

Clinical instrumental evaluation of the lifting and brightening efficacy of a cosmetic product for the face

TORSTONE SA **RIVOLI** **SERUM LUMIERE N°02**

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

Sede legale: Via Guido Rossa, 1 20024 Garbagnate M.se (MI) Italy, I P.I./C.F. 11093320155
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KEY PERSONNEL

Customer

TORSTONE SA
International Center Cointrin
Route de Pré-Bois, 20
Bât. C, 2è étage
CP1913
CH-1215 GENÈVE 15

Principal experimenter

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

Study director

Dr. Ileana DE PONTI
Chemist and pharmaceutical technologist
Complife Italia s.r.l.

Data analysis and report

Dr. Federica RUGGERI
Biologist
Complife Italia S.r.l.

Complife Italia S.r.l

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

COMPLIFE Italia S.r.l.

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

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STUDY DESIGN

1.1. Title

Clinical instrumental evaluation of the lifting and brightening efficacy of a cosmetic product for the face.

1.2. Aim of the study

The study is aimed to evaluate the effect (short term test) and efficacy (long term test) of a cosmetic product for the face in improving skin radiance and skin profilometry (in terms of decreasing wrinkle depth and improving skin smoothness) both after its first application and after a period of use.

In order to reach this goal, a clinical-instrumental study is carried out on 20 healthy female subjects, aged between 35 and 60 years old, clinically showing dull and uneven skin tone (50% of subjects showing skin redness and 50% showing dark spots due to ageing-photoageing) and visible crow's feet, forehead and nasolabial folds wrinkles

Product effect/efficacy are evaluated 30 minutes (T30min), 2 hours (T2h) and 24h (T24h) after its first application and after 7 (T7) and 28 (T28) days of use by means of non-invasive bioengineering techniques. The instrumental analysis is integrated with the clinical assessment carried out by the Dermatologist and by the self-assessment filled in by the enrolled volunteers.

1.3. Tested product

1.3.1. Information provided by the Customer

- ☒ Product name: **SERUM LUMIERE N°02 (code: lab-01432.7)**
- ☒ Way of use: apply twice a day (morning and evening) of face.
- ☒ The tested cosmetic product 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 tested cosmetic product was evaluated for its safety of use on human volunteers (safety assessment).
- ☒ INCI formula: AQUA (WATER), COCOS NUCIFERA (COCONUT) OIL, GLYCERIN, CAPRYLIC/CAPRIC TRIGLYCERIDE, HYDROGENATED PHOSPHATIDYLCHOLINE, UNDECANE, PROPANEDIOL, BUTYLENE GLYCOL, BUTYROSPERMUM PARKII (SHEA) BUTTER, PENTYLENE GLYCOL, TRIDECANE, SODIUM POLYSTYRENE SULFONATE, CAPRYLYL GLYCOL, SODIUM POTASSIUM ALUMINUM SILICATE, SORGHUM BICOLOR STALK JUICE, SYNTHETIC FLUORPHLOGOPITE, XANTHAN GUM, ETHYLHEXYLGLYCERIN, GLYCERYL STEARATE, SODIUM STEAROYL GLUTAMATE, CI 77891 (TITANIUM DIOXIDE), SQUALANE, BORON NITRIDE, NIACINAMIDE, PARFUM (FRAGRANCE), DIPROPYLENE GLYCOL, GLYCERYL CAPRYLATE, SILICA, TITANIUM DIOXIDE (CI77891), DISODIUM ADENOSINE TRIPHOSPHATE, GELLAN GUM, DIGLUCOSYL GALLIC ACID, HYDROLYZED OATS, CERAMIDE NP, POTASSIUM SORBATE, SODIUM BENZOATE, TIN OXIDE, TOCOPHEROL.

1.4. Ethical requirements

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

1. All the subjects participating in the study are healthy volunteers of at least 18 years old.
2. All of the subjects participating in the study are selected with the supervision of a dermatologist according to inclusion/not inclusion criteria.
3. Volunteers participation in the study was totally free.
4. All of the subjects participating in the study are informed of the aim and the design of the study.
5. All of the subjects participating in the study are informed of the possible risk involved in the study execution.
6. All of the subjects participating in the study give their informed consent signed at the beginning of the study.
7. Before volunteer exposure to the tested product, all relevant safety information about the product itself and each ingredient were collected and evaluated.
8. 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).
9. All of the precautions are taken in consideration in order to avoid excessive skin reactions.
10. If any unexpected/adverse skin reaction occurs, medical investigating specialist evaluates the severity of the

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reaction (reporting it in the volunteer's data collecting sheet) and proceeds with appropriate therapy.

1.5. Subjects

1.5.1. Subjects selection

The subjects participating in the study were selected by a board certified Dermatologist from a panel of healthy female volunteers, in accordance with the following inclusion/non-inclusion criteria.

1.5.1.1. Inclusion criteria

- ☒ Healthy female subjects
- ☒ Aged between 35 and 60 years old
- ☒ Caucasian ethnicity
- ☒ Subjects with all skin type (without any specific repartition)
- ☒ Subjects clinically dull and uneven skin tone (50% of subjects showing skin redness and 50% of subjects showing skin spots due to ageing-photoageing) and visible crow's feet, forehead and nasolabial folds wrinkles.
- ☒ Commitment to adhere strictly to the information reported in the study information form
- ☒ Commitment not to use for all the study length other topical products with an activity comparable to the products under study
- ☒ Commitment not to expose to the sun/solar lamps during the study period
- ☒ Subjects aware of the test procedure who have signed an informed consent form.

1.5.1.2. Non-inclusion criteria

- ☒ Subjects who do not fit the inclusion criteria
- ☒ Pregnant or nursing women
- ☒ Subjects that have shown allergies to cosmetic products, toiletries, sunscreens and/or topical drugs
- ☒ Subjects with skin pathologies in the test area
- ☒ Subjects under pharmacological treatment (both locally or systemically) that may interfere with the test execution
- ☒ Positive anamnesis for atopy (if this condition interferes with the test execution).

1.5.1.3. Study withdrawal

- ☒ Subjects not respecting the conditions described in the information form
- ☒ Occurrence of accidents, pathologies or conditions which could interfere with the study
- ☒ Subjects who no longer want to participate in the study.

1.6. Study procedure

The study is carried out as follow:

- **T0:** enrollment of 20 subjects according to inclusion/non-inclusion criteria. Instrumental and clinical analysis of the parameters under study (basal evaluation, T0);
- **SHORT TERM TEST:** instrumental evaluation of skin radiance, profilometry (wrinkle depth and Ra parameter in the crow's feet area) and skin pH* after 30minutes (T30min), 2 hours** (T2h) and 24hours*** (T24h) from the first product application. Moreover, volunteers are asked to express their opinion on tested product by answering to a questionnaire after its first application and at T30min.
 *skin pH measurement is performed in order to verify that the product doesn't alter skin conditions at T2h.
 **during the first 2 hours after product application, subjects remain in the test facility under controlled temperature and humidity conditions.
 ***during the first 24 hours after product application, subjects have to avoid to wash their face and to apply any products on face skin.
- **LONG TERM TEST:** instrumental evaluation of skin radiance and profilometry (wrinkle depth - crow's feet area, nasolabial folds and forehead lines - and Ra parameter in the crow's feet area) after 7 (T7) and 28 (T28) days of product use. Clinical evaluation of the skin complexion evenness. Moreover, digital pictures of the treated area are acquired and volunteers are asked to express their opinion on tested product by answering to a questionnaire.



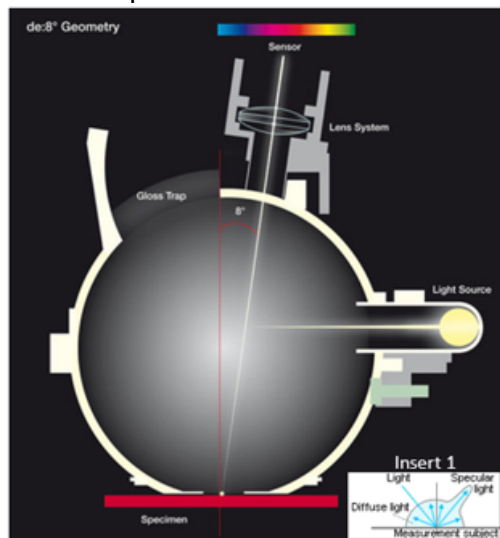
1.7. Materials and methods

In the sections here below the materials and methods used in this study are reported. All the study procedures are carried out under temperature and humidity controlled conditions (temperature 18-26°C and humidity 50±10%).

1.7.1. Skin radiance – T0, T30min, T2h, T24h, T7, T28

Skin radiance (or skin brightness), is the ability of the skin to reflect the light and it is measured using the gloss parameter (taken using the spectrophotometer/colorimeter CM-700D (Konica-Minolta). The instrument emits diffuse light that reaches the skin through an opening located at the extreme of the lighting sphere. A sensor located at 8 ° compared to the vertical axis of the opening detects then the reflected light and calculates a parameter known as "gloss". The gloss value is used in the management of the brilliance of the colour. For further information on the principle of the measurement and data analysis see box 1.

Box 1 – Gloss parameter



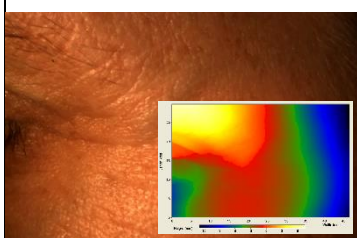
When light reach a surface it is reflected at the equal but opposite angle from the light source; this is called specularly reflected light. This specular component is reflected as if reflected by a mirror. The light that is not specularly reflected, but scattered in many directions, is called diffuse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

illuminate the sample. The relation between directional and diffuse reflection allows calculating the gloss component. The measuring system including gloss is named $di: 8^\circ$ whilst the measuring system excluding gloss is described as $de: 8^\circ$.

1.7.2. Skin profilometry – T0, T30min, T2h, T24h, T7, T28

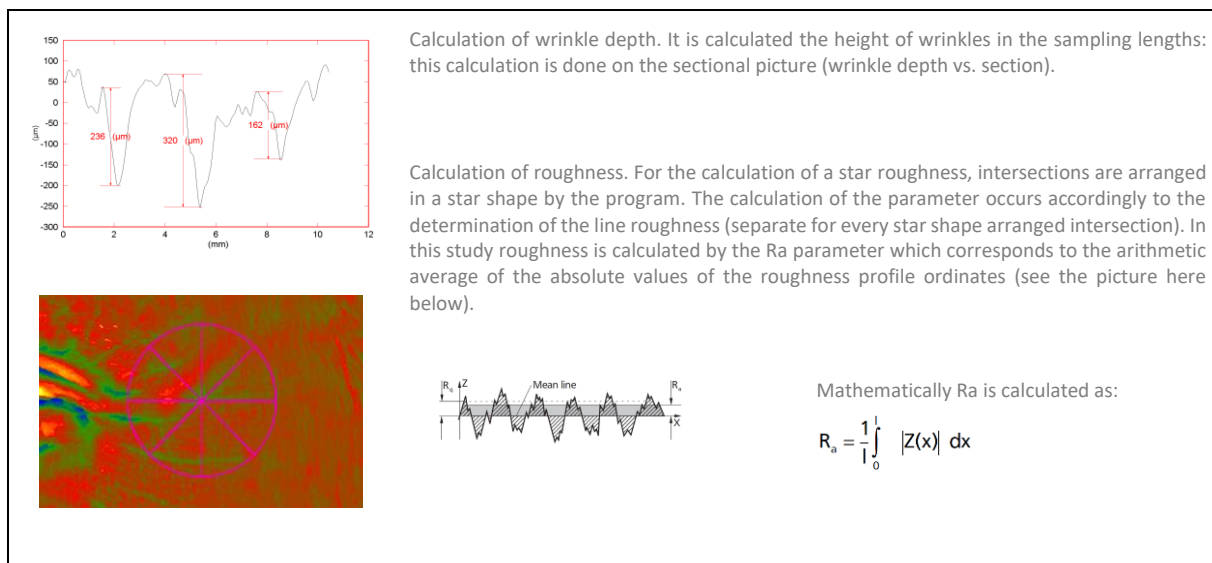
Skin surface is quantitatively assessed by Primos 3D (GFMeasstechnik GmbH). Primos 3D is a non-contact *in vivo* skin measurement device based on structured light projection. In conjunction with a comprehensive 3-D measurement and evaluation software, the sensor allows to evaluate skin surface properties (i.e. wrinkle depth, volume, roughness etc.). In this study wrinkle depth and Ra parameter (related to skin smoothness) are evaluated. For further information see box. 2.

BOX 2 - 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 have 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).





1.7.3. Skin pH – T0, T2h, T24h

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.

1.7.4. Clinical evaluation

Clinical evaluation is performed according to the clinical scores reported box 3. A separate evaluation is performed for subjects showing redness and skin spots due to ageing-photoageing.

SKIN COMPLEXION EVENNESS

BOX 3a - Clinical evaluation of skin complexion evenness at T0	Score	BOX 3b - Clinical evaluation of the improvement of skin complexion evenness at T28	Score
Skin complexion is not even; presence of cutaneous discolorations all over the face	1	No variation	1
Uneven complexion; presence of cutaneous discolorations in some parts of the face	2	Slight improvement	2
Fairly even complexion	3	Moderate improvement	3
Even complexion	4	Remarkable improvement	4

1.7.5 Digital macrophotography – T0, T28

Pictures of the treated area are acquired at each experimental monitored check by means of Visioface (Courage+Khazaka). Best cases (3 subjects) are reported in annex 1.

1.7.6. Self-assessment – after product application, T30min, T28

Volunteers are asked to express their opinion on product efficacy and properties by answering to a questionnaire.

1.8. Results and Statistics

1.8.1 Results

The Results are reported in their respective units in tables.

- 1) The mean values are calculated as:



$$m = \frac{\sum_{i=1}^n P_i}{n} \quad [1]$$

where:

n is the number of subjects who ended the study

P is the value of the parameter to be analyzed.

- 2) The mean standard error is calculated as:

$$SEM = \frac{\sqrt{\frac{\sum_{i=1}^n (P_i^2) - \frac{(\sum_{i=1}^n P_i)^2}{n}}{(n-1)}}}{\sqrt{n}} \quad [2]$$

- 3) The mean percentage variations were calculated as:

$$\overline{Var(\%)} = \sum_{i=1}^n \frac{P_i - P_0}{P_0} \quad [3]$$

where

P₀ is the value of the parameter to be analyzed at T₀;

P_i is the value of the parameter to be analyzed at monitored experimental times.

All the calculations are done using a Microsoft® Excel.

The results of self-assessment questionnaire 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 then divided by the total number of subjects → % of answers.

1.8.2. Statistical analysis

The instrumental data are submitted to 2-way Student's test t for paired data. Statistical analysis is carried out by means of a Microsoft® Excel worksheet. The variation is considered statistically significant when p value is <0.05. The statistical analysis foresees the comparison vs T₀. Only the data of subjects who ended the study as protocol directed were considered in the statistical analysis.

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 (eg. 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 product must be perceived by at least 60% of the subjects. Whenever reference values or threshold values exists that 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
19/05/2021	15/07/2021



1.10. Report change record

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
Draft 00	n.a.	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 s.r.l.
 - A copy of this report is kept on file at Complife s.r.l.
 - Both the informed consent and the information forms are kept on file at Complife s.r.l. for 10 years after the date of issue of the report

COMPLIFE Italia S.r.l.

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SUBJECTS DEMOGRAPHY

n	Vol ID	Age	Skin type
01	M0237R	58	mixed
02	M0253F	46	mixed
03	D1353D	53	mixed
04	D0106M	42	dry
05	B5476M	50	mixed
06	R4029M	54	dry
07	T1725S	49	oily
08	V3024C	58	mixed
09	M0217A	56	oily
10	P4759A	51	dry
11	M1104S	47	oily
12	P2090S	50	oily
13	D1532C	60	normal
14	R0855P	57	mixed
15	A1522C	41	mixed
16	C2404L	50	normal
17	M0837D	60	dry
18	A0677G	59	normal
19	F4104C	59	normal
20	S4700M	36	mixed
Mean		52	Oily 20%
Min		36	Mixed 40%
Max		60	Normal 20%
			Dry 20%

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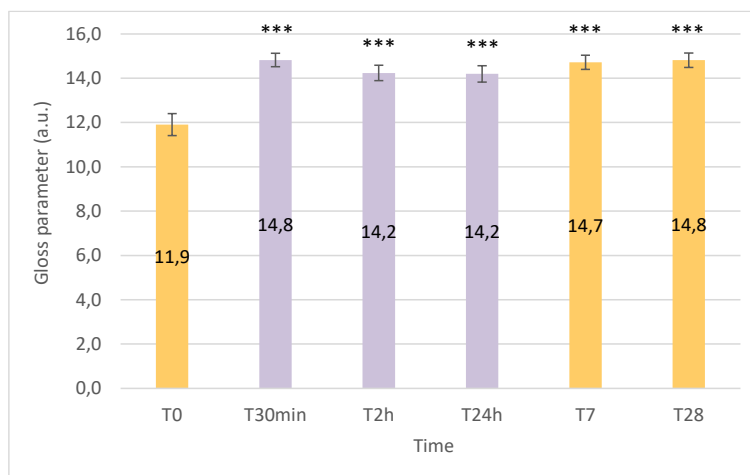
RESULTS

SKIN RADIANCE – GLOSS PARAMETER

TABLE 1. The table below reports the data obtained for each subject taking part in the study for the parameter under study. Data are expressed as arbitrary units (a.u.).

n	Vol ID	T0	T30min	T2h	T24h	T7	T28	% VARIATION VS. T0	T30min	T2h	T24h	T7	T28
01	M0237R	11,73	17,63	16,42	15,29	15,89	15,93		50,3%	40,0%	30,3%	35,5%	35,8%
02	M0253F	11,60	14,71	13,62	14,52	14,21	15,75		26,8%	17,4%	25,2%	22,5%	35,8%
03	D1353D	9,71	13,09	13,02	11,79	13,13	13,77		34,8%	34,1%	21,4%	35,2%	41,8%
04	D0106M	11,52	15,83	14,32	13,11	14,32	14,73		37,4%	24,3%	13,8%	24,3%	27,9%
05	B5476M	13,62	17,52	16,22	15,32	15,93	16,17		28,6%	19,1%	12,5%	17,0%	18,7%
06	R4029M	10,49	15,10	14,21	13,35	14,76	14,88		43,9%	35,5%	27,3%	40,7%	41,8%
07	T1725S	8,43	12,43	11,13	10,43	11,39	9,79		47,4%	32,0%	23,7%	35,1%	16,1%
08	V3024C	9,73	13,71	13,01	13,89	13,79	14,03		40,9%	33,7%	42,8%	41,7%	44,2%
09	M0217A	10,52	14,23	14,05	13,21	13,78	14,69		35,3%	33,6%	25,6%	31,0%	39,6%
10	P4759A	7,06	16,77	10,05	10,61	12,73	13,09		137,5%	42,4%	50,3%	80,3%	85,4%
11	M1104S	10,64	14,36	15,24	15,70	15,61	14,15		35,0%	43,2%	47,6%	46,7%	33,0%
12	P2090S	12,61	13,76	14,91	15,14	15,73	15,81		9,1%	18,2%	20,1%	24,7%	25,4%
13	D1532C	12,26	15,25	15,51	15,86	15,91	15,91		24,4%	26,5%	29,4%	29,8%	29,8%
14	R0855P	15,24	15,20	15,24	15,37	15,41	15,78		-0,3%	0,0%	0,9%	1,1%	3,5%
15	A1522C	13,50	14,60	14,98	15,55	15,01	15,71		8,1%	11,0%	15,2%	11,2%	16,4%
16	C2404L	14,73	14,97	14,23	14,67	14,14	14,86		1,6%	-3,4%	-0,4%	-4,0%	0,9%
17	M0837D	13,57	14,24	14,77	15,30	15,21	15,30		4,9%	8,8%	12,7%	12,1%	12,7%
18	A0677G	15,29	15,33	15,23	15,75	17,92	15,89		0,3%	-0,4%	3,0%	17,2%	3,9%
19	F4104C	12,79	13,56	13,71	14,21	14,15	14,87		6,0%	7,2%	11,1%	10,6%	16,3%
20	S4700M	13,11	14,06	14,85	14,87	15,29	15,15		7,2%	13,3%	13,4%	16,6%	15,6%
Mean		11,9	14,8	14,2	14,2	14,7	14,8		29,0%	21,8%	21,3%	26,5%	27,2%
SEM		0,5	0,3	0,3	0,4	0,3	0,3	Min	-0,3%	-3,4%	-0,4%	-4,0%	0,9%
t-test vs. T0		--	0,000	0,000	0,000	0,000	0,000	Max	137,5%	43,2%	50,3%	80,3%	85,4%

GRAPH 1. The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean $\pm$ SEM.



COMMENT: a statistically significant improvement of gloss parameter (related to skin brightness) is recorded at each experimental monitored check.

Note: the intra-group statistical analysis (vs. T0) is reported above the error bar in black color.

Legend: * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

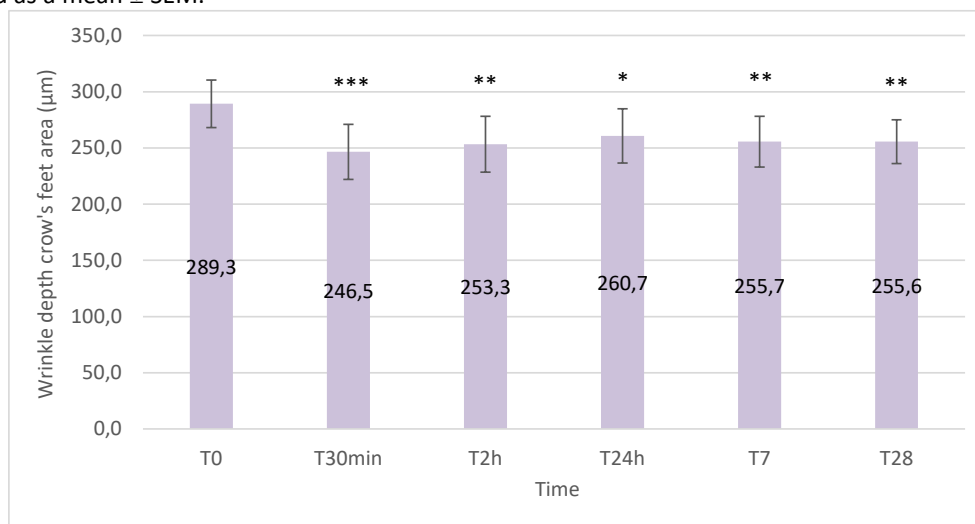


SKIN PROFILOMETRY – wrinkle depth - crow's feet area

TABLE 2. The table below reports the data obtained for each subject taking part in the study for wrinkle depth parameter. Data are expressed as μm .

n	Vol ID	T0	T30min	T2h	T24h	T7	T28	% VARIATION VS. T0	T30min	T2h	T24h	T7	T28
01	M0237R	329,7	204,5	217,0	224,0	286,4	252,1	-38,0%	-38,0%	-34,2%	-32,1%	-13,1%	-23,5%
02	M0253F	368,4	372,0	309,9	412,2	363,8	382,7	1,0%	1,0%	-15,9%	11,9%	-1,2%	3,9%
03	D1353D	380,6	350,2	373,7	340,4	309,2	287,7	-8,0%	-8,0%	-1,8%	-10,6%	-18,8%	-24,4%
04	D0106M	157,2	130,5	135,6	130,0	142,9	153,5	-17,0%	-17,0%	-13,7%	-17,3%	-9,1%	-2,4%
05	B5476M	250,4	225,6	243,2	274,3	226,5	199,0	-9,9%	-9,9%	-2,9%	9,5%	-9,5%	-20,5%
06	R4029M	221,0	169,9	205,5	243,1	187,7	207,3	-23,1%	-23,1%	-7,0%	10,0%	-15,1%	-6,2%
07	T1725S	331,6	253,3	324,3	362,0	209,7	275,9	-23,6%	-23,6%	-2,2%	9,2%	-36,8%	-16,8%
08	V3024C	257,3	265,8	262,7	236,8	238,1	212,3	3,3%	3,3%	2,1%	-8,0%	-7,5%	-17,5%
09	M0217A	243,5	215,4	163,9	209,0	242,2	262,3	-11,5%	-11,5%	-32,7%	-14,2%	-0,5%	7,7%
10	P4759A	335,6	319,0	326,0	303,7	335,7	312,5	-4,9%	-4,9%	-2,9%	-9,5%	0,0%	-6,9%
11	M1104S	232,4	131,8	100,4	115,5	178,7	171,3	-43,3%	-43,3%	-56,8%	-50,3%	-23,1%	-26,3%
12	P2090S	589,0	603,7	599,9	564,0	597,4	535,2	2,5%	2,5%	1,9%	-4,2%	1,4%	-9,1%
13	D1532C	308,9	222,6	242,4	229,0	233,7	242,0	-27,9%	-27,9%	-21,5%	-25,9%	-24,3%	-21,7%
14	R0855P	200,5	192,6	180,4	179,8	206,9	218,6	-3,9%	-3,9%	-10,0%	-10,3%	3,2%	9,0%
15	A1522C	284,5	228,5	241,2	243,8	246,0	270,0	-19,7%	-19,7%	-15,2%	-14,3%	-13,5%	-5,1%
16	C2404L	315,6	224,4	227,3	206,0	178,6	176,1	-28,9%	-28,9%	-28,0%	-34,7%	-43,4%	-44,2%
17	M0837D	336,2	331,1	371,4	377,9	326,3	320,9	-1,5%	-1,5%	10,5%	12,4%	-2,9%	-4,6%
18	A0677G	210,2	162,0	206,8	226,9	221,8	208,4	-22,9%	-22,9%	-1,6%	7,9%	5,5%	-0,9%
19	F4104C	252,9	169,1	173,2	189,1	238,5	251,2	-33,1%	-33,1%	-31,5%	-25,2%	-5,7%	-0,7%
20	S4700M	180,5	158,1	160,3	145,5	143,0	172,5	-12,4%	-12,4%	-11,2%	-19,4%	-20,8%	-4,4%
Mean		289,3	246,5	253,3	260,7	255,7	255,6	-16,2%	-16,2%	-13,7%	-10,8%	-11,8%	-10,7%
SEM		21,2	24,5	24,8	24,1	22,6	19,6	-43,3%	-43,3%	-56,8%	-50,3%	-43,4%	-44,2%
t-test vs. T0		--	0,000	0,002	0,017	0,002	0,002	3,3%	3,3%	10,5%	12,4%	5,5%	9,0%

GRAPH 2. The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean $\pm$ SEM.



COMMENT: a statistically significant decrease of wrinkle depth parameter is recorded at each experimental monitored check in the crow's feet area.

Note: the intra-group statistical analysis (vs. T0) is reported above the error bar in black color.

Legend: * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

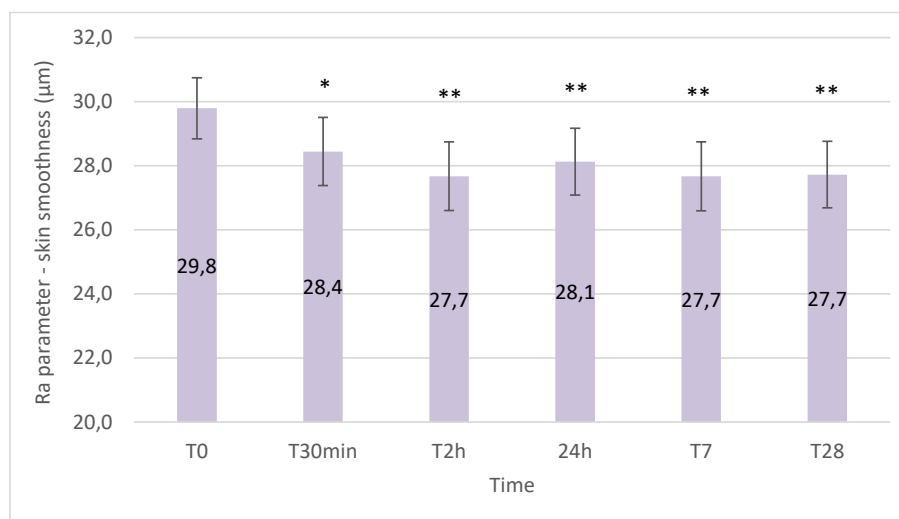


SKIN PROFILOMETRY – Ra parameter - crow's feet area

TABLES 3. The table below reports the data obtained for each subject taking part in the study for Ra parameter. Data are expressed as μm .

n	Vol ID	T0	T30min	T2h	24h	T7	T28	% VARIATION VS. T0
01	M0237R	37,7	34,6	30,9	36,2	36,7	33,7	-8,2%
02	M0253F	28,1	24,6	24,9	27,8	28,0	28,8	-12,5%
03	D1353D	31,6	30,6	31,0	34,7	29,4	29,4	-3,2%
04	D0106M	23,8	22,1	20,9	21,4	20,2	21,9	-7,1%
05	B5476M	32,2	28,5	29,8	30,6	26,8	24,4	-11,5%
06	R4029M	26,9	25,4	25,1	26,9	27,3	25,6	-5,6%
07	T1725S	26,2	28,9	27,5	26,4	24,7	24,1	10,3%
08	V3024C	35,0	28,7	30,4	29,8	31,4	32,2	-18,0%
09	M0217A	21,6	19,2	18,6	20,0	19,1	18,3	-11,1%
10	P4759A	27,8	26,8	25,3	28,1	24,6	22,4	-3,6%
11	M1104S	33,9	30,3	31,6	29,2	29,1	29,2	-10,6%
12	P2090S	36,5	39,3	38,5	37,4	39,5	38,5	7,7%
13	D1532C	28,8	26,6	21,8	25,9	25,4	27,1	-7,6%
14	R0855P	27,3	30,2	24,4	24,7	25,9	26,6	10,6%
15	A1522C	26,9	25,6	25,0	24,1	27,9	27,6	-4,8%
16	C2404L	31,1	29,5	31,5	28,8	26,4	28,4	-5,1%
17	M0837D	32,5	35,8	33,5	31,9	31,2	32,3	10,2%
18	A0677G	31,1	31,3	29,2	30,6	30,5	29,9	0,6%
19	F4104C	25,0	22,7	23,9	22,2	23,8	23,7	-9,2%
20	S4700M	31,8	28,1	29,6	25,8	25,4	30,3	-11,6%
Mean		29,8	28,4	27,7	28,1	27,7	27,7	-4,5%
SEM		1,0	1,1	1,1	1,0	1,1	1,0	-7,3%
t-test vs. T0		--	0,031	0,001	0,003	0,001	0,001	-5,7%
								-7,2%
								-7,0%
								-24,3%
								8,2%
								5,5%
								10,6%
								9,8%
								8,2%
								5,5%
								10,6%
								9,8%
								8,2%
								5,5%
								10,6%
								9,8%
								8,2%
								5,5%

GRAPH 3. The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean $\pm$ SEM.



COMMENT: a statistically significant decrease of Ra parameter is recorded at each experimental monitored check. A decrease of Ra parameter indicates an improvement of skin smoothness; for marketing purposes obtained values can be expressed in absolute values as an improvement of skin smoothness.

Note: the intra-group statistical analysis (vs. T0) is reported above the error bar in black color.

Legend: * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$.

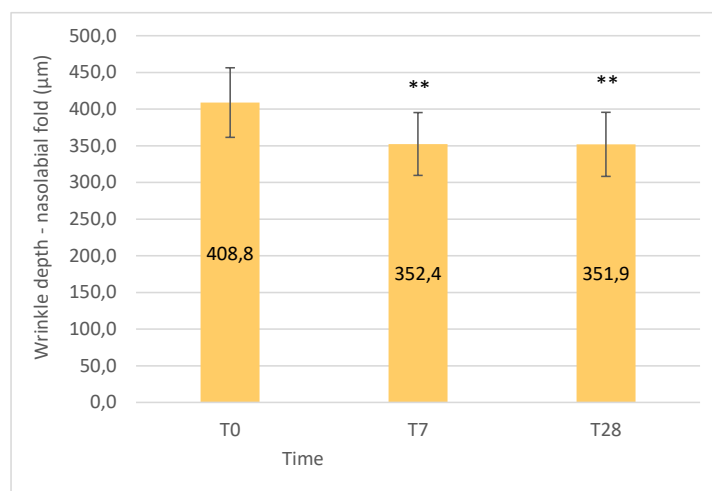


SKIN PROFILOMETRY – wrinkle depth – nasolabial folds

TABLES 4. The table below reports the data obtained for each subject taking part in the study for wrinkle depth parameter. Data are expressed as μm .

n	Vol ID	T0	T7	T28		T7	T28
01	M0237R	393,3	362,4	359,0	% VARIATION VS. T0	-7,9%	-8,7%
02	M0253F	290,1	253,1	277,8		-12,8%	-4,2%
03	D1353D	257,8	233,0	242,3		-9,6%	-6,0%
04	D0106M	177,8	143,7	173,5		-19,2%	-2,4%
05	B5476M	374,1	362,0	307,0		-3,2%	-17,9%
06	R4029M	294,7	248,8	234,0		-15,6%	-20,6%
07	T1725S	259,0	236,2	241,9		-8,8%	-6,6%
08	V3024C	509,8	406,3	434,7		-20,3%	-14,7%
09	M0217A	269,8	281,0	306,7		4,2%	13,7%
10	P4759A	188,0	188,7	192,4		0,4%	2,3%
11	M1104S	233,0	178,9	168,0		-23,2%	-27,9%
12	P2090S	514,2	364,1	339,0		-29,2%	-34,1%
13	D1532C	595,5	498,1	432,3		-16,4%	-27,4%
14	R0855P	511,4	449,4	457,2		-12,1%	-10,6%
15	A1522C	327,5	234,7	227,6		-28,3%	-30,5%
16	C2404L	822,5	891,1	928,4		8,3%	12,9%
17	M0837D	971,3	761,8	748,8		-21,6%	-22,9%
18	A0677G	223,9	208,9	189,3		-6,7%	-15,5%
19	F4104C	584,9	463,0	503,4		-20,8%	-13,9%
20	S4700M	377,6	283,1	275,5		-25,0%	-27,0%
Mean		408,8	352,4	351,9		-13,4%	-13,1%
SEM		47,4	42,8	43,6		Max	-29,2%
t-test vs. T0		--	0,001	0,003		Min	8,3%

GRAPH 4. The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean $\pm$ SEM.



COMMENT: a statistically significant decrease of wrinkle depth parameter is recorded at each experimental monitored check in the nasolabial fold.

Note: the intra-group statistical analysis (vs. T0) is reported above the error bar in black color.

Legend: * p<0.05; ** p<0.01; *** p<0.001.

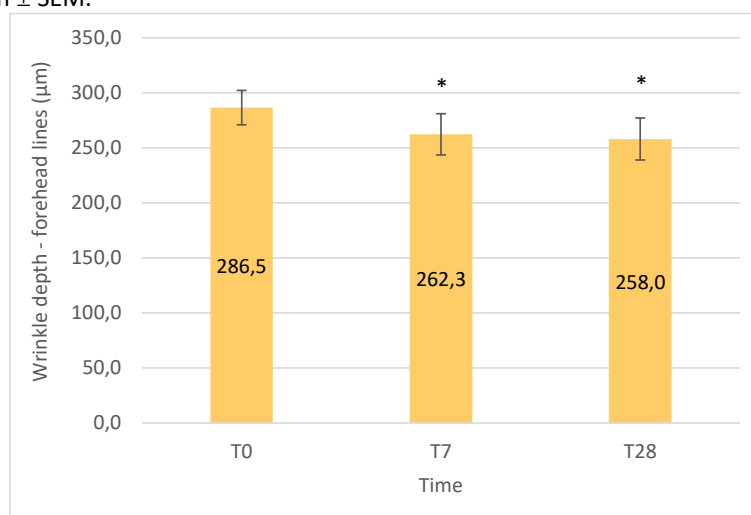


SKIN PROFILOMETRY – wrinkle depth – forehead

TABLES 5. The table below reports the data obtained for each subject taking part in the study for wrinkle depth parameter. Data are expressed as μm .

n	Vol ID	T0	T7	T28		T7	T28
01	M0237R	261,3	193,2	191,2	% VARIATION VS. T0	-26,1%	-26,8%
02	M0253F	208,3	189,5	189,5		-9,0%	-9,0%
03	D1353D	160,8	119,0	85,4		-26,0%	-46,9%
04	D0106M	272,0	295,5	289,8		8,6%	6,5%
05	B5476M	336,2	254,8	182,4		-24,2%	-45,7%
06	R4029M	240,7	247,4	256,7		2,8%	6,6%
07	T1725S	294,0	284,2	309,9		-3,3%	5,4%
08	V3024C	284,0	277,5	260,5		-2,3%	-8,3%
09	M0217A	257,8	229,8	239,4		-10,9%	-7,1%
10	P4759A	345,6	302,8	314,4		-12,4%	-9,0%
11	M1104S	411,2	466,9	370,3		13,5%	-9,9%
12	P2090S	340,6	360,1	378,4		5,7%	11,1%
13	D1532C	390,6	419,1	403,1		7,3%	3,2%
14	R0855P	252,9	223,7	263,9		-11,5%	4,3%
15	A1522C	268,0	217,4	213,8		-18,9%	-20,2%
16	C2404L	236,3	217,2	227,6		-8,1%	-3,7%
17	M0837D	301,0	317,3	329,5		5,4%	9,5%
18	A0677G	281,4	170,3	180,5		-39,5%	-35,9%
19	F4104C	412,0	273,6	345,1		-33,6%	-16,2%
20	S4700M	176,0	185,7	129,5		5,5%	-26,4%
Mean		286,5	262,3	258,0		-8,8%	-10,9%
SEM		15,7	18,8	19,1		Max	-39,5%
t-test vs. T0		--	0,038	0,017		Min	13,5%

GRAPH 5. The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean $\pm$ SEM.



COMMENT: a statistically significant decrease of wrinkle depth parameter is recorded at each experimental monitored check in the forehead.

Note: the intra-group statistical analysis (vs. T0) is reported above the error bar in black color.

Legend: * p<0.05; ** p<0.01; *** p<0.001.

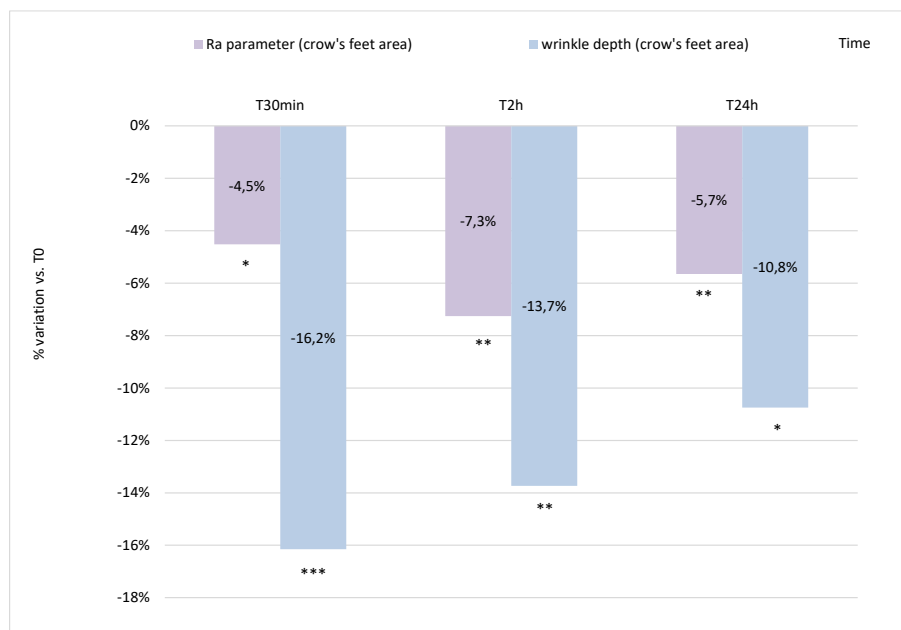


SKIN PROFILOMETRY – SHORT-TERM TEST SUMMARY LIFTING EFFECT

TABLE 6. The table below summarizes the mean % variation, min/max values and statistical analysis (p-value) obtained for skin profilometry parameters at each experimental monitored check.

		T30min	T2h	T24h
Ra parameter - skin smoothness (crow's feet area)	Mean of the % variation vs. T0	-4,5%	-7,3%	-5,7%
	t-test vs. T0 (p-value)	0,031	0,001	0,003
	MAX (maximum variation)	-18,0%	-24,3%	-18,9%
	MIN (minimum variation)	10,6%	5,5%	9,8%
Wrinkle depth (crow's feet area)	Mean of the % variation vs. T0	-16,2%	-13,7%	-10,8%
	t-test vs. T0 (p-value)	0,000	0,002	0,017
	MAX (maximum variation)	-43,3%	-56,8%	-50,3%
	MIN (minimum variation)	3,3%	10,5%	12,4%

GRAPH 6. The graph sets out the mean of the percentage variations obtained at each experimental time for skin profilometry parameters.



COMMENT: a statistically significant decrease of wrinkle depth and Ra parameter is recorded at each experimental monitored check (short-term test) underlying the lifting effect of the product. A decrease of Ra parameter indicates an improvement of skin smoothness; for marketing purposes obtained values can be expressed in absolute values as an improvement of skin smoothness.

Legend: * p<0.05; ** p<0.01; *** p<0.001.

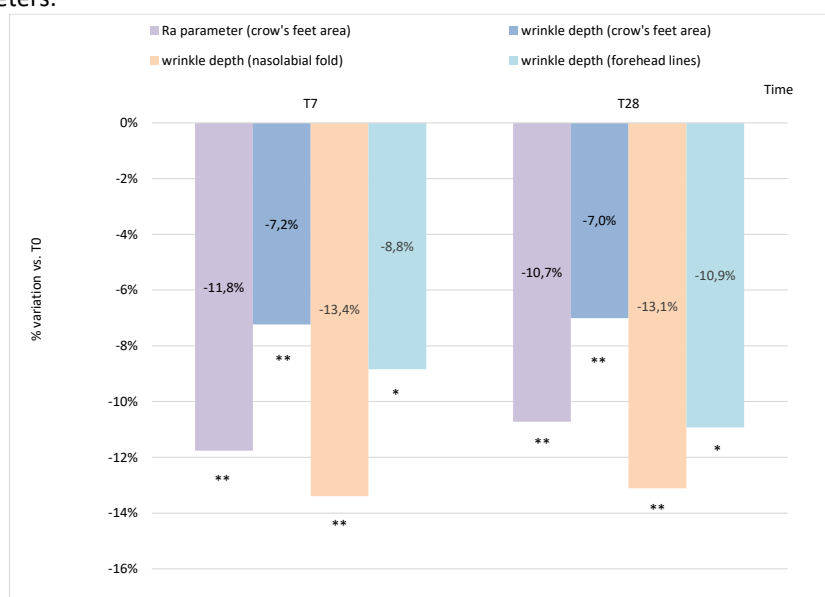


SKIN PROFILOMETRY – LONG-TERM TEST SUMMARY ANTI-WRINKLES EFFICACY

TABLE 7. The table below summarizes the mean % variation, min/max values and statistical analysis (p-value) obtained for skin profilometry parameters at each experimental monitored check.

		T7	T28
Ra parameter - skin smoothness (crow's feet area)	Mean of the % variation vs. T0	-11,8%	-10,7%
	t-test vs. T0 (p-value)	0,002	0,002
	MAX (maximum variation)	-43,4%	-44,2%
	MIN (minimum variation)	5,5%	9,0%
Wrinkle depth (crow's feet area)	Mean of the % variation vs. T0	-7,2%	-7,0%
	t-test vs. T0 (p-value)	0,001	0,001
	MAX (maximum variation)	-20,1%	-24,2%
	MIN (minimum variation)	8,2%	5,5%
Wrinkle depth (nasolabial fold)	Mean of the % variation vs. T0	-13,4%	-13,1%
	t-test vs. T0 (p-value)	0,001	0,003
	MAX (maximum variation)	-29,2%	-34,1%
	MIN (minimum variation)	8,3%	13,7%
Wrinkle depth (forehead lines)	Mean of the % variation vs. T0	-8,8%	-10,9%
	t-test vs. T0 (p-value)	0,038	0,017
	MAX (maximum variation)	-39,5%	-46,9%
	MIN (minimum variation)	13,5%	11,1%

GRAPH 7. The graph sets out the mean of the percentage variations obtained at each experimental time for skin profilometry parameters.



COMMENT: a statistically significant decrease of wrinkle depth (crow's feet area, nasolabial fold and forehead) and Ra parameter is recorded at each experimental monitored check, indicating the anti-wrinkles efficacy of the tested product. A decrease of Ra parameter indicates an improvement of skin smoothness; for marketing purposes obtained values can be expressed in absolute values as an improvement of skin smoothness.

Legend: * p<0.05; ** p<0.01; *** p<0.001.

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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

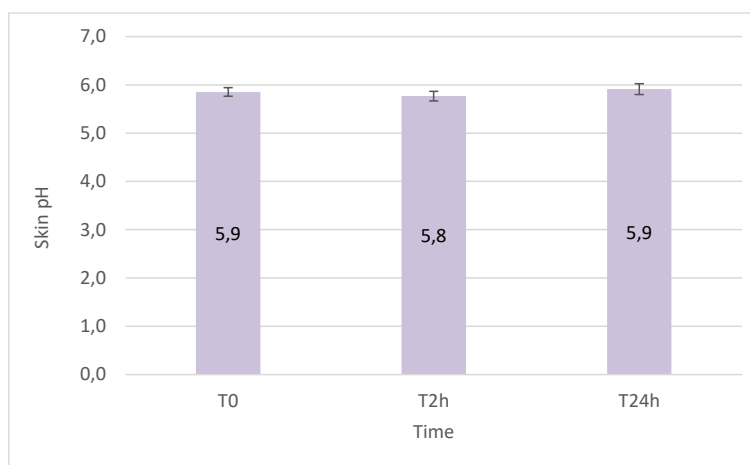


SKIN pH

TABLE 8. The table below reports the data obtained for each subject taking part in the study for the parameter under study. Data are expressed as pH values.

n	Vol ID	T0	T2h	T24h
01	M0237R	6,4	6,1	6,2
02	M0253F	6,3	5,9	6,3
03	D1353D	6,5	5,7	6,9
04	D0106M	6,2	6,5	6,4
05	B5476M	6,7	6,9	6,8
06	R4029M	6,3	5,8	6,7
07	T1725S	5,9	6,1	5,3
08	V3024C	5,7	5,3	5,7
09	M0217A	5,5	5,6	5,5
10	P4759A	5,9	6,3	6,4
11	M1104S	5,5	6,1	5,9
12	P2090S	5,6	5,7	5,7
13	D1532C	5,7	5,8	5,7
14	R0855P	5,6	5,3	5,6
15	A1522C	5,7	5,5	5,5
16	C2404L	5,5	5,5	5,4
17	M0837D	5,6	5,1	5,6
18	A0677G	5,6	5,3	5,5
19	F4104C	5,5	5,5	5,6
20	S4700M	5,5	5,5	5,5
Mean		5,9	5,8	5,9
SEM		0,1	0,1	0,1
t-test vs. T0		--	0,313	0,309

GRAPH 8. The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean $\pm$ SEM.



COMMENT: 2 hours and 24 hours after the first application, tested product doesn't alter the basal skin conditions; pH mean value is almost unvaried.



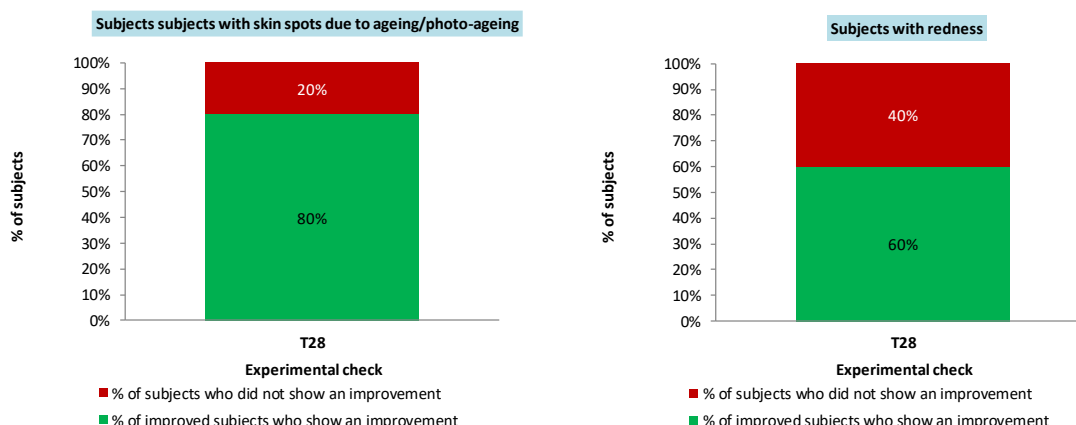
CLINICAL EVALUATION – SKIN COMPLEXION EVENNESS

TABLE 9a/b. The tables report the clinical scores assigned to each volunteer at each experimental time. Data are expressed according to scores reported in legend.

subjects with skin spots due to ageing/photo-ageing				subjects with redness			
n.	Vol ID	T0	T28	n.	Vol ID	T0	T28
01	M0237R	1	3	05	B5476M	2	3
02	M0253F	1	3	07	T1725S	2	1
03	D1353D	2	2	09	M0217A	2	2
04	D0106M	2	1	11	M1104S	1	1
06	R4029M	2	2	12	P2090S	1	1
08	V3024C	2	2	13	D1532C	2	2
10	P4759A	1	3	15	A1522C	2	2
14	R0855P	2	2	16	C2404L	2	1
18	A0677G	2	1	17	M0837D	2	2
20	S4700M	3	2	19	F4104C	2	2
Mean		1,8	2,1	Mean		1,8	1,7
SEM		0,2	0,2	SEM		0,1	0,2

BOX 3a - Clinical evaluation of skin complexion evenness at T0	Score	BOX 3b - Clinical evaluation of the improvement of skin complexion evenness at T28	Score
Skin complexion is not even; presence of cutaneous discolorations all over the face	1	No variation	1
Uneven complexion; presence of cutaneous discolorations in some parts of the face	2	Slight improvement	2
Fairly even complexion	3	Moderate improvement	3
Even complexion	4	Remarkable improvement	4

GRAPH 9a/b: The graphs report the percentage of subjects related to the effect.



Comment: an improvement of skin evenness complexion has been clinically recorded in 80% of the enrolled subjects showing skin spots due to ageing/photoageing and in 60% of volunteers showing skin redness. Indeed, an improvement of skin complexion evenness was recorded in 70% of the whole panel.



SELF-ASSESSMENT

TABLE 10a/b. The tables below summarize the results of the self-assessment questionnaire. The results are expressed as percentage (%) of subjects who expressed the same opinion among those proposed.

AFTER PRODUCT APPLICATION AND AFTER 30 MINUTES OF ITS USE

GLOBAL APPRECIATION OF THE PRODUCT

No.		Very pleasant	Pleasant	Neither pleasant nor unpleasant	Unpleasant	Very unpleasant	Positive answers
01	What do you think about the product aspect?	40,0%	50,0%	10,0%	0,0%	0,0%	90,0%
02	What do you think about the product texture?	30,0%	60,0%	10,0%	0,0%	0,0%	90,0%
03	What do you think about the product fragrance?	40,0%	50,0%	10,0%	0,0%	0,0%	90,0%
04	What do you think about product spreadability?	45,0%	50,0%	5,0%	0,0%	0,0%	95,0%
No.		Very good	Good	Not good	Bad		Positive answers
05	What do you think about product penetration?	35,0%	60,0%	5,0%	0,0%		95,0%
No.		Silky	Soft	Sticky	Oily		Positive answers
06	What is the after feel on the skin?	25,0%	40,0%	35,0%	0,0%		65,0%
No.		Very good	Good	Not good	Bad		Positive answers
07	What is your overall appreciation of this product?	25,0%	60,0%	15,0%	0,0%		85,0%

EVALUATION OF THE EFFICACY 30 MINUTES AFTER PRODUCT APPLICATION

No.		Intense	Moderate	Slightly	Not at all		Positive answers
08	Have you felt a tightening effect?	15,0%	15,0%	50,0%	20,0%		80,0%
09	Have you noticed an amelioration of skin smoothness (fines lines are less visible)?	10,0%	25,0%	45,0%	20,0%		80,0%
10	have you noticed an amelioration of skin brightness?	15,0%	20,0%	60,0%	5,0%		95,0%
No.	30min after the application, have you noticed that:	Agree	Moderately agree	Not completely agree	Not agree		Positive answers
11a	Your skin is brighter	25,0%	60,0%	10,0%	5,0%		85,0%
11b	Your skin is smoother	30,0%	40,0%	25,0%	5,0%		70,0%
11c	Wrinkles and fines lines are less visible	20,0%	25,0%	40,0%	15,0%		45,0%
11d	The overall face look appears refreshed and rested	25,0%	65,0%	5,0%	5,0%		90,0%

COMPLIFE Italia S.r.l.

info@complifegroup.com
complifeitalia@legaimail.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



AFTER 28 DAYS OF PRODUCT USE

EVALUATION OF THE EFFICACY AFTER 28 DAYS OF USE						
No. After 4 weeks of application, have you noticed that:		Agree	Moderately agree	Not completely agree	Positive answers	
01	Your skin is smoother	80,0%	20,0%	0,0%	100,0%	
02	Your skin is tightened (lifted look)	60,0%	25,0%	15,0%	85,0%	
03	Your skin is firmer	70,0%	20,0%	10,0%	90,0%	
04	Fine lines and wrinkles are less visible	65,0%	25,0%	10,0%	90,0%	
05	Your skin looks brighter	70,0%	25,0%	5,0%	95,0%	
06	Skin complexion looks more even and skin tone irregularities (redness and/or dark spots) less visible	60,0%	25,0%	15,0%	85,0%	
07	Dark spots and hyperpigmentation look less evident	40,0%	35,0%	25,0%	75,0%	
08	Skin is less prone to redness	55,0%	35,0%	10,0%	90,0%	
09	The overall face look appears refreshed and rested	75,0%	20,0%	5,0%	95,0%	
No. After 4 weeks of application, have you noticed that:		Strongly	Improved	Unchanged	Positive answers	
10	Dullness	40,0%	45,0%	15,0%	85,0%	
11	Uneven look	35,0%	35,0%	30,0%	70,0%	
12	Fines lines and wrinkles	40,0%	50,0%	10,0%	90,0%	
SUBSEQUENT USE OF THE PRODUCT						
No. Item		Yes	No		Positive answers	
13	Would you continue using this product?	80,0%	20,0%	---	80,0%	
No. Item		Luxe	Masstige	Mass market	Positive answers	
14	According to you, this product is sold in which market segment?	25,0%	65,0%	10,0%	---	
No. Item		Absolutely yes	Maybe	Probably not	Absolutely not	Positive answers
15	Would you buy this product independently from price?	40,0%	40,0%	20,0%	20,0%	80,0%

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complifegroup.com

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CONCLUSION

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

TORSTONE SA **SERUM LUMIERE N°02**

determines a general improvement of the analysed skin parameters both in the short and long term test.

In particular the product determines:

- An increase of the gloss parameter by +29.0% 30 minutes after its first application, by +21.8% at T2h, by +21.3% at T24h and respectively by +26.5% and by +27.2% after 7 and 28 days of use (brightening effect);
- A decrease of wrinkle depth parameter in the crow's feet area by -16.2% 30 minutes after its first application, by -13.7% at T2h, by -10.8% at T24h (lifting effect) and respectively by -11.8% and -10.7% after 7 and 28 days of use (anti-wrinkles efficacy);
- A decrease of Ra parameter (index of an improvement of skin smoothness) by 4.5% 30 minutes after its first application, by 7.3% at T2h, by 5.7% at T24 and respectively by 7.2% and 7.0% after 7 and 28 days of use;
- A decrease of wrinkle depth parameter in the nasolabial folds respectively by -13.4% and by -13.1% after 7 and 28 days of use (anti-wrinkles efficacy);
- A decrease of wrinkle depth parameter in the forehead respectively by -8.8% and by -10.9% after 7 and 28 days of use (anti-wrinkles efficacy).

*The reported % are referred to the mean variations of the analysed parameters versus T0.
Reported variations are statistically significant variation versus T0.*

Moreover, the product doesn't alter the basal skin conditions (any variation of the skin pH has been found).

The clinical analysis performed by the Dermatologist shows an improvement of skin complexion evenness in 70% of the whole panel, in particular it is observed:

- an improvement of skin complexion evenness in 80% of the subjects showing skin spots due to ageing-photo-ageing;
- an improvement of skin complexion evenness in 60% of the subjects showing skin redness.

Furthermore, the most of the enrolled volunteers positively judged the product for most of the monitored aspects.

No adverse skin reactions related or not related to the product were recorded during the study and the tested product was well tolerated by all the enrolled subjects.

Dermatologist

Dr Enza CESTONE

Data analysis and report

Dr Federica RUGGERI

Study director

Dr Ileana DE PONTI

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

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SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

Sede legale: Via Guido Rossa, 1 20024 Garbagnate M.se (MI) Italy, I.P.I./C.F. 11093320155
Capitale Sociale € 161.834 i.v., C.C.I.A.A. MI 1437929 - Registro Società N. 342215
Centro di Saggio operante in BPL - Sistema di gestione qualità certificato ISO 9001
Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N 030015309008)
Garbagnate M.se: Laboratorio di Prova Accreditato ACCREDIA LAB N 1318L (UNI CEI EN ISO/IEC 17025:2018)
L'elenco delle prove accreditate è consultabile su www.accredia.it



ANNEX 1 – DIGITAL PICTURES

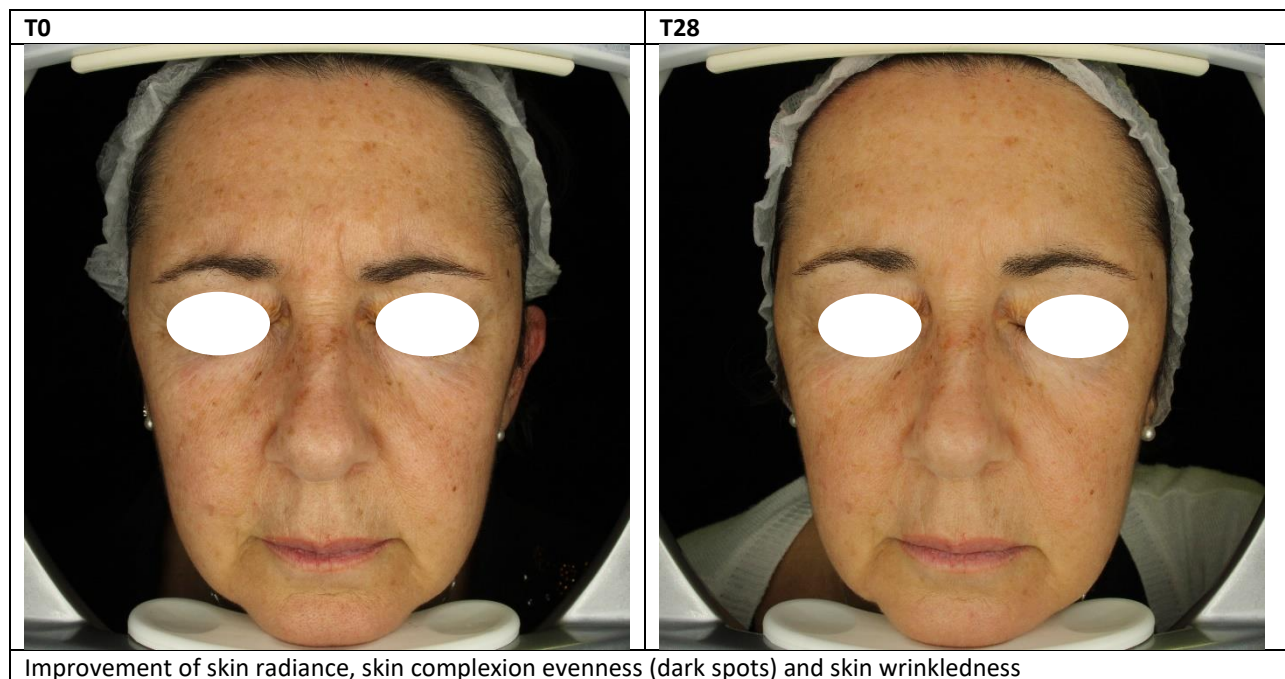


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