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CLINICAL AND INSTRUMENTAL EVALUATION OF THE EFFICACY OF A COSMETIC PRODUCT FOR FACE CARE

RIVOLI COSMÉTIQUES SA
RE-BALANCING EMULSION N 02
lab-02191.8

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STUDY DESIGN

1.1 Title

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

1.2. Aim of the study

The study is aimed at evaluating the efficacy of a cosmetic product for face care (emulsion) in improving skin barrier condition/function, skin radiance/brightness and skin erythema; moreover, its soothing activity is clinically investigated.
To reach this goal, a clinical study is carried out on 30 (33 enrolled) healthy Caucasian female subjects aged between 35 and 50 (±2) years old, exhibit clinical features consistent with sensitive skin, a condition characterized by both objective signs and subjective symptoms. Specifically, are enrolled individuals test positive in the stinging test (indicating increased cutaneous reactivity), showing visible clinical signs, such as diffuse redness (erythema) and, in some cases, telangiectasias (dilated superficial blood vessels) and report frequent subjective discomfort, including burning sensations, stinging and/or itching, who apply the product for 28 consecutive days on face according to the provided instructions.
The evaluations of interest are performed by means of non-invasive bioengineering techniques able to measure skin pH, transepidermal water loss (TEWL), skin radiance/brightness and skin erythema. The instrumental analysis is integrated with the dermatological evaluation of physical and functional signs to rate product efficacy and with the clinical evaluation of the soothing activity of the product on skin discomforts induced by stinging test* as detailed in the par.1.6.
**10% lactic acid aqueous solution is applied to the sensory innervation-rich (hypersensitive) skin of both alar grooves, to detect itching/stinging sensation that typically arise in sensitive subjects within few minutes.*

1.3. Tested product

1.3.1. Information provided by the Customer

- ☒ Product name: **RE-BALANCING EMULSION N 02 lab-02191.8**
- ☒ Way of use: apply twice a day (morning and evening) as a day and night treatment. Warm a pearl-sized dose of cream between palms. Spread lightly over the face, starting from the bridge of the nose and working outwards, then down towards the neck.
  For the evaluation of the soothing activity immediately after the first application (short term evaluation - see par.1.6.), the product is applied by the experimenter, by means of a soaked cotton swab, on right/left alar groove according to a previously defined randomization list. The contralateral side is treated with demineralized water and acts as negative control.
- ☒ The test 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 cosmetic product to be tested is safe under normal or reasonably foreseeable conditions of use.
- ☒ Qualitative INCI formula: AQUA (WATER), C10-18 TRIGLYCERIDES, COCOS NUCIFERA (COCONUT) OIL, PENTYLENE GLYCOL, HYDROGENATED COCO-GLYCERIDES, GLYCERIN, alpha-GLUCAN OLIGOSACCHARIDE, CAPRYLIC/CAPRIC TRIGLYCERIDE, HYDROGENATED PHOSPHATIDYLCHOLINE, MYRICA CERIFERA FRUIT WAX, RHUS VERNICIFLUA PEEL CERA, ZEA MAYS (CORN) STARCH, BUTYROSPERMUM PARKII (SHEA) BUTTER, MARIS AQUA (SEA WATER), POLYMNIA SONCHIFOLIA ROOT JUICE, SCLEROTIUM GUM, MALTODEXTRIN, PARFUM (FRAGRANCE), XANTHAN GUM, LEONTOPODIUM ALPINUM FLOWER/LEAF EXTRACT, BISABOLOL, SQUALANE, ALLANTOIN, LACTOBACILLUS, CERAMIDE NP, CODIUM TOMENTOSUM EXTRACT, CITRIC ACID, ARGININE, CI 42090 (BLUE 1 LAKE), HEXAMETHYLINDANOPYRAN, TETRAMETHYL ACETYLOCTAHYDRONAPHTHALENES.

1.4. Ethical requirements

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

I. All the subjects participating in the study are healthy volunteers of at least 18 years old.
II. All the subjects participating in the study, are selected with the supervision of a dermatologist according to inclusion/non-inclusion criteria.
III. The volunteer's participation in the study is free.
IV. All the subjects participating in the study are informed of the aim and the design of the study.
V. All the subjects participating in the study are informed of the possible risk involved in the study execution.
VI. All the subjects participating in the study give their informed consent signed at the beginning of the study.
VII. Before the volunteers are exposed to the product to be tested, all relevant safety information about the product

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itself and each ingredient are collected and evaluated.

VIII. All 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).

IX. All the precautions are taken in consideration in order to avoid excessive skin reactions.

X. In case of non-expected/adverse skin reaction occurrence, the medical experimenter evaluates the severity of the reaction (reporting it in the data collecting sheet) and proceeds with the appropriate therapy.

1.5. Subjects participating in the study

1.5.1. Subjects' enrolment

The subjects participating in the study are screened and enrolled in the study under the supervision of a board-certified dermatologist from a panel of healthy subjects, in accordance with the inclusion and non-inclusion criteria reported in the sections here below.

1.5.1.1. Inclusion criteria

- ☑ Healthy female subjects
- ☑ Caucasian ethnicity
- ☑ Aged between 35 and 50 (±2) years old
- ☑ Subjects with sensitive skin (positive to stinging test*) and red prone skin (e.g. subjects showing light telangiectasia)
- ☑ Subjects showing skin redness/telangiectasias and skin prone to burning/stinging/itching sensations are enrolled.
- ☑ Subjects registered with National Health Service (NHS)
- ☑ Subjects certifying the truthfulness of the personal data disclosed to the investigator
- ☑ Subjects able to understand the language used in the investigation centre and the information given by the investigator
- ☑ Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
- ☑ The pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) should be stable for at least one month without any changes expected or planned during the study
- ☑ Commitment not to change the daily routine or the lifestyle
- ☑ Subjects who have not been recently involved in any other similar study
- ☑ Subjects informed about the test procedures and who have signed a consent form.

**10% lactic acid aqueous solution is applied to the sensory innervation-rich (hypersensitive) skin of both alar grooves to detect itching/stinging sensation that typically arise in sensitive subjects within few minutes.*

1.5.1.2. Not-inclusion criteria

- ✘ Subject does not meet the inclusion criteria
- ✘ Subjects with acute or chronic diseases able to interfere with the outcome of the study or that are considered dangerous for the subject or incompatible with the study requirements
- ✘ Subjects participating or planning to participate in other clinical trials
- ✘ Subjects deprived of freedom by administrative or legal decision or under guardianship
- ✘ Subjects not able to be contacted in case of emergency
- ✘ Subjects admitted to a health or social facility
- ✘ Subjects planning a hospitalisation during the study
- ✘ Subjects who participated in a similar study without respecting an adequate washout period
- ✘ Subjects having an acute, chronic or progressive illness liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
- ✘ Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator
- ✘ Subjects having a skin disease or condition liable to interfere with the study data or considered by the Investigator hazardous for the subject or incompatible with the study requirements
- ✘ Subjects that have shown allergies or sensitivity to cosmetic products, drugs, patch or medical devices
- ✘ Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during

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the study (for the women of childbearing potential).

1.5.1.3. Withdrawal of subjects

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

1.6. Study development

The study is carried out as follows:

T0 – basal visit, before product use

- Enrolment of 33 subjects according to inclusion/non-inclusion criteria. Subjects are informed about test procedures and they are asked to sign a consent form and the authorization of the personal data treatment. The experimenter gives the product to be tested to the subjects for a 28-day period of use together with the informative form and the way of use. Each enrolled subject is instructed to immediately stop using the product on manifestation of intolerance towards the product itself, and to inform the experimenter;
- Instrumental evaluation of transepidermal water loss (TEWL), skin pH, skin radiance/brightness and skin erythema;
- Dermatological assessment of baseline skin condition;
- Application of a 10% lactic acid aqueous solution to the skin of on right/left alar groove according to a previously defined randomization list, in order to induce the itching/stinging sensation *(basal stinging test).* At **Tmax,** when the discomfort peaks its maximum sensation (approximately few minutes after the application of the 10% lactic acid aqueous solution), after 30 seconds **(T30'')** and within the next 10 minutes **(T1'/T2'/T3'/T4'/T5'/T6'/T7'/T8'/T9'/T10')** the experimenter records the intensity of the perceived discomfort refereed by the subject;
- Expert scoring of skin smoothness;
- Expert scoring of skin complexion evenness.

Product application on face according to provided instructions under the experimenter supervision;

Timm: immediately after the first application:

- instrumental evaluation of skin erythema
- dermatological assessment after product application

T15min: 15 minutes after the product application Instrumental evaluation of skin pH;

T2h: 2 hours after the product application Instrumental evaluation of transepidermal water loss;

T4h: 4 hours after the product application Instrumental evaluation of transepidermal water loss;

T1 – the day after the basal visit (evaluation of the soothing effect of the product after the first application - short term evaluation)

- Application of a 10% lactic acid aqueous solution to the skin of both alar grooves, in order to induce the itching/stinging sensation.
- **Tmax:** when the discomfort peaks its maximum sensation (approximately few minutes after the application of the 10% lactic acid aqueous solution) the experimenter records the intensity of the perceived discomfort referred by the subject and applies the tested product by means of a soaked cotton stick, on right/left alar groove according to a previously defined randomization list. The contralateral side is treated with demineralized water and acts as negative control.
- **Timm:** the experimenter records the intensity of the perceived discomfort referred by the subject immediately after the first product/demineralized water application.
- **T30'':** the experimenter records the intensity of the perceived discomfort referred by the subject 30 seconds after product/demineralized water application.
- **T1'/T2'/T3'/T4'/T5'/T6'/T7'/T8'/T9'/T10':** the experimenter records the intensity of the perceived discomfort referred by the subject 1/2/3/4/5/6/7/8/9 and 10 minutes after product/demineralized water application.

T1-T28: daily product home-use according to provided instructions.

T28 – final visit after 28 days of product use

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- Instrumental evaluation of transepidermal water loss (TEWL), skin radiance/brightness and skin erythema.
- Final stinging test to evaluate the product efficacy in reducing skin sensitivity after 28 days of repeated use (long term evaluation) by application of a 10% lactic acid aqueous solution to the skin (on right/left alar groove) and the clinical assessment of itching/stinging reaction at different time points **(Tmax/T30'' T1'/T2'/T3'/T4'/T5'/T6'/T7'/T8'/T9'/T10')** performed by the experimenter in collaboration with the subjects;
- Dermatological assessment;
- Expert scoring of skin smoothness;
- Expert scoring of skin complexion evenness;
- Subjects are asked to fill in a self-assessment questionnaire.

1.7. Materials and methods

Here below the parameters monitored during the study are reported. The instrumental evaluations are carried out in a temperature and humidity-controlled environment (respectively T= 18-26°C and RH= 50±10%). The subject, before each visit, observes a 15-20-minute acclimatization period in these conditions.

1.7.1. Skin pH

The used instrument is the SKIN pH-METER 905®, Courage + Khazaka GmbH. The measure is based on a combined electrode of high quality, in which both the glass electrode sensitive to H+ and the additional reference electrode are placed in the same site. It is connected to a handle probe containing the measurement electronics. Before the measurements, the SKIN pH-meter® 905 (Courage + Khazaka electronic GmbH) is calibrated using two buffer solutions with known pH (pH 4.01 and 1.7) as reference.
Measurement range: 0 to 12; accuracy: ± 0.1 pH.

1.7.2. Transepidermal Water Loss (TEWL)

The measurement of the transepidermal water loss is based on internationally recognized TEWAMETER® method. The used instrument is a Tewameter 300® (Courage+Khazaka, electronic GmbH).
Physical basis for the measurement is the Diffusion law discovered by Adolf Fick in 1855:

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

where:
A = surface in m², m = water transported (in g), t = time (h), D = diffusion constant (=0.0877 g/mm Hg), p = vapour pressure of the atmosphere (mm Hg), x = distance from skin surface to point of measurement (m)
The diffusion flow dm/dt indicates the mass per cm² being transported in a 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 vapour 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 analysed 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.

1.7.3. Skin radiance/brightness

The skin radiance/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.

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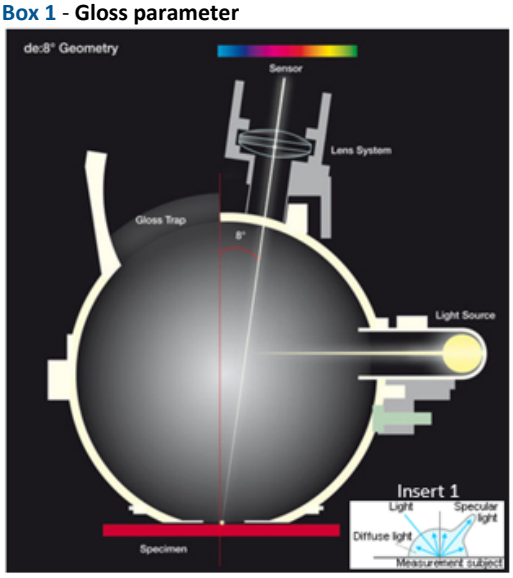
Box 1 - **Gloss parameter**



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° features an optical device which provides diffuse illumination (Ulbricht sphere). The light (Xenon lamp) is projected into a sphere. The interior of the sphere is coated with a white highly reflecting substance (barium sulphate, ceramic, special plastic) which reflects the light manifold. A shutter, an optical element inside the sphere, prevents the directional rays from reaching the measuring sample directly. The sample is positioned at an opening of the sphere and is illuminated from all directions with a close to perfect diffuse light. Through an opening at the top of the sphere the sensor is viewing the surface being measured with an angle of 8° to the vertical. In order to prevent reflection of specular light from the sample surface, the instrument feature a gloss trap. When the trap which is arranged with an angle of -8° to the viewing opening, is open, the light which would otherwise be reflected from the interior wall of the sphere, will be eliminated and can therefore not Illuminate the sample. The relation between directional and diffuse reflection allows calculating the gloss component. The measuring system including gloss is named di: 8° whilst the measuring system excluding gloss is described as de: 8°.

1.7.4. Skin redness (Erythema index)

Burning, mechanical pressure, heat, chemicals can induce the manifestation of skin redness (erythema). The MEXAMETER 18 specifically measures the haemoglobin content (erythema) in the skin. The measurement is based on the absorption principle. The special probe of the MEXAMETER 18 emits light of three defined wavelengths. A receiver measures the light reflected by the skin. The positions of emitter and receiver guarantee that only diffuse and scattered light is measured. Since the quantity of emitted light is defined, the quantity of light absorbed by the skin can be calculated. For erythema measurement, two different wavelengths are used to measure the skin absorption capacity. One of these wavelengths corresponds to the spectral absorption peak of haemoglobin. The other wavelength has been chosen to avoid other colour influences (e.g. bilirubin). The achieved results are shown on two clear digital displays on a scale from 0-999. It is important to underline that no standard references exist for erythema value. Erythema value is individual and sometimes depends on race or skin phototype. The probe is very sensitive and can discriminate among little colour differences.

1.7.5. Clinical scoring of the itching/stinging sensation

At defined timepoints the experimenter registers, with the collaboration of the subjects, the intensity of the perceived itching/stinging sensation according to the scores reported in the table below.

Table A. Clinical scoring of the itching/stinging sensation	Score
No reaction	**1**
Mild reaction	**2**
Moderate reaction	**3**
Severe reaction	**4**

1.7.6. Clinical evaluation of product soothing effect

Before the study start and at defined timepoints, the experimenter assesses physical signs (skin erythema, skin desquamation, skin oedema, skin dryness) and records functional signs as referred by the subjects (itching sensation, burning sensation, stinging sensation, tight feeling), according to scores reported in box 1a/1b.

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

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1.7.7. Expert scoring

Evaluations are performed by the experimenter according to the clinical scores reported in boxes below.

- **SKIN SMOOTHNESS**

Box 2. Skin smoothness at T0 and T28	Score
Not smooth skin	1
Poor smooth skin	2
Smooth skin	3
Well-smoothed skin	4

- **SKIN EVENNESS COMPLEXION (in terms of reduction of skin redness)**

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
The skin complexion is not uniform, there are discolorations all over the face	0	No variation	1
The skin complexion of the skin is uneven, there are discolorations on some parts of the face	0.5	Slight improvement	2
The skin complexion is quite uniform	1	Moderate improvement	3
The skin complexion is uniform	1.5	Remarkable improvement	4

1.7.8. Self-assessment

At the end of the study, subjects are asked to express their opinion on the study product by replying to a self-assessment 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:

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

where:
n is the number of subjects who ended the study
p is the value of the parameter to be analysed.

2) The mean standard error is calculated as:

$$SE = \frac{\sqrt{\frac{\sum_1^n (p_i^2) - \frac{\sum_1^n p_i^2}{n}}{(n-1)}}}{\sqrt{n}} \qquad [2]$$

3) The mean percentage variations were calculated as:

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

where:
P_o is the value of the parameter to be analyzed at T0
P_t is the value of the parameter to be analyzed at monitored experimental times.

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

1.8.2. Statistical analysis

The *instrumental data* are submitted to the 2-way Student's test t for paired data (intra-group analysis vs T0), while *clinical data* of the short-term stinging test are submitted to Wilcoxon signed test (intra-group analysis vs Tmax and inter-group analysis treated vs. control area at each experimental monitored time). Variations are considered statistically significant when p value is ≤ 0,05. Statistical analysis is performed using NCSS 10 software.

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1.8.3. Interpretation of results

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

1.9. Start/end date of the study

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

Start date	End date
30/05/2025	23/07/2025

1.10. Report change record

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

Rev. no	Date	Description
00	15/09/2025	First report release

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RESULTS

PANEL DEMOGRAPHY

TABLE A. The following table reports the age of the enrolled subjects.

no.	Vol. ID	Age
01	C6222M	41
02	S3930G	35
03	D7255C	47
04	Z5897I	41
05	B8237S	46
06	C8006D	43
07	F2471M	44
08	M7619F	48
09	B6588M	34
10	L9196C	36
11	C7141E	44
12	I9892M	41
13	D9763L	41
14	P6983M	50
15	D7597M	50
16	A8681C	36
17	P8696J	41
18	L9896N	48
19	L9315J	42
20	R6961M	33
21	G2906V	37
22	L7786C	35
23	C6700E	39
24	A9887M	44
25	S9780F	43
26	B7550S	50
27	G5051J	44
28	A6276S	48
29	S4671E	48
30	M9070V	43
31	T8219R	50
32	C4794S	40
33	S3368S	47
	Mean	42,7
	SE	0,9
	Min	33
	Max	50

Legend: SE = standard error

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SKIN pH

TABLE 1. The table below shows the data obtained for each subject participating in the study. Data are expressed as pH values.

no.	Vol. ID	T0	T15min		T15min
01	C6222M	5,5	5,3		-3,6%
02	S3930G	5,7	5,5		-3,5%
03	D7255C	5,9	5,8		-1,0%
04	Z5897I	4,8	4,7		-3,1%
05	B8237S	4,4	4,6		4,5%
06	C8006D	4,5	4,3		-4,4%
07	F2471M	4,2	4,6		9,5%
08	M7619F	4,5	4,5		0,0%
09	B6588M	5,7	5,8		1,4%
10	L9196C	4,1	4,3		4,9%
11	C7141E	4,4	4,6		4,5%
12	I9892M	4,6	4,5		-2,2%
13	D9763L	5,2	5,3		1,9%
14	P6983M	5,1	5,2		2,0%
15	D7597M	4,6	4,4		-4,3%
16	A8681C	4,2	4,0		-4,8%
17	P8696J	4,1	4,2		2,4%
18	L9896N	4,5	4,6		2,2%
19	L9315J	4,2	4,4		4,8%
20	R6961M	4,6	4,5		-2,2%
21	G2906V	4,4	4,5		2,3%
22	L7786C	4,2	4,3		2,4%
23	C6700E	5,1	4,9		-3,9%
24	A9887M	5,2	5,1		-1,9%
25	S9780F	4,4	4,5		2,3%
26	B7550S	4,7	4,8		2,1%
27	G5051J	5,1	5,1		0,0%
28	A6276S	5,2	5,0		-3,8%
29	S4671E	4,8	4,9		2,1%
30	M9070V	4,6	4,8		4,3%
31	T8219R	4,7	4,8		2,1%
32	C4794S	4,3	4,5		4,7%
33	S3368S	5,3	5,6		5,7%
	Mean	**4,8**	**4,8**		**0,8%**
	SE	0,09	0,08	Min	-4,8%
	t test vs. T0	---	0,274	Max	9,5%

Variation vs. T0

Legend: SE = standard error

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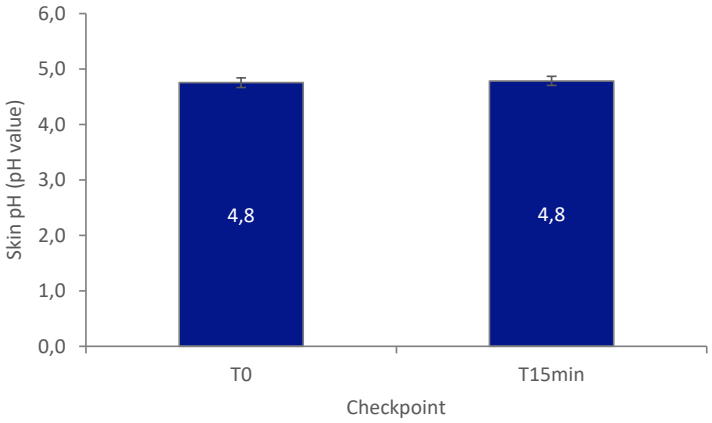
GRAPH 1. The graph shows the mean data obtained at each experimental time for the analysed parameter. Data are expressed as mean ± SE. Above the error bar the intragroup statistical analysis is reported as follow: *** p<0.001; ** p<0.01; * p<0.05.



COMMENT

As it is possible to notice, 15 minutes after the first product application, no significant variation of pH value is recorded.

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TRANSEPIDERMAL WATER LOSS (TEWL)

TABLE 2. The table reports the data obtained for each subject at each timepoint. Data are reported in g/h/m^2.

no.	Vol. ID	T0	T2h	T4h	T28		T2h	T4h	T28
01	C6222M	12,90	11,10	11,23	10,50		-14,0%	-12,9%	-18,6%
02	S3930G	14,00	12,66	13,11	10,90		-9,6%	-6,4%	-22,1%
03	D7255C	15,61	14,21	14,26	13,50		-9,0%	-8,6%	-13,5%
04	Z5897I	14,30	14,28	14,25	11,10		-0,1%	-0,3%	-22,4%
05	B8237S	14,20	12,36	11,60	11,70		-13,0%	-18,3%	-17,6%
06	C8006D	15,50	13,44	13,06	12,20		-13,3%	-15,7%	-21,3%
07	F2471M	14,60	13,25	13,20	14,20		-9,2%	-9,6%	-2,7%
08	M7619F	16,20	14,52	14,66	14,20		-10,4%	-9,5%	-12,3%
09	B6588M	9,00	8,27	7,60	8,20		-8,1%	-15,6%	-8,9%
10	L9196C	14,20	14,60	15,20	12,23		2,8%	7,0%	-13,9%
11	C7141E	13,50	12,80	13,80	10,50		-5,2%	2,2%	-22,2%
12	I9892M	14,90	14,50	12,90	12,90		-2,7%	-13,4%	-13,4%
13	D9763L	14,80	12,30	13,30	11,60		-16,9%	-10,1%	-21,6%
14	P6983M	14,50	14,20	12,50	11,80		-2,1%	-13,8%	-18,6%
15	D7597M	14,20	12,50	11,40	10,50		-12,0%	-19,7%	-26,1%
16	A8681C	14,30	12,50	11,30	12,50		-12,6%	-21,0%	-12,6%
17	P8696J	13,50	11,60	12,60	12,00		-14,1%	-6,7%	-11,1%
18	L9896N	14,40	13,42	14,70	12,20		-6,8%	2,1%	-15,3%
19	L9315J	15,50	14,20	13,20	13,10		-8,4%	-14,8%	-15,5%
20	R6961M	13,30	12,40	12,95	11,00		-6,8%	-2,6%	-17,3%
21	G2906V	13,50	12,20	11,10	10,90		-9,6%	-17,8%	-19,3%
22	L7786C	14,30	12,20	11,80	11,60		-14,7%	-17,5%	-18,9%
23	C6700E	13,60	11,50	10,60	9,80		-15,4%	-22,1%	-27,9%
24	A9887M	12,70	11,00	10,70	9,60		-13,4%	-15,7%	-24,4%
25	S9780F	13,02	10,50	10,00	10,20		-19,4%	-23,2%	-21,7%
26	B7550S	14,40	12,20	11,80	12,30		-15,3%	-18,1%	-14,6%
27	G5051J	14,20	13,70	12,20	10,70		-3,5%	-14,1%	-24,6%
28	A6276S	14,80	13,50	11,90	11,11		-8,8%	-19,6%	-24,9%
29	S4671E	13,50	11,70	10,50	9,60		-13,3%	-22,2%	-28,9%
30	M9070V	12,90	10,80	9,90	9,85		-16,3%	-23,3%	-23,6%
31	T8219R	14,50	14,20	13,80	12,10		-2,1%	-4,8%	-16,6%
32	C4794S	15,90	13,80	12,30	12,50		-13,2%	-22,6%	-21,4%
33	S3368S	12,50	10,50	10,20	9,70		-16,0%	-18,4%	-22,4%
	Mean	**14,04**	**12,63**	**12,23**	**11,42**		**-10,1%**	**-12,9%**	**-18,7%**
	SE	0,22	0,26	0,29	0,24	Max	-19,4%	-23,3%	-28,9%
	t test vs. T0	---	0,000	0,000	0,000	Min	2,8%	7,0%	-2,7%

Variation vs. T0

Legend: SE = standard error

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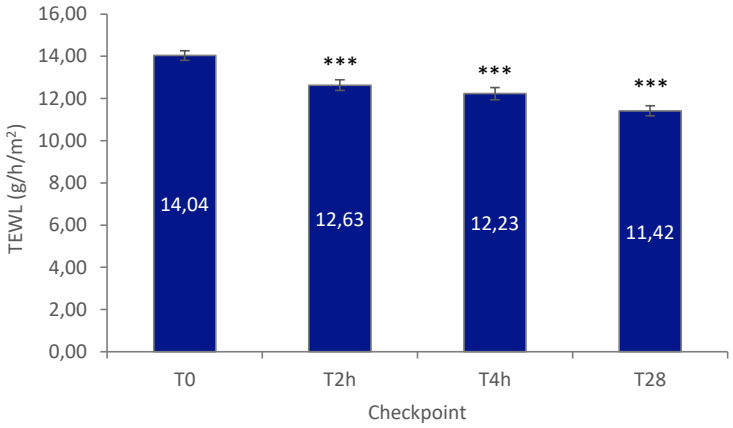
GRAPH 2. The graph reports the mean data obtained at each experimental time. Data are expressed as mean ± SE. Above the error bar the intragroup statistical analysis vs. T0 is reported as follows: * p<0.05; **p<0.01; ***p<0.001.



COMMENT

As it is possible to notice, the test product determines a statistically significant decrease of transepidermal water loss vs T0 by -10.1% and by -12.9% 2 and 4 hours after its first application, respectively. Moreover, after 28 days of product use, a statistically significant decrease of transepidermal water loss by -18.7% is recorded.

No significant variation of the monitored parameter is recorded in the untreated control area until 4 hours.

A decrease of this parameter indicates an improvement of skin barrier function/condition.

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SKIN RADIANCE/BRIGHTNESS – Gloss parameter

TABLE 3. The table reports the data obtained for each subject at each timepoint. Data are reported in arbitrary units (a.u.).

no.	Vol. ID	T0	Timm	T28		Timm	T28
01	C6222M	9,12	10,22	11,30		12,1%	23,9%
02	S3930G	11,52	12,36	12,58		7,3%	9,2%
03	D7255C	10,75	11,93	11,50		11,0%	7,0%
04	Z5897I	11,17	12,26	13,00		9,8%	16,4%
05	B8237S	13,51	15,28	14,50		13,1%	7,3%
06	C8006D	11,35	13,51	14,50		19,0%	27,8%
07	F2471M	12,77	14,55	14,50		13,9%	13,5%
08	M7619F	12,56	15,33	15,50		22,1%	23,4%
09	B6588M	10,56	12,28	11,55		16,3%	9,4%
10	L9196C	12,30	13,20	14,90		7,3%	21,1%
11	C7141E	15,40	14,90	15,80		-3,2%	2,6%
12	I9892M	12,60	13,90	14,20		10,3%	12,7%
13	D9763L	11,20	12,40	14,40		10,7%	28,6%
14	P6983M	12,50	14,80	13,07		18,4%	4,6%
15	D7597M	10,50	11,20	13,50		6,7%	28,6%
16	A8681C	10,90	11,50	12,70		5,5%	16,5%
17	P8696J	12,30	13,50	12,20		9,8%	-0,8%
18	L9896N	11,40	12,20	15,50		7,0%	36,0%
19	L9315J	13,40	14,10	14,90		5,2%	11,2%
20	R6961M	12,60	13,40	14,80		6,3%	17,5%
21	G2906V	11,60	13,20	14,50		13,8%	25,0%
22	L7786C	10,90	12,70	13,60		16,5%	24,8%
23	C6700E	12,20	13,40	14,80		9,8%	21,3%
24	A9887M	13,20	14,50	14,50		9,8%	9,8%
25	S9780F	14,40	15,20	15,90		5,6%	10,4%
26	B7550S	12,90	13,60	15,70		5,4%	21,7%
27	G5051J	13,10	14,20	15,90		8,4%	21,4%
28	A6276S	12,80	14,80	14,20		15,6%	10,9%
29	S4671E	10,50	12,40	13,90		18,1%	32,4%
30	M9070V	11,70	12,20	12,93		4,3%	10,5%
31	T8219R	12,60	13,50	14,80		7,1%	17,5%
32	C4794S	11,80	12,20	14,30		3,4%	21,2%
33	S3368S	10,30	11,90	12,90		15,5%	25,2%
	Mean	**12,01**	**13,23**	**14,03**		**10,4%**	**17,2%**
	SE	0,22	0,22	0,23	Min	-3,2%	-0,8%
	t test vs. T0	---	0,000	0,000	Max	22,1%	36,0%

Variation vs. T0

Legend: SE = standard error

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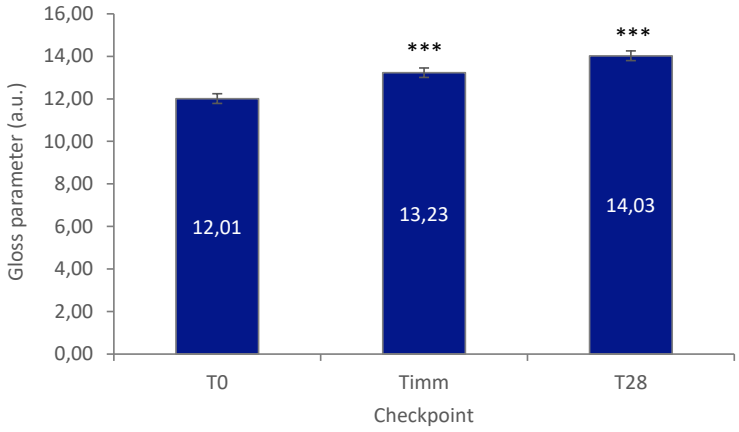
GRAPH 3. The graph reports the mean data obtained at each experimental time. Data are expressed as mean ± SE. Above the error bar the intragroup statistical analysis vs. T0 is reported as follows: * p<0.05; **p<0.01; ***p<0.001.



COMMENT

As it is possible to notice, a statistically significant increase of gloss parameter vs T0 by +10.4% immediately after the product application and by +17.2% after 28 days of use is recorded.

An increase of this parameter indicates an improvement of skin radiance/brightness.

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ERYTHEMA INDEX (SKIN REDNESS)

TABLE 4. The table reports the data obtained for each subject at each timepoint. Data are reported as arbitrary Mexameter® units (0-999).

no.	Vol. ID	T0	Timm	T28		Timm	T28
01	C6222M	274	250	220		-8,8%	-19,7%
02	S3930G	450	425	380		-5,6%	-15,6%
03	D7255C	375	326	330		-13,1%	-12,0%
04	Z5897I	325	350	295		7,7%	-9,2%
05	B8237S	350	336	346		-4,0%	-1,1%
06	C8006D	358	320	310		-10,6%	-13,4%
07	F2471M	420	416	460		-1,0%	9,5%
08	M7619F	348	354	315		1,7%	-9,5%
09	B6588M	603	581	458		-3,6%	-24,0%
10	L9196C	440	410	405		-6,8%	-8,0%
11	C7141E	470	430	390		-8,5%	-17,0%
12	I9892M	520	490	475		-5,8%	-8,7%
13	D9763L	410	380	350		-7,3%	-14,6%
14	P6983M	440	390	360		-11,4%	-18,2%
15	D7597M	420	410	370		-2,4%	-11,9%
16	A8681C	380	295	330		-22,4%	-13,2%
17	P8696J	354	347	317		-2,0%	-10,5%
18	L9896N	540	490	460		-9,3%	-14,8%
19	L9315J	342	320	300		-6,4%	-12,3%
20	R6961M	420	390	365		-7,1%	-13,1%
21	G2906V	540	480	420		-11,1%	-22,2%
22	L7786C	480	440	410		-8,3%	-14,6%
23	C6700E	490	420	390		-14,3%	-20,4%
24	A9887M	420	390	355		-7,1%	-15,5%
25	S9780F	480	430	410		-10,4%	-14,6%
26	B7550S	380	360	350		-5,3%	-7,9%
27	G5051J	390	350	340		-10,3%	-12,8%
28	A6276S	450	400	394		-11,1%	-12,4%
29	S4671E	420	390	360		-7,1%	-14,3%
30	M9070V	370	350	328		-5,4%	-11,4%
31	T8219R	410	380	370		-7,3%	-9,8%
32	C4794S	440	410	390		-6,8%	-11,4%
33	S3368S	470	400	420		-14,9%	-10,6%
	Mean	**423,6**	**391,2**	**368,9**		**-7,5%**	**-12,6%**
	SE	12,1	11,0	9,6	Max	-22,4%	-24,0%
	t test vs. T0	---	0,000	0,000	Min	7,7%	9,5%

Variation vs. T0

Legend: SE = standard error

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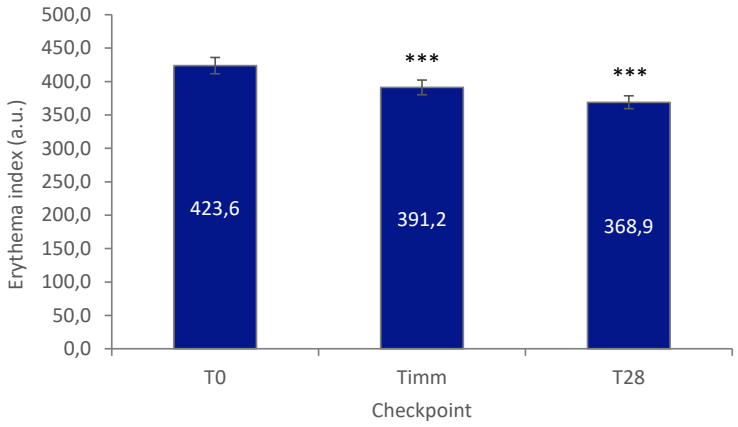
GRAPH 4. The graph shows the mean data obtained at each monitored check for the parameter under analysis. Data are reported as mean ± SE. Above the error bar the intragroup statistical analysis is reported as follows: *p<0.05; **p<0.01; ***p<0.001.



COMMENT

As it is possible to notice, a statistically significant decrease of erythema index vs T0 by -7.5% immediately after the product application and by -12.6% after 28 days of use is recorded.

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CLINICAL EVALUATION OF PRODUCT SOOTHING EFFECT

TABLE 5. The table reports the data obtained for each subject participating in the study for the analyzed skin parameters. Data are expressed according to the scores reported in the legend.

		Physical signs												Functional signs											
		Erythema			Oedema			Desquamation			Skin Dryness			Burning sensation			Itching sensation			Stinging sensation			Skin tightness		
no.	Vol. ID	T0	Timm	T28	T0	Timm	T28	T0	Timm	T28	T0	Timm	T28	T0	Timm	T28	T0	Timm	T28	T0	Timm	T28	T0	Timm	T28
01	C6222M	2	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	0	1	1	0
02	S3930G	2	1	2	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	1	1	0	1	0	0
03	D7255C	1	1	1	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	1	1	0	1	0	0
04	Z5897I	2	1	1	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	1	0	0	2	0	0
05	B8237S	2	1	1	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	1	0	0	2	1	0
06	C8006D	2	1	1	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	1	1	0	1	1	0
07	F2471M	2	1	2	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	2	1	0
08	M7619F	2	1	1	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	1	1	0
09	B6588M	3	2	2	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	1	0	0
10	L9196C	2	1	1	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0	1	0	0
11	C7141E	2	1	1	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	1	1	0
12	I9892M	2	1	1	0	0	0	0	0	0	0	0	0	1	0	0	2	0	0	1	1	0	1	0	1
13	D9763L	2	1	1	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	1	1	0	1	0	0
14	P6983M	1	1	0	0	0	0	0	0	0	0	0	0	1	0	0	1	1	0	1	0	0	1	1	0
15	D7597M	1	1	1	0	0	0	0	0	0	0	0	0	1	0	0	1	1	0	0	0	0	1	0	0
16	A8681C	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
17	P8696J	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	1	1	0
18	L9896N	2	1	1	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0
19	L9315J	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0
20	R6961M	1	1	1	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	0	0	0	0	0
21	G2906V	2	2	1	0	0	0	0	0	0	0	0	0	1	1	0	1	1	0	1	0	0	1	1	0
22	L7786C	2	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	0	0
23	C6700E	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
24	A9887M	1	1	1	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	0	0	1	1	0
25	S9780F	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0	0
26	B7550S	2	1	1	0	0	0	0	0	0	0	0	0	1	0	0	1	1	0	0	0	0	1	0	0
27	G5051J	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	1	0	0
28	A6276S	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	1	1	0
29	S4671E	2	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	0	0
30	M9070V	1	0	1	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	1	1	0
31	T8219R	2	1	1	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	1	0	0	1	1	0
32	C4794S	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	1	0
33	S3368S	1	1	1	0	0	0	0	0	0	0	0	0	1	0	0	1	1	0	1	0	0	1	0	0
	Mean	1,6	1,0	1,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,7	0,2	0,0	0,9	0,4	0,0	0,5	0,2	0,0	0,9	0,4	0,0
	SE	0,1	0,1	0,1	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,0	0,1	0,1	0,0	0,1	0,1	0,0	0,1	0,1	0,0	0,1	0,1	0,0
	Wicoxon vs T0	--			--			--			--			--			--			--			--		
	EVALUATED SUBJECTS	ERYTHEMA N=33			OEDEMA N=0			DESQUAMATION N=0			DRYNESS N=0			BURNING N=22			ITCHING N=29			STINGING N=18			TIGHTNESS N=28		
	% improved subjects	--	55%	55%	--	--	--	--	--	--	--	--	--	--	68%	100%	--	59%	100%	--	67%	100%	--	57%	96%
	% unchanged subjects	--	45%	45%	--	--	--	--	--	--	--	--	--	--	32%	0%	--	41%	0%	--	33%	0%	--	43%	4%
	% worsened subjects	--	0%	0%	--	--	--	--	--	--	--	--	--	--	0%	0%	--	0%	0%	--	0%	0%	--	0%	0%

Legend: SE = standard error | 0. No/None; 1. Very mild; 2. Mild; 3. Moderate; 4. Severe.

NOTE: *Oedema, desquamation and dryness results are not submitted to a statistical analysis.*

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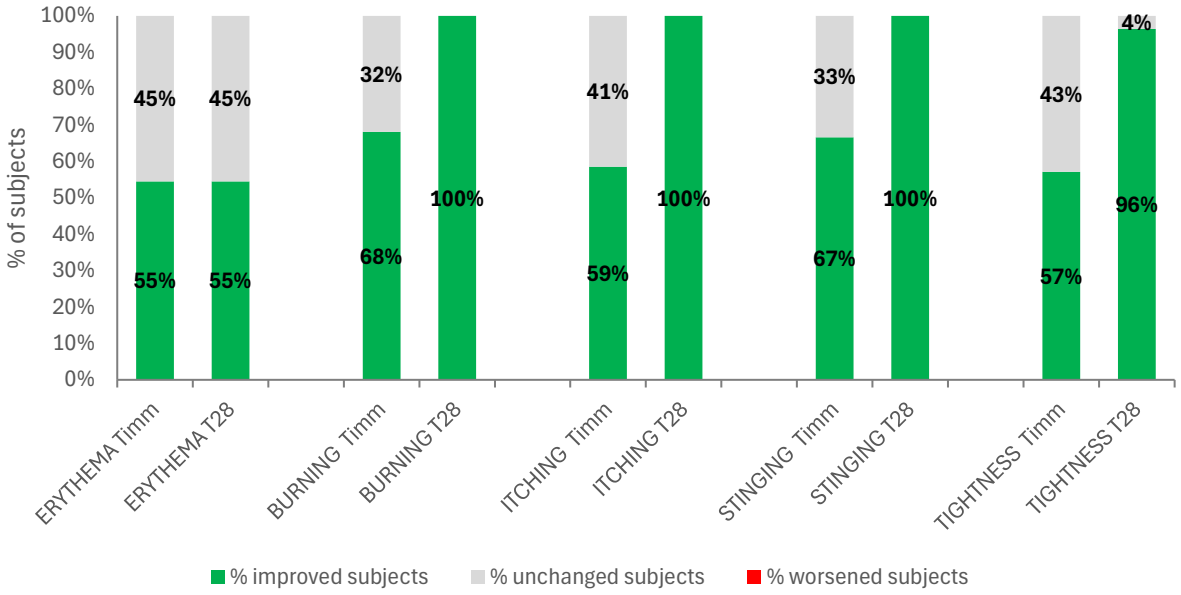
GRAPH 5. The graph shows the percentage of subjects related to the effect.



COMMENT: as it is possible to notice immediately after the single product application and after 28 days of use a statistically significant improvement of skin discomforts (erythema, burning sensation, itching sensation, stinging sensation, skin tightness) is observed.
In particular:

- a clinically relevant decrease of **skin erythema** in 55% of the enrolled subjects both at Timm and at T28 (clinical sign evaluated on N=33 subjects showing skin erythema at baseline). No subjects show a worsening of basal skin condition.

- a clinically relevant decrease of **burning sensation** in 68% of the enrolled subjects at Timm and in 100% of them at T28 (clinical sign evaluated on N=22 subjects referring burning sensation at baseline). No subjects show a worsening of basal skin condition.

- a clinically relevant decrease of **itching sensation** in 59% of the enrolled subjects at Timm and in 100% of them at T28 (clinical sign evaluated on N=29 subjects referring itching sensation at baseline). No subjects show a worsening of basal skin condition.

- a clinically relevant decrease of **stinging sensation** in 67% of the enrolled subjects at Timm and in 100% of them at T28 (clinical sign evaluated on N=18 subjects referring stinging sensation at baseline). No subjects show a worsening of basal skin condition.

- a clinically relevant decrease of **skin tightness** in 57% of the enrolled subjects at Timm and in 96% of them at T28 (clinical sign evaluated on N=28 subjects referring skin tightness at baseline). No subjects show a worsening of basal skin condition.

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

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CLINICAL SCORING OF THE ITCHING/STINGING SENSATION AFTER THE FIRST PRODUCT USE (IMMEDIATE SOOTHING PRODUCT EFFECT- SHORT TERM EVALUATION)

To evaluate the immediate soothing effect of the tested product a 10% lactic acid aqueous solution was applied to the skin of both alar grooves, in order to induce a skin discomfort (itching/stinging sensation); at Tmax, when the discomfort peaks its maximum sensation (approximately few minutes after the application of the lactic acid) the experimenter, in collaboration with the subjects, scored the intensity of the perceived discomfort and applied the tested product by means of a soaked cotton stick, on right/left alar groove according to a previously defined randomization list. The contralateral side is treated with demineralized water and acts as negative control.
Itching/stinging sensation was assessed at Timm (immediately after tested product/demineralized water application), after 30 seconds (T30'') and within the next 10 minutes (T1', T2' T3', T4', T5', T6' T7', T8', T9', T10') as per protocol.

TABLE 6a. Table below reports the clinical scores registered for each subject participating in the study in treated area (treated with the tested product). Raw data are expressed as: 1. No reaction; 2. Mild reaction; 3. Moderate reaction; 4. Severe reaction.

TREATED AREA (TESTED PRODUCT)

n.	Vol ID	Tmax	Timm	T30''	T1'	T2'	T3'	T4'	T5'	T6'	T7'	T8'	T9'	T10'
01	C6222M	3	3	3	2	2	2	1	1	1	1	1	1	1
02	S3930G	4	4	3	3	2	2	1	1	1	1	1	1	1
03	D7255C	4	3	3	2	2	1	1	1	1	1	1	1	1
04	Z5897I	3	3	2	2	1	1	1	1	1	1	1	1	1
05	B8237S	4	4	4	3	2	2	1	1	1	1	1	1	1
06	C8006D	4	4	4	3	3	3	2	2	1	1	1	1	1
07	F2471M	4	3	3	2	2	1	1	1	1	1	1	1	1
08	M7619F	3	2	2	2	2	2	1	1	1	1	1	1	1
09	B6588M	4	4	3	3	2	2	2	2	1	1	1	1	1
10	L9196C	3	3	3	2	2	2	1	1	1	1	1	1	1
11	C7141E	4	4	4	3	3	3	2	2	2	2	2	1	1
12	I9892M	3	2	2	2	2	1	1	1	1	1	1	1	1
13	D9763L	4	3	2	2	1	1	1	1	1	1	1	1	1
14	P6983M	4	3	3	3	2	2	1	1	1	1	1	1	1
15	D7597M	3	3	3	3	3	3	3	2	2	2	2	2	1
16	A8681C	4	3	2	2	2	1	1	1	2	2	1	1	1
17	P8696J	4	4	4	4	3	3	3	2	2	2	2	1	1
18	L9896N	4	3	3	2	2	2	1	1	1	1	1	1	1
19	L9315J	3	3	3	2	2	2	1	1	1	1	1	1	1
20	R6961M	4	3	2	2	1	1	1	1	1	1	1	1	1
21	G2906V	4	4	4	3	3	3	2	2	2	2	1	1	1
22	L7786C	3	2	2	2	1	1	1	1	1	1	1	1	1
23	C6700E	4	4	3	3	2	2	2	1	1	1	1	1	1
24	A9887M	4	4	4	3	2	2	2	2	1	1	1	1	1
25	S9780F	4	3	3	2	2	2	1	1	1	1	1	1	1
26	B7550S	4	4	4	3	3	2	2	2	1	1	1	1	1
27	G5051J	3	3	2	2	2	1	1	1	1	1	1	1	1
28	A6276S	4	3	3	2	2	1	1	1	1	1	1	1	1
29	S4671E	3	2	2	2	2	2	1	1	1	1	1	1	1
30	M9070V	3	3	3	2	2	2	1	1	1	1	1	1	1
31	T8219R	4	4	4	3	3	2	2	1	1	1	1	1	1
32	C4794S	4	3	3	2	2	2	1	1	1	1	1	1	1
33	S3368S	4	4	4	4	3	3	2	2	1	1	1	1	1
	Mean	3,7	3,2	3,0	2,5	2,1	1,9	1,4	1,3	1,2	1,2	1,1	1,0	1,0
	SE	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,0	0,0	0,0
	Wilcoxon test vs Tmax	--	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000
	Wilcoxon test vs CTR	0,157	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,002	0,034	0,317	1,000	1,000

Legend. CTR = control area

TABLE 6b. Table below reports the clinical scores registered for each subject participating in the study in control area

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(treated with demineralized water). Raw data are expressed as: 1. No reaction; 2. Mild reaction; 3. Moderate reaction; 4. Severe reaction.

CONTROL AREA (DEMINERALIZED WATER)

n.	Vol ID	Tmax	Timm	T30''	T1'	T2'	T3'	T4'	T5'	T6'	T7'	T8'	T9'	T10'
01	C6222M	4	3	3	3	3	3	2	2	2	2	1	1	1
02	S3930G	4	4	4	3	3	2	2	2	2	1	1	1	1
03	D7255C	4	4	3	3	3	2	2	1	1	1	1	1	1
04	Z5897I	3	3	2	2	2	2	1	1	1	1	1	1	1
05	B8237S	4	4	4	4	3	3	3	2	2	1	1	1	1
06	C8006D	4	4	4	4	3	3	3	2	1	1	1	1	1
07	F2471M	4	4	3	3	3	2	2	1	1	1	1	1	1
08	M7619F	3	3	3	3	3	3	3	3	2	1	1	1	1
09	B6588M	4	4	4	4	3	3	3	3	2	2	2	1	1
10	L9196C	3	3	4	4	3	2	1	1	1	1	1	1	1
11	C7141E	4	4	4	3	3	3	3	3	2	2	2	1	1
12	I9892M	3	3	3	3	3	3	2	2	2	2	1	1	1
13	D9763L	4	4	3	3	2	2	2	1	1	1	1	1	1
14	P6983M	4	4	4	3	3	3	2	2	2	1	1	1	1
15	D7597M	3	3	3	3	3	3	3	3	2	2	2	2	1
16	A8681C	4	4	4	3	3	2	2	1	1	1	1	1	1
17	P8696J	4	4	4	4	4	3	3	3	2	2	2	1	1
18	L9896N	4	4	4	3	3	3	2	2	2	2	1	1	1
19	L9315J	4	4	3	3	3	2	2	2	1	1	1	1	1
20	R6961M	4	4	3	2	2	1	1	1	1	1	1	1	1
21	G2906V	4	4	4	3	3	3	3	3	2	2	1	1	1
22	L7786C	3	2	2	2	2	2	2	2	1	1	1	1	1
23	C6700E	4	4	4	3	3	3	2	2	2	2	1	1	1
24	A9887M	4	4	3	3	3	3	3	2	1	1	1	1	1
25	S9780F	4	4	4	3	3	3	2	2	2	2	1	1	1
26	B7550S	4	4	4	3	3	3	3	2	2	2	1	1	1
27	G5051J	3	3	3	3	2	2	1	1	1	1	1	1	1
28	A6276S	4	4	4	3	3	2	2	1	1	1	1	1	1
29	S4671E	3	3	3	3	3	2	2	2	1	1	1	1	1
30	M9070V	3	3	3	3	3	2	2	2	1	1	1	1	1
31	T8219R	4	4	4	4	4	4	3	2	1	1	1	1	1
32	C4794S	4	4	3	3	3	3	2	2	2	1	1	1	1
33	S3368S	4	4	4	4	3	3	2	2	1	1	1	1	1
	Mean	3,7	3,7	3,5	3,1	2,9	2,6	2,2	1,9	1,5	1,3	1,1	1,0	1,0
	SE	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,0	0,0
	Wilcoxon test vs Tmax	--	0,157	0,007	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000	0,000

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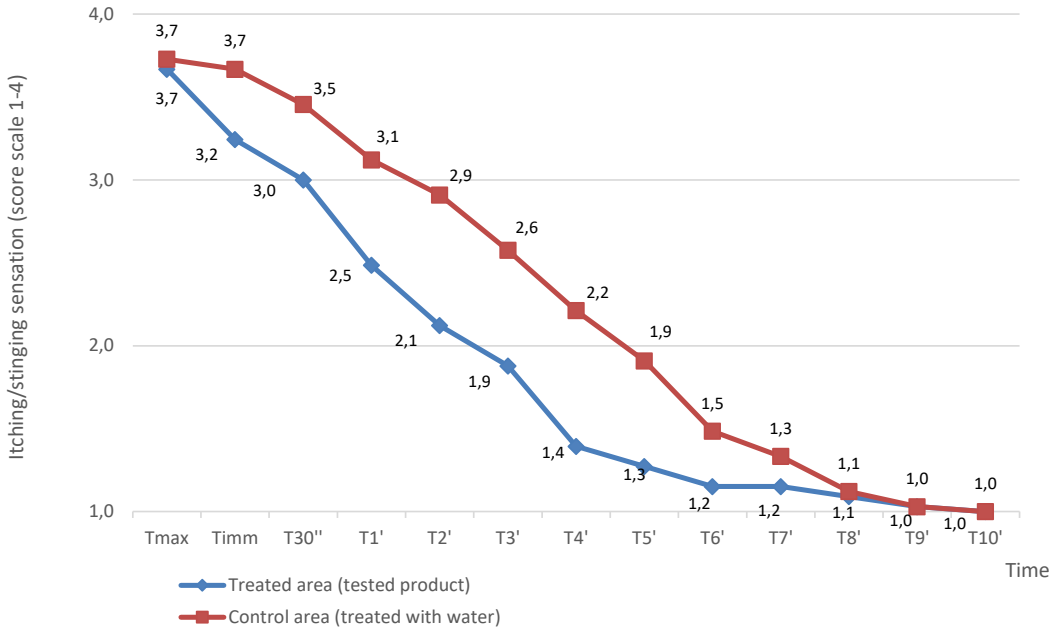
GRAPH 6. The graph shows the mean data obtained at each monitored check for the parameter under analysis.



COMMENT

The single product application determines a statistically significant decrease of the itching/stinging sensation induced by the lactic acid solution, starting from Timm (and at each following monitored time).

A physiological decrease of the itching/stinging sensation is recorded also in the skin control site treated with demineralized water starting from T30'', but the inter-group statistical analysis highlights that the decrease of the sensation is faster due to the application of the tested product (Wilcoxon test TREATED vs CONTROL AREA $p<0.05$) from Timm to T7'.

As it is possible to notice, the discomfort induced by lactic acid completely disappears in all the enrolled subjects within 10 minutes in both skin areas.

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CLINICAL EVALUATION OF PRODUCT EFFICACY IN REDUCING SKIN SENSITIVITY (LONG-TERM EVALUATION)

TABLES 7a/6b. The tables report the clinical scores recorded for each subject at baseline (T0), before study product use, and after 28 days of treatment. Data are expressed as skin reaction (itching/stinging sensation) induced by the application of a lactic acid diluted solution (at 10%) in the alar groove. Itching/stinging reaction is assessed few minutes after the lactic acid solution application (Tmax = few minutes after lactic acid application, when the sensation reaches its maximum peak), after 30 seconds (T30'') and then within the next 10 minutes (T1', T2' T3', T4', T5', T6' T7', T8', T9', T10') as per protocol.

T0

n.	Vol ID	Tmax	T30''	T1'	T2'	T3'	T4'	T5'	T6'	T7'	T8'	T9'	T10'	AUC
01	C6222M	4	4	3	3	3	3	2	2	2	1	1	1	12,8
02	S3930G	4	4	3	3	3	2	2	2	1	1	1	1	10,8
03	D7255C	4	4	3	3	2	2	1	1	1	1	1	1	7,8
04	Z5897I	4	3	3	3	2	2	2	1	1	1	1	1	8,3
05	B8237S	4	4	4	4	3	2	2	2	1	1	1	1	12,5
06	C8006D	3	3	3	3	2	2	1	1	1	1	1	1	7,0
07	F2471M	4	3	3	3	3	2	2	1	1	1	1	1	9,3
08	M7619F	3	3	3	3	3	3	2	2	1	1	1	1	11,0
09	B6588M	4	4	3	3	3	3	3	2	2	1	1	1	13,8
10	L9196C	4	4	4	3	3	2	2	1	1	1	1	1	10,5
11	C7141E	4	3	3	3	3	3	3	2	2	2	1	1	14,3
12	I9892M	3	3	3	2	2	1	1	1	1	1	1	1	5,0
13	D9763L	4	4	3	2	2	1	1	1	1	1	1	1	5,8
14	P6983M	4	4	4	3	3	3	2	2	1	1	1	1	12,5
15	D7597M	3	3	4	3	3	3	2	1	1	1	1	1	10,8
16	A8681C	4	4	3	3	3	2	2	1	1	1	1	1	9,8
17	P8696J	4	4	3	2	3	2	2	2	2	1	1	1	10,8
18	L9896N	4	4	4	3	3	2	2	2	2	1	1	1	12,5
19	L9315J	4	3	2	2	2	1	1	1	1	1	1	1	4,5
20	R6961M	4	4	3	2	2	2	1	1	1	1	1	1	6,8
21	G2906V	4	4	4	3	3	2	2	2	2	1	1	1	12,5
22	L7786C	3	3	3	3	3	2	2	2	2	1	1	1	11,0
23	C6700E	4	3	3	3	3	2	2	2	2	1	1	1	11,3
24	A9887M	4	4	4	3	3	2	2	1	1	1	1	1	10,5
25	S9780F	3	3	3	2	2	2	2	2	1	1	1	1	8,0
26	B7550S	4	4	4	3	3	3	2	2	2	2	1	1	14,5
27	G5051J	4	4	3	2	2	2	1	1	1	1	1	1	6,8
28	A6276S	4	4	4	3	3	3	2	2	1	1	1	1	12,5
29	S4671E	3	3	3	3	2	2	2	1	1	1	1	1	8,0
30	M9070V	4	3	3	3	3	2	2	2	1	1	1	1	10,3
31	T8219R	4	4	4	3	3	3	2	2	2	2	1	1	14,5
32	C4794S	4	4	4	3	3	3	2	2	1	1	1	1	12,5
33	S3368S	4	4	3	3	2	2	2	1	1	1	1	1	8,8
	Mean	3,8	3,6	3,3	2,8	2,7	2,2	1,8	1,5	1,3	1,1	1,0	1,0	10,2
	SE	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,0	0,0	0,0	0,5

Legend. **1.** No reaction; **2.** Mild reaction; **3.** Moderate reaction; **4.** Severe reaction.
AUC= area under the curve

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T28

n.	Vol ID	Tmax	T30''	T1'	T2'	T3'	T4'	T5'	T6'	T7'	T8'	T9'	T10'	AUC
01	C6222M	4	3	3	2	2	2	2	2	2	1	1	1	9,3
02	S3930G	3	3	3	3	2	1	1	1	1	1	1	1	6,0
03	D7255C	3	3	2	2	1	1	1	1	1	1	1	1	3,3
04	Z5897I	3	2	2	2	2	2	2	1	1	1	1	1	5,8
05	B8237S	3	3	2	2	2	1	1	1	1	1	1	1	4,3
06	C8006D	3	3	2	2	1	1	1	1	1	1	1	1	3,3
07	F2471M	2	2	2	2	2	1	1	1	1	1	1	1	3,5
08	M7619F	3	3	3	3	2	2	2	1	1	1	1	1	8,0
09	B6588M	2	2	2	2	2	1	1	1	1	1	1	1	3,5
10	L9196C	3	2	2	1	1	1	1	1	1	1	1	1	1,8
11	C7141E	3	3	2	2	2	2	2	2	1	1	1	1	7,3
12	I9892M	3	3	3	2	2	1	1	1	1	1	1	1	5,0
13	D9763L	2	2	2	2	2	1	1	1	1	1	1	1	3,5
14	P6983M	2	2	2	2	2	2	1	1	1	1	1	1	4,5
15	D7597M	3	3	3	2	2	2	2	2	2	1	1	1	9,0
16	A8681C	3	2	2	2	2	2	1	1	1	1	1	1	4,8
17	P8696J	2	2	2	2	2	2	1	1	1	1	1	1	4,5
18	L9896N	3	3	2	2	2	2	1	1	1	1	1	1	5,3
19	L9315J	2	2	2	2	2	2	1	1	1	1	1	1	4,5
20	R6961M	3	3	2	2	2	1	1	1	1	1	1	1	4,3
21	G2906V	2	2	2	2	2	2	2	2	2	1	1	1	7,5
22	L7786C	3	3	3	2	2	2	2	2	2	1	1	1	9,0
23	C6700E	2	2	2	2	2	1	1	1	1	1	1	1	3,5
24	A9887M	4	4	3	3	3	2	2	1	1	1	1	1	9,8
25	S9780F	2	2	2	2	2	2	2	2	1	1	1	1	6,5
26	B7550S	2	2	2	2	2	2	2	2	2	2	1	1	8,5
27	G5051J	3	3	2	2	2	1	1	1	1	1	1	1	4,3
28	A6276S	2	2	2	2	2	2	2	2	1	1	1	1	6,5
29	S4671E	2	2	2	2	2	1	1	1	1	1	1	1	3,5
30	M9070V	4	4	3	3	3	2	2	1	1	1	1	1	9,8
31	T8219R	3	3	2	2	2	2	2	1	1	1	1	1	6,3
32	C4794S	3	2	2	2	2	1	1	1	1	1	1	1	3,8
33	S3368S	3	3	3	3	2	2	2	1	1	1	1	1	8,0
	Mean	2,7	2,6	2,3	2,1	2,0	1,6	1,4	1,2	1,2	1,0	1,0	1,0	5,7
	SE	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,1	0,0	0,0	0,0	0,4
	t test T0 vs T28													0,000

Legend. **1.** No reaction; **2.** Mild reaction; **3.** Moderate reaction; **4.** Severe reaction.
AUC= area under the curve

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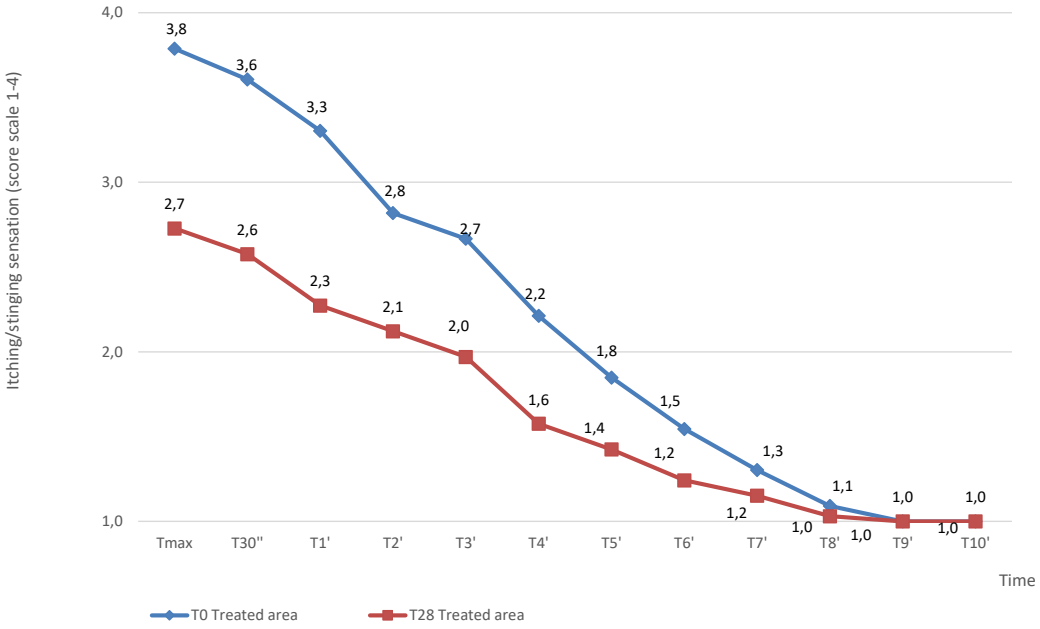
GRAPH 7. The graph shows the data obtained at each timepoint after the application of a lactic acid diluted solution (at 10%) in the alar groove.



COMMENT

After 28 days of product use, the intensity of lactic acid-induced itching/stinging reaction is reduced, since the calculated AUC is significantly decreased (intra-group statistical analysis vs. T0). A decrease of the calculated AUC indicates that the skin is less reactive to acid lactic stimulation.

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EXPERT SCORING: SKIN SMOOTHNESS

TABLE 8. The table below reports the obtained data for each volunteer. Data are expressed according to the scale reported in the box below.

no.	Vol. ID	T0	T28
01	C6222M	1	2
02	S3930G	2	3
03	D7255C	2	3
04	Z5897I	2	3
05	B8237S	2	3
06	C8006D	2	3
07	F2471M	2	3
08	M7619F	2	3
09	B6588M	2	3
10	L9196C	2	3
11	C7141E	2	3
12	I9892M	1	3
13	D9763L	2	3
14	P6983M	2	3
15	D7597M	2	3
16	A8681C	2	3
17	P8696J	2	3
18	L9896N	1	3
19	L9315J	1	2
20	R6961M	2	3
21	G2906V	2	3
22	L7786C	1	3
23	C6700E	2	3
24	A9887M	1	2
25	S9780F	2	3
26	B7550S	2	3
27	G5051J	1	3
28	A6276S	2	3
29	S4671E	1	2
30	M9070V	1	2
31	T8219R	2	3
32	C4794S	2	3
33	S3368S	2	3
	Mean	**1,7**	**2,8**
	SE	0,1	0,1
	Wilcoxon test vs. T0	---	0,000

Legend. SE: standard error

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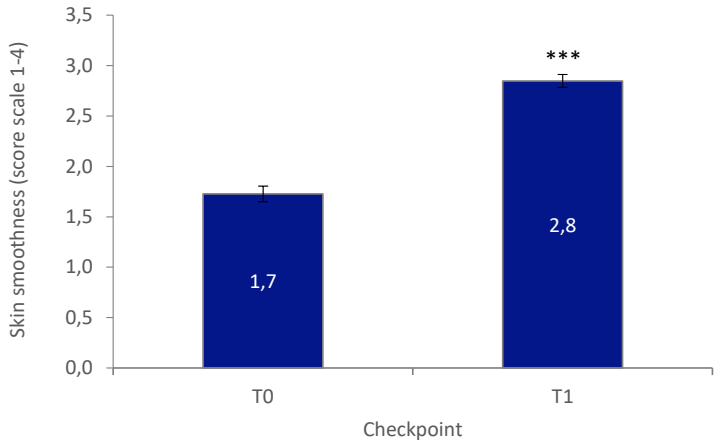
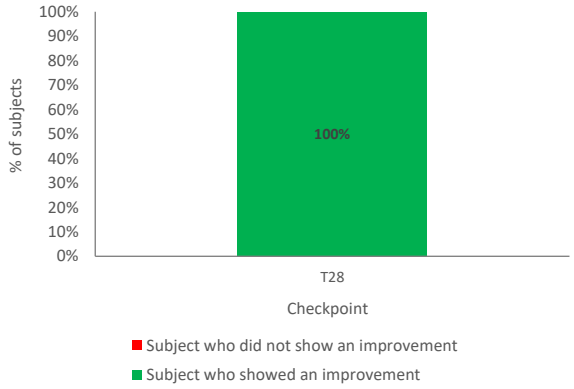
GRAPH 8a. The graph reports the mean data obtained at each experimental time. Data are expressed as mean ± SE. Above the error bar the intragroup statistical analysis vs. T0 is reported as follows: * p<0.05; **p<0.01; ***p<0.001.



GRAPH 8b. The graph reports the percentage of subjects related to the effect.



COMMENT: as it is possible to notice, the tested product determines a clinically relevant and statistically significant improvement of skin smoothness in 100% of the enrolled subjects after 28 days of use.
The positive effect of the product on the measured parameter is confirmed if more than 50% of the subjects register an improvement

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EXPERT SCORING: SKIN EVENNESS COMPLEXION

TABLE 9. The table below reports the obtained data for each volunteer. Data are expressed according to the scale reported in the box below.

no.	Vol. ID	T0	T28
01	C6222M	2	2
02	S3930G	2	4
03	D7255C	2	1
04	Z5897I	2	1
05	B8237S	2	1
06	C8006D	2	2
07	F2471M	2	1
08	M7619F	2	2
09	B6588M	2	1
10	L9196C	3	1
11	C7141E	2	2
12	I9892M	3	2
13	D9763L	2	1
14	P6983M	2	3
15	D7597M	2	1
16	A8681C	3	1
17	P8696J	2	1
18	L9896N	2	1
19	L9315J	2	2
20	R6961M	3	2
21	G2906V	2	2
22	L7786C	2	2
23	C6700E	2	2
24	A9887M	2	3
25	S9780F	2	2
26	B7550S	3	2
27	G5051J	2	3
28	A6276S	2	2
29	S4671E	1	3
30	M9070V	2	3
31	T8219R	2	3
32	C4794S	2	2
33	S3368S	2	2
	Mean	**2,1**	**1,9**
	SE	0,1	0,1

Legend. SE: standard error

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
The skin complexion is not uniform, there are discolorations all over the face	0	No variation	1
The skin complexion of the skin is uneven, there are discolorations on some parts of the face	0.5	Slight improvement	2
The skin complexion is quite uniform	1	Moderate improvement	3
The skin complexion is uniform	1.5	Remarkable improvement	4

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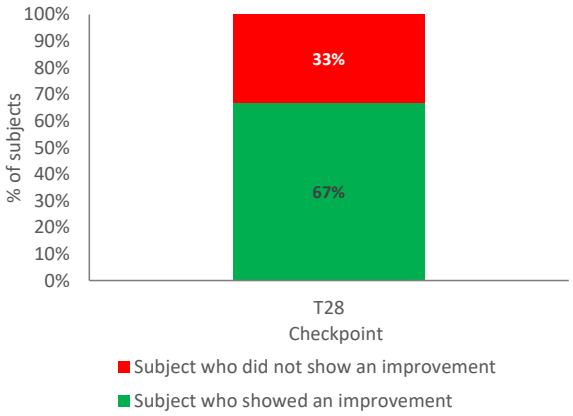
GRAPH 9. The graph reports the percentage of subjects related to the effect.



COMMENT: as it is possible to notice, the tested product determines a clinically relevant improvement of skin evenness complexion in 67% of the enrolled subjects after 28 days of use.
The positive effect of the product on the measured parameter is confirmed if more than 50% of the subjects register an improvement.

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SELF-ASSESSMENT QUESTIONNAIRE

TABLE 10a. The table summarizes the results of the self-assessment questionnaire at Timm. Results are calculated as percentage of subjects who assigned a judgment among those proposed.

GLOBAL APPRECIATION OF THE PRODUCT

No.	Items	Very pleasant	Pleasant	Neither pleasant nor unpleasant	Unpleasant	Very unpleasant	Positive answers
01	What do you think about the product aspect?	45,5%	54,5%	0,0%	0,0%	0,0%	100,0%
02	What do you think about the product texture?	48,5%	51,5%	0,0%	0,0%	0,0%	100,0%
03	What do you think about the product fragrance?	54,5%	42,4%	3,0%	0,0%	0,0%	97,0%
04	What do you think about product spreadibility?	45,5%	51,5%	3,0%	0,0%	0,0%	97,0%

No.	Item	Very good	Good	Not good	Bad	Positive answers
05	What do you think about product penetration?	57,6%	42,4%	0,0%	0,0%	100,0%

No.	Item	Silky	Soft	Sticky	Oily	Positive answers
06	What is the after feel effect on the skin?	45,5%	48,5%	6,1%	0,0%	93,9%

No.	Item	Very good	Good	Not good	Bad	Positive answers
07	What is your overall appreciation of this product?	57,6%	42,4%	0,0%	0,0%	100,0%

APPRECIATION OF IMMEDIATE PRODUCT PERFORMANCE

No.	Item	Yes, absolutely	Yes, mildly	Yes, slightly	Not	Positive answers
08	After application, are tingling sensations soothed?	31,0%	27,6%	10,3%	31,0%	69,0%
09	After application, are pulling sensations soothed?	42,9%	17,9%	10,7%	28,6%	71,4%
10	After application burning sensations soothed?	54,5%	13,6%	9,1%	22,7%	77,3%
11	Immediately after the application, does the skin appear more hydrated?	81,8%	18,2%	0,0%	0,0%	100,0%
12	After application, does the skin appear softer?	84,8%	15,2%	0,0%	0,0%	100,0%
No.						
13	Free comments	See table 10b				

Legend: Positive answers → % of subjects who gave positive judgement very pleasant/pleasant, very good/good, silky/soft, yes, absolutely/yes, mildly/yes, slightly.

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TABLE 10b. Free comments.

no.	Free comments
01	--
02	Very satisifed
03	Very pleasant to apply
04	Excellent product
05	Excellent product
06	--
07	Good spreadability
08	--
09	Good product
10	--
11	Very easy to spread
12	Easy to apply
13	--
14	--
15	Excellent product
16	Excellent product
17	Good product
18	I like it
19	--
20	--
21	I like it
22	--
23	Good spreadability
24	--
25	Excellent product
26	--
27	--
25	Excellent product
26	I like it
27	Excellent product
28	Easy to apply
29	Excellent product
30	Hydrating product

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TABLE 10c. The table summarizes the results of the self-assessment questionnaire at T28. Results are calculated as percentage of subjects who assigned a judgment among those proposed.

No.	Items After 28 days of application, have you noticed that	Agreed	Moderately agreed	Not completely agreed	Not agreed	Positive answers
01	Your skin is more moisturized	69,7%	27,3%	3,0%	0,0%	97,0%
02	Your skin appears healthier revived, fresher	60,6%	33,3%	3,0%	3,0%	93,9%
03	Your skin appears brighter and smoother	54,5%	39,4%	3,0%	3,0%	93,9%
04	Redness and burning sensations seem reduced	72,7%	27,3%	0,0%	0,0%	100,0%
05	Skin discomforts (tingling, pulling,etc.) are soothed	78,8%	21,2%	0,0%	0,0%	100,0%
06	Skin seems less prone to redness and less sensitive	66,7%	33,3%	0,0%	0,0%	100,0%
07	Skin appear more resilient to external aggressions	72,7%	27,3%	0,0%	0,0%	100,0%
08	Skin uniformity is improved	36,4%	63,6%	0,0%	0,0%	100,0%
No.	**Item After 28 days of application, the following skin issues seem improved:**	**Strongly**	**Improved**	**Unchanged**	**Aggravated**	**Positive answers**
09	Skin dryness	30,3%	66,7%	3,0%	0,0%	97,0%
10	Skin discomforts	33,3%	60,6%	6,1%	0,0%	93,9%
11	Skin redness	27,3%	63,6%	9,1%	0,0%	90,9%
12	Skin sensitivity	39,4%	51,5%	9,1%	0,0%	90,9%
13	Lack of skin brightness	54,5%	42,4%	3,0%	0,0%	97,0%
SUBSEQUENT USE OF THE PRODUCT						
No.	**Item**	**Luxe**	**Masstige**	**Mass market**		**Positive answers**
14	According to you, this product is sold in which market segment?	63,6%	33,3%	3,0%	--	--
No.	**Item**	**Very good**	**Good**	**Not good**	**Bad**	**Positive answers**
15	What is your overall appreciation of this product in terms of efficacy?	84,8%	15,2%	0,0%	0,0%	100,0%
No.	**Item**	**Absolutely yes**	**Maybe**	**Probably not**	**Absolutely not**	**Positive answers**
16	Would you continue using this product?	87,9%	12,1%	0,0%	0,0%	100,0%
17	Would you buy this product independently from price?	54,5%	39,4%	3,0%	3,0%	93,9%
18	Would you suggest this product to your acquaintance?	87,9%	9,1%	0,0%	3,0%	97,0%

Legend: Positive answers → % of subjects who gave positive judgement agreed/moderately agreed, strongly/improved, very good/good, absolutely yes/maybe.

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CONCLUSIONS

According to the obtained results we can conclude that the tested product

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determined in subjects with sensitive skin, skin redness/telangiectasias and skin prone to burning/stinging/itching sensations:

- a statistically significant decrease of transepidermal water loss vs T0 by -10.1% at T2h, by -12.9% at T4h and by -18.7% at T28; *a decrease of this parameter indicates an improvement of skin barrier function/condition;*
- a statistically significant increase of gloss parameter vs T0 by +10.4% at Timm and +17.2% at T28; *an increase of this parameter indicates an improvement of skin radiance/brightness;*
- a statistically significant decrease of erythema index vs T0 by -7.5% at Timm and by -12.6% at T28;
- a clinically relevant improvement of skin discomforts (erythema, burning sensation, itching sensation, stinging sensation, skin tightness) at Timm and T28;
- a clinically relevant and statistically significant improvement of skin smoothness in 100% of the enrolled subjects at T28;
- a clinically relevant improvement of skin evenness complexion in 67% of the enrolled subjects at T28.

Moreover, the product showed an immediate *soothing effect* on skin discomfort induced by lactic acid. In fact, the single product application determined a statistically significant decrease of the itching/stinging sensation starting from Timm, immediately after its application; the decrease of skin discomfort sensation perceived by the subjects is faster due to the application of the tested product, compared to the physiological decrease highlighted in the control area.

Furthermore, after 28 days of product use skin is less reactive to acid lactic stimulation.

In addition, the test product was positively judged by most of the enrolled subjects for all the investigated parameters.

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