CLINICAL EVALUATION OF THE EFFICACY OF A COSMETIC PRODUCT FOR MATURE SKIN

TORSTONE SA

RIVOLI
Crème Nutrition Intense
005-OWBN-Y

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STUDY DESIGN

1.1. Title

Clinical evaluation of the efficacy of a cosmetic product for mature skin.

1.2. Aim of the study

The study is aimed to evaluate the efficacy of a cosmetic product intended to mature skin. 40 volunteers aged between 45 and 65 years old are selected to take part in the trial in accordance with the inclusion criteria laid down in the study design: in particular, subjects showing mature skin with/or slightly dry skin and periocular/perilabiale wrinkles are enrolled. Moreover, according to specific customer request, volunteers are enrolled with no facial hair. The study foresees the application of the tested product during two months, on face and décolleté. The interested parameters are monitored at baseline (T0) and both in the short (20 volunteers) and long (20 volunteers) term test as described below.

The study is carried out under dermatological supervision – according to the ethical principles of Helsinki declaration.

1.3. Tested Product

1.3.1. Information provided by the Customer

- Product name:

TORSTONE SA
RIVOLI
Crème Nutrition Intense
005-OWBN-Y

- The tested cosmetic product conforms to REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30th November 2009 on cosmetic products (recast) (Text with EEA relevance) and to its annexes The cosmetic products were evaluated for its safety of use on human volunteers (safety assessment)
- Qualitative INCI formula: filed

1.4. Ethical requirements

The study was carried out in compliance with the following ethical requirements:

- All of the subjects participating in the study are healthy volunteers at least 18 years old.
- All of the subjects participating in the study are selected under the supervision of a dermatologist according to inclusion/non-inclusion criteria (see respective paragraph “Inclusion criteria” and “Non-inclusion Criteria”).
- Volunteer participation in the study is totally free.
- All of the subjects participating in the study are informed of the aim and the nature of the study.
- All of the subjects participating in the study are informed of the potential risks involved.
- All of the subjects participating in the study give their informed consent signed at the beginning of the study.
- Before volunteers were exposed to the product to be tested, all relevant safety information about the product itself and each ingredient were collected and evaluated.

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- All of the study procedures are carried out in accordance with the ethical principles for the medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and successive amendments)
- All necessary precautions were taken to avoid adverse skin reactions.
- If unexpected/adverse skin reactions occur, the dermatologist evaluates the severity of the reaction (and report it in the data collecting sheet) and if necessary proceed with the appropriate therapy.

1.5. Subject selection

1.5.1. Volunteer recruitment

40 volunteers with are recruited to take part in the test in accordance with the following inclusion and non-inclusion criteria:

1.5.1.1. Inclusion criteria

- Healthy female subjects
- Aged between 45 and 65 years old
- Caucasian
- Subjects showing mature skin with/or slightly dry skin and periocular/perilabiale wrinkles
- Subjects with no facial hair
- Commitment of subjects to strictly follow the informative form
- Commitment not to use products similar to those of the tested product during all the study
- Commitment not to change the normal daily routine
- Subjects informed on test purposes and that have signed an informed consent form

1.5.1.2. Non - inclusion criteria

- ✘ Subjects who don't fit the inclusion criteria
- ✘ Pregnant or breastfeeding women
- ✘ Past history of allergy to cosmetics, sunscreens and/ or topical medications
- ✘ Subjects under pharmacological both locally and systemically treatment (if this condition interferes with the test execution)
- ✘ Subjects with dermatological problems in the test area
- ✘ Positive anamnesis for atopy (if this condition interferes with the test execution)

1.5.2. Withdrawal criteria

Participants are withdrawn if:

- ✘ They do not respect the trial Information Sheet that they receive after recruitment
- ✘ They suffer any illness or accident or develop any condition during the study which could affect the outcome of the study
- ✘ They no longer wish to participate in the study.

1.6. Execution of the study

After the enrolment the dermatologist evaluates the physiological (T0) skin conditions by means of not invasive skin bioengineering techniques. The study foresees the application of the tested product during two months, on face and décolleté. The parameters to be evaluated are performed at baseline (T0) and both in the short and long term test as described below:

SHORT TERM TEST - on 20 volunteers - tested product is applied on face in the test facility under the supervision of the experimenter. Volunteers remain in a temperature and humidity controlled room during the test period. According to a randomization scheme tested product is applied to one hemi-face while the contralateral side remains untreated and acts as control.

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Monitored parameters are evaluated at T0 (baseline) and 15 minutes (T15min), 2 (T2h), 4 (T4h) and 8 (T8h) hours after the single product application.
LONG TERM TEST - on 20 volunteers - the study foresees a bi-daily product application, morning and evening, to the volunteers' face and décolleté. The amount of product to be applied is provided by a proportioning plump, to have the same volume for each application (three pushes of pump to be applied on the face and three pushes of pump to be applied on the neck and décolleté). Measurements are performed on clean face and/or décolleté at baseline (T0) and after 15 (T15), 30 (T30) and 60 (T60) days of use. In the paragraphs here below the evaluated skin parameters are reported.

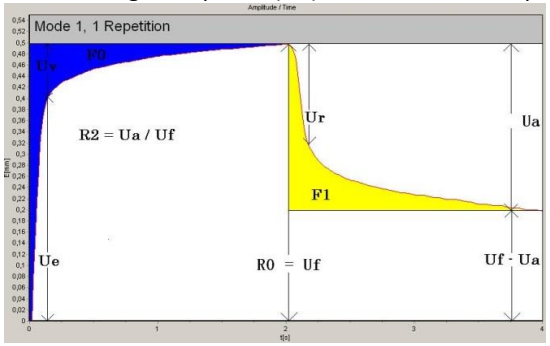
1.7. MATERIALS AND METHODS

1.7.1. Skin elasticity and firmness - SHORT TERM TEST + LONG TERM TEST (FACE AND DECOLLETE)

Skin elasticity measurement is based on the suction/elongation method and the subsequent release of the skin inside the opening of the instrument device. 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. The instrument used for measuring is the CUTOMETER® MPA 580 (Courage+Khazaka, electronic GmbH). For further details see box 1.

BOX 1 - SKIN ELASTICITY

The measurement of the skin elasticity is based on skin suction/elongation principle after a negative and constant pressure stimulation and on its subsequent release when the stimulus finishes. The figure below shows graphically the behaviour of the skin in the suction/elongation phase (FO) and in the release phase (F1).



As it is possible to notice in the figure, the skin reacts to the negative pressure stimulation in a biphasic manner characterized by a first rapid elongation phase (Ue) followed by a second phase in which one the skin tends to oppose to the stimulation (Uv) reaching its maximum deformation state. In bibliography the first phase of the curve is known as the elastic component of the skin while the second part characterizes the viscoelastic component of the skin, mainly represented by skin plastic component. Similar is the behaviour of the skin at the end of the negative pressure stimulation during the release phase. Indeed, if in phase (Ur) the skin tends to return to its basal state - due to its elastic qualities - in a second phase the plastic component exceeds the elastic component, decreasing the velocity of re-deformation of the skin (Ua-Ur) until maintaining the skin in a deformed state (Uf-Ua); this phenomenon is known as hysteresis.
In this study the skin elasticity is calculated as the ratio between the residual deformation and the maximum elongation of the skin or Ua/Uf. This ration is known in literature as R2 and 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. Moreover, in this clinical study, R0 parameter= e(a)=Uf= first greatest amplitude, the highest point of the first curve is evaluated; this parameter has an implication on skin firmness.

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1.7.2. Evaluation of skin moisturizing - SHORT TERM TEST + LONG TERM TEST (FACE)

The measurement of the skin moisture is based on the internationally recognized CORNEOMETER® method (Courage+Khazaka, electronic GmbH).This measurement is based on the dielectric constant of water. The probe shows changes of capacitance according to the moisture content of the measuring object. An electric scatter field penetrates the very first layer of the skin and determines the dielectricity.

1.7.3. Trans Epidermal Water Loss (TEWL) – SHORT TERM TEST + LONG TERM TEST (FACE)

Trans epidermal water loss is measured by means of the internationally recognized TEWAMETER® method. The instrument used is a Tewameter 300® (Courage+Khazaka, electronic GmbH).

The following equation which represents the Diffusion law (discovered by Adolf Fick in 1855) is the basis for the measurement

$$\frac{dm}{dt} = -D \cdot A \cdot \frac{dp}{dx}$$

where:

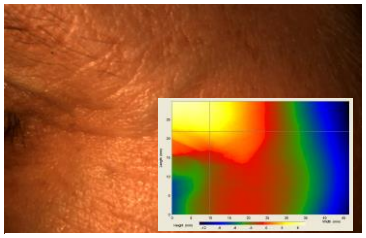
A=surface in m² | water transported (in g) - | time (h) - | diffusion constant (=0.0877 g/mhmm Hg) | vapor pressure of the atmosphere (mm Hg) - | distance from skin surface to point of measurement (m)

The diffusion flow dm/dt indicates the mass per cm² which is transported in a specific period of time. It is proportional to the area A and the change of concentration per distance (dp/dx). D is the diffusion coefficient of water vapor in the air. This law is only valid within a homogenous diffusion zone, which is approximately formed by a hollow cylinder. The resulting density gradient is measured indirectly by two pairs of sensors (temperature and relative humidity) and is analyzed by a microprocessor. The measuring head of the probe is a narrow hollow cylinder (10 mm diameter and 20 mm height), in order to minimize influences of air turbulence inside the probe.

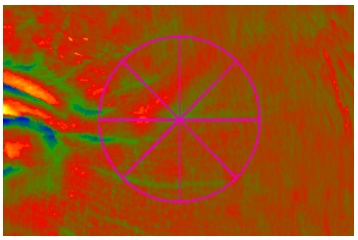
1.7.4. Evaluation of skin surface properties - LONG TERM TEST (FACE AND DECOLLETE)

Skin surface properties are quantitatively assessed by Primos 3D (GFMesstechnik 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. winkle depth, volume, roughness etc.). In this study wrinkle depth is evaluated in the crow's feet area (eye contour) and around the lips; moreover Rz parameter (skin wrinkledness) is evaluated. 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 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).



Calculation of roughness. 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 roughness is calculated the Ra parameter. Ra parameter is the arithmetic average of the absolute values of the roughness profile ordinates (see the picture here below).

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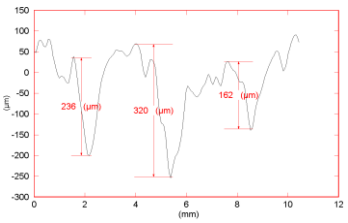

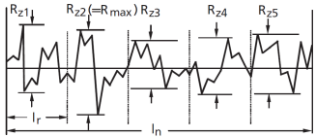

Mathematically Rz is calculated as:

$$R_z = \frac{1}{n}(R_{z1} + R_{z2} + \ldots + R_{zn})$$

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).

1.7.5. Clinical-dermatological evaluation - LONG TERM TEST (FACE)

Clinical evaluation concerning the improvement of the overall quality of the skin is performed by the dermatologist according to the clinical scores reported in box 2.

Box 2. Improvement of the overall quality of the skin	Score
No variation	**1**
Slight improvement	**2**
Moderate improvement	**3**
Remarkable improvement	**4**

1.7.6. Digital images – T0/T30/T60 (FACE AND DECOLLETE)

Digital images of the treated areas to assess product effect are acquired by using a digital reflex camera. Best 10 images are reported in annex 1.

1.7.7. Self-assessment - SHORT TERM TEST + LONG TERM TEST

The subjects are asked to express their opinion regarding tested product by means of a questionnaire (9 questions) to be fulfilled before (baseline) and after the single product application (at the end of the short term test). Moreover, at the end of the long term test volunteers are asked to express their opinion about product efficacy by means of a questionnaire (23 questions).

1.8. Results and Statistic

1.8.1 Results

The Results are reported in their respective units in tables.

1) The mean values are calculated as:

$$m = \frac{\sum_{1}^{20} P}{20} \qquad [1]$$

where
P is the value of the parameter to be analysed.

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2) The standard error of the mean is calculated as:

$$SEM = \frac{\sqrt{\frac{\sum_{1}^{20}(p_i^2) - \frac{\sum_{1}^{20} p_i^2}{20}}{(20-1)}}}{\sqrt{20}} \qquad [2]$$

3) The mean percentage variations were calculated as:

$$\overline{Var(\%)} = \sum_{1}^{20} \frac{P_T - P_0}{P_0} \qquad [3]$$

where:

is the value of the parameter to be nalysed at T0
P_t is the value of the parameter to be nalysed at the following experimental checks

All the calculations were done by using a Microsoft® Excel worksheet.

1.8.2. Statistical analysis

The data are subject to the bilateral Student t test for paired data.

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RESULTS: PANEL DEMOGRAPHY

TABLE A/B. Tables below report volunteers' age.

LONG TERM TEST

n	Vol ID	T0
01	B1644O	61
02	R0329O	62
03	Z2132N	47
04	G2713G	52
05	C2576V	58
06	P2716P	50
07	C0544S	59
08	Z1236R	62
09	F0121F	64
10	G2821A	67
11	L2406L	61
12	S2049G	63
13	S1388A	45
14	C1267R	51
15	N1500A	65
16	B1401C	67
17	T2481D	51
18	C0771F	47
19	C1576G	53
20	V1228M	55
	Mean	57,0
	SEM	1,6

SHORT TERM TEST

n	Vol ID	T0
01	R0340L	47
02	P1794P	44
03	P1562L	46
04	D0106M	46
05	I0170M	65
06	M2000D	50
07	A2098T	47
08	Z2097M	50
09	F2070C	54
10	C0085N	58
11	S0872M	61
12	C1620T	47
13	A0849R	59
14	T1434E	46
15	S1258E	58
16	B1081G	56
17	C1963A	49
18	C1576G	53
19	C0766L	48
20	C2155P	48
	Mean	51,6
	SEM	1,3

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RESULTS: SKIN ELASTICITY (R2 PARAMETER) – short term test

TABLE 1a/b. Tables below show skin elasticity values (R2 parameter) recorded for each subject ON FACE during the short term test study.

TESTED PRODUCT

n	Vol ID	T0	T15min	T2h	T4h	T8h
01	R0340L	0,6730	0,7036	0,7301	0,6900	0,6901
02	P1794P	0,7772	0,8172	0,8280	0,7995	0,7827
03	P1562L	0,7991	0,8411	0,8474	0,8426	0,8349
04	D0106M	0,7030	0,7371	0,7713	0,7479	0,7210
05	I0170M	0,5995	0,6070	0,6270	0,6292	0,6071
06	M2000D	0,6612	0,7327	0,7458	0,7198	0,6938
07	A2098T	0,6452	0,6950	0,6870	0,6718	0,6620
08	Z2097M	0,8023	0,8849	0,8708	0,8752	0,8297
09	F2070C	0,6557	0,6653	0,6688	0,6634	0,6630
10	C0085N	0,4889	0,5269	0,5210	0,5287	0,5068
11	S0872M	0,7104	0,7439	0,7519	0,7321	0,7289
12	C1620T	0,8086	0,8412	0,8473	0,8293	0,8255
13	A0849R	0,6807	0,7146	0,7170	0,6999	0,6873
14	T1434E	0,7880	0,8228	0,8375	0,8188	0,7878
15	S1258E	0,6485	0,6922	0,7093	0,6973	0,6861
16	B1081G	0,7434	0,7817	0,7946	0,7797	0,7684
17	C1963A	0,7816	0,8316	0,8379	0,8114	0,7998
18	C1576G	0,7787	0,8148	0,8195	0,7889	0,7822
19	C0766L	0,6733	0,7329	0,7403	0,7297	0,6943
20	C2155P	0,7676	0,7945	0,7912	0,7797	0,7714
	Mean	0,7093	0,7491	0,7572	0,7417	0,7261
	SEM	0,0	0,0	0,0	0,0	0,0
	TEST.T vs T0		0,000	0,000	0,000	0,000

VARIATION VS. T0	T15min	T2h	T4h	T8h
	4,5%	8,5%	2,5%	2,5%
	5,1%	6,5%	2,9%	0,7%
	5,3%	6,0%	5,4%	4,5%
	4,9%	9,7%	6,4%	2,6%
	1,3%	4,6%	5,0%	1,3%
	10,8%	12,8%	8,9%	4,9%
	7,7%	6,5%	4,1%	2,6%
	10,3%	8,5%	9,1%	3,4%
	1,5%	2,0%	1,2%	1,1%
	7,8%	6,6%	8,1%	3,7%
	4,7%	5,8%	3,1%	2,6%
	4,0%	4,8%	2,6%	2,1%
	5,0%	5,3%	2,8%	1,0%
	4,4%	6,3%	3,9%	0,0%
	6,7%	9,4%	7,5%	5,8%
	5,2%	6,9%	4,9%	3,4%
	6,4%	7,2%	3,8%	2,3%
	4,6%	5,2%	1,3%	0,4%
	8,9%	10,0%	8,4%	3,1%
	3,5%	3,1%	1,6%	0,5%
	5,6%	6,8%	4,7%	2,4%
max	10,8%	12,8%	9,1%	5,8%
min	1,3%	2,0%	1,2%	0,0%

CONTROL AREA

n	Vol ID	T0	T15min	T2h	T4h	T8h
01	R0340L	0,7260	0,6947	0,7030	0,7437	0,7505
02	P1794P	0,7859	0,8023	0,8030	0,7857	0,7723
03	P1562L	0,8024	0,8316	0,7947	0,7960	0,8172
04	D0106M	0,7000	0,7060	0,6900	0,6979	0,7010
05	I0170M	0,6176	0,6270	0,6370	0,6275	0,6201
06	M2000D	0,6526	0,7000	0,6770	0,6747	0,6675
07	A2098T	0,6498	0,6470	0,6210	0,6081	0,6047
08	Z2097M	0,8735	0,8895	0,8670	0,8750	0,8759
09	F2070C	0,6481	0,6459	0,6408	0,6308	0,6370
10	C0085N	0,4863	0,4970	0,5010	0,5042	0,4970
11	S0872M	0,6844	0,6886	0,6767	0,6746	0,6852
12	C1620T	0,7915	0,7894	0,7853	0,7820	0,7961
13	A0849R	0,6951	0,7051	0,6899	0,6853	0,6728
14	T1434E	0,7900	0,7877	0,7898	0,7850	0,7716
15	S1258E	0,6560	0,6532	0,6497	0,6445	0,6420
16	B1081G	0,7312	0,7220	0,7249	0,7179	0,7394
17	C1963A	0,7794	0,7748	0,7683	0,7638	0,7846
18	C1576G	0,7851	0,7753	0,7675	0,7630	0,7891
19	C0766L	0,6662	0,6610	0,6553	0,6431	0,6590
20	C2155P	0,7632	0,7599	0,7523	0,7443	0,7527
	Mean	0,7142	0,7179	0,7097	0,7074	0,7118
	SEM	0,0	0,0	0,0	0,0	0,0
	TEST.T vs T0		0,321	0,158	0,063	0,499

VARIATION VS. T0	T15min	T2h	T4h	T8h
	-4,3%	-3,2%	2,4%	3,4%
	2,1%	2,2%	0,0%	-1,7%
	3,6%	-1,0%	-0,8%	1,8%
	0,9%	-1,4%	-0,3%	0,1%
	1,5%	3,1%	1,6%	0,4%
	7,3%	3,7%	3,4%	2,3%
	-0,4%	-4,4%	-6,4%	-6,9%
	1,8%	-0,7%	0,2%	0,3%
	-0,3%	-1,1%	-2,7%	-1,7%
	2,2%	3,0%	3,7%	2,2%
	0,6%	-1,1%	-1,4%	0,1%
	-0,3%	-0,8%	-1,2%	0,6%
	1,4%	-0,7%	-1,4%	-3,2%
	-0,3%	0,0%	-0,6%	-2,3%
	-0,4%	-1,0%	-1,8%	-2,1%
	-1,3%	-0,9%	-1,8%	1,1%
	-0,6%	-1,4%	-2,0%	0,7%
	-1,2%	-2,2%	-2,8%	0,5%
	-0,8%	-1,6%	-3,5%	-1,1%
	-0,4%	-1,4%	-2,5%	-1,4%
	0,6%	-0,6%	-0,9%	-0,3%
max	7,3%	3,7%	3,7%	3,4%
min	-4,3%	-4,4%	-6,4%	-6,9%

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GRAPH 1. Graph below shows skin elasticity mean values (R2 parameter) recorded during the short term test study.

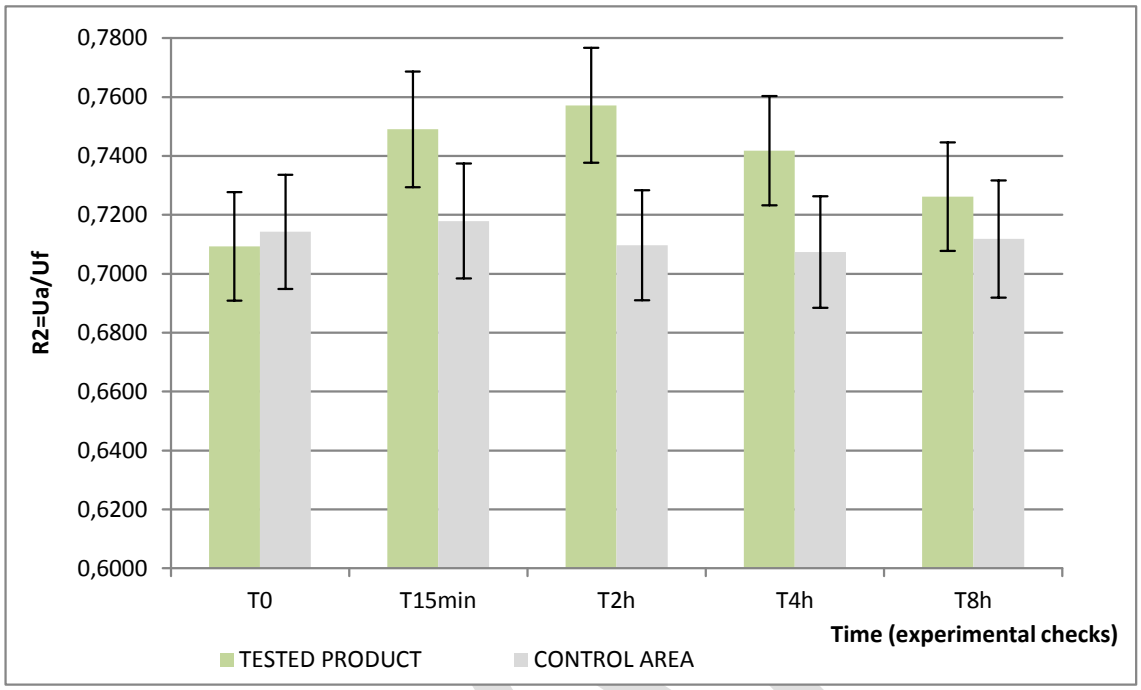

TABLE 1c. Table below shows the inter-group statistical analysis (TESTED PRODUCT vs CONTROL AREA). A p value <0.05 indicates a statistically significant data.

INTERGROUP STATISTICAL ANALYIS	
experimental check	p-VALUE
T0 vs T0	0,3369
T15min vs T15min	0,0000
T2h vs T2h	0,0000
T4h vs T4h	0,0001
T8h vs T8h	0,0356

COMMENT: The single product application determines a statistically significant improvement of skin elasticity (R2 parameter) at each experimental monitored check, both compared to baseline and control area. No variations are monitored in control area.

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RESULTS: SKIN FIRMNESS (R0 PARAMETER) – short term test

TABLE 2a/b. Tables below show skin firmness values (R0 parameter) recorded for each subject ON FACE during the short term test study.

TESTED PRODUCT

n	Vol ID	T0	T15min	T2h	T4h	T8h
01	R0340L	0,3880	0,3570	0,3610	0,3710	0,3850
02	P1794P	0,4260	0,4060	0,4070	0,4080	0,4050
03	P1562L	0,4430	0,4130	0,4150	0,4090	0,4250
04	D0106M	0,3780	0,3690	0,3670	0,3570	0,3680
05	I0170M	0,2920	0,2870	0,2710	0,2790	0,2800
06	M2000D	0,4450	0,4410	0,4120	0,4390	0,4160
07	A2098T	0,5440	0,5260	0,5210	0,5210	0,5030
08	Z2097M	0,5210	0,5080	0,5040	0,5050	0,5170
09	F2070C	0,5170	0,4990	0,5010	0,5110	0,5180
10	C0085N	0,4500	0,4470	0,4430	0,4460	0,4490
11	S0872M	0,3150	0,3060	0,3020	0,3080	0,3120
12	C1620T	0,4030	0,3810	0,3750	0,3820	0,3910
13	A0849R	0,2980	0,2740	0,2770	0,2830	0,2810
14	T1434E	0,2990	0,2710	0,2750	0,2880	0,2920
15	S1258E	0,2860	0,2800	0,2770	0,2810	0,2890
16	B1081G	0,3820	0,3690	0,3630	0,3700	0,3750
17	C1963A	0,3620	0,3440	0,3490	0,3520	0,3450
18	C1576G	0,3910	0,3790	0,3750	0,3830	0,3780
19	C0766L	0,4080	0,3890	0,3830	0,3870	0,3760
20	C2155P	0,2750	0,2510	0,2540	0,2650	0,2580
	Mean	0,3912	0,3749	0,3716	0,3773	0,3782
	SEM	0,0	0,0	0,0	0,0	0,0
	TEST.T vs T0		0,000	0,000	0,000	0,000

VARIATION VS. T0	T15min	T2h	T4h	T8h
	-8,0%	-7,0%	-4,4%	-0,8%
	-4,7%	-4,5%	-4,2%	-4,9%
	-6,8%	-6,3%	-7,7%	-4,1%
	-2,4%	-2,9%	-5,6%	-2,6%
	-1,7%	-7,2%	-4,5%	-4,1%
	-0,9%	-7,4%	-1,3%	-6,5%
	-3,3%	-4,2%	-4,2%	-7,5%
	-2,5%	-3,3%	-3,1%	-0,8%
	-3,5%	-3,1%	-1,2%	0,2%
	-0,7%	-1,6%	-0,9%	-0,2%
	-2,9%	-4,1%	-2,2%	-1,0%
	-5,5%	-6,9%	-5,2%	-3,0%
	-8,1%	-7,0%	-5,0%	-5,7%
	-9,4%	-8,0%	-3,7%	-2,3%
	-2,1%	-3,1%	-1,7%	1,0%
	-3,4%	-5,0%	-3,1%	-1,8%
	-5,0%	-3,6%	-2,8%	-4,7%
	-3,1%	-4,1%	-2,0%	-3,3%
	-4,7%	-6,1%	-5,1%	-7,8%
	-8,7%	-7,6%	-3,6%	-6,2%
	-4,4%	-5,2%	-3,6%	-3,3%
min	-0,7%	-1,6%	-0,9%	1,0%
max	-9,4%	-8,0%	-7,7%	-7,8%

CONTROL AREA

n	Vol ID	T0	T15min	T2h	T4h	T8h
01	R0340L	0,4090	0,4170	0,4010	0,4080	0,4080
02	P1794P	0,3570	0,3540	0,3560	0,3560	0,3640
03	P1562L	0,3680	0,3760	0,3750	0,3680	0,3720
04	D0106M	0,3850	0,3980	0,3810	0,3840	0,3860
05	I0170M	0,2720	0,2760	0,2750	0,2700	0,2730
06	M2000D	0,4260	0,4200	0,4290	0,4260	0,4270
07	A2098T	0,4540	0,4500	0,4540	0,4750	0,4660
08	Z2097M	0,5690	0,5880	0,5910	0,5670	0,5570
09	F2070C	0,5160	0,5430	0,5410	0,5150	0,5270
10	C0085N	0,4730	0,4610	0,4690	0,4780	0,4710
11	S0872M	0,3170	0,3230	0,3230	0,3290	0,3240
12	C1620T	0,4230	0,4240	0,4190	0,4220	0,4250
13	A0849R	0,3080	0,3050	0,3110	0,3190	0,3130
14	T1434E	0,3090	0,3110	0,3000	0,3050	0,3120
15	S1258E	0,2750	0,2830	0,2790	0,2740	0,2800
16	B1081G	0,3780	0,3750	0,3820	0,3800	0,3740
17	C1963A	0,3510	0,3590	0,3600	0,3550	0,3570
18	C1576G	0,3880	0,3960	0,4000	0,3910	0,3850
19	C0766L	0,3990	0,4020	0,4110	0,3990	0,3810
20	C2155P	0,2890	0,2870	0,2910	0,2990	0,2840
	Mean	0,3833	0,3874	0,3874	0,3860	0,3843
	SEM	0,0	0,0	0,0	0,0	0,0
	TEST.T vs T0		0,056	0,052	0,069	0,542

VARIATION VS. T0	T15min	T2h	T4h	T8h
	2,0%	-2,0%	-0,2%	-0,2%
	-0,8%	-0,3%	-0,3%	2,0%
	2,2%	1,9%	0,0%	1,1%
	3,4%	-1,0%	-0,3%	0,3%
	1,5%	1,1%	-0,7%	0,4%
	-1,4%	0,7%	0,0%	0,2%
	-0,9%	0,0%	4,6%	2,6%
	3,3%	3,9%	-0,4%	-2,1%
	5,2%	4,8%	-0,2%	2,1%
	-2,5%	-0,8%	1,1%	-0,4%
	1,9%	1,9%	3,8%	2,2%
	0,2%	-0,9%	-0,2%	0,5%
	-1,0%	1,0%	3,6%	1,6%
	0,6%	-2,9%	-1,3%	1,0%
	2,9%	1,5%	-0,4%	1,8%
	-0,8%	1,1%	0,5%	-1,1%
	2,3%	2,6%	1,1%	1,7%
	2,1%	3,1%	0,8%	-0,8%
	0,8%	3,0%	0,0%	-4,5%
	-0,7%	0,7%	3,5%	-1,7%
	1,0%	1,0%	0,7%	0,3%
min	5,2%	4,8%	4,6%	2,6%
max	-2,5%	-2,9%	-1,3%	-4,5%

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GRAPH 2. Graph below shows skin firmness mean values (R0 parameter) recorded during the short term test study.

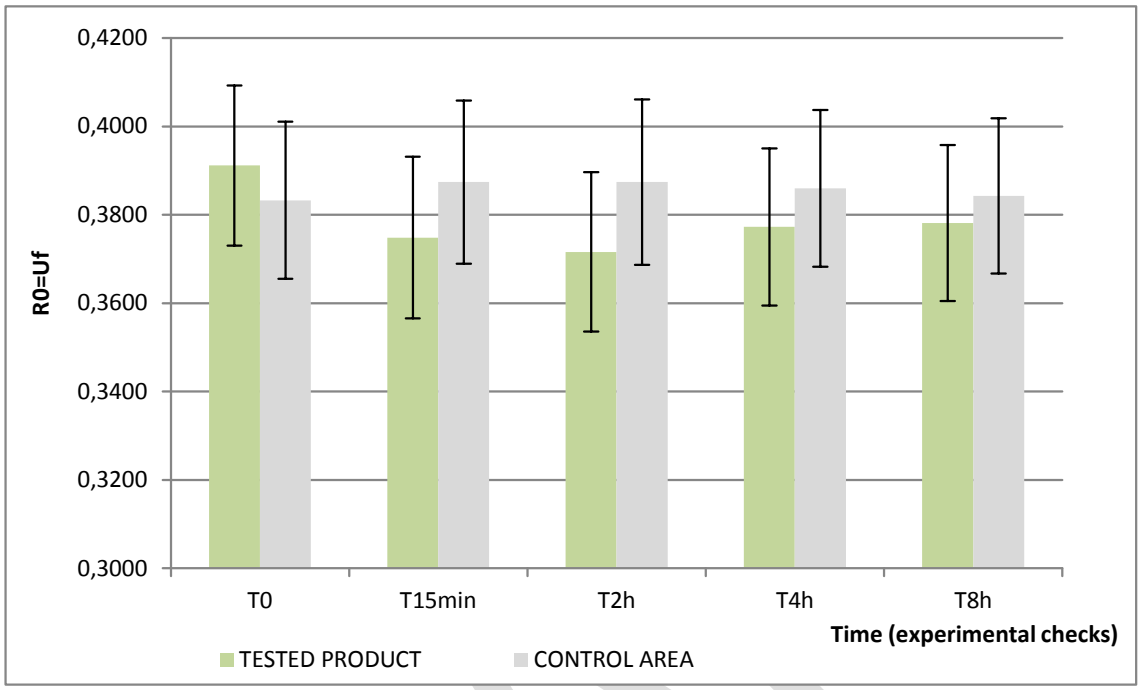

TABLE 2c. Table below shows the inter-group statistical analysis (TESTED PRODUCT vs CONTROL AREA). A p value <0.05 indicates a statistically significant data.

INTERGROUP STATISTICAL ANALYSIS	
experimental check	p-VALUE
T0 vs T0	0,3203
T15min vs T15min	0,1526
T2h vs T2h	0,0568
T4h vs T4h	0,2109
T8h vs T8h	0,2873

COMMENT: The single product application determines a statistically significant improvement of skin firmness (recorded as a decrease of R0 parameter) at each experimental monitored check, compared to baseline. No variations are monitored in control area.

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RESULTS: SKIN MOISTURIZING – short term test

TABLE 3a/b. Tables below show skin moisturizing index (corneometric units) recorded for each subject ON FACE during the short term test study.

TESTED PRODUCT

n	Vol ID	T0	T15min	T2h	T4h	T8h
01	R0340L	29,0	42,8	41,5	38,4	32,8
02	P1794P	30,8	46,0	39,4	38,7	38,0
03	P1562L	32,6	40,1	40,8	38,4	37,0
04	D0106M	30,3	40,9	42,6	43,9	42,6
05	I0170M	30,1	47,2	48,7	48,5	47,5
06	M2000D	28,7	36,8	36,9	34,0	31,9
07	A2098T	36,7	47,4	47,8	47,2	46,6
08	Z2097M	41,5	57,4	46,6	47,1	47,0
09	F2070C	32,1	42,9	44,1	39,3	38,6
10	C0085N	44,0	58,2	51,0	48,2	46,9
11	S0872M	37,7	47,5	45,3	41,9	41,4
12	C1620T	48,7	62,4	62,0	58,7	57,6
13	A0849R	30,1	45,4	43,8	40,4	39,6
14	T1434E	40,4	45,2	44,9	42,8	42,2
15	S1258E	39,5	52,5	53,9	50,5	47,9
16	B1081G	30,8	47,7	48,2	45,3	43,6
17	C1963A	23,4	37,8	38,9	35,2	32,5
18	C1576G	40,8	55,3	56,2	54,2	50,1
19	C0766L	30,5	47,2	48,5	47,6	40,4
20	C2155P	29,0	36,4	36,9	36,2	33,6
	Mean	34,3	46,9	45,9	43,8	41,9
	SEM	1,4	1,6	1,4	1,5	1,5
	TEST.T vs T0		0,000	0,000	0,000	0,000

VARIATION VS. T0

	T15min	T2h	T4h	T8h
	47,6%	**43,1%**	**32,4%**	**13,1%**
	49,4%	27,9%	25,6%	23,4%
	23,0%	**25,2%**	**17,8%**	**13,5%**
	35,0%	**40,6%**	**44,9%**	**40,6%**
	56,8%	**61,8%**	**61,1%**	**57,8%**
	28,2%	**28,6%**	**18,5%**	**11,1%**
	29,2%	30,2%	28,6%	27,0%
	38,3%	**12,3%**	**13,5%**	**13,3%**
	33,6%	37,4%	22,4%	20,2%
	32,3%	15,9%	9,5%	6,6%
	26,1%	**20,2%**	**11,2%**	**9,9%**
	28,2%	**27,3%**	**20,5%**	**18,3%**
	50,7%	**45,6%**	**34,4%**	**31,6%**
	11,9%	**11,2%**	**6,0%**	**4,5%**
	32,8%	**36,4%**	**27,7%**	**21,2%**
	54,9%	**56,5%**	**47,1%**	**41,4%**
	61,4%	**66,1%**	**50,3%**	**38,6%**
	35,5%	**37,7%**	**32,8%**	**22,8%**
	54,8%	**59,0%**	**56,1%**	**32,5%**
	25,6%	**27,2%**	**24,9%**	**16,0%**
	37,8%	35,5%	29,3%	23,2%
max	61,4%	66,1%	61,1%	57,8%
min	11,9%	11,2%	6,0%	4,5%

CONTROL AREA

n	Vol ID	T0	T15min	T2h	T4h	T8h
01	R0340L	30,1	28,7	30,3	30,1	31,8
02	P1794P	31,0	31,2	31,4	31,5	31,7
03	P1562L	35,3	35,6	36,6	36,0	35,1
04	D0106M	28,6	28,2	28,0	30,1	30,7
05	I0170M	33,7	33,2	33,2	32,8	35,7
06	M2000D	26,9	27,0	28,0	27,9	27,3
07	A2098T	36,0	**35,0**	35,0	34,3	36,8
08	Z2097M	40,3	43,6	44,1	42,0	42,2
09	F2070C	35,0	34,7	34,8	34,7	33,8
10	C0085N	43,7	43,8	43,7	45,2	43,9
11	S0872M	36,2	36,5	35,8	36,1	37,4
12	C1620T	50,6	51,8	50,6	52,2	52,9
13	A0849R	31,7	32,2	31,9	30,8	31,5
14	T1434E	42,4	43,8	43,9	42,9	44,0
15	S1258E	40,8	41,3	40,9	39,4	37,0
16	B1081G	30,2	29,7	29,4	29,8	28,7
17	C1963A	24,8	25,9	26,1	26,9	25,7
18	C1576G	41,6	43,4	42,8	43,9	43,3
19	C0766L	31,7	32,1	32,0	32,7	32,9
20	C2155P	31,1	32,1	32,3	32,2	33,2
	Mean	35,1	35,5	35,5	35,6	35,8
	SEM	1,4	1,6	1,5	1,5	1,5
	TEST.T vs T0		0,104	0,081	0,078	0,055

VARIATION VS. T0

	T15min	T2h	T4h	T8h
	-4,7%	0,7%	**0,0%**	**5,6%**
	0,6%	**1,3%**	**1,6%**	2,3%
	0,8%	**3,7%**	**2,0%**	**-0,6%**
	-1,4%	-2,1%	**5,2%**	**7,3%**
	-1,5%	-1,5%	-2,7%	**5,9%**
	0,4%	**4,1%**	3,7%	**1,5%**
	-2,8%	-2,8%	-4,7%	2,2%
	8,2%	**9,4%**	**4,2%**	4,7%
	-0,9%	**-0,6%**	**-0,9%**	-3,4%
	0,2%	**0,0%**	**3,4%**	**0,5%**
	0,9%	-1,0%	**-0,2%**	**3,4%**
	2,3%	**-0,1%**	**3,1%**	**4,6%**
	1,7%	**0,8%**	**-2,8%**	**-0,5%**
	3,2%	**3,3%**	**1,1%**	**3,7%**
	1,1%	**0,2%**	**-3,5%**	-9,4%
	-1,8%	-2,8%	-1,5%	-5,1%
	4,6%	**5,4%**	**8,6%**	**4,0%**
	4,3%	**2,9%**	**5,4%**	**4,2%**
	1,3%	**0,9%**	**3,2%**	**3,6%**
	3,3%	**3,9%**	**3,6%**	**6,8%**
	1,0%	1,3%	1,5%	2,1%
max	8,2%	9,4%	8,6%	7,3%
min	-4,7%	-2,8%	-4,7%	-9,4%

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GRAPH 3. Graph below shows skin moisturizing mean values (corneometric units) recorded during the short term test study.

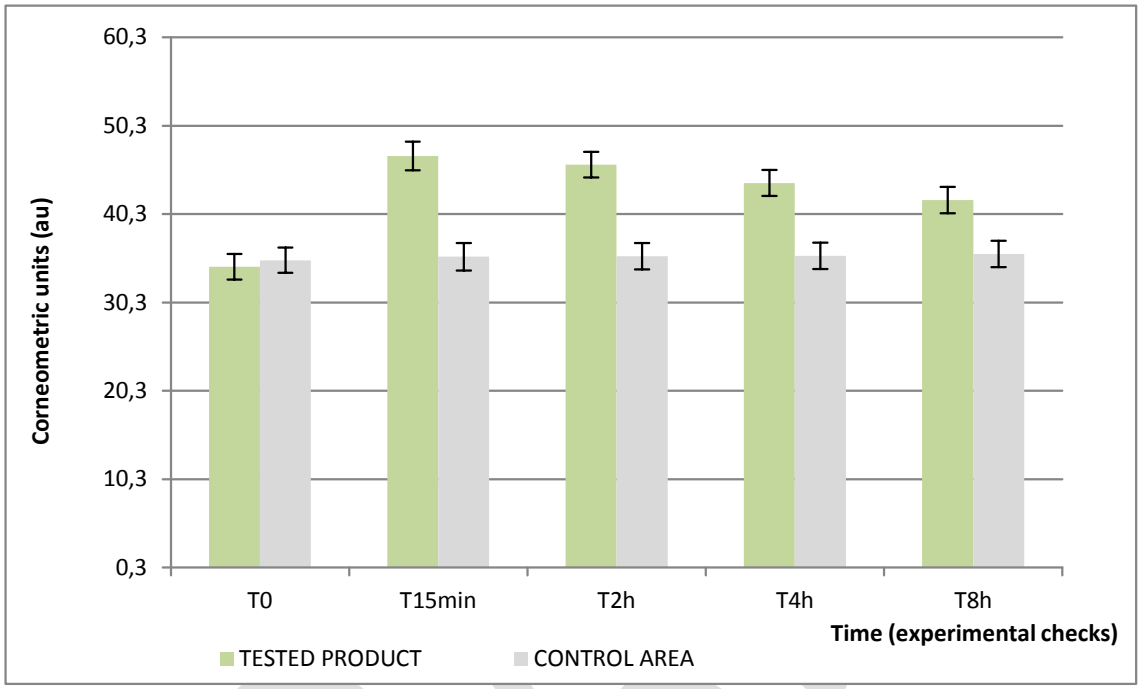

TABLE 3c. Table below shows the inter-group statistical analysis (TESTED PRODUCT vs CONTROL AREA). A p value <0.05 indicates a statistically significant data.

INTERGROUP STATISTICAL ANALYSIS	
experimental check	p-VALUE
T0 vs T0	0,0527
T15min vs T15min	0,0000
T2h vs T2h	0,0000
T4h vs T4h	0,0000
T8h vs T8h	0,0000

COMMENT: The single product application determines a statistically significant improvement of skin moisturizing index at each experimental monitored check, both compared to baseline and control area. No variations are monitored in control area.

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RESULTS: TRANS EPIDERMAL WATER LOSS – short term test

TABLE 4a/b. Tables below show trans epidermal water loss value (TEWL) recorded for each subject ON FACE during the short term test study.

TESTED PRODUCT

n	Vol ID	T0	T15min	T2h	T4h	T8h
01	R0340L	11,0	11,5	10,0	10,0	10,8
02	P1794P	22,0	21,5	19,7	19,5	21,0
03	P1562L	20,6	19,0	17,3	18,0	18,7
04	D0106M	14,1	12,8	13,4	13,7	13,5
05	I0170M	14,7	13,1	13,0	13,0	13,3
06	M2000D	13,6	13,8	13,6	13,4	13,0
07	A2098T	16,5	14,4	15,3	15,8	15,6
08	Z2097M	18,2	17,7	17,8	17,4	16,4
09	F2070C	12,6	11,1	11,2	12,1	11,6
10	C0085N	12,7	12,0	12,0	11,7	12,4
11	S0872M	15,3	14,5	15,0	15,3	15,5
12	C1620T	17,1	16,5	16,2	16,7	16,9
13	A0849R	19,9	18,5	16,6	16,4	18,0
14	T1434E	18,7	18,0	18,3	19,2	19,9
15	S1258E	11,2	9,9	9,5	10,4	11,1
16	B1081G	8,8	8,1	7,9	8,8	9,1
17	C1963A	11,9	9,1	9,5	9,5	9,5
18	C1576G	9,8	9,5	9,7	10,0	9,3
19	C0766L	18,9	16,5	14,7	15,2	15,4
20	C2155P	8,5	7,9	7,6	8,0	8,3
	Mean	14,8	13,8	13,4	13,7	14,0
	SEM	0,9	0,9	0,8	0,8	0,8
	TEST.T vs T0		0,000	0,000	0,001	0,002

CONTROL AREA

n	Vol ID	T0	T15min	T2h	T4h	T8h
01	R0340L	13,9	14,0	13,7	13,8	13,5
02	P1794P	25,6	25,5	26,0	25,0	26,5
03	P1562L	20,2	20,0	20,6	20,0	19,9
04	D0106M	12,9	12,4	12,5	12,6	12,2
05	I0170M	14,0	14,0	14,1	13,9	14,3
06	M2000D	11,2	11,5	10,9	11,7	11,2
07	A2098T	15,3	15,3	15,1	15,4	15,9
08	Z2097M	16,0	16,6	16,5	17,0	16,0
09	F2070C	11,2	11,2	11,5	11,3	11,5
10	C0085N	12,0	12,3	11,7	11,8	11,3
11	S0872M	15,6	15,8	16,1	16,2	15,8
12	C1620T	17,7	17,5	17,4	17,4	17,9
13	A0849R	20,2	20,1	21,2	21,3	21,7
14	T1434E	18,5	18,8	19,2	19,5	19,9
15	S1258E	12,3	12,2	12,8	12,5	12,1
16	B1081G	9,0	9,2	9,5	9,7	9,0
17	C1963A	12,2	12,0	12,1	12,3	12,7
18	C1576G	10,2	10,5	10,0	10,5	10,9
19	C0766L	18,3	18,9	19,7	19,4	20,1
20	C2155P	8,2	8,5	8,3	8,0	8,5
	Mean	14,7	14,8	14,9	15,0	15,0
	SEM	1,0	1,0	1,0	1,0	1,1
	TEST.T vs T0		0,168	0,057	0,054	0,051

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GRAPH 4. Graph below shows TEWL mean values (g/h/m^2) recorded during the short term test study.

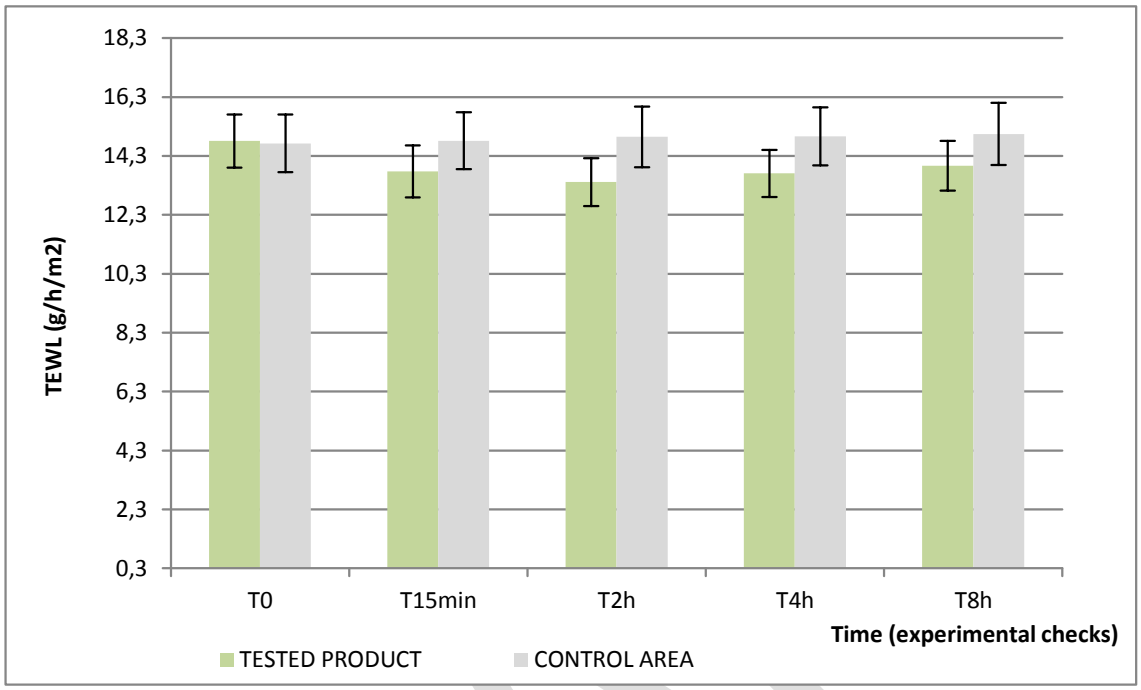

TABLE 4c. Table below shows the inter-group statistical analysis (TESTED PRODUCT vs CONTROL AREA). A p value <0.05 indicates a statistically significant data.

INTERGROUP STATISTICAL ANALYIS	
experimental check	p-VALUE
T0 vs T0	0,8087
T15min vs T15min	0,0036
T2h vs T2h	0,0074
T4h vs T4h	0,0124
T8h vs T8h	0,0241

COMMENT: The single product application maintains the values of trans epidermal water loss during the test period.

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RESULTS: SELF-ASSESMENT – short term test

Before (at baseline) and after the single product application (at the end of the short term test) volunteers are asked to fulfill a questionnaire.

Question 1	My skin feels dry or moisturized	
	% of answers	
	BEFORE	AFTER
Very dry	0,0%	0,0%
Dry	25,0%	10,0%
Slightly dry	40,0%	0,0%
Moisturized normal	30,0%	65,0%
Well moisturized	5,0%	25,0%
Very well moisturized	0,0%	0,0%
Total	100%	100%

Question 2	My skin seems sensitive	
	% of answers	
	BEFORE	AFTER
Very sensitive	15,0%	10,0%
Sensitive	35,0%	30,0%
Slightly sensitive	25,0%	20,0%
Normal	25,0%	40,0%
Total	100%	100%

Question 3	My skin feels uncomfortably tensioned	
	% of answers	
	BEFORE	AFTER
Very tensioned	5,0%	0,0%
Tensioned	25,0%	0,0%
Slightly tensioned	30,0%	35,0%
Very slightly tensioned	20,0%	45,0%
No tensions	20,0%	20,0%
Total	100%	100%

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Question 4	My skin feels stressed or relaxed	
	% of answers	
	BEFORE	AFTER
Very stressed	10,0%	0,0%
Stressed	40,0%	10,0%
Slightly stressed	30,0%	45,0%
Relaxed	20,0%	45,0%
Total	100%	100%

Question 5	My skin feels irritated	
	% of answers	
	BEFORE	AFTER
Very irritated	0,0%	0,0%
Irritated	15,0%	0,0%
Slightly irritated	30,0%	10,0%
Calmed and soothed a bit	40,0%	35,0%
Calmed and soothed	15,0%	45,0%
Very calmed and soothed	0,0%	10,0%
Total	100%	100%

Question 6	My skin feels weel nourished	
	% of answers	
	BEFORE	AFTER
Absolutely not nourished	5,0%	0,0%
Only a bit nourished	50,0%	25,0%
Well nourished	45,0%	70,0%
Very well nourished	0,0%	5,0%
Total	100%	100%

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Question 7	My skin feels soft and and smooth when touched, or rough	
	% of answers	
	BEFORE	AFTER
Very soft and smooth	0,0%	5,0%
Soft and smooth	20,0%	30,0%
Only slightly soft and smooth	40,0%	55,0%
It feels slightly rough	35,0%	10,0%
Rough	5,0%	0,0%
Very rough	0,0%	0,0%
Total	100%	100%

Question 8	My skin and complexion looks	
	% of answers	
	BEFORE	AFTER
Very dull and pale	5,0%	0,0%
Dull and pale	30,0%	25,0%
Slightly dull and pale	20,0%	20,0%
Slightly luminous and radiant	35,0%	40,0%
Luminous and radiant	10,0%	10,0%
Very luminous and radiant	0,0%	5,0%
Total	100%	100%

Question 9	My skin feels without protection or protected	
	% of answers	
	BEFORE	AFTER
Withour protection	15,0%	0,0%
Slightly without protection	30,0%	10,0%
A bit protected	40,0%	40,0%
Protected	15,0%	50,0%
Very protected	0,0%	0,0%
Total	100%	100%

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RESULTS: SKIN ELASTICITY (R2 PARAMETER) – long term test

TABLE 5a/b. Tables below show skin elasticity values (R2 parameter) recorded for each subject ON FACE and ON DECOLLETE during the long term test study.

FACE

n	Vol ID	T0	T15	T30	T60	VARIATION VS. T0 T15	T30	T60
01	B1644O	0,6253	0,6833	0,7012	0,7154	9,3%	12,1%	14,4%
02	R0329O	0,5388	0,5823	0,5954	0,6067	8,1%	10,5%	12,6%
03	Z2132N	0,7764	0,8036	0,8594	0,8612	3,5%	10,7%	10,9%
04	G2713G	0,6567	0,6697	0,6739	0,6805	2,0%	2,6%	3,6%
05	C2576V	0,7534	0,7865	0,7993	0,7871	4,4%	6,1%	4,5%
06	P2716P	0,6523	0,6842	0,7094	0,7155	4,9%	8,8%	9,7%
07	C0544S	0,5956	0,6760	0,6989	0,6954	13,5%	17,3%	16,8%
08	Z1236R	0,6824	0,7321	0,7508	0,7639	7,3%	10,0%	11,9%
09	F0121F	0,7260	0,7695	0,7380	0,7540	6,0%	1,7%	3,9%
10	G2821A	0,7258	0,7352	0,7861	0,8333	1,3%	8,3%	14,8%
11	L2406L	0,6467	0,6766	0,6973	0,7122	4,6%	7,8%	10,1%
12	S2049G	0,6037	0,6211	0,6285	0,6417	2,9%	4,1%	6,3%
13	S1388A	0,7678	0,8012	0,8195	0,8225	4,4%	6,7%	7,1%
14	C1267R	0,7590	0,7692	0,7817	0,7993	1,3%	3,0%	5,3%
15	N1500A	0,6060	0,6367	0,6412	0,6566	5,1%	5,8%	8,3%
16	B1401C	0,6188	0,6415	0,6778	0,6889	3,7%	9,5%	11,3%
17	T2481D	0,7654	0,7918	0,8003	0,8135	3,4%	4,6%	6,3%
18	C0771F	0,6013	0,6317	0,6532	0,6619	5,1%	8,6%	10,1%
19	C1576G	0,7829	0,8125	0,8239	0,8448	3,8%	5,2%	7,9%
20	V1228M	0,6515	0,6727	0,6915	0,7195	3,3%	6,1%	10,4%
	Mean	0,6768	0,7089	0,7264	0,7387	4,9%	7,5%	9,3%
	SEM	0,0	0,0	0,0	0,0	max 13,5%	17,3%	16,8%
	TEST.T vs T0		0,000	0,000	0,000	min 1,3%	1,7%	3,6%

DECOLLETE

n	Vol ID	T0	T15	T30	T60	VARIATION VS. T0 T15	T30	T60
01	B1644O	0,6764	0,6780	0,6812	0,7015	0,2%	0,7%	3,7%
02	R0329O	0,5670	0,5952	0,6154	0,6251	5,0%	8,5%	10,2%
03	Z2132N	0,8493	0,8576	0,8731	0,8976	1,0%	2,8%	5,7%
04	G2713G	0,7820	0,7940	0,8221	0,8447	1,5%	5,1%	8,0%
05	C2576V	0,8072	0,8220	0,8500	0,8751	1,8%	5,3%	8,4%
06	P2716P	0,8266	0,8450	0,8616	0,8788	2,2%	4,2%	6,3%
07	C0544S	0,5767	0,6340	0,6818	0,6341	9,9%	18,2%	10,0%
08	Z1236R	0,4866	0,5120	0,5502	0,5708	5,2%	13,1%	17,3%
09	F0121F	0,6892	0,7084	0,7811	0,8048	2,8%	13,3%	16,8%
10	G2821A	0,7066	0,7239	0,7566	0,8051	2,4%	7,1%	13,9%
11	L2406L	0,7592	0,7897	0,7913	0,8044	4,0%	4,2%	6,0%
12	S2049G	0,7650	0,7838	0,7845	0,7989	2,5%	2,5%	4,4%
13	S1388A	0,8193	0,8316	0,8332	0,8327	1,5%	1,7%	1,6%
14	C1267R	0,8496	0,8523	0,8591	0,8589	0,3%	1,1%	1,1%
15	N1500A	0,6497	0,6691	0,6634	0,6829	3,0%	2,1%	5,1%
16	B1401C	0,6255	0,6599	0,6935	0,7022	5,5%	10,9%	12,3%
17	T2481D	0,7836	0,8032	0,8316	0,8521	2,5%	6,1%	8,7%
18	C0771F	0,6382	0,6542	0,6822	0,7038	2,5%	6,9%	10,3%
19	C1576G	0,8338	0,8538	0,8517	0,8619	2,4%	2,1%	3,4%
20	V1228M	0,7023	0,7344	0,7403	0,7577	4,6%	5,4%	7,9%
	Mean	0,7197	0,7401	0,7602	0,7747	3,0%	6,1%	8,1%
	SEM	0,0	0,0	0,0	0,0	max 9,9%	18,2%	17,3%
	TEST.T vs T0		0,000	0,000	0,000	min 0,2%	0,7%	1,1%

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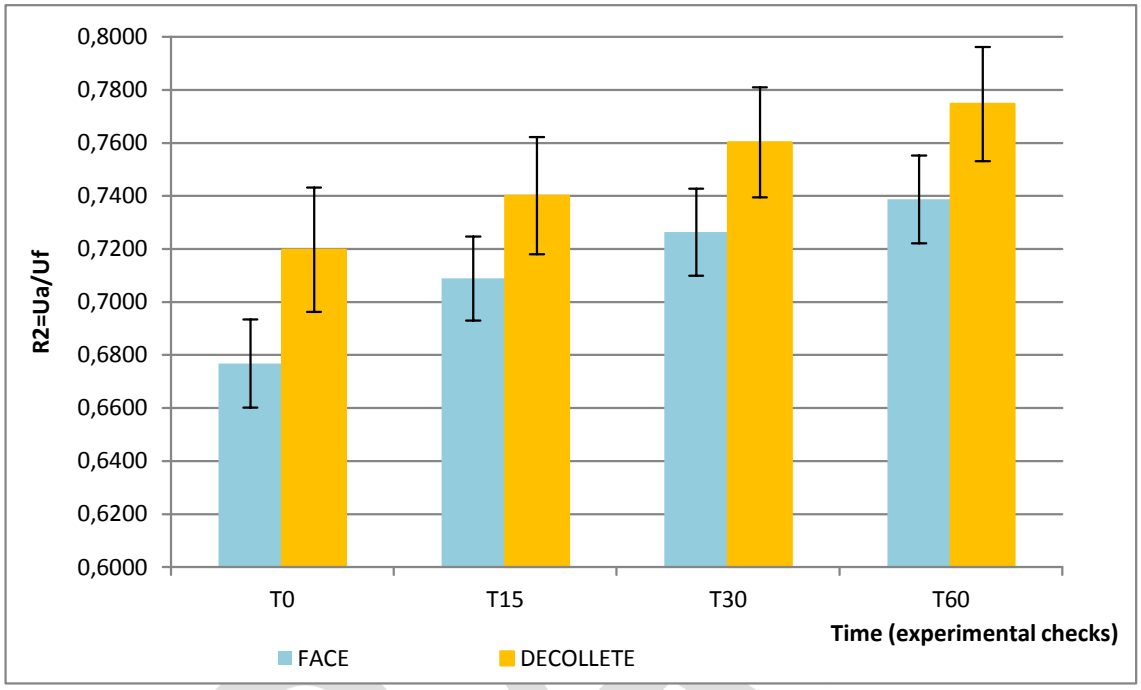
GRAPH 5. Graph below shows skin elasticity mean values (R2 parameter) recorded during the long term test study.



COMMENT: The use of the product, under test conditions, determines a statistically significant improvement of skin elasticity (R2 parameter) at each experimental monitored check, both on face and décolleté.

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RESULTS: SKIN FIRMNESS (R0 PARAMETER) – long term test

TABLE 6a/b. Tables below show skin firmness values (R0 parameter) recorded for each subject ON FACE and ON DECOLLETE during the long term test study.

FACE

n	Vol ID	T0	T15	T30	T60	VARIATION VS. T0 T15	T30	T60
01	B1644O	0,4750	0,4690	0,4525	0,4320	-1,3%	-4,7%	-9,1%
02	R0329O	0,2469	0,2400	0,2380	0,2270	-2,8%	-3,6%	-8,1%
03	Z2132N	0,3220	0,2800	0,2560	0,2520	-13,0%	-20,5%	-21,7%
04	G2713G	0,5360	0,4360	0,4320	0,4350	-18,7%	-19,4%	-18,8%
05	C2576V	0,3690	0,3400	0,3340	0,3270	-7,9%	-9,5%	-11,4%
06	P2716P	0,2195	0,2030	0,2010	0,1980	-7,5%	-8,4%	-9,8%
07	C0544S	0,5910	0,4630	0,4480	0,4520	-21,7%	-24,2%	-23,5%
08	Z1236R	0,4440	0,4330	0,4230	0,4090	-2,5%	-4,7%	-7,9%
09	F0121F	0,3310	0,3340	0,3290	0,3260	0,9%	-0,6%	-1,5%
10	G2821A	0,3830	0,3550	0,3720	0,3300	-7,3%	-2,9%	-13,8%
11	L2406L	0,2890	0,2870	0,2620	0,2590	-0,7%	-9,3%	-10,4%
12	S2049G	0,3270	0,3210	0,2920	0,2480	-1,8%	-10,7%	-24,2%
13	S1388A	0,3660	0,3550	0,3380	0,3310	-3,0%	-7,7%	-9,6%
14	C1267R	0,4150	0,4040	0,3950	0,3860	-2,7%	-4,8%	-7,0%
15	N1500A	0,2210	0,2170	0,2010	0,1990	-1,8%	-9,0%	-10,0%
16	B1401C	0,3720	0,3690	0,3460	0,3420	-0,8%	-7,0%	-8,1%
17	T2481D	0,2430	0,2380	0,2310	0,2250	-2,1%	-4,9%	-7,4%
18	C0771F	0,4490	0,4260	0,4040	0,3980	-5,1%	-10,0%	-11,4%
19	C1576G	0,3940	0,3880	0,3820	0,3760	-1,5%	-3,0%	-4,6%
20	V1228M	0,3030	0,2740	0,2580	0,2320	-9,6%	-14,9%	-23,4%
	Mean	0,3648	0,3416	0,3297	0,3192	-5,5%	-9,0%	-12,1%
	SEM	0,0	0,0	0,0	0,0	min 0,9%	-0,6%	-1,5%
	TEST.T vs T0		0,006	0,000	0,000	max -21,7%	-24,2%	-24,2%

DECOLLETE

n	Vol ID	T0	T15	T30	T60	VARIATION VS. T0 T15	T30	T60
01	B1644O	0,4450	0,4070	0,4010	0,3890	-8,5%	-9,9%	-12,6%
02	R0329O	0,2225	0,2100	0,2080	0,2010	-5,6%	-6,5%	-9,7%
03	Z2132N	0,4580	0,4200	0,3560	0,3420	-8,3%	-22,3%	-25,3%
04	G2713G	0,5550	0,5310	0,5300	0,5230	-4,3%	-4,5%	-5,8%
05	C2576V	0,3320	0,3370	0,3340	0,3280	1,5%	0,6%	-1,2%
06	P2716P	0,4762	0,3870	0,3510	0,3480	-18,7%	-26,3%	-26,9%
07	C0544S	0,3780	0,3880	0,3480	0,3220	2,6%	-7,9%	-14,8%
08	Z1236R	0,4850	0,3750	0,4230	0,4150	-22,7%	-12,8%	-14,4%
09	F0121F	0,3990	0,4150	0,3390	0,3350	4,0%	-15,0%	-16,0%
10	G2821A	0,3170	0,2960	0,2920	0,2900	-6,6%	-7,9%	-8,5%
11	L2406L	0,2740	0,2530	0,2450	0,2310	-7,7%	-10,6%	-15,7%
12	S2049G	0,2830	0,2720	0,2670	0,2490	-3,9%	-5,7%	-12,0%
13	S1388A	0,3320	0,3210	0,3010	0,2980	-3,3%	-9,3%	-10,2%
14	C1267R	0,3460	0,3410	0,3280	0,3220	-1,4%	-5,2%	-6,9%
15	N1500A	0,1970	0,1920	0,1850	0,1790	-2,5%	-6,1%	-9,1%
16	B1401C	0,2350	0,2290	0,2030	0,1990	-2,6%	-13,6%	-15,3%
17	T2481D	0,2680	0,2520	0,2380	0,2350	-6,0%	-11,2%	-12,3%
18	C0771F	0,2460	0,2370	0,2190	0,2130	-3,7%	-11,0%	-13,4%
19	C1576G	0,3930	0,3890	0,3850	0,3640	-1,0%	-2,0%	-7,4%
20	V1228M	0,2820	0,2680	0,2520	0,2370	-5,0%	-10,6%	-16,0%
	Mean	0,3462	0,3260	0,3103	0,3010	-5,2%	-9,9%	-12,7%
	SEM	0,0	0,0	0,0	0,0	min 4,0%	0,6%	-1,2%
	TEST.T vs T0		0,008	0,000	0,000	max -22,7%	-26,3%	-26,9%

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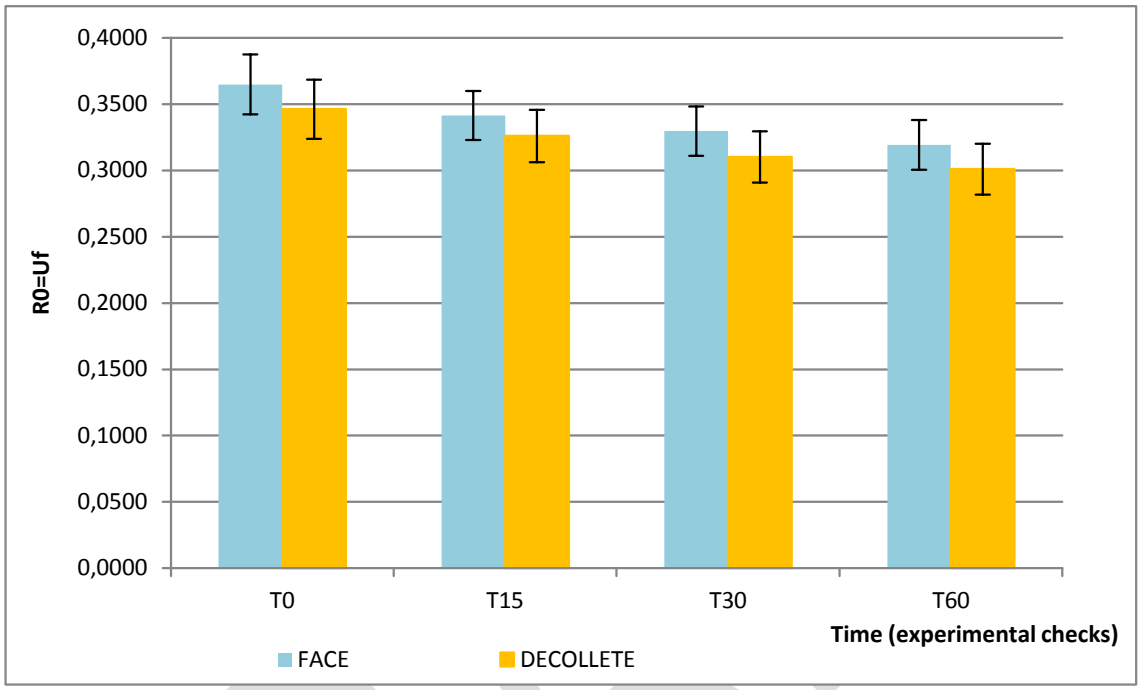
GRAPH 6. Graph below shows skin firmness mean values (R0 parameter) recorded during the long term test study.



COMMENT: The use of the product, under test conditions, determines a statistically significant improvement of skin firmness (recorded as a decrease of R0 parameter) at each experimental monitored check, both on face and décolleté.

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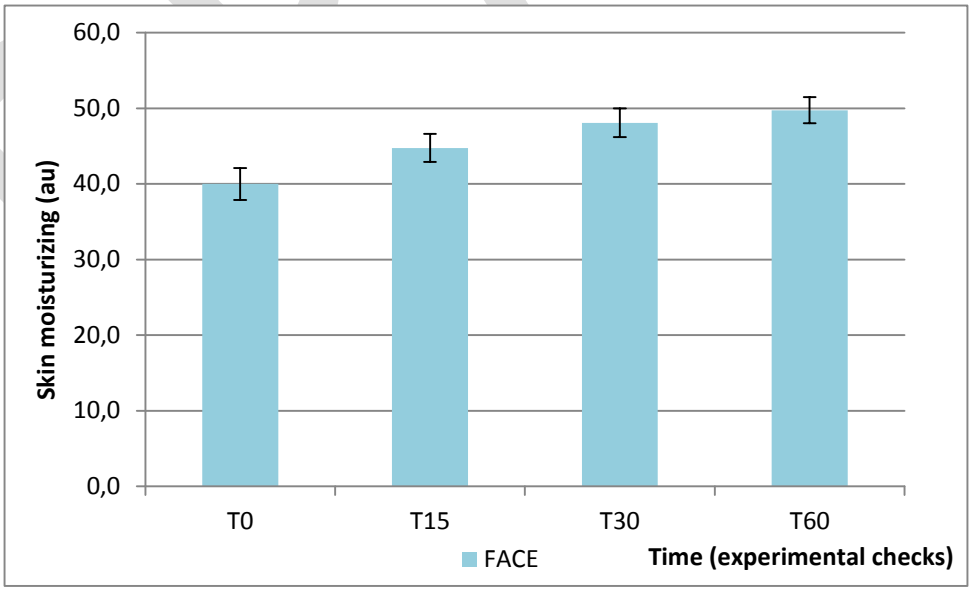
RESULTS: SKIN MOISTURIZING – long term test

TABLE 7. Tables below show skin moisturizing index (corneometric units) recorded for each subject ON FACE during the long term test study.

FACE

n	Vol ID	T0	T15	T30	T60	VARIATION VS. T0 T15	T30	T60
01	B1644O	32,7	36,7	44,3	48,0	12,2%	35,5%	46,8%
02	R0329O	37,4	39,9	41,6	45,6	6,7%	11,2%	21,9%
03	Z2132N	37,9	48,2	50,9	51,0	27,2%	34,3%	34,6%
04	G2713G	48,3	51,6	53,8	55,3	6,8%	11,4%	14,5%
05	C2576V	46,7	48,4	57,7	60,3	3,6%	23,6%	29,1%
06	P2716P	52,6	54,6	56,2	58,4	3,8%	6,8%	11,0%
07	C0544S	36,5	42,5	47,4	49,1	16,4%	29,9%	34,5%
08	Z1236R	57,6	58,7	61,2	63,4	1,9%	6,3%	10,1%
09	F0121F	56,0	58,1	64,7	63,4	3,8%	15,5%	13,2%
10	G2821A	30,8	44,7	45,0	44,9	45,1%	46,1%	45,8%
11	L2406L	36,1	40,5	42,2	43,2	12,2%	16,7%	19,7%
12	S2049G	35,6	39,5	42,3	44,2	11,0%	18,9%	24,2%
13	S1388A	28,4	32,3	35,7	38,8	13,9%	25,9%	36,7%
14	C1267R	49,7	52,2	55,5	56,1	5,0%	11,7%	13,0%
15	N1500A	32,2	37,8	38,1	43,7	17,2%	18,2%	35,4%
16	B1401C	22,6	27,2	32,7	35,4	20,4%	44,6%	56,9%
17	T2481D	39,9	45,3	47,2	48,5	13,6%	18,4%	21,6%
18	C0771F	40,6	45,9	49,8	47,3	13,1%	22,7%	16,4%
19	C1576G	44,6	51,1	51,9	53,2	14,7%	16,4%	19,2%
20	V1228M	33,6	39,8	43,4	45,2	18,5%	29,2%	34,5%
	Mean	40,0	44,8	48,1	49,7	13,4%	22,2%	27,0%
	SEM	2,1	1,9	1,9	1,7	max 45,1%	46,1%	56,9%
	TEST.T vs T0		0,000	0,000	0,000	min 1,9%	6,3%	10,1%

GRAPH 7. Graph below shows skin moisturizing mean values (corneometric units) recorded during the long term test study.



COMMENT: The use of the product, under test conditions, determines a statistically significant improvement of skin moisturizing on face at each experimental monitored check.

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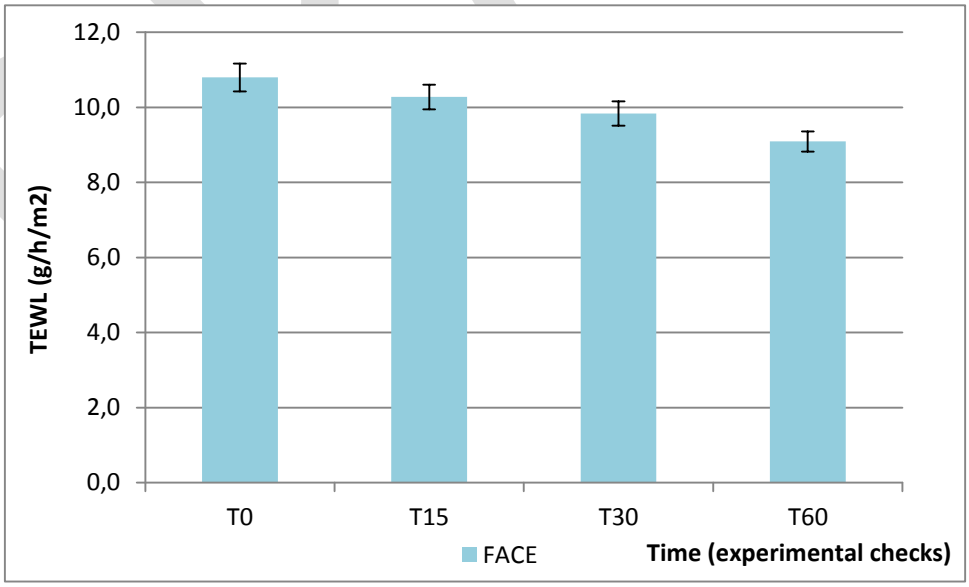
RESULTS: TRANS EPIDERMAL WATER LOSS – long term test

TABLE 8. Tables below show trans epidermal water loss value (TEWL) recorded for each subject ON FACE during the long term test study.

n	Vol ID	FACE T0	FACE T15	FACE T30	FACE T60
01	B1644O	10,7	9,7	9,5	8,9
02	R0329O	9,7	9,5	9,3	8,8
03	Z2132N	11,0	10,8	10,2	9,5
04	G2713G	12,7	12,1	12,1	11,3
05	C2576V	11,0	9,8	9,5	9,0
06	P2716P	7,8	7,7	7,6	7,2
07	C0544S	12,3	12,0	10,2	9,8
08	Z1236R	10,7	10,5	10,3	9,7
09	F0121F	12,7	11,0	10,8	10,0
10	G2821A	12,8	12,1	12,0	11,0
11	L2406L	8,5	8,3	8,1	7,9
12	S2049G	10,2	9,8	9,2	8,8
13	S1388A	9,5	9,1	8,7	8,2
14	C1267R	11,6	11,1	10,5	9,4
15	N1500A	13,1	12,5	11,9	10,3
16	B1401C	12,3	11,2	10,5	10,2
17	T2481D	11,9	11,3	10,8	8,9
18	C0771F	10,6	10,1	9,6	7,8
19	C1576G	9,1	9,8	9,6	8,5
20	V1228M	7,7	7,1	6,3	6,6
	Mean	10,8	10,3	9,8	9,1
	SEM	0,4	0,3	0,3	0,3
	TEST.T vs T0		0,000	0,000	0,000

GRAPH 8. Graph below shows trans epidermal water loss values (g/h/m^2) recorded during the short term test study.



COMMENT: The use of the product under test conditions maintains the values of trans epidermal water loss during the test period (it shows a positive tendency on the monitored parameter).

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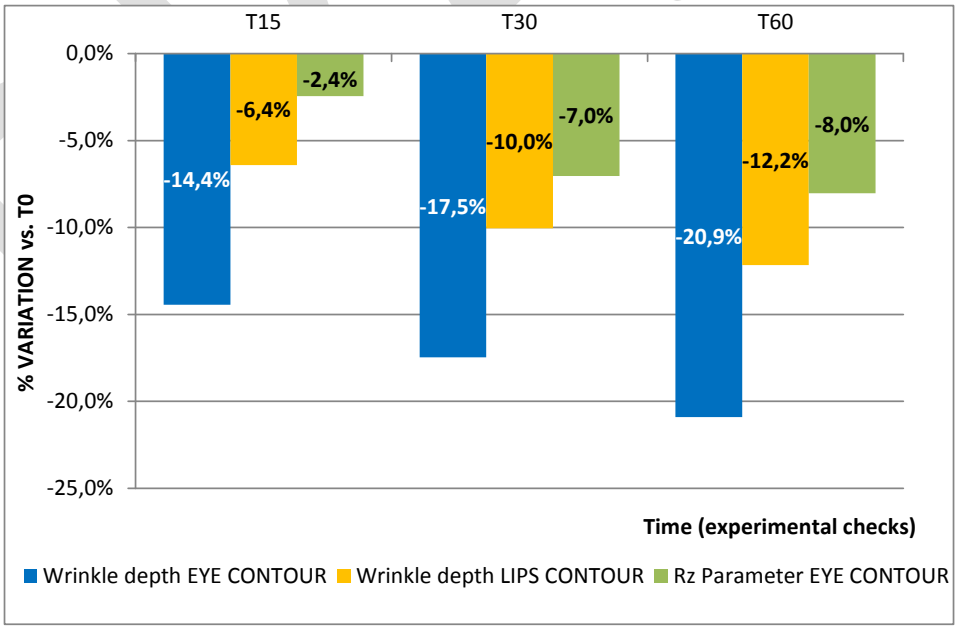
RESULTS: SKIN PROFILOMETRY – long term test

TABLE 9 - The table indicates the mean of the percentage variations vs. T0, the statistical analysis, maximum and minimum variations obtained for wrinkle depth parameter evaluated on the eye contour and on the lips contour and for Rz parameter (related to skin wrinkledness) evaluated on the eye contour at each experimental check.

		RIVOLI Crème Nutrition Intense 005-OWBN-Y HB-A-09 Batch 060912		
		T15	T30	T60
Wrinkle depth EYE CONTOUR (FACE)	Mean of the % variation	-14,4%	-17,5%	-20,9%
	t-test vs. T0	0,000	0,000	0,000
	MAX (maximum variation)	-29,9%	-35,8%	-36,9%
	MIN (minimum variation)	7,1%	-6,3%	-8,2%
Wrinkle depth LIPS CONTOUR	Mean of the % variation	-6,4%	-10,0%	-12,2%
	t-test vs. T0	0,001	0,000	0,000
	MAX (maximum variation)	-21,9%	-29,5%	-30,2%
	MIN (minimum variation)	4,4%	7,4%	4,9%
Rz Parameter (skin wrinkledness) EYE CONTOUR (FACE)	Mean of the % variation	-2,4%	-7,0%	-8,0%
	t-test vs. T0	0,007	0,000	0,000
	MAX (maximum variation)	-6,5%	-17,5%	-16,7%
	MIN (minimum variation)	8,1%	-2,7%	-2,7%

GRAPH 9 - The graph indicates the mean of the percentage variations vs. T0 obtained for the monitored parameters.



COMMENT: The use of the product under test conditions determines an improvement of all the profilometric monitored parameters.

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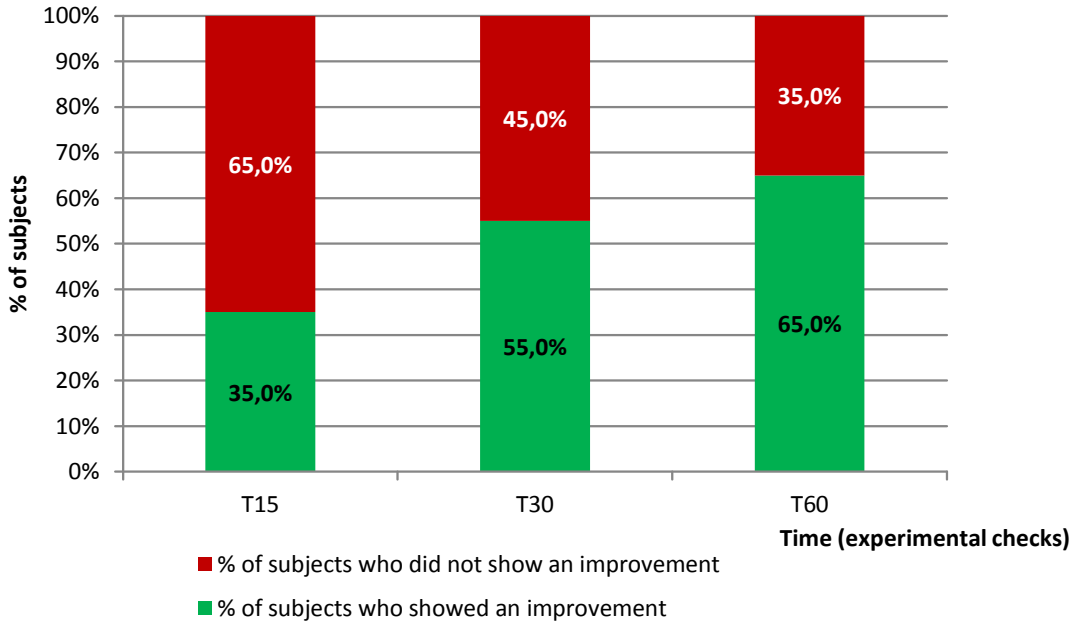
RESULTS: CLINICAL EVALUATION | IMPROVEMENT OF THE OVERALL QUALITY OF THE SKIN – long term test

TABLE 10 - The table reports the clinical score scales performed by the dermatologist after 15, 30 and 60 days of product use.

n	Vol ID	T15	T30	T60
01	B1644O	2	1	1
02	R0329O	1	1	2
03	Z2132N	1	2	2
04	G2713G	1	1	1
05	C2576V	1	2	2
06	P2716P	1	1	1
07	C0544S	1	2	2
08	Z1236R	1	2	2
09	F0121F	2	2	2
10	G2821A	1	1	1
11	L2406L	1	2	2
12	S2049G	2	2	2
13	S1388A	1	1	1
14	C1267R	2	2	3
15	N1500A	1	1	1
16	B1401C	2	2	2
17	T2481D	2	2	2
18	C0771F	1	1	1
19	C1576G	2	2	2
20	V1228M	1	1	2
	Mean	1,4	1,6	1,7
	SEM	0,1	0,1	0,1

Improvement of the overall quality of the skin	Score
No variation	1
Slight improvement	2
Moderate improvement	3
Remarkable improvement	4

GRAPH 10 - The graph reports the percentage of subjects related to the effect.



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RESULTS: SELF-ASSESMENT – short term test

At the end of the study the subjects are asked to express their opinion regarding tested product by means of a questionnaire.

Question 1	Do you feel your skin moisturized	
	% of answers	Number of subjects
Much more	35,0%	7
More	55,0%	11
No change	10,0%	2
Less	0,0%	0
Much less	0,0%	0
Total	100%	20

Question 2	Do you feel your skin smoothed and calmed	
	% of answers	Number of subjects
Much more	30,0%	6
More	55,0%	11
No change	15,0%	3
Less	0,0%	0
Much less	0,0%	0
Total	100%	20

Question 3	Do you feel your skin comfortable	
	% of answers	Number of subjects
Much more	35,0%	7
More	50,0%	10
No change	15,0%	3
Less	0,0%	0
Much less	0,0%	0
Total	100%	20

Question 4	Do you feel your skin less stressed	
	% of answers	Number of subjects
Much more	25,0%	5
More	50,0%	10
No change	15,0%	3
Less	5,0%	1
Much less	5,0%	1
Total	100%	20

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Question 5	Do you feel your skin well and deeply nourished	
	% of answers	Number of subjects
Much more	40,0%	8
More	50,0%	10
No change	10,0%	2
Less	0,0%	0
Much less	0,0%	0
Total	100%	20

Question 6	Do you feel your skin soft and smooth when touched	
	% of answers	Number of subjects
Much more	35,0%	7
More	55,0%	11
No change	10,0%	2
Less	0,0%	0
Much less	0,0%	0
Total	100%	20

Question 7	Do you feel your skin well protected	
	% of answers	Number of subjects
Much more	35,0%	7
More	50,0%	10
No change	15,0%	3
Less	0,0%	0
Much less	0,0%	0
Total	100%	20

Question 8	Your skin shows a better skin complexion	
	% of answers	Number of subjects
Much more	30,0%	6
More	50,0%	10
No change	15,0%	3
Less	5,0%	1
Much less	0,0%	0
Total	100%	20

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Question 13	Your skin of neck and décolleté shows visibily less wrinkles	
	% of answers	Number of subjects
Much more	10,0%	2
More	50,0%	10
No change	20,0%	4
Less	15,0%	3
Much less	5,0%	1
Total	100%	20

Question 14	Your skin on the eye contour shows visibily less wrinkles	
	% of answers	Number of subjects
Much more	20,0%	4
More	45,0%	9
No change	20,0%	4
Less	10,0%	2
Much less	5,0%	1
Total	100%	20

Question 15	Your skin around the lips shows visibily less wrinkles	
	% of answers	Number of subjects
Much more	15,0%	3
More	50,0%	10
No change	20,0%	4
Less	10,0%	2
Much less	5,0%	1
Total	100%	20

Question 16	Your skin looks firmer and plumped	
	% of answers	Number of subjects
Much more	25,0%	5
More	60,0%	12
No change	15,0%	3
Less	0,0%	0
Much less	0,0%	0
Total	100%	20

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Question 17	Your face skin looks younger	
	% of answers	Number of subjects
Much more	20,0%	4
More	60,0%	12
No change	20,0%	4
Less	0,0%	0
Much less	0,0%	0
Total	100%	20

Question 18	Your skin of neck and décolleté looks younger	
	% of answers	Number of subjects
Much more	20,0%	4
More	55,0%	11
No change	25,0%	5
Less	0,0%	0
Much less	0,0%	0
Total	100%	20

Question 19	Your skin looks radiant and luminous	
	% of answers	Number of subjects
Much more	20,0%	4
More	70,0%	14
No change	10,0%	2
Less	0,0%	0
Much less	0,0%	0
Total	100%	20

Question 20	Do you like the soft and rich texture of this product	
	% of answers	Number of subjects
Yes very much	55,0%	11
Yes	40,0%	8
Somewhat	5,0%	1
Don't know	0,0%	0
Not at all	0,0%	0
Total	100%	20

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Question 21	This product is one of the most nutritious, which I have ever tested or used	
	% of answers	Number of subjects
Yes	75,0%	15
No	25,0%	5
Total	100%	20

Question 22	Would you continue to use this product?	
	% of answers	Number of subjects
Yes	90,0%	18
No	10,0%	2
Total	100%	20

Question 23	Would you buy this product (regardless of cost)?	
	% of answers	Number of subjects
Very certainly	60,0%	12
Certainly	25,0%	5
Pehaps	10,0%	2
Probably not	0,0%	0
Certainly not	5,0%	1
Total	100%	20

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CONCLUSIONS

In accordance with the exposed results we can conclude that

TORSTONE SA
RIVOLI
Crème Nutrition Intense
005-OWBN-Y

results in a statistically significant improvement of skin conditions both in the short and long term test.
After the first product application an improvement of skin elasticity, firmness and moisturizing are monitored. These effects are also recorded at the end of the long term test. Furthermore, in the long term test, an improvement in skin profilometry (recorded as a decrease of wrinkle depth in the eye and lips contour and as a decrease of skin wrinkledness) is monitored.
Tested product is well tolerated by the enrolled subjects: no adverse skin reactions were monitored during the test period. Moreover, the most part of the enrolled volunteers positively judge the product.

San Martino Siccomario, 19th June 2015

Experimenter	Quality Control
Dott.ssa Enza Cestone	Dott.ssa Eleonora Spartà

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