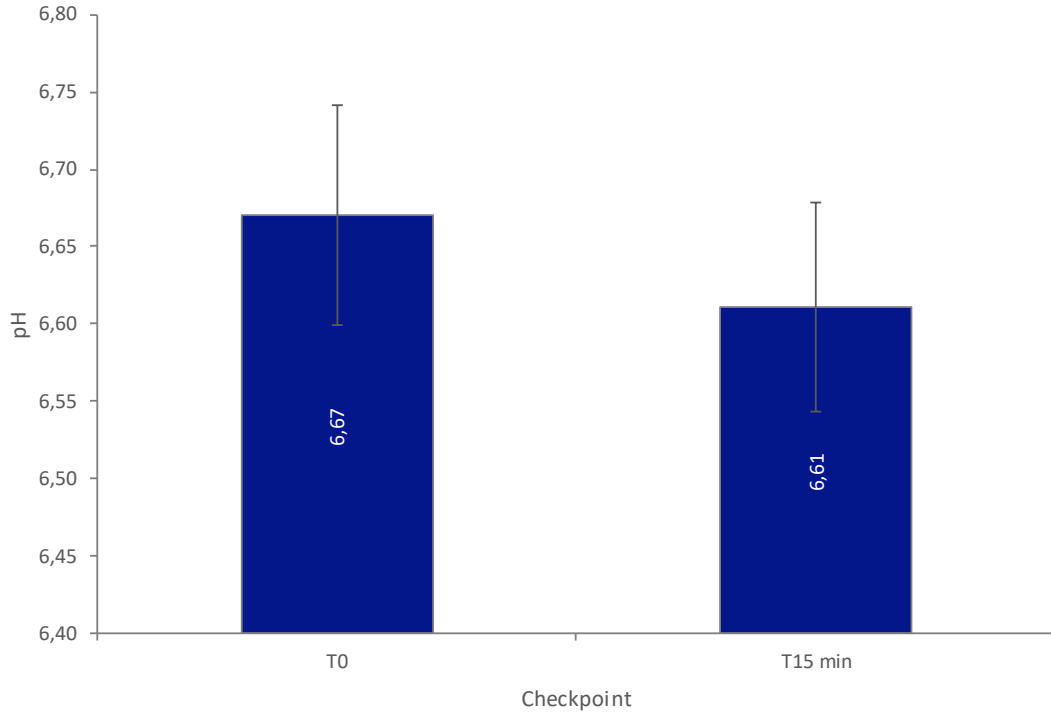
**TABLE 8** - The table below shows the data obtained for each subject participating in the study. Data are expressed as pH values.

| no. | Vol. ID       | T0          | T15 min     |                  | T15 min      |
|-----|---------------|-------------|-------------|------------------|--------------|
| 01  | S4252R        | 6,61        | 6,56        | Variation vs. T0 | -0,8%        |
| 02  | M0476P        | 6,94        | 6,64        |                  | -4,3%        |
| 03  | P7029A        | 6,97        | 6,83        |                  | -2,0%        |
| 04  | L1086A        | 6,58        | 6,17        |                  | -6,2%        |
| 05  | I4588E        | 6,47        | 6,57        |                  | 1,5%         |
| 06  | C5001G        | 6,16        | 6,11        |                  | -0,8%        |
| 07  | P4280M        | 6,6         | 6,41        |                  | -2,9%        |
| 08  | C1227F        | 6,56        | 6,57        |                  | 0,2%         |
| 09  | S1741G        | 6,62        | 6,61        |                  | -0,2%        |
| 10  | P4545D        | 6,57        | 6,44        |                  | -2,0%        |
| 11  | C1267R        | 6,57        | 6,65        |                  | 1,2%         |
| 12  | D5365P        | 6,61        | 6,78        |                  | 2,6%         |
| 13  | B5498S        | 7,15        | 7,08        |                  | -1,0%        |
| 14  | C4970G        | 6,89        | 6,52        |                  | -5,4%        |
| 15  | P5128O        | 6,17        | 6,25        |                  | 1,3%         |
| 16  | N5078M        | 6,08        | 6,18        |                  | 1,6%         |
| 17  | F5103R        | 6,76        | 6,76        |                  | 0,0%         |
| 18  | I5978L        | 7,18        | 7,09        |                  | -1,3%        |
| 19  | S6370P        | 7,17        | 7,15        |                  | -0,3%        |
| 20  | P5231S        | 6,24        | 6,21        |                  | -0,5%        |
| 21  | C5228R        | 6,68        | 6,71        |                  | 0,4%         |
| 22  | M5192P        | 7,16        | 7,15        |                  | -0,1%        |
|     | Mean          | <b>6,67</b> | <b>6,61</b> |                  | <b>-0,9%</b> |
|     | SE            | 0,1         | 0,1         | Min              | -6,2%        |
|     | t test vs. T0 | ---         | 0,079       | Max              | 2,6%         |





**GRAPH 8** - The graph shows the mean data obtained at each experimental time for the analysed parameter. Data are expressed as mean  $\pm$  SE. Above the error bar the statistical analysis is reported as follow: \*\*\*  $p < 0.001$  vs T0; \*\*  $p < 0.01$  vs T0; \*  $p < 0.05$  vs T0.



**COMMENT**

Test product doesn't alter the basal skin pH 15 minutes after its first application.

**COMPLIFE Italia S.r.l.**

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

Sedi principali:  
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504



**OPHTHALMOLOGICAL EVALUATION OF PRODUCT TOLERABILITY**

**TABLE 9** - The table below reports the physical (assessed by the ophthalmologist) and functional (self-reported by subjects) signs at each timepoint, according to the score reported in the legend below.

| no. | Vol. ID | Physical signs |     |     |                     |     |     |             |     |     | Functional signs       |     |     |                            |     |     |                   |     |     |        |     |     |   |
|-----|---------|----------------|-----|-----|---------------------|-----|-----|-------------|-----|-----|------------------------|-----|-----|----------------------------|-----|-----|-------------------|-----|-----|--------|-----|-----|---|
|     |         | Vasodilatation |     |     | Periocular swelling |     |     | Lacrimation |     |     | Foreign body sensation |     |     | Itching/Stinging sensation |     |     | Burning sensation |     |     | Others |     |     |   |
|     |         | T0             | T14 | T28 | T0                  | T14 | T28 | T0          | T14 | T28 | T0                     | T14 | T28 | T0                         | T14 | T28 | T0                | T14 | T28 | T0     | T14 | T28 |   |
| 01  | S4252R  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 02  | M0476P  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 03  | P7029A  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 04  | L1086A  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 05  | I4588E  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 06  | C5001G  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 07  | P4280M  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 08  | C1227F  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 09  | S1741G  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 10  | P4545D  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 11  | C1267R  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 12  | D5365P  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 13  | B5498S  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 14  | C4970G  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 15  | P5128O  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 16  | N5078M  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 17  | F5103R  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 18  | I5978L  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 19  | S6370P  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 20  | P5231S  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 21  | C5228R  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |
| 22  | M5192P  | 0              | 0   | 0   | 0                   | 0   | 0   | 0           | 0   | 0   | 0                      | 0   | 0   | 0                          | 0   | 0   | 0                 | 0   | 0   | 0      | 0   | 0   | 0 |

Legend. 0. No, 1. Very mild, 2. Mild, 3. Moderate, 4. Severe.



### SELF-ASSESSMENT QUESTIONNAIRE

**TABLE 10a** - the table summarizes the results of the self-assessment questionnaire. Results are calculated as percentage (%) of subjects who assigned a judgment (among those proposed).

#### AFTER FIRST PRODUCT APPLICATION

| No. | Items   | Very pleasant   | Pleasant    | Neither pleasant nor unpleasant | Unpleasant | Very unpleasant | Positive answers |
|-----|---|-----------------|-------------|---------------------------------|------------|-----------------|------------------|
| 01  | What do you think about the product aspect and color? | 54,5%           | 40,9%       | 4,5%                            | 0,0%       | 0,0%            | 95,5%            |
| 02  | What do you think about the product texture?          | 36,4%           | 59,1%       | 4,5%                            | 0,0%       | 0,0%            | 95,5%            |
| 03  | What do you think about product's smell?*             | 50,0%           | 45,5%       | 4,5%                            | 0,0%       | 0,0%            | 95,5%            |
| 04  | What do you think about product application?          | 45,5%           | 50,0%       | 4,5%                            | 0,0%       | 0,0%            | 95,5%            |
| No. | Items   | Very good       | Good        | Not good                        | Poor       |                 | Positive answers |
| 05  | What do you think about product penetration?          | 45,5%           | 45,5%       | 9,1%                            | 0,0%       |                 | 90,9%            |
| No. | Items   | Silky           | Soft        | Sticky                          | Oily       |                 |                  |
| 06  | What is the after feel on the skin?                   | 31,8%           | 31,8%       | 36,4%                           | 0,0%       |                 |                  |
| No. | Items   | Very good       | Good        | Not good                        | Poor       |                 | Positive answers |
| 07  | What is your overall appreciation of this product?*   | 31,8%           | 63,6%       | 4,5%                            | 0,0%       |                 | 95,5%            |
| No. | Items   | Yes, absolutely | Yes, mildly | Yes, slightly                   | No         |                 | Positive answers |
| 08  | After the application, does the skin appear hydrated? | 50,0%           | 31,8%       | 13,6%                           | 4,5%       |                 | 95,5%            |
| 09  | After application, does the skin appear softer?       | 31,8%           | 40,9%       | 27,3%                           | 0,0%       |                 | 100,0%           |

#### Legend

Positive answers → % of subjects who gave positive judgement as “very pleasant” or “pleasant” or “very good” or “good” or “yes, absolutely” or “yes, mildly”

The percentages are rounded off, this is why the sum of these percentages may be different from 100%.

\*see annex I

**TABLE 10b** - The table summarizes the results of the self-assessment questionnaire. Results are calculated as percentage

Page 29 out 32

#### COMPLIFE Italia S.r.l.

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

Sedi principali:  
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 | +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 | +39.0382.25504



(%) of subjects who assigned a judgment (among those proposed).

**AFTER 28 DAYS OF PRODUCT APPLICATION**

| No. | After 28 days weeks of application, have you noticed that:  | Agree             | Moderately agreed     | Not completely agreed | Not agreed     | Positive answers |
|-----|---|-------------------|-----------------------|-----------------------|----------------|------------------|
| 01  | Your skin is more moisturized   | 68,2%             | 31,8%                 | 0,0%                  | 0,0%           | 100,0%           |
| 02  | Your skin appears better protected and less prone to skin issues due to exposure to external aggressions (dullness, more visible fine lines, redness, dark spots) | 40,9%             | 54,5%                 | 4,5%                  | 0,0%           | 95,5%            |
| 03  | Your skin is smoother   | 63,6%             | 31,8%                 | 4,5%                  | 0,0%           | 95,5%            |
| 04  | Fine lines and wrinkles are less visible  | 45,5%             | 40,9%                 | 13,6%                 | 0,0%           | 86,4%            |
| 05  | Your skin appears more elastic and firmer   | 68,2%             | 27,3%                 | 4,5%                  | 0,0%           | 95,5%            |
| 06  | Your face appears fuller and the skin plumper   | 50,0%             | 36,4%                 | 13,6%                 | 0,0%           | 86,4%            |
| No. | After 28 days of application, the following skin issues seem improved:  | Strongly          | Improved              | Unchanged             | Aggravated     | Positive answers |
| 07  | Lack of skin plumpness  | 27,3%             | 45,5%                 | 22,7%                 | 4,5%           | 72,7%            |
| 08  | Visible signs of fatigue, tired look  | 22,7%             | 50,0%                 | 22,7%                 | 4,5%           | 72,7%            |
| 09  | Lack of skin firmness and elasticity  | 27,3%             | 50,0%                 | 18,2%                 | 4,5%           | 77,3%            |
| 10  | Skin sagging  | 36,4%             | 36,4%                 | 27,3%                 | 0,0%           | 72,7%            |
| 11  | Lack of skin smoothness   | 27,3%             | 50,0%                 | 22,7%                 | 0,0%           | 77,3%            |
| No. | SUBSEQUENT USE OF THE PRODUCT   | Luxe              | Masstige              | Mass market           |                |                  |
| 12  | According to you, this product is sold in which market segment?*  | 40,9%             | 59,1%                 | 0,0%                  | ---            |                  |
| No. | Items   | Very good         | Good                  | Not good              | Bad            | Positive answers |
| 13  | What is your overall appreciation of this product in terms of efficacy?   | 36,4%             | 59,1%                 | 4,5%                  | 0,0%           | 95,5%            |
| No. | Items   | Absolutely yes    | Maybe                 | Probably not          | Absolutely not | Positive answers |
| 14  | Would you continue using this product?*   | 63,6%             | 31,8%                 | 4,5%                  | 0,0%           | 95,5%            |
| No. | Items   | All over the year | Just in spring/summer |                       |                |                  |
| 15  | If you would you continue using this product, when would you apply it?  | 63,6%             | 36,4%                 | ---                   | ---            |                  |
| No. | Items   | Absolutely yes    | Maybe                 | Probably not          | Absolutely not | Positive answers |
| 16  | Would you buy this product independently from price? *  | 18,2%             | 72,7%                 | 9,1%                  | 0,0%           | 90,9%            |
| 17  | Would you suggest this product to your acquaintance? *  | 77,3%             | 18,2%                 | 4,5%                  | 0,0%           | 95,5%            |

**Legend**

Positive answers → % of subjects who gave positive judgement as “strongly” “improved” or “pleasant” or “agree” or “moderately agreed” or “very good” or “good” or “absolutely yes” or “maybe”

The percentages are rounded off, this is why the sum of these percentages may be different from 100%.

\*see annex I



## CONCLUSIONS

On the basis of the obtained results, it is possible to conclude that the treatment

# RIVOLI COSMÉTIQUES SA

## L'EAU DE JOUR N'02 Formula code lab-01414.22

determined:

- an improvement of skin moisturization basal mean values respectively by 61.0% at T15min and 40.7% at T1h and by 27.0% both at T14 and T28;
- an improvement of R2 parameter (**skin elasticity**) respectively by 2.8% at T14 and 6.0% at T28%. R2 values are directly proportional to the degree of skin elasticity. An increase of this parameter is indicative of an improvement of skin elasticity;
- an improvement of R0 parameter (**skin firmness**) respectively by 5.3% at T14 and by 13.5% at T28;
- an improvement of **wrinkle depth** parameter by 12.3% at T14 and 18.7% at T28;
- an improvement of **wrinkle volume** by 7.1% at T14 and 9.8% at T28%;
- an improvement of Ra parameter (**skin smoothness**) by 7.2% at T28;

Reported % variations are statistically significant vs. T0.

The pH mean value remains almost unvaried 15 minutes after the first product use, index that it doesn't alter the basal skin conditions.

Moreover, the product is positively judged by most of the subjects participating in the study for all the investigated aspects.

Furthermore the product  
**HAS BEEN OPHTHALMOLOGICALLY TESTED,  
IT WAS WELL TOLERATED AND IT IS SAFE FOR ITS USE UNDER THE TEST CONDITIONS.**

**Dermatologist**

**Dr Enza Cestone**

**Ophthalmologist**

**Dr Francesco Sandolo**

**In vivo data analysis and report**

**Dr Ludovica Germani**

**Quality control**

**Dr Beatrice Tenconi**

### COMPLIFE Italia S.r.l.

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

Sedi principali:  
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 | +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 | +39.0382.25504



|           |  |
|-----------|--|
| Customer  | RIVOLI COSMÉTIQUES SA                  |
| Record no | H.E.HU.MP.NAA02.020.10.00_IT0003762/22 |
| Date      | 14/10/2022                             |

## ANNEX I

### Statement on report results extension to the formula lab-01414.24.

Based on the analysis of the qualitative and quantitative composition, the results reported in this study, performed on the formulation lab-01414.22, can be extended to the formulation lab-01414.24 (both containing the perfume Dreaming Night, in the formula lab-01414.22 at 0.2% and at in the formula lab-01414.24 at 0.1%).

However in the self-assessment questionnaire, the results indicated with an asterisk (\*) may be to some extent influenced by perfume and are therefore only partially valid for the formula lab-01414.24.

**INCI formula lab-01414.24:** AQUA (WATER), PROPANEDIOL, NIACINAMIDE, 1,2-HEXANEDIOL, GLYCERIN, PROPYLENE GLYCOL, CAPRYLOYL/CAPROYL ANHYDRO METHYL GLUCAMIDE, FUMARIC ACID, PARFUM (FRAGRANCE), POLYDATIN GLUCOSIDE, CITRIC ACID, SODIUM CITRATE, METHYLGLUCOSIDE PHOSPHATE, COPPER LYSINATE/PROLINATE, CITRUS LIMON (LEMON) FRUIT EXTRACT, FUMARIA OFFICINALIS FLOWER/LEAF/STEM EXTRACT, DISODIUM ACETYL GLUCOSAMINE PHOSPHATE, CI 14700 (RED 4).

## COMPLIFE Italia S.r.l.

info@complifegroup.com  
complifeitalia@legalmail.it  
complifegroup.com

Sedi principali:  
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138  
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

