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# Soothing Efficacy of a Cosmetic Ingredient on Skin Discomforts Induced by Mechanical, Chemical and Environmental Stress Agents

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## Abstract

The skin sensitive syndrome is a widespread condition with an impact on the quality of life of the affected subjects. Cosmetics may be formulated specifically for sensitive skin conditions, alleviating the relative symptoms. The present study aimed at evaluating the efficacy of a natural extract containing polysaccharides from *Opuntia ficus-indica* (cladodes extract), biophenols from *Olea Europaea* (olive leaves extract) and flavonoids from *Capparis spinosa* (caper fruit) on skin discomfort induced by different stressors such as skin redness and skin barrier function alteration by shaving/epilation; neurogenic mediated by capsaicin; and skin redness induced by UV exposure. Three randomized double-blind, controlled studies were carried out on 20 Caucasian subjects. Product efficacy was measured by means of both instrumental measures (redness and transepidermal water loss, TEWL) and by subjective scoring of the functional signs (itching/stinging and burning sensations) induced by each stressor. The active ingredient showed to decrease: the skin redness and the TEWL after shaving/epilation, the capsaicin-induced skin discomforts and the UV-induced skin redness. Our results demonstrate the ingredient efficacy in decreasing the skin discomforts induced by physical, chemical and environmental agents. The soothing and protective activities besides this cosmetic ingredient might be used in formulations for sensitive skin condition management.

**Keywords:** Sensitive skin • Natural bioactives • Opuntia ficus-indica • Olea Europaea • Capparis spinosa

## Introduction

The skin is the first protective barrier of our body to external and environmental stressors and constitutes the first line of defense against them. The totality of these environmental stressors, known also as skin exposome [1], alters the skin barrier efficiency leading to skin sensitivity. The skin sensitive syndrome is a widely reported dermatological complaint with a prevalence of 50-60% among men and 60-70% among women [2]. Due to its subjective symptoms and the lack of clearly visible manifestation, in the past the sensitive skin condition has been underestimated or even neglected; however, nowadays is well recognized as a widespread condition having an impact on the quality of life of the affected subjects [3]. When exposed to subliminal physical, chemical, or thermal stressors, patients with sensitive skin syndrome usually experience skin discomforts such as stinging, pruritus, pain, burning and tingling sensations [4]. Sensitive skin can affect all body sites even if the face is the most commonly reported site, probably due to a thinner barrier, a higher number of nerve endings and its exposure to the environment [3]. The pathophysiology of sensitive skin syndrome is intricate and not well understood. Neurogenic- [5-7] and immune-related effects [8,9] and alteration of the skin barrier function [10,11] have been clearly identified by mechanistic studies as the three major components in the sensitive skin condition pathogenesis. Therefore, in these cases, cosmetic products need to be formulated taking into consideration the sensitive skin, formulating finished formula effective in alleviating sensitive skin symptoms [12,13] to avoid their exacerbation.

In the current study, we were interested in investigating the efficacy of a natural cosmetic ingredient (SKIN SAVE™, Bionap Srl, 95032 Piano Tavola Belpasso, CT, Italy) containing polysaccharides from *Opuntia ficus-indica* L. (cladodes extract), biophenols from *Olea Europaea* L. (olive leaves extract) and flavonoids from *Capparis spinosa* L. (caper fruit) on skin discomfort induced by different stressors such as mechanical, chemical and environmental. Previous *in vitro* studies demonstrated an antiallergic and antihistaminic effect of a Capparis spinosa extract [14]; while flavonoids have been shown to inhibit histamine release and expression of proinflammatory cytokines in mast cells [15]. On humans, the ingredient showed to decrease the erythema extent in subjects undergoing radiation therapy after breast-conserving surgery [16]. This study aims to further investigate and explore in more detail the product efficacy in alleviating the skin discomforts induced by two physical (skin redness and skin barrier function alteration by shaving/epilation and skin redness induced by UV exposure) and one chemical (neurogenic mediated capsaicin stinging sensation) agents. These acute stressors alter the physical barrier of the skin causing dryness, sensitive skin, tightening, stinging, burning and redness, among others.

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# Materials and Methods

## Settings and locations

The studies aimed to assess the soothing efficacy on the skin discomforts induced after epilation/shaving and capsaicin stinging test were carried out in the Complife Italia Srl facility located in Biella (Corso San Maurizio, 25, 13900, Biella, BI). The study aimed to assess the soothing on theskin discomforts induced by UV-radiation was carried out in the Complife Italia Srl facility located in Pavia (Via Monsignor Angelini 21, 27028, S. Martino Siccomario, PV). Complife Italia Srl is an independent international group of laboratories for *in vitro*, chemical, microbiological and clinical testing of cosmetics, medical devices and nutraceuticals.

## Intervention

The test item was a natural cosmetic ingredient (SKIN SAVE™, Bionap Srl, 95032 Piano Tavola Belpasso, CT, Italy) containing polysaccharides from *Opuntia ficus-indica* L. (cladodes extract), biophenols from *Olea Europaea* L. (olive leaves extract) and flavonoids from *Capparis spinosa* L. (caper fruit). The concentration (w/w) of each single extract is as follows: 13-15% *Opuntia ficus-indica* extract, 15-18% *Olea Europaea* extract, 18-20% *Capparis spinosa* extract and 47-54% maltodextrin.

The ingredient was added to a cosmetic formula (cream) at 1.5%, w/w. The ingredient list of the active cream was as follows: Aqua/Water, Caprylic/capric triglyceride, sodium acrylate/sodium acryloyldimethyl taurate copolymer, propanediol, dicaprylyl ether, glyceryl stearate citrate, oleyl erucate, olea europaea (olive) leaf extract, opuntia ficus-indica stem extract, capparis spinosa fruit extract, maltodextrin, squalane, sodium phytate, alcohol, xanthan gum, tocopherol, phenoxyethanol, ethyhexylglycerin, citric acid.

The placebo cream contained the same ingredients except for the active ingredient (Olea Europaea (Olive) Leaf extract, Opuntia Ficus-Indica Stem Extract, Capparis Spinosa Fruit Extract, Maltodextrin).

Both the active and the placebo products were applied under controlled conditions as described here below.

- **Soothing efficacy on epilation/shaving:** 2 mg/cm$^2$ of both the active and the placebo creams were applied on the left/right side of the face (shaving efficacy) or on the left/right side of the legs (epilation).
- **Soothing efficacy on capsaicin:** both the active and the placebo creams were applied on the nasolabial fold using a cotton swab.
- **Soothing efficacy on UV radiation:** 2 mg/cm$^2$ of both the active and the placebo creams were applied in two selected areas of the back after UV-R exposure.

## Study design description

The soothing efficacy of the ingredient was tested in three independent clinical trials as described in the sections here below. The design of each trial was single-center, randomized (half-face/body product application), double-blind and placebo-controlled.

All the study procedures were conducted in compliance with the ethical principles for medical 131 research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18$^{th}$ WMA General Assembly Helsinki, Finland, June 1964 and amendments). A signed informed consent form and the consent release form for the publication of photographs were obtained from all the subjects participating in the study before any study-related procedure took place.

As recommended by Colipa (now Cosmetics Europe) guidelines the test product was assessed for its safety of use before the study took place [17]. According to the EU cosmetic Regulation no. 1223/2009, the cosmetic product must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use and must be assessed for its safety of use before human subjects are exposed to it and as such, further ethical approval is not required.

**Assessment of the soothing efficacy on the skin discomforts induced by shaving and epilation:** This trial aimed to assess the efficacy of the ingredient in soothing the skin discomforts (skin redness and itching/stinging and burning sensations) induced by shaving and epilation. To reach this goal, ten (n=10) male and ten (n=10) female subjects were enrolled by a board-certified dermatologist. Inclusion criteria were age between 18 and 65 years old (extremes included), sensitive skin and skin prone to irritation after shaving (for men) and waxing (for women). Exclusion criteria were chosen to recruit a healthy study population.

The product soothing efficacy was measured 30 minutes after its application by means of both instrumental measures and subjective assessment. Skin erythema was measured using a tristimulus colorimeter (Mexameter® MX 18, Courage + Khazaka electronic GmbH, Cologne, Germany) while TEWL was measured using an open chamber evaporimeter (Tewameter® TM 300, Courage + Khazaka electronic GmbH, Cologne, Germany). Skin discomforts (itching/stinging and burning sensations), after shaving/epilation, were evaluated according to the following clinical scoring system: 0 no discomfort, 1 very slight discomfort, 2 slight discomfort, 3 moderate discomfort and 4 strong discomfort. The soothing efficacy, 30 minutes after product application, was evaluated according to the following clinical scoring system: 0 no effect, 1 mild effect, 2 sufficient effect, 3 fairly good effect, 4 good effect and 5 very good effect. At the end of the study, subjects were asked to give their opinion on product efficacy and their overall satisfaction. Digital pictures of the legs were taken using a digital camera (Nikon D300, Nikon, Tokyo, Japan) to show product efficacy in decreasing skin redness.

Cross-polarized digital pictures of the face were taken with VISIA®-CR (Canfield Scientific Europe, BV, Utrecht, Netherlands). The study timeline is summarized in Table 1.

**Assessment of the soothing efficacy on the skin discomforts induced by capsaicin stinging test:** This trial aimed to assess the efficacy of the ingredient in soothing the skin discomforts (stinging/burning and itching sensation) induced by capsaicin. To reach this goal twenty (n=20) male and female (no specific repartition) subjects were enrolled by a board-certified dermatologist. Inclusion criteria were age over 18 years old and sensitivity to the capsaicin-induced stinging sensation. Exclusion criteria were chosen to recruit a healthy study population. The stinging sensation was induced by a 10% capsaicin hydroalcoholic solution. The capsaicin solution was applied on both the left and right nasolabial folds (alar grooves) using a cotton pad. The active and the placebo products were then applied (using a cotton pad) when the stinging sensation was at its maximum (approximately 2/3 minutes after capsaicin solution application). The soothing efficacy was then assessed for 10 minutes at fixed intervals (Figure 1). The stinging/burning and the itching

**Table 1.** Timeline of the assessment of the soothing efficacy on the skin discomforts induced by shaving and epilation.

| Checkpoints | Shaving (n=10 male) | Epilation (n=10 female) |
|---|---|---|
| T-1 | Measurement of the baseline value of TEWL and erythema index | |
| | **Shaving with disposable razor blade** | **Legs waxing (epilation) by a beautician** |
| | ↓↓↓ | ↓↓↓ |
| | **Product application (2 mg/cm$^2$) by the investigator** | |
| T0* | Approximately 10 minutes after shaving: measurement of TEWL and erythema index, andproducts application | |
| T30 min* | 30 minutes after product application: measurement of TEWL, erythema index, soothing effecton itching/stinging and burning sensation (subjective evaluation), self-assessment questionnaire | |


**Figure 1.** Timeline of the assessment of the soothing efficacy on the capsaicin induced stinging sensation. T0capsaicin application; Tmax maximum stinging reaction (approximately 2/3 minutes) from capsaicin application, product application; T1st immediately after product application; T1-T10 1, 2, 3, 4, 5 and 10 minutesafter product application. Digital pictures.

sensation were evaluated according to the following clinical scoring system: 1 no reaction, 2 mild reaction, 3 moderate reaction and 4 severe reaction. Cross-polarized digital pictures of the face were taken with VISIA®-CR (Canfield Scientific Europe, BV, Utrecht, Netherlands). The capsaicin-induced skin redness was then shown using the RBX® algorithm applied to the VISIA®-CR pictures, as described by Ramazan and colleagues [18].

**Assessment of the soothing efficacy on the skin discomforts induced by UVA+B radiation:** This trial aimed to assess the efficacy of the ingredient in reducing the skin discomforts (erythema) induced by exposure to UVA+B radiation. To reach this goal twenty (n=20) male and female (no specific repartition) subjects were enrolled by a board-certified dermatologist. Inclusion criteria were age over 18 years old and skin phototype in the range I-III (Fitzpatrick classification). Exclusion criteria were chosen to recruit a healthy study population.

Before starting the main test, the provisional minimal erythemal dose (MED, the lowest dose of ultraviolet radiation that produces the first perceptible unambiguous erythema with defined borders) was determined by applying a preliminary series of UV exposures based on the skin phototype. The UV dose corresponding to the MED was then visually assessed 20 ± 4 hours after UV exposure.

The skin erythema was induced by a UV dose corresponding to a 1.5 MED UVA+B dose. The source of UVA+B radiation was a Multiport 601–300 W Solar simulator (Solar® Light Co., Inc., Philadelphia, PA, USA) compliant with ISO 24444:2010 standard requirements. The UVB dose was adjusted with a PMA 2103 LLG SUV detector (Solar® Light Co., Inc., Philadelphia, PA, USA). The solar simulator output was compliant with ISO 24444 requirements (Supplementary Figure S1) [19]. Skin erythema was measured using a tristimulus colorimeter (Mexameter® MX 18, Courage + Khazaka electronic GmbH, Cologne, Germany) before UV exposure and after 30 minutes, 1 hour and 2 hours after the first products application and 14 hours after the second products application. The study timeline is summarized in Table 2.

## Randomization and masking

The randomization list was created by the study director (V.N.) using PASS 11 (version 11.0.10, PASS, LLC. Kaysville, UT, USA) statistical software running on Windows Server 2019 Standard 64- bit edition (Microsoft, Redmond, WA, USA). Half of the subjects received the active product on the left side of the face/body and half of the subjects received the placebo product on the right side of the face/body. The randomization list was stratified with a 1:1 allocation rate using the "Efron's biased coin" algorithm. The allocation sequence was then concealed, while a masked allocation sequence was then prepared to be used by the staff applying the product. Subjects, investigators and collaborators were blinded.

## Statistical methods

We used a two-way Student's t-test for parametric data, while a Wilcoxon (intragroup analysis) or Mann–Whitney test (intergroup analysis) was used for non-parametric data. Before any statistical analysis took place the normal distribution of each dataset was checked by Shapiro–Wilk W test. The statistical analysis was carried out using NCSS 10 (version 10.0.7 for Windows; NCSS, Kaysville, UT, USA) running on Windows Server 2019 Standard 64-bit edition (Microsoft, Redmond, WA, USA). A $p<0.05$ was considered statistically significant. The level of significance was reported as follows: * $p<0.05$, ** $p<0.01$ and *** $p<0.001$.

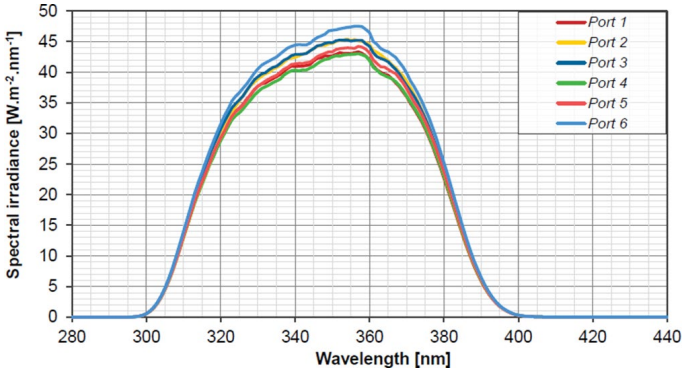


**Figure S1.** Spectral irradiance of each port (UV output) of the solar simulator.

# Results

## Soothing efficacy on the skin discomforts induced by shaving/epilation

A single application of the active product showed a statistically significant reduction in the rednessreaction induced both by shaving and epilation (Table 3). The overall increase of the skin redness, after shaving/epilation and before the treatment with active and placebo formulas, was by 28.2% and 22.9%, respectively. However, epilation induced more severe skin redness before treatment (+40.9% and +32.0%, in the active and placebo groups, respectively) than shaving (+15.4% and +13.7%, in the active and placebo groups respectively). Thirty minutes after the active product application the overall (shaving and epilation) erythema index decreased by 16.3% with a maximum value recorded of -33%, while in the placebo-treated half-face/body the reduction of the erythema index was by - 8.1%. The reduction of the erythema index caused by epilation, 30 minutes after products application, was by 23.1% and by 11.1%, in the active and in the placebo half-body, respectively. The reduction of the erythema index caused by shaving, 30 minutes after products application, was by 9.5% and by 5.1%, in the active and in the placebo treated half-face, respectively. Differences between active and placebo-treated skin sites were statistically significant and clinically evident (Figure 2).

The product application was also effective in reducing the TEWL after both shaving and epilation (Table 3). After 30 minutes from products application, the overall TEWL reduction was by 8.9% and by 6.3%, in the active and in the treated half-face/body, respectively. The product effect in reducing the TEWL was by 7.4% and by 13.5% for epilation and shaving respectively. Differences between active and placebo-treated skin sites were not statistically significant even if a positive trend effect was observed for the active product application. In the active-treated group, the itching/stinging sensation was decreased in 76% (100% epilation and 50% shaving) of the subjects, while the burning sensation was decreased in 63% (67% epilation and 60% shaving) of the subjects (Table 3).

The clinical/instrumental measurement was also perceived by the subjects participating in the study (Table 4). The subjects scored the product effective for all the questionnaire items.

## Soothing efficacy on the skin discomforts induced by capsaicin stinging test

A single application of the active product showed a statistically significant

**Table 2.** Timeline of the assessment of the soothing efficacy on the skin discomforts induced by UVA+B radiation.

| Checkpoints | Control (untreated) area | Treated areas |
|---|---|---|
| T-1 | Measurement of the baseline value of erythema index | |
| **Exposure to a fixed dose (1.5 MED) of UVA+B** | | |
| T0* | Measurement of the erythema index 20 ± 4 hours after UVA+B exposure | |
| **Products (active/placebo) application (2mg/cm²) by the investigator.** | | |
| T30 min* | Measurement of the erythema index value 30 minutes after products application. | |
| T1 h* | Measurement of the erythema index value 1 hour after the first products application. | |
| T2 h* | Measurement of the erythema index value 2 hours after the first products application. | |
| **Products (active/placebo) application (2 mg/cm²) by the subjects, approximately 8 hours after the 1st product application.** | | |
| T24 h** | Measurement of the erythema index value 24 hours after products application and 14 hoursafter the second products application. | |

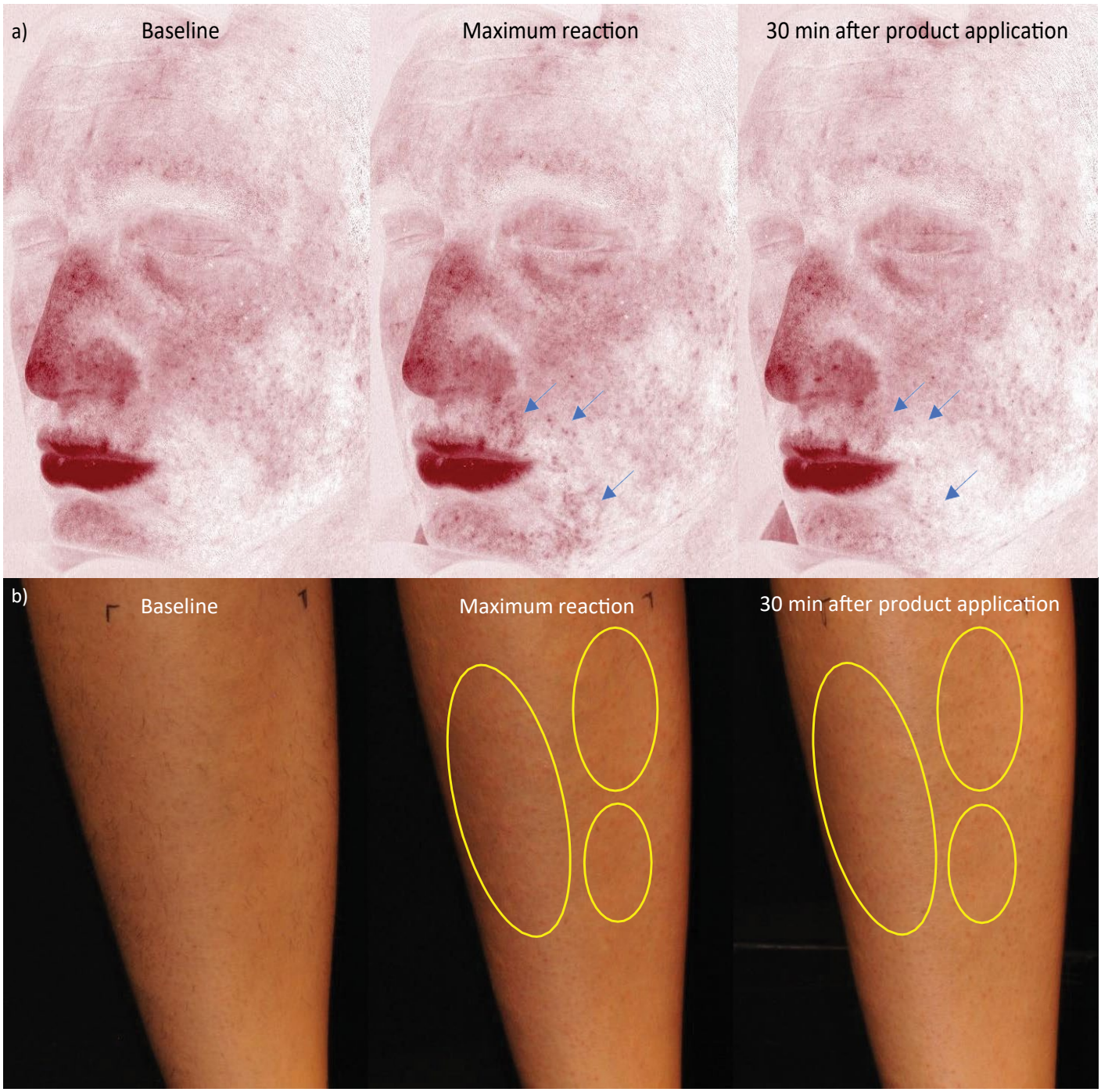


**Figure 2. a)** RBX® red pictures. The pictures show the skin redness component of the skin before and after shaving and product use. As It is possible to notice, the test product determines a decrease of the skin redness induced by shaving (arrows). **b)** Digital pictures. The pictures show the product effect in decreasing the skin redness induced by epilation (circles).

reduction in the stinging/burning sensation. When compared to the baseline, a reduction of the stinging sensation was recorded immediately after the first product application and at all the checkpoints. A statistically significant decrease in the stinging sensation, immediately after the first product application, was recorded also in the skin site treated with the placebo formula. However, both the intensity of the effect and the time course of the capsaicin stinging/burning sensation were most favorable for the active treated site (Figure 3a). Interestingly, at the end of the test (after 10 minutes from products application) the capsaicin stinging/burning reaction was almost extinguished (no reaction) in the active treated site, while it remained higher (mild reaction) in the placebo treated skin site. During the capsaicin test we also investigated the itching sensation. This sensation was recorded in 14 (out of 20) subjects. The itching sensation in the active-treated skin area was completely extinguished 4 minutes after product application, while remained higher in the placebo-treated skin area (Figure 3b). The active product was then effective in halving the itching sensation resolution time. The intergroup (active vs. placebo) statistical analysis output highlights a faster decrease of the stinging sensation in the active group. The scoring of the stinging/burning and itching reaction was lower in the active group at all the checkpoints.

## Soothing efficacy on the skin discomforts induced by UV radiation

The application of the active product showed a statistically significant reduction of the skin redness induced by the exposure to 1.5 MED UVA+B radiation up to 2 hours from product application. The decrease in skin redness was by 14.9%, 18.4% and 16.4%, respectively after 30 minutes, 1 and 2 hours from active product application. The variation of skin redness within the placebo group was not statistically significant. Interestingly, in the placebo-

**Table 3.** Erythema index and TEWL after shaving/epilation and product application. In bracket is reported the percentage variation vs. T0 or the % of subjects showing an improvement. * statistically significant vs. placebo; T0 after shaving/epilation. The itching/stinging and burning sensation was scored at baseline as follows: 0 no discomfort, 1 very slight discomfort, 2 slight discomfort, 3 moderate discomfort, 4 strong discomfort. The soothing efficacy, 30 minutes after product application, was evaluated according to the following clinical scoring system: 0 no effect, 1 mild effect, 2 sufficient effect, 3 fairly good effect, 4 good effect, 5 very good effect.

| | | Active | | | Placebo | | |
|---|---|---|---|---|---|---|---|
| | | T-1 | T0 | T30 min | T-1 | T0 | T30 min |
| Erythema index | Overall | 326.1 ± 33.4 | 393.3 ± 33.9 | 338.1 ± 33.8 (-16.3%, *) | 333.5 ± 34.3 | 393.2 ± 36.4 | 366.9 ± 36.8 (-8.1%, *) |
| | Shaving | 193.5 ± 24.4 | 259.4 ± 24.8 | 200.6 ± 21.6 (-9.5%, *) | 193.0 ± 21.4 | 246.8 ± 20.7 | 221.4 ± 25.2 (-5.1%) |
| | Epilation | 458.8 ± 14.7 | 527.3 ± 15.3 | 475.6 ± 13.0 (-23.1%, *) | 474.0 ± 11.5 | 539.5 ± 19.9 | 512.3 ± 19.5 (-11.1%) |
| TEWL | Overall | 10.2 ± 0.8 | 12.4 ± 1.0 | 10.9 ± 0.7 (-8.9%) | 10.1 ± 0.8 | 12.7 ± 1.2 | 11.6 ± 0.9 (-6.3%) |
| | Shaving | 10.7 ± 0.5 | 13.2 ± 0.9 | 11.3 ± 0.6 (-13.5%) | 10.7 ± 0.6 | 13.4 ± 1.0 | 11.9 ± 0.6 (-9.4%) |
| | Epilation | 9.7 ± 1.5 | 11.6 ± 1.7 | 10.5 ± 1.3 (-7.4%) | 9.5 ± 1.5 | 12.0 ± 2.2 | 11.2 ± 1.8 (-3.1%) |
| Itching/stinging | Overall | --- | 2.4 ± 0.2 | 1.2 ± 0.3 (76%) | --- | 2.2 ± 0.2 | 1.0 ± 0.3 (53%) |
| | Shaving | --- | 2.1 ± 0.1 | 0.8 ± 0.4 (50%) | --- | 2.3 ± 0.8 | 0.8 ± 0.4 (38%) |
| | Epilation | --- | 2.7 ± 0.3 | 1.7 ± 0.3 (100%) | --- | 2.2 ± 0.3 | 1.2 ± 0.4 (67%) |
| Burning | Overall | --- | 1.9 ± 0.2 | 1.1 ± 0.2 (63%) | --- | 1.8 ± 0.2 | 0.9 ± 0.2 (53%) |
| | Shaving | --- | 2.0 ± 0.2 | 1.0 ± 0.4 (60%) | --- | 2.1 ± 0.2 | 0.9 ± 0.3 (50%) |
| | Epilation | --- | 1.8 ± 0.2 | 1.1 ± 0.4 (67%) | --- | 1.6 ± 0.2 | 0.9 ± 0.4 (56%) |

**Table 4.** Self-assessment questionnaire output. Data are reported as % of subjects giving a particular response to each questionnaire item. Positive answers are the sum of the scores "Completely agree" and "Agree".

| No. | Item | Completely agree | Agree | Disagree | Completely disagree | Positive answers |
|---|---|---|---|---|---|---|
| 1 | The skin feels more comfortable | 0.00% | 90.0% | 100% | 0.00% | 90.00% |
| 2 | The product reduces the irritating effect of epilation | 0.00% | 70.0% | 30.00% | 0.00% | 70.00% |
| 3 | The product soothes epilation burn | 0.00% | 90.00% | 10.00% | 0.00% | 90.00% |
| 4 | The product provides immediate soothing sensation | 0.00% | 80.00% | 20.00% | 0.00% | 80.00% |
| 5 | The product improves skin redness | 0.00% | 60.00% | 40.00% | 0.00% | 60.00% |
| 6 | The product soothes itching | 0.00% | 80.00% | 20.00% | 0.00% | 80.00% |
| 7 | The overall skin appearance is improved | 0.00% | 80.00% | 20.00% | 0.00% | 80.00% |
| 8 | Satisfied of the result of the treatment | 0.00% | 80.00% | 20.00% | 0.00% | 80.00% |
| 9 | Would you suggest the use? | 0.00% | 80.00% | 20.00% | 0.00% | 80.00% |
| 10 | Are you going to continue the use? | 0.00% | 80.00% | 20.00% | 0.00% | 80.00% |

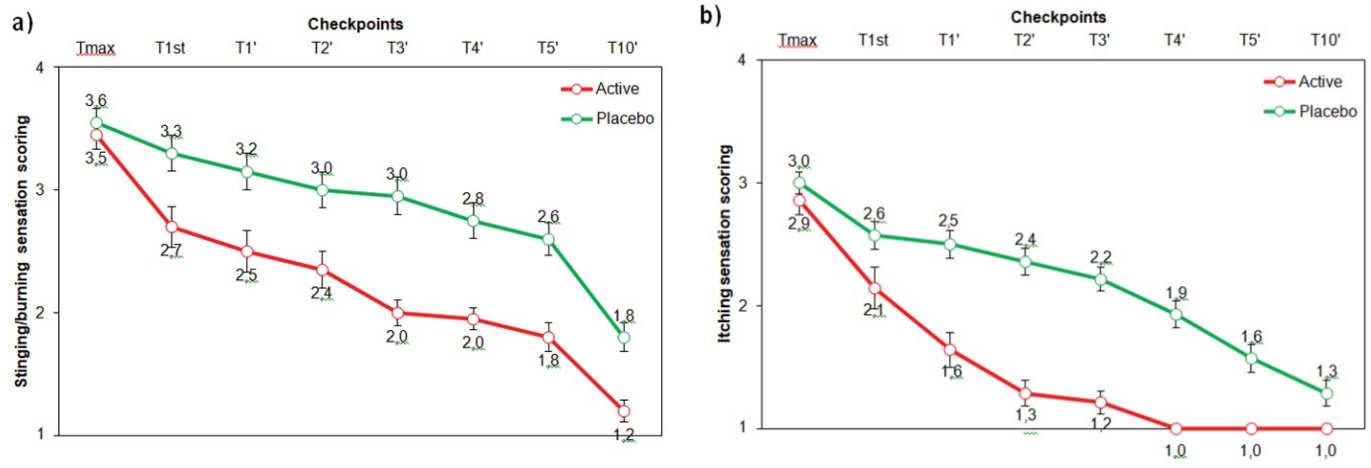


**Figure 3.** Capsaicin stinging test results. **a)** Stinging/burning sensation and **b)** Itching sensation. Clinical scoring of stinging sensation at each checkpoint. Data are reported as mean ± SEM.

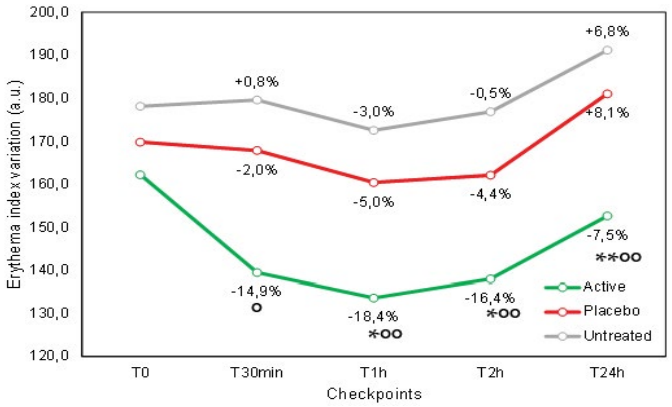


**Figure 4.** Mean variation of skin redness on data normalized *vs.* baseline. Data are reported as mean variation vs. baseline, while in the legend is reported the percentage variation of the normalized data vs. the baseline value. Statistical analysis (active vs. placebo) is reported as follows: * p<0.05, ** p<0.01. Statistical analysis (active vs. untreated) is reported as follows: ° p<0.05, °° p<0.01.

treated skin site there was an exacerbation of the skin redness by +8.1%; while, even if not statistically significant, in the active treated skin site the skin redness was taken under control (-7.5%).

In the untreated area (negative control) the skin redness reaction was stable (nearly unchanged) over time. The intergroup (active vs. placebo) statistical analysis output highlights a faster decrease of skin redness in the active group (Figure 4).

## Discussion

Sensitive skin is a complex syndrome. Among others, the neurosensorial dysfunction and inflammatory processes lead to a decreased skin tolerance threshold and to skin erythema [20,21]. The objective of this study was to evaluate the efficacy of a natural active cosmetic ingredient for sensitive skin and more in general for all the skin discomforts caused by skin barrier disruption and erythema. Regarding the treatment of the sensitive skin syndrome, the use of skin care formulations with soothing effects is recommended [12,13,22].

The tested active product was a natural ingredient containing polysaccharides from *Opuntia ficus-indica* L. (cladodes extract), biophenols from *Olea Europaea* L. (olive leaves extract) and flavonoids from *Capparis spinosa* L. (caper fruit); polyphenols have already been reported to have *in vitro* antiallergic, antihistaminic and anti-inflammatory effects [14,15] as well as this active has been reported to decrease the erythema extent in subjects undergoing radiation therapy after breast- conserving surgery [16].

Using different skin stressors (mechanical, chemical and environmental), we tested the ability of the active ingredient in soothing the skin discomforts induced by shaving and epilation, capsaicin application on the skin and UV radiation.

## Conclusion

The results on the effectiveness of the active ingredient provided evidence for immediate and long- term relief of the skin symptoms such as redness, stinging, itching and burning sensation caused by physical, chemical and environmental stress. Interestingly, even if the difference between placebo and active was not statistically significant, the skin barrier to water (TEWL) alteration induced by shaving/epilation was also improved. A non-statistically significant difference would be expected immediately after product application since repetitive stress is required to induce stable barrier damage.

By counteracting the effects of physical, chemical and environmental stress and damage to the skin barrier, cosmetic formulas containing this active ingredient could provide effective care for sensitive skin.

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## Conflict of Interest

The authors declare that there is no conflict of interest associated with this manuscript.

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