

CLINICAL EVALUATION OF THE REPAIRING EFFECT OF A COSMETIC PRODUCT ON SKIN ALTERATIONS INDUCED BY A CHEMICAL AGENT

RIVOLI COSMÉTIQUES SA
RIVOLI GENÈVE Le Visage NIGHT CREAM

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Customer	RIVOLI COSMÉTIQUES SA
Record no	H.E.HU.MP.NSO00.035.08.00_IT0005082/22
Date	rev 01 by 13/12/2022

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STUDY DESIGN

1.1 Title

Clinical evaluation of the repairing effect of a cosmetic product on skin alterations induced by a chemical agent.

1.2. Aim of the study

The aim of the study is to evaluate the efficacy of a cosmetic product in repairing (in terms of restoring the skin barrier function) skin alterations caused by a chemical agent (solution of SLS, sodium lauryl sulphate, at 2%); moreover, skin pH is monitored. In order to reach this goal, a clinical study is carried out on 35 healthy female subjects enrolled by a board-certified dermatologist according to specific inclusion and non-inclusion criteria.

Product repairing effect is evaluated 30 minutes, 1 hour, 2 and 24 hours after its first application on altered skin by means of non-invasive bioengineering techniques able to measure transepidermal water loss (TEWL); moreover, at T2h and T24h skin pH is monitored. The study is carried out versus a control area submitted to SLS but untreated.

1.3. Test product

1.3.1. Information provided by the Customer

- Product name: **RIVOLI GENÈVE Le Visage NIGHT CREAM**
- Way of use: 2mg/cm² of tested product is applied once by the Experimenter on defined area of the back of each subject.
- The tested cosmetic product conforms to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) and to its annexes.
- The cosmetic product to be tested is safe under normal or reasonably foreseeable conditions of use.
- Qualitative INCI formula: AQUA (WATER), CAPRYLIC/CAPRIC TRIGLYCERIDE, SQUALANE, PENTYLENE GLYCOL, BUTYROSPERMUM PARKII (SHEA) BUTTER, BUTYLENE GLYCOL, HYDROGENATED PHOSPHATIDYLCHOLINE, HYDROXYPROPYL STARCH PHOSPHATE, GLYCERIN, CAPRYLYL GLYCOL, PANTHENYL TRIACETATE, TOCOPHERYL ACETATE, AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER, ADENOSINE TRIPHOSPHATE, CARBOMER, HYDROLYZED OAT PROTEIN, NIACINAMIDE, PARFUM (FRAGRANCE), TAMARINDUS INDICA SEED GUM, ACETYL TYROSINE, XANTHAN GUM, SODIUM HYDROXIDE, DIPOTASSIUM PHOSPHATE, VITIS VINIFERA (GRAPE) VINE EXTRACT, PROLINE, CERAMIDE NP, HYDROLYZED VEGETABLE PROTEIN, PVP, DISODIUM EDTA, PEG-12 GLYCERYL LAURATE, PEG-35 CASTOR OIL, TOCOPHEROL

1.4. Ethical requirements

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

- I. All of the subjects participating in the study are healthy volunteers of at least 18 years old.
- II. All of the subjects participating in the study, were selected with the supervision of a dermatologist according to inclusion/non-inclusion criteria.
- III. The volunteer's participation in the study was free.
- IV. All of the subjects participating in the study were informed of the aim and the design of the study.
- V. All of the subjects participating in the study were informed of the possible risk involved in the study execution.
- VI. All of the subjects participating in the study gave their informed consent signed at the beginning of the study.
- VII. Before the volunteers will be exposed to the product to be tested, all relevant safety information about the product itself and each ingredient are collected and evaluated.
- VIII. All of the study procedures are carried out in accordance with the ethical principles for the medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and successive amendments) and taking inspiration from the general principle of the Good Clinical Practice.
- IX. All of the precautions shall be taken in consideration in order to avoid excessive skin reactions.
- X. In case of non-expected/adverse skin reaction occurrence, the medical experimenter will evaluate the severity of the reaction (reporting it in the data collecting sheet) and as a consequence he will proceed with the appropriate therapy.

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1.5. Subjects participating in the study

1.5.1. Subjects' enrolment

The subjects participating in the study were selected from a panel of healthy subjects in accordance with the following inclusion/non-inclusion criteria.

1.5.1.1. Inclusion criteria

- Thirty-five (n=35) healthy female subjects
- Caucasian ethnicity
- Aged between 40 and 50 (± 2) years old
- Skin phototype II, III and IV according to Fitzpatrick classification
- 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

- Subject not satisfying 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)
- Positive history for atopy or hypersensitive skin.

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 design

The study is carried out by selecting 2 skin areas on the low part of the back of each subject that are initially treated by the application of a patch containing a water solution of SLS at 2% in order to induce skin alterations* (increase of skin redness and TEWL). The SLS solution is applied by means of Finn Chambers (large) on Scanpor, a 12 mm diameter aluminium disk. The applied quantity is sufficient to fill the chamber without overflowing from it when applied to the skin (50 µl). The patches are left in contact with the skin surface for 24 hours.

The study is carried out in comparison to an untreated skin area (control area); the area of application of the product is defined according to a previous defined randomization list on the low of the back of the subjects. The product is applied on the concerned area in the laboratory in a quantity equal to 2mg/cm² by the Experimenter.

*The induced skin alterations are transient, not harmful for the health of the subjects and they spontaneously disappear.

The study is carried out according to the following scheme:

Timepoints	Control area – Untreated area	Treated area
T-1	Evaluation of transepidermal water loss (TEWL) and skin pH before the application of the SLS patch on volunteers' back (baseline values)	
-	2% SLS PATCH APPLICATION (patches are left in contact with the skin surface for 24 hours)	
-		PATCH REMOVAL
T0	TEWL and skin pH evaluation 15min after patch removal	
-	-	Product application by the experimenter
T30min*	TEWL evaluation 30 minutes after product application	
T1h*	TEWL evaluation 1 hour after product application	
T2h*	TEWL and skin pH evaluation 2 hours after product application	
T24h**	TEWL and skin pH evaluation 24 hours after product application	

*During the 2 hours after product application the subjects remain in laboratory in a room under controlled temperature and humidity conditions.

** Until T24h subjects do not apply any product or wash both treated and untreated areas.

1.7. Materials and methods

In the following paragraphs the materials and methods used in this study are reported. Measurements are taken under temperature (T) and relative humidity (RH) controlled conditions, as follows: T= 18-26°C C and RH = 50 ± 10%.

1.7.1. Transepidermal Water Loss (TEWL)

Trans epidermal water loss is measured using a Tewameter® TM 300 (Courage+Khazaka, electronic GmbH). The following equation which represents the Diffusion law (discovered by Adolf Fick in 1855) is the basis for the measurement:

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

where:

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

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



1.7.2. 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.

1.8. Results and Statistics

1.8.1. Results

The results are reported in tables in their respective units.

- 1) The mean values are calculated as:

$$m = \frac{\sum_{i=1}^{20} p_i}{20} \quad [1]$$

where: p is the value of the parameter to be analysed.

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

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

where: p is the value of the parameter to be analysed, n is the number of subjects

- 3) The mean percentage variations were calculated as:

$$\overline{Var(\%)} = \sum_{i=1}^{20} \frac{X_T - X_0}{X_0} \quad [3]$$

Where: X₀ is the value of the parameter to be analysed at T0 or T-1, X_t is the value of the parameter to be analysed in the further monitored experimental times.

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

1.8.2. Statistical analysis

Data are submitted to two-way paired Student's t-test. The intra-group statistical analysis is carried out on raw data vs baseline (T-1) and vs T0 (after SLS patch removal). The inter-group statistical analysis is carried out on the % variations obtained in the treated vs untreated area at each experimental time.

p-value <0.05 is considered statistically significant.

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) 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).

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Our studies are conducted inspiring by the general principle of the Good Clinical Practice and in Compliance with declaration of Helsinki. In general for all clinical in vivo studies we follow the best practice for claim substantiation evidence expressed by Technical document on cosmetic claims- ANNEX II and if present we follow or take inspiration by normative (as ISO for sunscreen) or guidelines as EEMCO guidance (European Expert Group on Efficacy Measurement of Cosmetics and other Topical Products) or cosmetic Europe guidelines (Guidelines for the evaluation of the efficacy of cosmetics products, May 2008) as well as by the instruction of use provided by the supplier of each instrument or from publication. Thanks to our experience we defined our internal standard operative procedures for each skin evaluation, instrumental, clinical and self-assessment.

Our quality Management System is certified according to ISO 9001:2015.

1.10. Start/end date of the study

The table here below reports the dates of the study.

Start of study management and enrolment	End of study management and enrolment	Test execution (first included subject)	Test execution (last included subject)	Study End Date (draft report delivery)
10/10/2022	07/11/2022	08/11/2022	23/11/2022	02/12/2022

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	05/12/2022	First release
01	13/12/2022	Dates of study added

-
- 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.

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RESULTS

TRANSEPIDERMAL WATER LOSS (TEWL) EVALUATION

TABLE 1a. In the tables below TEWL values obtained for each volunteer in the treated skin site are reported. Data are expressed as g/h/m².

TREATED AREA																
n.	Vol ID	PART 1					PART 2					PART 3				
		T-1	T0	T30min	T1h	T2h	T24h	T0	T30min	T1h	T2h	T30min	T1h	T2h	T24h	
01	V4252M	5,7	45,3	29,0	26,5	22,6	30,3	39,6	23,3	20,8	16,9	24,6	-41,2%	-47,5%	-57,3%	-37,9%
02	M5662R	7,8	42,8	27,0	28,4	26,4	21,3	35,0	19,2	20,6	18,6	13,5	-45,1%	-41,1%	-46,9%	-61,4%
03	M6574B	5,8	36,5	32,4	34,6	25,5	20,5	30,7	26,6	28,8	19,7	14,7	-13,4%	-6,2%	-35,8%	-52,1%
04	C4090C	9,6	36,0	24,1	17,6	19,2	16,7	26,4	14,5	8,0	9,6	7,1	-45,1%	-69,7%	-63,6%	-73,1%
05	L7014F	8,9	27,7	16,6	15,1	11,3	11,9	18,8	7,7	6,2	2,4	3,0	-59,0%	-67,0%	-87,2%	-84,0%
06	A5705E	6,7	51,0	45,6	48,6	44,6	56,8	44,3	38,9	41,9	37,9	50,1	-12,2%	-5,4%	-14,4%	13,1%
07	D5570A	8,6	37,6	30,3	28,7	28,7	24,2	29,0	21,7	20,1	20,1	15,6	-25,2%	-30,7%	-30,7%	-46,2%
08	S5389G	9,0	56,5	46,9	34,1	32,3	45,2	47,5	37,9	25,1	23,3	36,2	-20,2%	-47,2%	-50,9%	-23,8%
09	D4201C	7,1	39,2	35,6	39,0	35,3	39,7	32,1	28,5	31,9	28,2	32,6	-11,2%	-0,6%	-12,1%	1,6%
10	Y4276N	6,1	37,2	31,3	28,6	21,0	19,8	31,1	25,2	22,5	14,9	13,7	-19,0%	-27,7%	-52,1%	-55,9%
11	T6926M	11,5	30,1	27,5	29,4	31,0	31,1	18,6	16,0	17,9	19,5	19,6	-14,0%	-3,8%	4,8%	5,4%
12	S6924B	7,3	55,2	46,5	47,1	41,2	44,4	47,9	39,2	39,8	33,9	37,1	-18,2%	-16,9%	-29,2%	-22,5%
13	N4388M	6,8	37,9	19,5	15,1	12,3	15,5	31,1	12,7	8,3	5,5	8,7	-59,2%	-73,3%	-82,3%	-72,0%
14	C1421F	6,2	45,1	48,4	38,9	33,5	31,6	38,9	42,2	32,7	27,3	25,4	8,5%	-15,9%	-29,8%	-34,7%
15	G4384A	6,9	44,0	34,7	25,9	23,3	23,6	37,1	27,8	19,0	16,4	16,7	-25,1%	-48,8%	-55,8%	-55,0%
16	M2000D	7,8	41,3	38,7	39,1	33,9	30,2	33,5	30,9	31,3	26,1	22,4	-7,8%	-6,6%	-22,1%	-33,1%
17	R3160L	8,2	53,2	44,5	45,6	40,0	43,6	45,0	36,3	37,4	31,8	35,4	-19,3%	-16,9%	-29,3%	-21,3%
18	A3660C	11,1	30,3	28,2	26,4	19,1	16,5	19,2	17,1	15,3	8,0	5,4	-10,9%	-20,3%	-58,3%	-71,9%
19	P7084S	7,8	77,2	68,7	55,9	38,0	25,4	69,4	60,9	48,1	30,2	17,6	-12,2%	-30,7%	-56,5%	-74,6%
20	D4433A	8,3	80,6	64,3	67,3	65,2	50,8	72,3	56,0	59,0	56,9	42,5	-22,5%	-18,4%	-21,3%	41,2%
21	M6707C	16,8	47,6	37,7	35,0	22,0	20,9	30,8	20,9	18,2	5,2	4,1	-32,1%	-40,9%	-83,1%	-86,7%
22	A6993S	10,1	73,8	54,6	54,6	53,8	33,9	63,7	44,5	44,5	43,7	23,8	-30,1%	-30,1%	-31,4%	-62,6%
23	G5182M	13,5	60,3	23,1	26,6	26,7	28,0	46,8	9,6	13,1	13,2	14,5	-79,5%	-72,0%	-71,8%	-69,0%
24	Q6056T	10,0	50,1	25,0	23,1	20,1	18,2	40,1	15,0	13,1	10,1	8,2	-62,6%	-67,3%	-74,8%	-79,6%
25	S5065L	10,9	76,3	29,1	30,7	31,8	30,0	65,4	18,2	19,8	20,9	19,1	-72,2%	-69,7%	-68,0%	-70,8%
26	S3804D	8,1	53,8	50,7	34,5	36,7	33,4	45,7	42,6	26,4	28,6	25,3	-6,8%	-42,2%	-37,4%	-44,6%
27	B4667B	8,9	36,6	36,4	39,1	39,1	34,2	27,7	27,5	30,2	30,2	25,3	-0,7%	9,0%	9,0%	-8,7%
28	M4428S	8,3	40,5	30,7	28,9	28,3	24,2	32,2	22,4	20,6	20,0	15,9	-30,4%	-36,0%	-37,9%	-50,6%
29	R5349N	9,0	53,7	55,0	49,9	41,8	42,0	44,7	46,0	40,9	32,8	33,0	2,9%	-8,5%	-26,6%	-26,2%
30	B3529I	9,4	72,4	44,5	42,6	42,2	32,2	63,0	35,1	33,2	32,8	22,8	-44,3%	-47,3%	-47,9%	-63,8%
31	B3685R	23,5	86,0	62,8	67,0	64,2	55,8	62,5	39,3	43,5	40,7	32,3	-37,1%	-30,4%	-34,9%	-48,3%
32	P6972D	5,1	45,2	41,6	33,8	27,6	28,1	40,1	36,5	28,7	22,5	23,0	-9,0%	-28,4%	-43,9%	-42,6%
33	B3805S	6,4	30,7	21,7	16,0	12,8	9,4	24,3	15,3	9,6	6,4	3,0	-37,0%	-60,5%	-73,7%	-87,7%
34	L5417A	12,9	50,6	51,0	49,2	48,3	44,9	37,7	38,1	36,3	35,4	32,0	1,1%	-3,7%	-6,1%	-15,1%
35	C6216F	12,1	45,4	22,9	22,8	35,9	32,2	33,3	10,8	10,7	23,8	20,1	-67,6%	-67,9%	-28,5%	-39,6%
		9,2	49,4	37,9	35,6	32,4	30,5	40,2	28,7	26,4	23,2	21,3	-27,9%	-34,0%	-42,5%	-46,8%
		Mean	9,2	49,4	37,9	35,6	32,4	30,5					TR vs UNT	0,000	0,000	0,000
		SE	0,6	2,6	2,3	2,3	2,2	2,0								
		t-Test vs. T-1	----	0,000	0,000	0,000	0,000									
		t-Test vs. TO	----	----	0,000	0,000	0,000	0,000								

SE: standard error

TR: treated area

UNT: untreated (control) area

NOTES:

PART 1 of the tables report the raw data of TEWL expressed as g/h/m².

PART 2 of the tables report the data of TEWL normalized vs T-1 (skin basal values); these data are useful to highlight the variation of TEWL induced by SLS patches.

PART 3 of the tables report the % variations of TEWL values at each experimental time after the product application. These data can be used for marketing purposes in order to express the TEWL % variation both in the treated and untreated areas.

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TABLE 1b. In the tables below TEWL values obtained for each volunteer in the untreated (control) skin site are reported. Data are expressed as g/h/m².

n.	Vol ID	CONTROL AREA (UNTREATED)														
		PART 1			PART 2			PART 3								
T-1	T0	T30min	T1h	T2h	T24h	TO	T30min	T1h	T2h	T24h	T30min	T1h	T2h	T24h		
01	V4252M	5,8	47,5	41,8	44,7	41,6	41,9	41,7	36,0	38,9	35,8	36,1	-13,7%	-6,7%	-14,1%	-13,4%
02	A5662R	8,9	42,5	34,5	32,6	32,9	33,1	33,6	25,6	23,7	24,0	24,2	-23,8%	-29,5%	-28,6%	-28,0%
03	M6574B	5,4	32,9	29,5	28,1	28,6	30,4	27,5	24,1	22,7	23,2	25,0	-12,4%	-17,5%	-15,6%	-9,1%
04	C4090C	9,9	37,1	36,3	32,3	31,0	31,1	27,2	26,4	22,4	21,1	21,2	-2,9%	-17,6%	-22,4%	-22,1%
05	L7014F	7,5	27,4	25,0	22,4	18,9	15,9	19,9	17,5	14,9	11,4	8,4	-12,1%	-25,1%	-42,7%	-57,8%
06	A5705E	7,3	46,4	47,7	40,4	40,2	58,5	39,1	40,4	33,1	32,9	51,2	3,3%	-15,3%	-15,9%	30,9%
07	D5570A	7,1	26,5	27,4	27,9	25,4	24,6	19,4	20,3	20,8	18,3	17,5	4,6%	7,2%	-5,7%	-9,8%
08	S5389G	8,0	53,1	39,5	39,3	39,5	33,7	45,1	31,5	31,3	31,5	25,7	-30,2%	-30,6%	-30,2%	-43,0%
09	D4201C	6,9	40,8	41,8	40,3	48,3	44,4	33,9	34,9	33,4	41,4	37,5	2,9%	-1,5%	22,1%	10,6%
10	Y4276N	6,0	36,7	29,1	29,5	24,2	25,3	30,7	23,1	23,5	18,2	19,3	-24,8%	-23,5%	-40,7%	-37,1%
11	T6926M	10,6	28,7	29,1	27,5	28,7	27,4	18,1	18,5	16,9	18,1	16,8	2,2%	-6,6%	0,0%	-7,2%
12	S6924B	7,8	54,4	57,7	53,1	57,0	46,8	46,6	49,9	45,3	49,2	39,0	7,1%	-2,8%	5,6%	-16,3%
13	N4388M	7,0	37,0	20,6	24,7	24,1	26,3	30,0	13,6	17,7	17,1	19,3	-54,7%	-41,0%	-43,0%	-35,7%
14	C1421F	5,9	46,0	44,8	38,3	40,6	41,8	40,1	38,9	32,4	34,7	35,9	-3,0%	-19,2%	-13,5%	-10,5%
15	G4384A	7,1	39,3	37,5	33,7	32,8	33,7	32,2	30,4	26,6	25,7	26,6	-5,6%	-17,4%	-20,2%	-17,4%
16	M2000D	7,4	40,6	41,6	35,7	32,3	38,7	33,2	34,2	28,3	24,9	31,3	3,0%	-14,8%	-25,0%	-5,7%
17	R3160L	8,5	54,1	50,6	43,2	41,8	36,1	45,6	42,1	34,7	33,3	27,6	-7,7%	-23,9%	-27,0%	-39,5%
18	A3660C	11,3	29,4	27,7	25,0	27,7	24,9	18,1	16,4	13,7	16,4	13,6	-9,4%	-24,3%	-9,4%	-24,9%
19	P7084S	6,0	70,8	72,1	74,7	63,2	52,8	64,8	66,1	68,7	57,2	46,8	2,0%	6,0%	-11,7%	-27,8%
20	D4433A	9,5	80,0	70,4	68,2	78,9	66,9	70,5	60,9	58,7	69,4	57,4	-13,6%	-16,7%	-1,6%	-18,6%
21	M6707C	18,2	49,6	52,7	40,2	31,4	38,7	31,4	34,5	22,0	13,2	20,5	9,9%	-29,9%	-58,0%	-34,7%
22	A6993S	11,4	69,9	68,0	71,8	71,0	61,8	58,5	56,6	60,4	59,6	50,4	-3,2%	3,2%	1,9%	-13,8%
23	G5182M	10,1	53,7	48,7	46,0	42,4	36,1	43,6	38,6	35,9	32,3	26,0	-11,5%	-17,7%	-25,9%	-40,4%
24	Q6056T	9,0	53,1	58,1	50,1	48,0	48,2	44,1	49,1	41,1	39,0	39,2	11,3%	-6,8%	-11,6%	-11,1%
25	S5065L	9,0	75,2	59,2	32,3	38,2	34,4	66,2	50,2	23,3	29,2	25,4	-24,2%	-64,8%	-55,9%	-61,6%
26	S3804D	8,2	51,0	57,8	50,0	46,0	48,2	42,8	49,6	41,8	37,8	40,0	15,9%	-2,3%	-11,7%	-6,5%
27	B4667B	7,6	31,0	37,6	41,5	36,6	38,5	23,4	30,0	33,9	29,0	30,9	28,2%	44,9%	23,9%	32,1%
28	M4428S	8,3	40,3	41,2	34,5	30,1	34,7	32,0	32,9	26,2	21,8	26,4	2,8%	-18,1%	-31,9%	-17,5%
29	R5349N	6,9	59,9	60,9	60,9	60,3	60,3	53,0	54,0	54,0	53,4	53,4	1,9%	1,9%	0,8%	0,8%
30	B3529I	12,3	73,1	64,4	58,5	61,0	53,8	60,8	52,1	46,2	48,7	41,5	-14,3%	-24,0%	-19,9%	-31,7%
31	B3685R	22,7	84,2	73,0	72,2	67,1	72,1	61,5	50,3	49,5	44,4	49,4	-18,2%	-19,5%	-27,8%	-19,7%
32	P6972D	6,4	42,5	37,9	35,0	37,5	30,4	36,1	31,5	28,6	31,1	24,0	-12,7%	-20,8%	-13,9%	-33,5%
33	S3805S	5,3	33,8	27,6	31,5	29,4	34,7	28,5	22,3	26,2	24,1	29,4	-21,8%	-8,1%	-15,4%	3,2%
34	L5417A	12,3	57,7	59,3	55,2	56,6	65,6	45,4	47,0	42,9	44,3	53,3	3,5%	-5,5%	-2,4%	17,4%
35	C6216F	12,4	40,4	37,1	37,5	39,2	44,0	28,0	24,7	25,1	26,8	31,6	-11,8%	-10,4%	-4,3%	12,9%
		9,0	48,2	45,4	42,3	41,5	41,0	39,2	36,4	33,3	32,5	32,1	-6,6%	-14,2%	-16,9%	-16,8%
	Mean	0,6	2,6	2,5	2,4	2,5	2,3									
	SE	0,6	0,000	0,000	0,000	0,000	0,000									
	t-Test vs. T-1	----	0,000	0,000	0,000	0,000	0,000									
	t-Test vs. TO	----	----	0,008	0,000	0,000	0,000									

SE: standard error

NOTES:

PART 1 of the tables report the raw data of TEWL expressed as g/h/m².

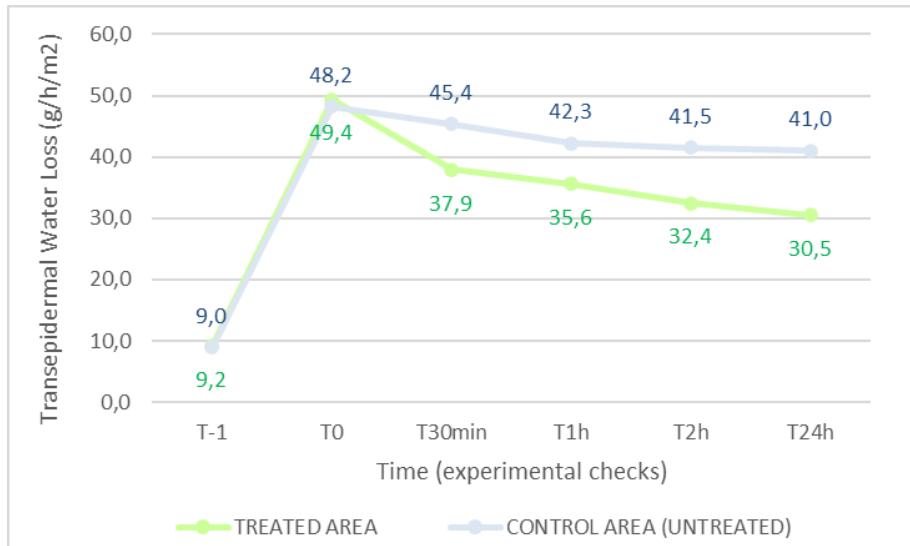
PART 2 of the tables report the data of TEWL normalized vs T-1 (skin basal values); these data are useful to highlight the variation of TEWL induced by SLS patches.

PART 3 of the tables report the % variations of TEWL values at each experimental time after the product application. These data can be used for marketing purposes in order to express the TEWL % variation both in the treated and untreated areas.



GRAPHS 1a-b-c. The graphs below show the variation of transepidermal water loss (TEWL) at each experimental monitored time on the two skin sites.

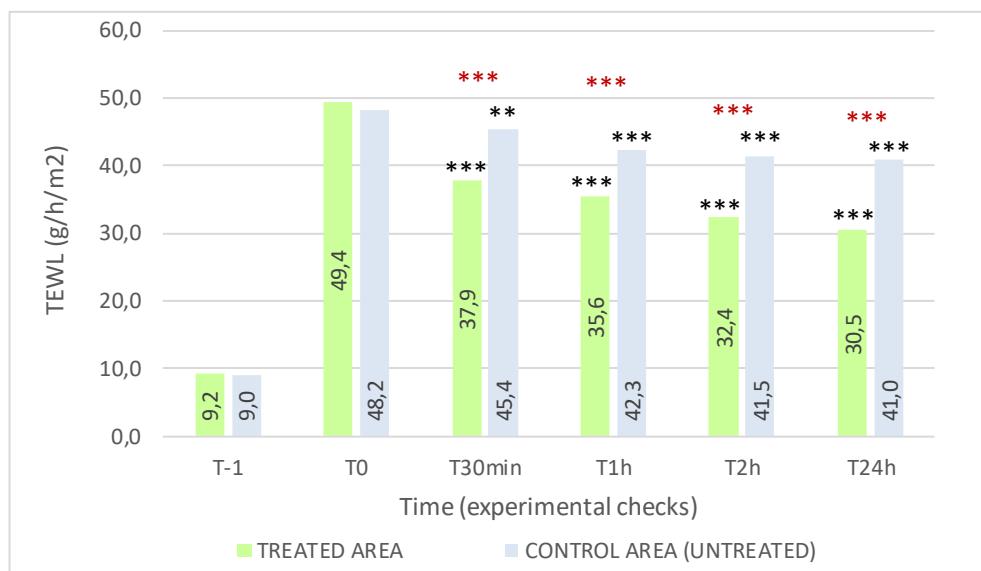
GRAPH 1a (PART 1 OF TABLES 1a/b) - Mean values TEWL starting from basal values (T-1).



GRAPH 1b (PART 2 and 3 OF TABLES 1a/b) - Mean variation of TEWL on data normalized versus basal values (T-1). The graph shows the TEWL values caused by SLS patch and its % variation after product application.



GRAPH 1c - The data of the statistical analysis are reported as asterisks (see notes and legend below).



COMMENT

As it is possible to notice, the application of tested product determines a statistically significant decrease of the SLS-induced TEWL increase 30minutes, 1 hour, 2 hours and 24 hours after its single application (intra-group statistical analysis vs. T0), respectively by -27.9% at T30min, -34.0% at T1h, -42.5% at T2h and -46.8% at T24h.

It can also be noticed that in untreated (control) area, a physiological decrease of TEWL values is recorded starting from T30min, but variations recorded in treated area are statistically higher at each experimental timepoint (inter-group statistical analysis TR vs. UNT).

According to the above reported results, we can be concluded that the product is effective in repairing the cutaneous barrier function alterations (TEWL increase) induced by a chemical irritant (SLS).

NOTES

Black asterisk in the graph report the intra-group (vs T0) statistical analysis.

Red asterisk in the graph report the inter-group (TREATED vs UNTREATED AREA) statistical analysis.

LEGEND

* p<0.05 / **p<0.01 / *** p<0.001



SKIN pH EVALUATION

TABLE 2a/b. In the tables below skin pH values obtained for each volunteer in the treated and untreated (control) skin sites are reported. Data are expressed as pH units.

TREATED AREA				CONTROL AREA (UNTREATED)											
n.	Vol ID	T-1	T0	T2h	T24h	n.	T-1	T0	T2h	T24h	n.	T0	T2h	T24h	
01	V4252M	5,4	6,6	6,1	6,2	01	22,2%	13,0%	14,8%		01	5,6	6,8	6,6	6,4
02	A5662R	5,3	7,0	6,3	5,3	02	32,1%	18,9%	0,0%		02	5,9	7,1	6,5	5,6
03	M6574B	5,9	6,3	5,9	5,9	03	6,8%	0,0%	0,0%		03	5,7	6,5	6,2	6,3
04	C4090C	6,0	6,8	6,3	5,9	04	13,3%	5,0%	-1,7%		04	5,3	6,2	5,8	5,8
05	L7014F	6,1	6,7	5,8	5,9	05	9,8%	-4,9%	-3,3%		05	6,2	6,6	6,4	6,0
06	A5705E	5,7	6,5	6,3	5,7	06	14,0%	10,5%	0,0%		06	5,4	6,4	6,1	5,9
07	D5570A	5,3	7,2	6,1	6,6	07	35,8%	15,1%	24,5%		07	5,2	7,1	6,7	6,1
08	S5389G	5,7	7,3	6,5	5,6	08	28,1%	14,0%	-1,8%		08	5,4	7,3	6,4	5,5
09	D4201C	5,3	7,1	6,5	5,9	09	34,0%	22,6%	11,3%		09	5,4	7,2	6,3	5,8
10	Y4276N	5,8	6,9	6,4	6,1	10	19,0%	10,3%	5,2%		10	5,7	6,8	6,2	5,8
11	T6926M	5,7	6,5	6,3	5,9	11	14,0%	10,5%	3,5%		11	5,9	6,1	6,2	5,9
12	S6924B	5,4	6,8	6,6	5,8	12	25,9%	22,2%	7,4%		12	5,6	6,7	6,6	6,4
13	N4388M	5,6	6,6	6,1	5,6	13	17,9%	8,9%	0,0%		13	5,8	6,7	6,3	5,7
14	C1421F	5,5	6,4	6,0	5,6	14	16,4%	9,1%	1,8%		14	5,4	6,3	5,9	5,7
15	G4384A	5,5	6,5	6,1	5,6	15	18,2%	10,9%	1,8%		15	5,7	6,8	5,8	5,8
16	M2000D	5,6	6,0	5,9	6,0	16	7,1%	5,4%	7,1%		16	5,3	6,2	5,9	5,8
17	R3160L	5,6	6,1	5,8	5,7	17	8,9%	3,6%	1,8%		17	5,3	6,2	5,7	5,8
18	A3660C	5,8	6,2	6,0	5,9	18	6,9%	3,4%	1,7%		18	5,7	6,3	5,9	5,8
19	P7084S	5,4	7,0	6,6	5,1	19	28,2%	20,8%	-6,1%		19	5,8	7,3	6,5	5,9
20	D4433A	5,6	6,4	6,5	5,3	20	14,7%	16,5%	-4,8%		20	5,6	6,4	6,1	5,2
21	M6707C	4,6	5,5	5,5	5,8	21	20,5%	19,9%	26,6%		21	4,6	5,3	5,8	5,6
22	A6993S	5,1	6,2	5,8	5,7	22	20,8%	12,6%	10,7%		22	5,5	6,2	5,8	5,8
23	G5182M	5,2	5,5	5,5	5,1	23	4,2%	5,2%	-2,3%		23	5,2	5,5	5,5	5,0
24	Q6056T	5,1	5,3	5,4	5,3	24	3,1%	4,1%	3,1%		24	5,1	5,5	5,5	5,5
25	S5065L	5,4	6,5	5,6	5,9	25	18,8%	3,3%	7,9%		25	5,4	6,3	5,9	5,7
26	S3804D	5,0	5,8	5,4	5,5	26	16,7%	8,5%	10,9%		26	4,7	5,8	5,0	5,2
27	B4667B	5,6	6,3	6,3	6,1	27	12,7%	12,3%	8,8%		27	5,4	6,3	6,2	6,0
28	M4428S	4,4	4,7	4,7	4,5	28	6,8%	5,9%	3,4%		28	4,4	5,1	5,0	5,0
29	R5349N	5,0	6,6	5,8	5,3	29	33,1%	16,5%	6,2%		29	4,7	6,7	5,9	5,2
30	B3529I	5,1	6,8	5,5	5,2	30	32,0%	6,4%	1,6%		30	5,2	6,1	6,2	5,4
31	B3685R	4,9	6,0	5,8	5,8	31	23,8%	19,3%	18,6%		31	4,8	6,2	5,9	5,7
32	P6972D	5,3	5,2	5,8	5,5	32	-0,2%	10,5%	4,2%		32	5,2	5,6	5,9	5,1
33	B3805S	5,3	5,4	5,4	5,5	33	2,1%	2,3%	3,2%		33	5,5	5,5	5,4	5,3
34	L5417A	5,1	6,6	6,7	5,2	34	29,4%	32,2%	1,8%		34	4,9	6,2	7,0	5,5
35	C6216F	4,9	5,5	5,1	5,4	35	12,9%	5,5%	10,5%		35	4,8	5,5	4,8	4,8
	Mean	5,4	6,3	6,0	5,6		17,4%	10,9%	5,1%			5,3	6,3	6,0	5,7
	SE	0,1	0,1	0,1	0,1		0,552	0,185	0,393			0,1	0,1	0,1	0,1
	t-Test vs. T-1	---	0,000	0,000	0,000		---	---	---			---	0,000	0,000	0,000
	t-Test vs. T0	---	---	0,000	0,000		---	---	---			---	0,000	0,000	0,000
	t-Test vs. UNT	---	---	---	---		---	---	---			---	0,0%	-1,3%	-3,6%

SE: standard error

UNT: untreated (control) area

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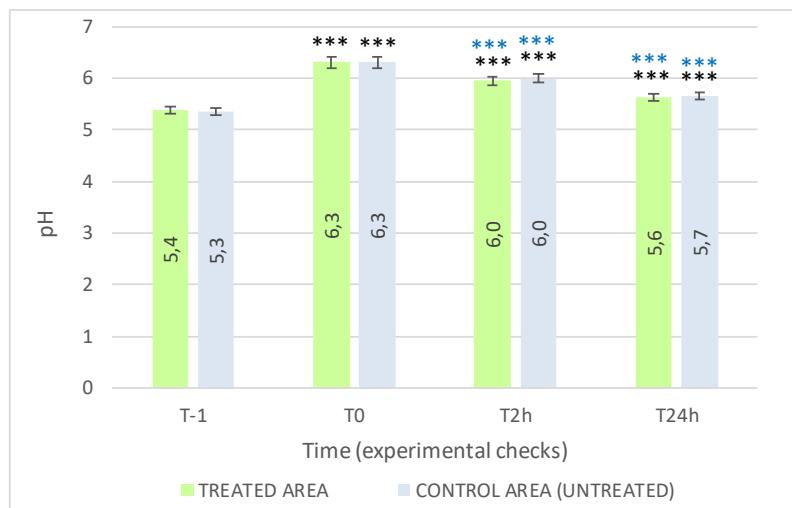
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Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N 030015309008)

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GRAPH 2. The graph shows the mean data obtained at each monitored checkpoint for the analysed parameter. Data are expressed as mean ± SE.



NOTES

Black asterisk in the graph report the intra-group (vs T-1) statistical analysis.

Blue asterisk in the graph report the intra-group (vs T0) statistical analysis.

LEGEND

* p<0.05 / **p<0.01 / *** p<0.001

COMMENT

15 minutes after patch removal, skin pH values are statistically higher compared to baseline values (inter-group statistical analysis T0 vs. T-1).

At the following monitored timepoints (T2h and T24h) skin pH values are still significantly higher compared to baseline values (vs. T-1) even if significantly decreased compared to T0 values, both in treated and untreated (control) areas.

No significant differences are monitored between variations recorded in the two skin sites (inter-group statistical analysis).



Customer	RIVOLI COSMÉTIQUES SA
Record no	H.E.HU.MP.NSO00.035.08.00_IT0005082/22
Date	rev 01 by 13/12/2022

CONCLUSION

According to the results elsewhere reported in this document, we can conclude that the application of

RIVOLI COSMÉTIQUES SA RIVOLI GENÈVE Le Visage NIGHT CREAM

is effective in repairing the cutaneous barrier function alterations induced by a chemical irritant (SLS) at each experimental timepoint (since a decrease of TEWL values is recorded, respectively by -27.9% at T30min, -34.0% at T1h, -42.5% at T2h and -46.8% at T24h after its single application).

In particular, it can be noticed that in untreated area, a physiological decrease of TEWL values is recorded starting from T30min, but in the skin site treated with CRÈME DE NUIT RÉPARATRICE, TEWL decrease is significantly higher.

Recorded variations are statistically significant ($p<0.05$) compared to T0 values (after SLS patch removal) and to those recorded in untreated area at each experimental timepoint (intra- and inter-group statistical analysis).

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