

**CLINICAL AND INSTRUMENTAL EVALUATION OF THE
PURIFYING AND BRIGHTENING IMMEDIATE EFFECT OF A
COSMETIC MASK.
STUDY UNDER OPHTHALMOLOGICAL CONTROL**

RIVOLI COSMÉTIQUES SA

DETOX & PURIFYING FACE MASK



Customer	RIVOLI COSMÉTIQUES SA
Record no	H.E.HU.MP.NRA01.035.01.00_IT0000157/24
Date	Rev01 by 04/04/2024

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STUDY DESIGN

1.1. Title

Clinical and instrumental evaluation of the purifying and brightening immediate effect of a cosmetic mask. Study under ophthalmological control.

1.2. Aim of the study

The study is aimed to evaluate the immediate efficacy of a cosmetic product (mask) aimed to improve skin brightness and reduce skin pores appearance. Moreover, the product tolerability is evaluated.

To this end, a clinical-instrumental study is carried out on 35 healthy female subjects, aged between 30 and 60 years old (average age 45 y.o.), living in polluted area, showing normal to mixed skin, with dilated skin pores and dull skin.

Instrumental evaluations are carried out at baseline (T0) and around 15 minutes after product removal (T1) by means of bioengineering techniques able to measure skin pH and 1 hour after product removal (T1h) by means of bioengineering techniques able to measure skin brightness (see more details in results section). The instrumental analysis is integrated with the image analysis of pores size at T1. Product tolerability is evaluated by means of the ophthalmological analysis of both subjective (self-reported) and objective (scored by the experimenter) local tolerance reactions occurrence after product removal (T1). Moreover, immediately after product removal (Timm), subjects are asked to express their opinion on tested product by answering to a questionnaire.

1.3. Tested Product

1.3.1. Information provided by the Customer

- Product name: **DETOX & PURIFYING FACE MASK**
- Way of use: apply a thick layer to cleansed skin on the face and upper neck. Leave to act for a maximum of 10 minutes. Remove with a damp cotton cloth or rinse well with warm water.
- The cosmetic product to be tested conforms to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) and to its annexes.
- The cosmetic product to be tested is safe under normal or reasonably foreseeable conditions of use.
- INCI formula: AQUA (WATER), GLYCERIN, COCOS NUCIFERA (COCONUT) OIL, KAOLIN, HECTORITE, PROPANEDIOL, CETEARYL OLIVATE, CAPRYLIC/CAPRIC TRIGLYCERIDE, HYDROGENATED PHOSPHATIDYLCHOLINE, PALMITIC ACID, SALICYLIC ACID, STEARIC ACID, DECYL OLEATE, SORBITAN OLIVATE, BUTYROSPERMUM PARKII (SHEA) BUTTER, CI 77947, PENTYLENE GLYCOL, CAPRYLYL GLYCOL, PARFUM (FRAGRANCE), TOCOPHERYL ACETATE, XANTHAN GUM, ETHYLHEXYLGLYCERIN, SQUALANE, DIPROPYLENE GLYCOL, GLYCERYL CAPRYLATE, TETRASODIUM GLUTAMATE DIACETATE, CERAMIDE NP, PHAEOACTYLUM TRICORNUTUM EXTRACT, EPIGALLOCATECHIN GALLATYL GLUCOSIDE, TOCOPHEROL, SODIUM HYDROXIDE, HYDROGENATED PALM GLYCERIDES CITRATE.

1.4. Ethical requirements

The study is carried out according to the ethical requirements listed here below.

- I. All participants in the study are healthy volunteers, aged over 18 years old.
- II. All participants in the study are screened and enrolled under the supervision of a dermatologist, according to specific inclusion/non-inclusion criteria.
- III. Volunteers' participation in the study is free.
- IV. All participants in the study are informed of the aim and the nature of the study.
- V. All participants in the study are informed of the possible risks involved in the study.
- VI. All participants in the study sign a written consent form before the study begins.
- VII. Before volunteers are exposed to the tested product, all safety information regarding the product and its individual ingredients are assessed.
- VIII. All study procedures are carried out in compliance with the ethical principles for medical research (Ethical Principles for Medical Research Involving Human Subjects, Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and its amendment).
- IX. All precautions are taken in order to avoid adverse reactions occurrence.
- X. In case of non-expected/adverse reaction occurrence the medical investigating specialist evaluates the severity of the reaction (reporting it in the data collecting sheet of the volunteer) and consequently proceeds with the appropriate therapy.



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1.5. Subjects

1.5.1. Subjects' selection

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

1.5.1.1. Inclusion criteria

- Healthy female subjects
- Aged between 30 and 60 years old (average age 45 y.o.)
- Subjects living in polluted area
- Subjects showing normal to mixed skin with dilated skin pores
- Subjects with dull skin
- Caucasian ethnicity
- Subjects registered with National Health Service (NHS)
- Subjects certifying the truthfulness of the personal data disclosed to the investigator
- Subjects able to understand the language used in the investigation center and the information given by the investigator
- Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
- The pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) should be stable for at least one month without any changes expected or planned during the study
- Commitment not to change the daily routine or the lifestyle
- Subjects who have not been recently involved in any other similar study
- Absence of previous allergy for topical products
- Commitment not to use during the study period other products with the same effect of the tested product
- Subjects informed about the test procedures and who have signed a consent form.

1.5.1.2. Non-inclusion criteria

- Subjects who do 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 treatment incompatible with the requirements of the study
- 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 to cosmetic products, toiletries, medications, patches or cosmetic devices
- Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential).

1.5.1.3. Study withdrawal

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



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1.6. Study development

The study is carried out as follow:

- **T0:** thirty-five healthy female subjects are selected according to the inclusion criteria of the study; subjects are informed about study modalities and procedures and they are asked to sign a consent form and the authorization of the personal data treatment.
Instrumental evaluation of skin brightness and skin pH, digital pictures acquisition (Visia-CR) and ophthalmological evaluation of baseline conditions in order to monitor product tolerability.
- **Timm:** subjects are asked to express their opinion on tested product by answering to a questionnaire immediately after product removal.
- **T1:** instrumental evaluation of skin pH and image analysis of pores surface and ophthalmological evaluation on 35 subjects around 15 after product removal*.

**Time necessary to permit to the product to penetrate after mask removal; if the product is not well absorbed the results could be less evident and the probes can get dirty if the product is still on the skin / the measures could be affected by the product/water still present on the skin.*

- **T1hour:** instrumental evaluation of skin brightness and digital pictures acquisition (Visia-CR) on 25 subjects around 1 hour after product removal (see more details in results section).

1.7. Materials and methods

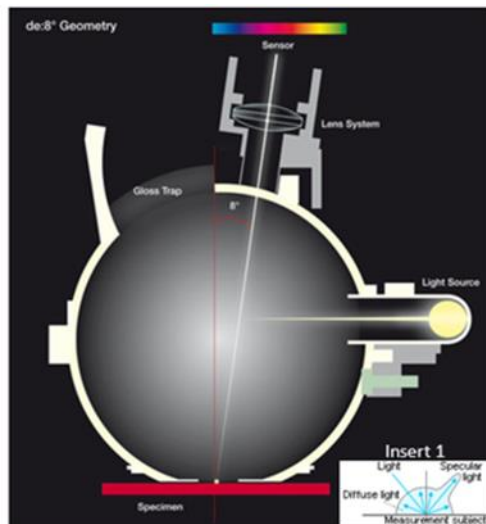
Here below are reported the parameters monitored during the study. The instrumental evaluations are carried out in a temperature and humidity-controlled environment (respectively T= 18-26°C and RH= 50±10%).

The subject, before each visit, observes a 15-20-minute acclimatization period in these conditions.

1.7.1. Skin brightness

Skin brightness is the ability of the skin to reflect the light (Fig 1) and it is measured by 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 and for the evaluation of the improvement of dull skin.

Figure 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°.



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1.7.2. 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

1.7.3. Pores size

On pictures acquired by Visia-CR an image analysis with a dedicated software is carried out in order to evaluate pores percentage (as surface occupied by pores) and total pores number in the analyzed area. For each volunteer, the measurement is carried out in a standardized area of the face at all experimental time (Fig. 2).

Figure 2. Examples of Visia-CR pictures



1.7.4. Digital pictures

Digital pictures of the face are acquired by means of Visia®-CR (Canfield Scientific). The instrument ensures a reproducible subject positioning between timepoints and acquires pictures using different light modalities, in order to enhance visualization of the skin features to analyse.

Figure 3. Examples of Visia-CR pictures: a) Standard general white lighting clinical image. b) Parallel polarized image.



The best 5 cases of digital pictures showing an improvement of face skin appearance – skin brightness and skin pores are delivered to the Customer.

1.7.5. Ophthalmological evaluation of product tolerability

Before the study start and at the end of the study, the ophthalmologist assesses physical signs (lacrimation, vasodilatation, periocular swelling) and records with the collaboration of the enrolled subject functional signs (foreign body sensation, itching sensation, stinging sensation, burning sensation, other) according to scores reported in box 1a/1b.



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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

1.7.6. Overall evaluation of product tolerability

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

The product is ultimately classified as:

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

1.7.7. Self-assessment questionnaire

Immediately after product removal (Timm), volunteers are asked to express their opinion on tested product by answering to a questionnaire.

1.8. Results and statics

1.8.1. Results

The results are reported in tables in their respective units.

1) Mean values are calculated as follows:

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

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

2) Percentages are calculated as follows:

$$\%var. vs. T_0 = \left(\sum_{i=1}^n \frac{p_t - p_0}{p_0} \right) \times 100$$

or

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

where: p_t is the value of the parameter under analysis after product use; p_0 is the value of the parameter under analysis before product application; n is the number of subjects participating in the study.

3) The standard error of data is calculated as:

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

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

All the calculations are done using a Microsoft® Office worksheet.

The results of self-assessment questionnaire are calculated as percentage (%) of subjects who assigned a determined judgment (among those proposed). For each question, the number of subjects related to each judgment is counted → (number of subjects) and this number is then divided by the total number of subjects → % of answers.



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1.8.2. Statistical analysis

The instrumental data are submitted to paired Student t test (intra-group analysis vs T0). Variations are considered statistically significant when the p value is <0.05.

1.9. Interpretation of results

The study here above reported was designed to demonstrate the test product claim(s) in the current framework proposed by Commission Regulation (EU) No 655/2013. Endpoints are measured using techniques currently accepted in the cosmetic field while biases are minimized by procedure(s) standardization according to ISO 9001 Quality Management System. Data are analyzed and interpreted by skilled technician according to both descriptive and inferential statistical analysis procedures. Due to the lack of reference values in the cosmetic field, statistical significance (for instrumental analysis) and percentage of subjects showing an effect (for clinical/sensorial endpoints) are the primary criterion to evaluate the correspondence between the proposed claim(s) and the study output(s). In particular intragroup (vs. T0) or intergroup (e.g. active vs. placebo, treated vs non treated) statistical analysis criterion to reject the null hypothesis (no product effect) is set at p<0.05. For clinical evaluations, the positive effect of the product on the evaluated parameter is confirmed if more than 50% of the subjects register an improvement. Finally, for the self-assessment questionnaires, the performance and the pleasantness of the product must be perceived by at least 60% of the subjects. Whenever reference values or threshold values exist, those values are used to validate product claim(s).

1.10. Start/end date of study

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

Start date	End date
10/01/2024	01/03/2024

1.11. 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	08/03/2024	Release of the report
01	04/04/2024	Release of the second report according to Customer requests

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



PANEL DEMOGRAPHY

Table A. The following table reports the characteristic of enrolled subjects.

no.	Vol. ID	Age	Skin type	Contact lenses wearer	Eyeglasses wearer	Sensitive skin	Sensitive eyes	Eyes colour
01	C5246P	54	COMBINATION	NO	YES	YES	NO	GREEN
02	C5434G	34	COMBINATION	NO	NO	NO	NO	BROWN
03	V6030I	39	COMBINATION	NO	YES	YES	NO	GREEN
04	F7301S	46	NORMAL	YES	YES	NO	NO	BROWN
05	R5425A	37	COMBINATION	NO	NO	NO	YES	BROWN
06	D5966T	59	NORMAL	NO	YES	NO	NO	BLUE
07	C5489M	36	COMBINATION	NO	NO	NO	NO	BROWN
08	C5639A	48	COMBINATION	NO	YES	YES	YES	GREEN
09	C7500A	34	COMBINATION	YES	YES	YES	YES	BROWN
10	T5783L	55	COMBINATION	NO	NO	YES	NO	BROWN
11	R5463M	36	NORMAL	NO	NO	YES	YES	BLUE
12	B8330C	49	NORMAL	NO	YES	NO	YES	BROWN
13	P5361I	40	COMBINATION	NO	NO	NO	NO	BROWN
14	P7510L	52	COMBINATION	NO	YES	NO	NO	BROWN
15	C4970G	58	COMBINATION	YES	YES	NO	NO	BROWN
16	L4924M	58	COMBINATION	NO	NO	YES	NO	GREEN
17	T8196V	45	COMBINATION	NO	YES	NO	NO	BROWN
18	C5444S	52	COMBINATION	NO	YES	YES	YES	BLUE
19	P7327M	35	COMBINATION	NO	NO	YES	NO	BROWN
20	L5748M	56	NORMAL	NO	YES	NO	YES	BROWN
21	F8587E	51	COMBINATION	NO	YES	NO	NO	BROWN
22	P5231S	47	NORMAL	NO	NO	YES	YES	BROWN
23	C8200M	49	NORMAL	NO	NO	YES	YES	BROWN
24	N7961F	36	NORMAL	NO	NO	YES	YES	BROWN
25	C6575A	45	COMBINATION	YES	YES	YES	YES	GREEN
26	C8466E	37	COMBINATION	NO	NO	NO	NO	BROWN
27	T5849A	58	NORMAL	NO	NO	YES	YES	BROWN
28	R8460A	40	NORMAL	NO	NO	YES	YES	BROWN
29	P6021A	57	COMBINATION	NO	YES	NO	NO	BROWN
30	D8141A	47	NORMAL	NO	YES	YES	YES	BLUE
31	C7182L	35	COMBINATION	YES	YES	YES	NO	BLUE
32	F8190A	30	COMBINATION	NO	NO	YES	NO	BROWN
33	D5817J	30	COMBINATION	YES	YES	NO	NO	BROWN
34	G5156C	49	COMBINATION	YES	YES	YES	YES	GREEN
35	D8183L	40	NORMAL	YES	YES	NO	YES	GREEN
Mean		45,0						
Min		30						
Max		59						

NOTE:

All enrolled subjects showed visible erythema after mask removal that totally disappeared after 1 hour. In particular:

- VOL 09: immediately after mask application, the volunteer reported mild stinging sensation that disappeared immediately after mask removal.
- VOL 11: immediately after mask application, the volunteer reported mild sensation of warmth and mild burning sensation that disappeared 15 minutes after mask removal.
- VOL 12: immediately after mask application, the volunteer reported mild stinging sensation that disappeared immediately after mask removal.

According to the dermatologist opinion the onset of the described signs could be expected considering the category of the product and its mechanism of action.



RESULTS SKIN BRIGHTNESS

Table 1. The table reports the obtained data for each volunteer (25 subjects out of 35 enrolled*). Data are reported as arbitrary units (a.u.).

no.	Vol. ID	T0	T1hour		T1hour
11	R5463M	11,4	14,6		28,4%
12	B8330C	10,8	18,1		68,2%
13	P5361I	12,4	13,9		12,1%
14	P7510L	10,2	13,9		36,5%
15	C4970G	8,9	13,9		56,4%
16	L4924M	8,9	13,7		54,1%
17	T8196V	10,5	16,6		58,1%
18	C5444S	12,3	15,7		27,5%
19	P7327M	10,1	15,6		54,4%
20	L5748M	10,4	15,0		44,0%
21	F8587E	10,7	14,7	Variation vs. T0	37,7%
22	P5231S	10,7	14,7		37,7%
23	C8200M	9,0	11,6		29,5%
24	N7961F	10,4	13,0		24,0%
25	C6575A	10,6	10,2		-3,8%
26	C8466E	11,9	14,7		23,8%
27	T5849A	8,7	12,6		45,7%
28	R8460A	8,7	13,1		51,6%
29	P6021A	11,1	17,1		54,4%
30	D8141A	12,4	14,7		19,1%
31	C7182L	10,8	15,4		41,8%
32	F8190A	8,1	13,3		64,0%
33	D5817J	9,7	13,4		37,8%
34	G5156C	9,0	12,3		36,8%
35	D8183L	11,2	15,7		39,7%
	Mean	10,3	14,3		39,2%
	SE	0,25	0,35	Min	-3,8%
	t test vs. T0	---	0,000	Max	68,2%

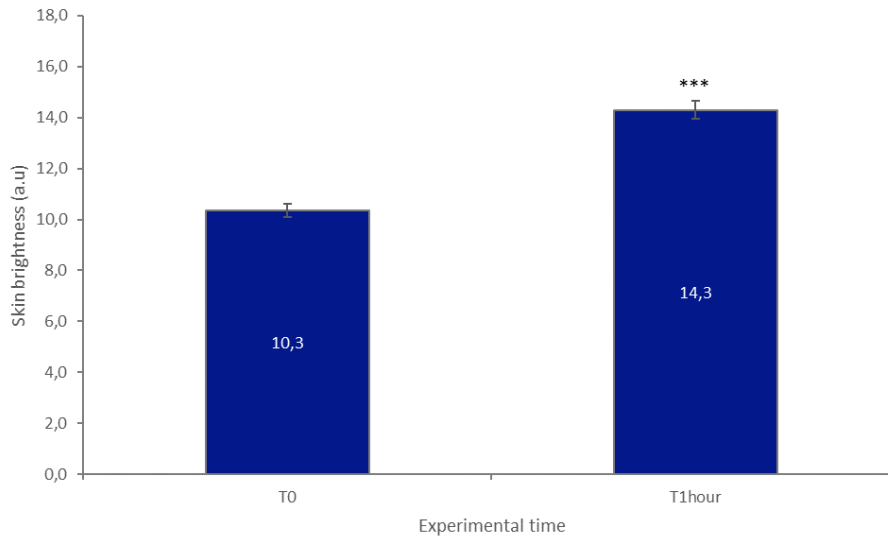
Legend:

SE: standard error

*due to the onset visible erythema up to 1 hour after removing the mask in all enrolled subjects, it was decided to take the measurement of skin brightness 1 hour after mask removal rather than after 15 minutes as per protocol, according with the Customer. The first 10 subjects were excluded from the measurement since it was taken after 15 minutes.



Graph 1. 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, the tested product determines a statistically significant improvement of gloss parameter by +39.2%, 1 hour after its removal.

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



SKIN pH

Table 2. The table reports the obtained data for each volunteer (35 subjects out of 35 enrolled). Data are expressed as pH units.

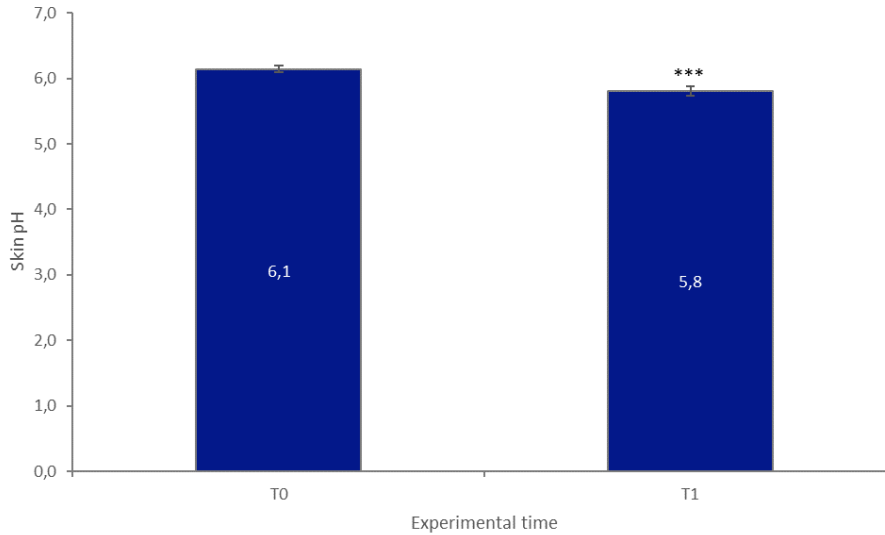
no.	Vol. ID	T0	T1
01	C5246P	5,8	6,4
02	C5434G	6,3	6,1
03	V6030I	5,7	5,8
04	F7301S	5,9	5,0
05	R5425A	6,0	5,2
06	D5966T	6,4	5,2
07	C5489M	6,1	5,4
08	C5639A	6,0	5,9
09	C7500A	6,1	5,9
10	T5783L	5,8	5,4
11	R5463M	6,1	5,4
12	B8330C	6,4	5,8
13	P5361I	6,0	4,9
14	P7510L	6,1	5,9
15	C4970G	6,4	6,0
16	L4924M	5,8	5,7
17	T8196V	6,1	6,0
18	C5444S	6,2	5,9
19	P7327M	5,9	5,3
20	L5748M	6,1	5,8
21	F8587E	5,9	5,6
22	P5231S	5,9	5,7
23	C8200M	5,9	5,7
24	N7961F	6,6	6,2
25	C6575A	6,6	7,0
26	C8466E	6,2	5,9
27	T5849A	5,9	6,3
28	R8460A	6,4	5,2
29	P6021A	6,4	6,0
30	D8141A	6,0	6,4
31	C7182L	6,3	6,3
32	F8190A	6,0	5,6
33	D5817J	6,6	5,7
34	G5156C	6,5	6,1
35	D8183L	6,9	6,6
	Mean	6,1	5,8
	SE	0,0	0,1
	t test vs. T0	---	0,000

Legend:

SE: standard error



Graph 2. 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, the tested product determines a statistically significant variation of skin pH, 15 minutes after its removal.

Although a statistically significant decrease of the parameter is recorded, pH values recorded at T15min remain physiological and the variation could be related to the formulation of the product.



PORES SIZE - % area occupied by pores

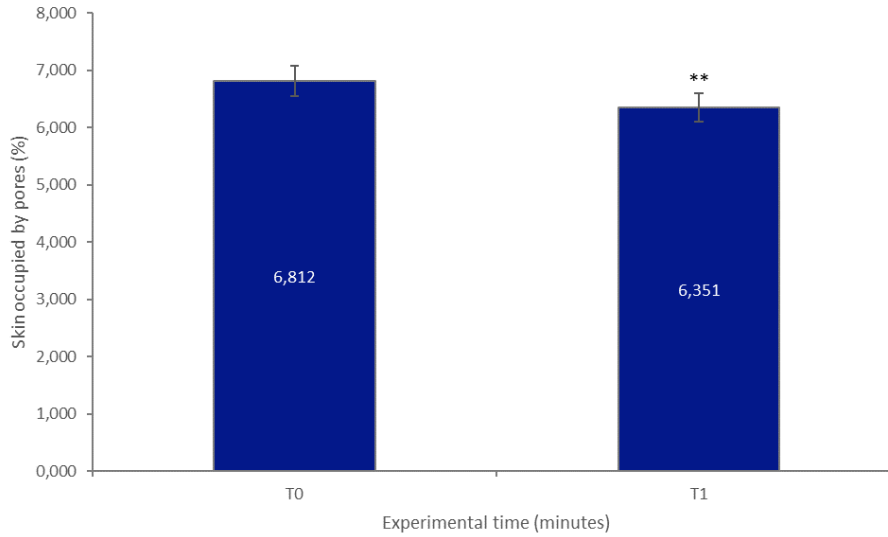
Table 3. The table reports the obtained data for each volunteer (35 subjects out of 35 enrolled). Data are expressed as % area occupied by pores.

no.	Vol. ID	T0	T1	T1
01	C5246P	6,336	5,971	-0,365
02	C5434G	9,798	6,901	-2,897
03	V6030I	7,077	6,003	-1,074
04	F7301S	5,157	3,950	-1,207
05	R5425A	5,244	5,656	0,412
06	D5966T	7,889	7,170	-0,719
07	C5489M	6,206	5,602	-0,604
08	C5639A	7,181	6,548	-0,633
09	C7500A	5,594	5,572	-0,022
10	T5783L	8,215	7,752	-0,463
11	R5463M	3,770	4,186	0,416
12	B8330C	7,627	7,183	-0,444
13	P5361I	8,545	9,120	0,575
14	P7510L	6,403	6,559	0,156
15	C4970G	4,802	5,070	0,268
16	L4924M	6,063	5,325	-0,738
17	T8196V	7,450	6,957	-0,493
18	C5444S	9,516	9,280	-0,236
19	P7327M	6,629	6,581	-0,048
20	L5748M	8,258	8,400	0,142
21	F8587E	5,077	5,401	0,324
22	P5231S	6,840	6,876	0,036
23	C8200M	7,123	5,842	-1,281
24	N7961F	4,347	4,157	-0,190
25	C6575A	9,077	9,121	0,044
26	C8466E	7,074	6,861	-0,213
27	T5849A	8,906	7,031	-1,875
28	R8460A	6,322	5,621	-0,701
29	P6021A	7,593	6,494	-1,099
30	D8141A	7,784	6,239	-1,545
31	C7182L	5,104	4,623	-0,481
32	F8190A	4,564	4,123	-0,441
33	D5817J	8,506	8,199	-0,307
34	G5156C	5,096	4,913	-0,183
35	D8183L	7,239	7,007	-0,232
Mean		6,812	6,351	-0,461
SE		0,262	0,240	Max -2,897
t test vs. T0		---	0,001	Min 0,575

Legend:
SE: standard error



Graph 3. 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, the tested product determines a statistically significant decrease of pores size (as % area occupied by pores) by -0,461, 15 minutes after its removal.



PORES SIZE – total pores number

Table 4. The table reports the obtained data for each volunteer (35 subjects out of 35 enrolled). Data are expressed as number.

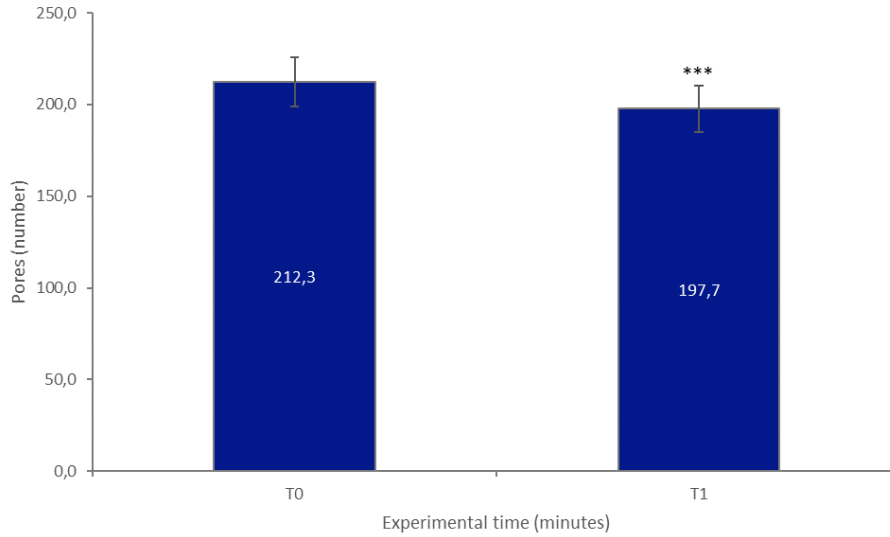
no.	Vol. ID	T0	T1	T1
01	C5246P	121	120	-0,8%
02	C5434G	367	304	-17,2%
03	V6030I	209	173	-17,2%
04	F7301S	112	93	-17,0%
05	R5425A	169	178	5,3%
06	D5966T	333	280	-15,9%
07	C5489M	345	294	-14,8%
08	C5639A	347	311	-10,4%
09	C7500A	222	210	-5,4%
10	T5783L	347	333	-4,0%
11	R5463M	181	192	6,1%
12	B8330C	195	189	-3,1%
13	P5361I	336	363	8,0%
14	P7510L	150	151	0,7%
15	C4970G	200	210	5,0%
16	L4924M	144	122	-15,3%
17	T8196V	215	200	-7,0%
18	C5444S	218	185	-15,1%
19	P7327M	195	181	-7,2%
20	L5748M	300	301	0,3%
21	F8587E	204	211	3,4%
22	P5231S	141	131	-7,1%
23	C8200M	128	114	-10,9%
24	N7961F	146	151	3,4%
25	C6575A	293	319	8,9%
26	C8466E	252	242	-4,0%
27	T5849A	111	87	-21,6%
28	R8460A	176	175	-0,6%
29	P6021A	256	216	-15,6%
30	D8141A	224	180	-19,6%
31	C7182L	139	137	-1,4%
32	F8190A	151	108	-28,5%
33	D5817J	252	216	-14,3%
34	G5156C	140	128	-8,6%
35	D8183L	112	116	3,6%
Mean		212,3	197,7	-6,8%
SE		13,3	12,7	Max -28,5%
t test vs. T0		---	0,000	Min 8,9%

Legend:

SE: standard error



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, the tested product determines a statistically significant decrease of total pores number by -6.8%, 15 minutes after its removal.



OPHTHALMOLOGICAL EVALUATION OF PRODUCT TOLERABILITY

Table 5. The table below reports the dermatological physical (assessed by the ophthalmologist) and functional (self-reported by subjects) signs recorded at each timepoint, according to scores reported in the legend.

no.	Vol. ID	Physical signs						Functional signs						Others	
		Vasodilatation		Periocular swelling		Lacrimation		Foreign body sensation		Itching/Stinging sensation		Burning sensation			
		T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1	T0	T1
01	C5246P	0	0	0	0	0	0	0	0	0	0	0	0	0	0
02	C5434G	0	0	0	0	0	0	0	0	0	0	0	0	0	0
03	V6030I	0	0	0	0	0	0	0	0	0	0	0	0	0	0
04	F7301S	0	0	0	0	0	0	0	0	0	0	0	0	0	0
05	R5425A	0	0	0	0	0	0	0	0	0	0	0	0	0	0
06	D5966T	0	0	0	0	0	0	0	0	0	0	0	0	0	0
07	C5489M	0	0	0	0	0	0	0	0	0	0	0	0	0	0
08	C5639A	0	0	0	0	0	0	0	0	0	0	0	0	0	0
09	C7500A	0	0	0	0	0	0	0	0	0	0	0	0	0	0
10	T5783L	0	0	0	0	0	0	0	0	0	0	0	0	0	0
11	R5463M	0	0	0	0	0	0	0	0	0	0	0	0	0	0
12	B8330C	0	0	0	0	0	0	0	0	0	0	0	0	0	0
13	P5361I	0	0	0	0	0	0	0	0	0	0	0	0	0	0
14	P7510L	0	0	0	0	0	0	0	0	0	0	0	0	0	0
15	C4970G	0	0	0	0	0	0	0	0	0	0	0	0	0	0
16	L4924M	0	0	0	0	0	0	0	0	0	0	0	0	0	0
17	T8196V	0	0	0	0	0	0	0	0	0	0	0	0	0	0
18	C5444S	0	0	0	0	0	0	0	0	0	0	0	0	0	0
19	P7327M	0	0	0	0	0	0	0	0	0	0	0	0	0	0
20	L5748M	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21	F8587E	0	0	0	0	0	0	0	0	0	0	0	0	0	0
22	P5231S	0	0	0	0	0	0	0	0	0	0	0	0	0	0
23	C8200M	0	0	0	0	0	0	0	0	0	0	0	0	0	0
24	N7961F	0	0	0	0	0	0	0	0	0	0	0	0	0	0
25	C6575A	0	0	0	0	0	0	0	0	0	0	0	0	0	0
26	C8466E	0	0	0	0	0	0	0	0	0	0	0	0	0	0
27	T5849A	0	0	0	0	0	0	0	0	0	0	0	0	0	0
28	R8460A	0	0	0	0	0	0	0	0	0	0	0	0	0	0
29	P6021A	0	0	0	0	0	0	0	0	0	0	0	0	0	0
30	D8141A	0	0	0	0	0	0	0	0	0	0	0	0	0	0
31	C7182L	0	0	0	0	0	0	0	0	0	0	0	0	0	0
32	F8190A	0	0	0	0	0	0	0	0	0	0	0	0	0	0
33	D5817J	0	0	0	0	0	0	0	0	0	0	0	0	0	0
34	G5156C	0	0	0	0	0	0	0	0	0	0	0	0	0	0
35	D8183L	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

COMMENT

No adverse event related to tested product was recorded during the study.

Tested product is ophthalmologically tested and well tolerated by all the enrolled subjects.

None of the subjects showed the onset of dermatological physical or functional signs. All subjects tolerated the test product during the study period; neither Adverse Events (AE) nor Serious Adverse Events (SAE) were recorded.



SELF-ASSESSMENT QUESTIONNAIRE

Table 6a. The table shows the obtained data related to the self-assessment of the subject taking part in the study **immediately after product removal**. Results are calculated as percentage (%) of subjects who expressed the same opinion among those proposed.

No.	Items	Very pleasant	Pleasant	Neither pleasant nor unpleasant	Unpleasant	Very unpleasant	Positive answers
01	What do you think about the product aspect?	22,9%	54,3%	22,9%	0,0%	0,0%	77,1%
02	What do you think about the product texture?	31,4%	62,9%	5,7%	0,0%	0,0%	94,3%
03	What do you think about the product smell?	14,3%	65,7%	17,1%	2,9%	0,0%	80,0%
04	What do you think about product application?	31,4%	62,9%	2,9%	2,9%	0,0%	94,3%
05	What do you think about product leave-on phase (skin doesn't tight, is not dry, etc.)?	28,6%	40,0%	14,3%	14,3%	2,9%	68,6%
No.	Items	Very easily removed	Easily removed	Comparable to similar products	Not easily removable	--	Positive answers
06	What do you think about product rinse-off phase?	22,9%	48,6%	20,0%	8,6%	--	91,4%
No.	Items	Silky	Soft	Sticky	Dry	--	Positive answers
07	How is the after feel effect on the skin?	45,7%	48,6%	2,9%	2,9%	--	94,3%
No.	Items	Very good	Good	Not pleasant	Not good	--	Positive answers
08	What is your overall appreciation of this product?	28,6%	65,7%	5,7%	0,0%	--	94,3%
No.	Items	Intense	Moderate	Slightly	Not at all	--	Positive answers
09*	After product removal, have you noticed an amelioration of skin brightness?	34,3%	34,3%	28,6%	2,9%	--	97,1%
10	After product removal, have you found that pores are less visible/dilated?	22,9%	34,3%	37,1%	5,7%	--	94,3%
11	After product removal, have you noticed that skin complexion is more even?	20,0%	51,4%	28,6%	0,0%	--	100,0%
12	After product removal, have you got the impression that your skin is purified and pores unclogged?	31,4%	31,4%	31,4%	5,7%	--	94,3%
No.	After product removal, have you noticed that:	Agreed	Moderately agreed	Not completely agreed	Not agreed	--	Positive answers
13	Your skin is brighter	48,6%	48,6%	2,9%	0,0%	--	97,1%
14	Your skin is smoother	71,4%	20,0%	8,6%	0,0%	--	91,4%
15	Pores and skin breakouts are less visible	20,0%	74,3%	2,9%	2,9%	--	94,3%
16	Skin complexion appears refreshed, healthier and brighter	51,4%	42,9%	2,9%	2,9%	--	94,3%
No.	Items	Open question					
17	Other comments	see free comments					

Legend:

*For question n.09, 15 subjects answered 1 hour after product removal.

Positive answers for question from 01 to 05 → % of subjects who gave positive judgement (very pleasant, pleasant)

Positive answers for question 06 → % of subjects who gave positive judgement (very easily removed, easily removed, comparable to similar products)



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Positive answers for question 07 → % of subjects who gave positive judgement (silky, soft)
 Positive answers for question 08 → % of subjects who gave positive judgement (very good, good)
 Positive answers for question from 09 to 12 → % of subjects who gave positive judgement (intense, moderate, slightly)
 Positive answers for question from 13 to 16 → % of subjects who gave positive judgement (agreed, moderately agreed)
 The percentages are rounded off, this is why the sum of these percentages may be different from 100%.

Table 6b. The table shows the answers relating to question no. 17 of the previous questionnaire (table 6a).

Question n. 17 - Free comments
Brighter skin
Pleasant texture, I notice any improvements after application
Pleasant texture, not good smell
Freshness sensation on skin
Skin tightness sensation after removal
Good product, I would buy it
Pasty texture, difficult to remove it but leaves the skin smooth
Good product
Mild stinging sensation during the application
It does not dry out skin, it does not sting, you could do it every day
Mild burning sensation also after removal
Mild stinging sensation during the application
Not very pleasant during application time
Good product, silky skin
Not fully satisfied
Smooth skin but mild tightness sensation
It dried out my pimples
Good product
Product I would buy
Pleasant product even if it dry a little the skin
Quite satisfied
I would recommend it
Skin tightness sensation after removal
Smooth skin but slightly dry skin
Mild stinging sensation during the application
Very silky skin
Soft skin
Luminous effect
Excellent product
Difficult to remove
Fast and effective product
I like it
Good product
Pleasant but after removal it leaves a mild redness
After the removal I feel the need to apply a moisturizing cream



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Record no	H.E.HU.MP.NRA01.035.01.00_IT0000157/24
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CONCLUSIONS

According to the obtained results it is possible to conclude that the tested product:

RIVOLI COSMÉTIQUES SA DETOX & PURIFYING FACE MASK

determines:

- a statistically significant increase of **skin brightness** by +39.2%, 1 hour after its removal;
- a statistically significant decrease of pores size (as **% area occupied by pores**) by -0,461, 15 minutes after its removal;
- a statistically significant decrease of **total pores number** by -6.8%, 15 minutes after its removal.

Moreover, most of the enrolled volunteers positively judged the tested product for all the monitored aspects.

The product has been ophthalmologically tested and it was well tolerated and it is safe for its use under the test conditions.

During the study period no subjects experienced the onset of any ophthalmological new physical or functional signs, or the worsening of the pre-existing signs recorded at baseline.

Dermatologist

Dr. Gloria Roveda

Ophthalmologist

Dr. Francesco Sandolo

Quality Control

Dr. Francesca De Gennaro

Data analysis and report

Dr. Benedetta Ciano

