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"A multi-dimensional approach for antiperspirants evaluation"

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1. Introduction

The deodorant and antiperspirant category represents one of the most relevant segments of the cosmetic industry, playing an essential role in daily personal care routines and significantly impacting consumer comfort, hygiene, and well-being [1]. Antiperspirant action is primarily mediated by aluminum-based salts, which temporarily obstruct the ducts of the sweat glands, thereby reducing perspiration. Deodorant efficacy, in turn, is mainly achieved through the use of antibacterial agents that inhibit the growth of odor-causing bacteria [2]. The effectiveness of these formulations has historically been the main focus of the industry, which continuously invests in technologies aimed at enhancing performance and extending the duration of protection [1,3].

However, the pursuit of high performance should not overlook the need for skin care, particularly when considering the anatomical and physiological peculiarities of the axillary region. Axillary skin tends to be more humid and is frequently exposed to external aggressors, such as friction from natural movement, regular hair removal, and the continuous use of cosmetic products. These conditions make it especially vulnerable to irritation, itching, and post-inflammatory hyperpigmentation [4]. Furthermore, the axillary region harbors a diverse microbiota, the balance of which is crucial for maintaining skin health. Prolonged use of occlusive or antimicrobial products may disrupt this microbial equilibrium, contributing to skin barrier dysfunctions [5].

In this context, the development of formulations that not only provide effective deodorant and antiperspirant action but also promote axillary skin health becomes increasingly relevant (skincareification). This study presents the development and evaluation of a novel antiperspirant formulation containing ingredients designed to offer multiple benefits for the armpits, including dermoprotective and microbiota-modulating properties. The formulation promotes comprehensive axillary skin care while maintaining high functional performance. It responds to growing consumer demand for multifunctional cosmetic products and represents a significant advancement in the evolution of modern antiperspirants.

2. Materials and Methods

2.1. Ethical compliance

The clinical trials were conducted under Resolution 466/12 of the National Council of Health on Regulatory Guidelines and Standards for Research Involving Humans. The research protocol received approval from the Institutional Ethics Committee. Only

participants who voluntarily consented to participate by signing the Informed Consent Form, after receiving a complete explanation of the study, the risks involved, and the necessary procedures for adherence to the study, were included. The citation of participants was carried out through anonymized codes, maintaining the confidentiality of personal information and complying with the guidelines of LGPD.The study's data collection and processing were conducted in compliance with current Brazilian legislation on data protection and other applicable Brazilian regulations for clinical trials, always respecting the confidentiality of the data, privacy, and non-stigmatization of participants.

2.2. Development, stability and safety evaluation of the formulation

An oil-in-water (O/W) emulsion was developed, specifically designed for roll-on application. The emulsifying system consisted of a combination of steareth-2 and steareth-21, while the antiperspirant active used was aluminum zirconium pentachlorohydrate. Additional skin care ingredients, such as moisturizing agents and a prebiotic compound, were incorporated to promote skin barrier function and support axillary microbiota balance. A detailed list of these components is provided in the Results section.

The physicochemical stability of the formulation was evaluated in accordance with the guidelines established by the Brazilian Health Regulatory Agency [6]. The parameters assessed included color, odor, appearance, viscosity, and pH of samples stored at 5 ± 2°C, 25 ± 2°C, and 40 ± 2°C for a period of 91 days.

All ingredients in the formulation were assessed to be safe for use as cosmetic ingredients. After the assessment of the toxicological endpoints, following SCCS (Scientific Committee on Consumer Safety) guidelines, and the ingredients safety approval, safety clinical trials data were assessed to confirm the product compatibility to the skin and its acceptability. In accordance with the Cosmetic Product Safety Evaluation Guide [7], an Open Test and an In-Use Acceptability Study were conducted to assess the safety of the formulation. Assessed by dermatologists, these studies aimed to confirm the absence of risk for primary and/or cumulative irritation and to capture any discomfort sensations reported by volunteers under normal or reasonably foreseeable use conditions.

2.3. Evaluation of Deodorant and Antiperspirant Efficacy

The deodorant and antiperspirant effects of the formulation were assessed in a randomized, controlled clinical study involving 60 participants, aged between 18 and 60 years, of Caucasian and Afrobrazilian ethnicities. Prior to the intervention, participants were instructed to refrain from using any deodorant, cream, or topical product in the axillary region for 17 days, during which they were to cleanse the area exclusively with a neutral soap provided by the researchers. To ensure the absence of residual aluminum in the axillary region, a qualitative screening test was conducted before product application. On the first day of the study, the axillary area was washed and dried under researcher supervision following a standardized protocol. A measured dose of 0.401 ± 0.001 g of the investigational product was applied to a delimited axillary area of 100 cm². The application was performed once daily for three consecutive days on one axilla, while the contralateral axilla remained untreated to serve as a control. After each application, participants remained in a controlled environment for 30 minutes to ensure complete drying and film formation.

Deodorant efficacy was evaluated 72 hours after the last application, using the sensory olfactory method according to ASTM E1207-14: *Standard Guide for Sensory Evaluation of Axillary Deodorancy* [8]. Odor intensity was assessed by three trained

evaluators using an 11 point scale (0 = no odor; 10 = extremely strong odor), with intra-subject comparison between the treated and untreated axillae.

Antiperspirant efficacy was assessed via gravimetric analysis, as described in the *Guidelines for Effectiveness Testing of OTC Antiperspirant Drug Products*, FDA [9]. Sweat production was quantified under standardized conditions, 72 hours after the last application, to evaluate the reduction in perspiration attributable to the investigational product.

2.4. Evaluation of Axillary Microbiota

The axillary microbiota of 36 volunteers were collected in conjunction with the clinical evaluation of deodorant and antiperspirant efficacy, as described in the previous section. To monitor microbiota modulation throughout the study, four time points were defined: before the conditioning period (T−17), after the conditioning period and prior to the first application of the investigational product (T0), immediately after the last application (T3), and 72 hours after the final application (T72).

The microbiota samples were collected using a sterile cotton swab, which was passed over the axillary region for 30 seconds, and stored in 1.5 mL Eppendorf tubes. For microbiota analysis, quantitative Polymerase Chain Reaction (qPCR) was performed to assess the abundance of three microorganisms: *Staphylococcus epidermidis* (a beneficial microorganism commonly found on the skin), *Staphylococcus aureus* (an opportunistic pathogen associated with skin dysbiosis, such as atopic dermatitis), and *Corynebacterium xerosis* (a bacterium linked to skin infections and malodor).

DNA extraction was carried out using the MagMAX™ Microbiome Ultra Nucleic Acid Isolation Kit (Thermo Scientific), and the King Fisher Duo Prime automatic DNA extractor (Thermo Scientific). The extracted DNA was then subjected to qPCR analysis using TaqMan™ Fast Advanced Master Mix and primers specific to each microorganism. The qPCR reaction was conducted in 96-well plates, with fluorescence detection performed using the Step One Plus real-time PCR system (Applied Biosystems). A standard curve for each organism was constructed for quantification, with concentrations ranging from 10^5 to 10^1 molecules. Statistical analysis was performed using ANOVA followed by the Tukey post-hoc test to identify significant differences between the groups at each time point.

2.5. Assessment of Axillary Erythema and Dryness

The aim of this study was to evaluate the efficacy of the investigational product in reducing axillary erythema and dryness, caused by the use of a depilatory blade, after 3, 5, and 7 days of in-home use. The efficacy of the investigational product was compared with a control antiperspirant (placebo), which did not contain the skin care blend.

The research subjects were instructed to perform daily armpit hair removal using a shaving razor provided by the laboratory for 7 consecutive days (injury process). The research subjects also received a neutral soap, non-bactericidal, unscented for armpits cleaning. During the 7 days, the research subjects were instructed to stop using any cosmetics or dermatological products in the armpit area. During the period of in-home use, the research subjects were instructed to apply the investigational product in one armpit and the placebo in the other armpit. The determination of the application of the investigational product and the placebo was randomized between the armpits [10].

The clinical efficacy was assessed by the researcher at the start of the study and after 3, 5, and 7 days of in-home use, focusing on the reduction of erythema and dryness. These conditions were evaluated using a 5-point hedonic scale based on standard images representing varying intensities of erythema and dryness. The investigational product was

considered effective if there was a significant reduction in the clinical scale after treatment, compared to the baseline. Subjects were instructed to apply the investigational product twice daily, once in the morning and once in the evening.

The perceived efficacy was evaluated by the research subjects themselves, using a Visual Analogue Scale (VAS) to assess the tolerability and effectiveness of the product under real-use conditions. Participants completed a questionnaire independently, with the head researcher explaining the meaning of each attribute to be rated before the assessment. The responses were given confidentially, without any interference from the researcher.

The significance of reduction in intensity of erythema and dryness skin of armpits due to the application of the investigational product, in comparison to the placebo, was assessed by the bimodal paired Student's t-test method, considering a 95% confidence interval, to the data calculated from the variation of erythema (Var. erythema = IEt0 – IEti) and the data calculated from the variation of dryness skin of armpits (Var. dryness = IDt0 – IDti) for the investigational product and placebo. IE represents the intensity of erythema and ID represents the intensity of dryness, with subscript 't0' indicating baseline values and 'ti' denoting values obtained after 3, 5, and 7 days of in-home application. Data were recorded and analyzed using Microsoft® Office Excel 2019 (Microsoft Corp., USA) for measurements and GraphPad™ Prism® 8.00 (GraphPad Software, San Diego, CA, USA) for statistical analysis.

2.6. Assessment of skin hydration

The aim of this study was to evaluate the effect on skin hydration of the antiperspirant formulation developed in this work, which contains a skin care complex. A total of ten healthy research subjects completed the study, with a mean age of 32 ± 14 years. All participants were classified as Fitzpatrick phototype III, with 70% identifying as female and 30% as male. Prior to the study, participants were instructed to refrain from using any cosmetic products on their forearms for at least 48 hours.

On the day of the evaluation, subjects remained in a controlled environment (20 °C ± 2; relative humidity 50% ± 5) for 30 minutes to allow for physiological acclimatization. After this stabilization period, FTIR/ATR spectra were collected from predefined sites on the forearms to obtain baseline measurements. The investigational product was then applied, and additional spectral measurements were obtained at 15 minutes, 2, 4, and 8 hours post-application. This experimental design allowed for the monitoring of temporal changes in the skin's spectral profile, enabling indirect assessment of hydration improvement based on alterations in specific infrared absorption bands associated with water content in the stratum corneum.

2.7. Assessment of reduction in axillary hyperpigmentation

To evaluate the potential effect of the investigational product on the reduction in armpits hyperpigmentation, Calendula officinalis flower extract was incorporated into the formulation in addition to the skin care complex. This modification aimed to enhance the formulation's ability to reduce underarm dark spots, as calendula extract possesses anti-inflammatory properties [11] that could help prevent post-inflammatory hyperpigmentation when used in combination with the skin care ingredients. The methodology consisted in the assessment of the reduction in armpits hyperpigmentation by mexametry technique (Mexameter® MX 18) through melanin measurements, at the beginning of the study and after 30, 60 and 90 days of home use of the investigational product.

3. Results

The results obtained from clinical and instrumental evaluations demonstrate the performance of the investigational product in terms of stability, safety, and efficacy. The findings encompass key aspects of axillary skin care, including improvements in skin condition, hydration, modulation of the microbiota, and its ability to reduce axillary erythema and dryness.Together, these tests aim to provide data that support the multifunctionality and benefits for the axillary skin of the formulation.

3.1. Development, stability and safety evaluation of the formulation

Table 1 presents the composition of the formulation developed in this study, highlighting the blend of ingredients for axillary skin care, which includes humectant, occlusive, antioxidant, and prebiotic agents. This approach aimed to optimize axillary skin care, focusing on strengthening the skin barrier, maintaining hydration, and promoting microbiota balance.

Table 1. List of ingredients used in the antiperspirant formulation.

INCI Name	Function
Aqua	Vehicle
Aluminum Zirconium Pentachlorohydrate	Antiperspirant active
Steareth-2; Steareth-21	Emulsifiers
Isopropyl Myristate	Emollient
Caprylyl Glycol, Disodium Edta, Hydroxyacetophenone	Stabilizers
Canola Oil; Glycerin; Helianthus Annuus (Sunflower) Seed Oil; Trehalose; Tocopheryl Acetate	**Skin Care Complex**

The formulation demonstrated stability after 91 days of study under the evaluated conditions (5 ± 2°C, 25 ± 2°C, and 40 ± 2°C for a period of 91 days), with no significant changes observed in the assessed parameters.

During the safety assessment, none of the participants reported any distinct sensation of discomfort or presented any clinical signs directly attributable to the product application. Furthermore, thorough dermatological evaluation confirmed that no participant developed any cutaneous lesions associated with the use of the test product throughout the study period.

3.2. Deodorant and Antiperspirant Efficacy

The deodorant efficacy of the investigational product was assessed by comparing the intensity of axillary odor between treated and untreated armpits (control armpits). After 72 hours of the last application, the formulation promoted a 24.2% reduction in underarm malodor compared to the untreated armpit. Additionally, 100% of the participants demonstrated a perceivable reduction in unpleasant odor, highlighting the product's effective deodorant action under real-use conditions.

The antiperspirant efficacy was evaluated through quantitative measurements of sweating, comparing the treated and untreated axillae. According to the established criteria, a product must induce at least a 20% reduction in sweating in 50% or more of the participants to claim 72-hour protection. In this study, 96.67% of the participants achieved a sweating reduction of 20% or more after 72 hours of the last application, demonstrating the high antiperspirant performance of the investigational product.

3.3. Axillary microbiota

The qPCR analysis compared the volunteers through four timepoints and showed that *S. epidermidis* counts significantly increased after 3 days (T3) of stimulation and reduced levels after 72 hours of use. For *S. aureus*, there was a significant reduction in the population at T3, while at T72h its levels were reestablished. For *C. xerosis* we also observed a reduction at T0 and T3, but at T72h, its levels were reestablished and there was no statistical difference when compared to the levels found at T-17 (control condition) (Figure 1).

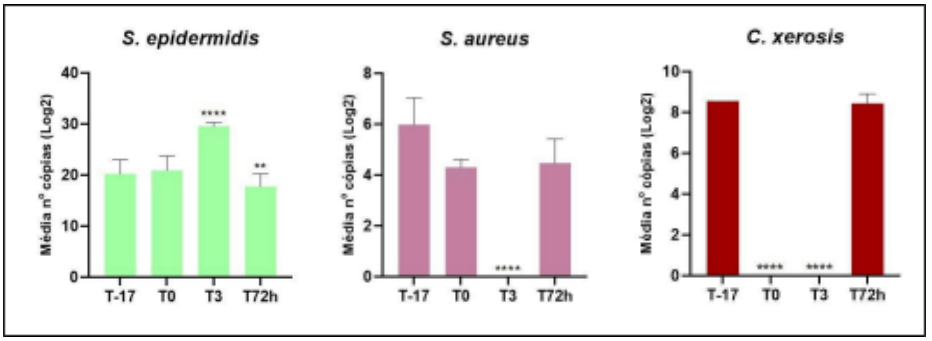

Figure 1: *S. epidermidis, S. aureus, C. xerosis* quantification from T-17d, T0d, T3d and 72 hours of treatment with the deodorant product. ANOVA – post-hoc Tukey Test.

3.4. Axillary skin care

Figures 2 and 3 illustrate the mean values of the intensity of erythema and dryness of the skin armpits obtained in the clinical evaluation, respectively.

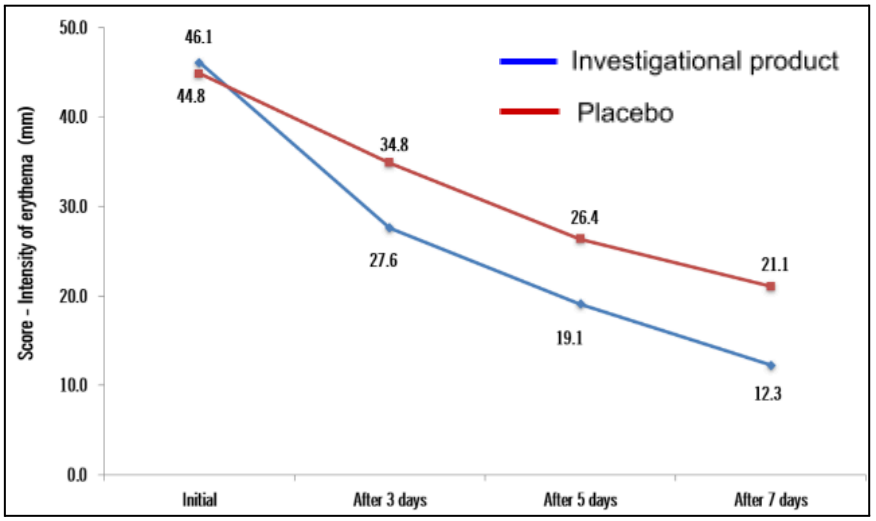

Figure 2: Mean erythema intensity of armpit skin (clinical evaluation)(n=33).

A statistically significant reduction ($p<0.05$) in axillary erythema intensity was observed following treatment with the investigational antiperspirant formulation containing the skin care complex after 3, 5, and 7 days of use. The investigational product resulted in a reduction of 40.1% in erythema intensity after 3 days, 58.6% after 5 days, and 73.4% after 7 days. In contrast, the placebo (antiperspirant without the skin care complex) promoted reductions of 22.3%, 41.2%, and 53.0% at the same respective time points.

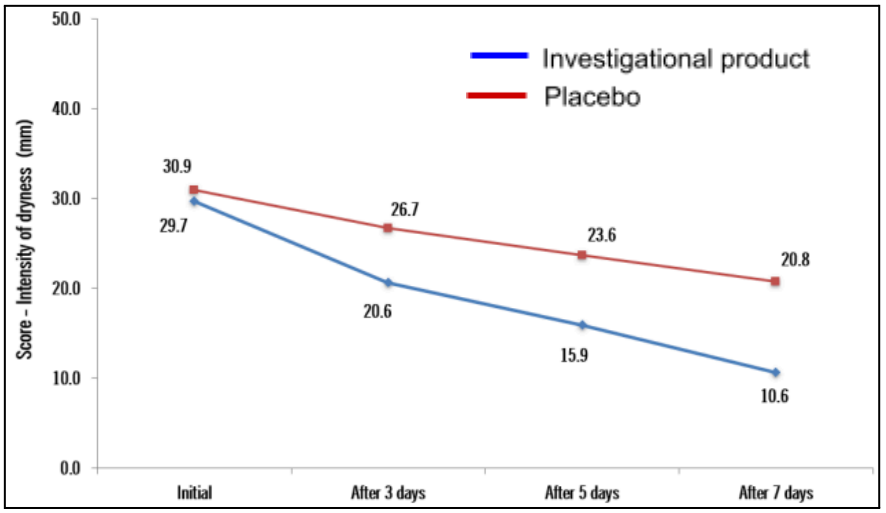

Figure 3: Mean dryness intensity of armpit skin (clinical evaluation) (n=33).

In terms of skin dryness, the investigational formulation also demonstrated a statistically significant improvement after 3, 5, and 7 days of application, with reductions of 30.6%, 46.4%, and 64.3%, respectively. Treatment with the placebo resulted in lower reductions in dryness: 13.7% after 3 days, 23.5% after 5 days, and 32.8% after 7 days of use. In all evaluated time points, the investigational product showed significantly superior performance compared to the placebo ($p<0.05$).

These findings suggest that the investigational antiperspirant formulation, enriched with a skin care complex, is more effective than the placebo in reducing both erythema and dryness of the axillary skin following repeated use.

In addition to the instrumental assessments, self-reported data regarding perceived efficacy were collected to evaluate subjective skin sensations following application of the investigational product. At baseline (post-injury condition), 97% of participants reported experiencing a burning sensation. After 3, 5, and 7 days of home use of the investigational product, improvements of 60.0%, 84.0%, and 95.9% were reported, respectively. Itching was initially reported by 79% of participants and showed progressive improvement, with reductions of 69.5% after 3 days, 86.1% after 5 days, and 91.1% after 7 days. Tingling sensation, reported by 45% of participants at baseline, also demonstrated notable improvement, with reductions of 83.3%, 95.5%, and 97.0% after 3, 5, and 7 days of use, respectively. These findings indicate that the investigational product contributed to a progressive reduction in discomfort-related symptoms, supporting its skin-soothing properties during home use conditions.

3.5. Skin hydration

According to the study protocol and procedures used to evaluate the increase in skin hydration after application of the antiperspirant formulation containing the skin care complex, it was possible to observe that the formula provided a significant increase in skin hydration after 15 minutes, 2, 4 and 8 hours of application, when compared to the control (skin without application of any products). The formulation kept the skin moisturized for up to 8 hours after application and increased the level of skin hydration for up to 26.1%.

3.6. Axillary hyperpigmentation

In order to assess the reduction in armpits hyperpigmentation, Calendula Officinalis Flower Extract was incorporated into the formulation under investigation. This addition was

strategically implemented to optimize the product's efficacy, enhancing its ability to improve skin tone consistency and contribute to overall skin care benefits.

According to the study protocol and the procedures used to assess the efficacy of the investigational product, it was possible to observe that the antiperspirant formulation containing the skincare complex and the calendula extract provided reduction in armpits hyperpigmentation after 30 days of home use, when compared to the initial skin condition. It reduced the armpit hyperpigmentation for up to 16,6%.

4. Discussion

The axillary region is particularly susceptible to daily stressors such as friction, hair removal, and the application of topical products, necessitating specialized care to maintain its physiological integrity [4]. In this context, we developed an antiperspirant formulation enriched with a skin care complex aimed at enhancing axillary skin health without compromising its primary functions of odor and sweat control.

The formulation incorporated a blend of ingredients recognized for their dermatological benefits. Canola oil and Helianthus annuus (sunflower) seed oil are rich in linoleic acid (omega-6), an essential fatty acid that plays a critical role in maintaining and restoring the skin's barrier function [12]. Their topical application has been associated with enhanced epidermal lipid synthesis, reduced transepidermal water loss, and attenuation of inflammatory responses, being considered effective emollients for supporting skin barrier integrity and improving skin conditions [13]. Glycerin is a well-established humectant that enhances skin hydration by attracting and retaining water in the stratum corneum, thereby improving skin elasticity and contributing to the maintenance of the cutaneous barrier function [14]. Tocopheryl acetate, a stable form of vitamin E, acts as a potent antioxidant that helps protect the skin from oxidative stress, supports the maintenance of skin barrier integrity, and contributes to reducing inflammation and photoaging [15]. Trehalose is a disaccharide known for its moisture-retaining and cell-protective properties, which help preserve skin hydration, stabilize cellular membranes under stress, and may contribute to maintaining skin microbiota homeostasis by supporting a balanced and less inflammatory cutaneous environment [16,17].

To ensure that the inclusion of these skin-beneficial ingredients did not compromise the product's primary functions, we evaluated its antiperspirant and deodorant efficacy over a 72-hour period. The active antiperspirant agent, aluminum zirconium pentachlorohydrate, is recognized for its high efficacy in reducing sweat production. Its mechanism involves forming temporary plugs within the sweat ducts, thereby minimizing perspiration [18]. Our results confirmed that the addition of the skin care complex did not impair the product's functional performance, achieving 72 hours of deodorant and antiperspirant protection.

Skin care benefits were assessed through parameters such as erythema, dryness, and hydration. The study demonstrated significant improvements in erythema and dryness after 7 days of product use compared to a formulation lacking the skin care complex. The hydration level of the stratum corneum directly influences its mechanical properties. When water content in the stratum corneum falls below 10%, its flexibility diminishes, making it more susceptible to mechanical stress and damage [19]. Our study demonstrated significant improvements in skin hydration at all evaluated time points following the application of the product containing the skin care complex. These findings suggest that the inclusion of these ingredients effectively strengthens the skin barrier and restores hydration balance, leading to reduced irritation and enhanced skin hydration.

Limited literature exists on the influence of cosmetic formulations on the axillary microbiota. Some studies indicate that the use of deodorants and antiperspirants can significantly alter the bacterial composition of the axilla [20], but few have established a direct correlation between such alterations and clinical outcomes. Our research suggests that incorporating a prebiotic active ingredient into an antiperspirant formulation may render it more compatible with the axillary microbiota and could enhance its deodorant action. This is evidenced by the modulation of certain species, with an increase in *S. epidermidis* and maintenance of *S. aureus* and *C. xerosis* levels. Based on the results obtained, it can be observed that the product did not negatively affect the skin's microbiota. Although the deodorant slightly increased the population of *S. epidermidis* at T3, this effect was reversed after 72 hours, with the product maintaining the levels of this microorganism. For both *S. aureus* and *C. xerosis*, microorganisms associated with skin infections and bad odor, the use of the product was able to control the growth of these bacteria at T3; however, after discontinuation of use, the product maintained levels similar to those found in the control condition (T-17). Therefore, it can be suggested that the deodorant product preserves the skin's first line of defense, being microbiome-friendly.

In summary, this study elucidates the beneficial effects of a multifunctional antiperspirant formulation enriched with a skin care complex. It demonstrates that it is possible to develop an antiperspirant formula with additional skin care benefits without compromising stability, safety, or efficacy. Through rational formulation design based on the use of skin-beneficial ingredients and microbiota-balancing technology, we achieved a product with expanded performance, offering both functional and dermatological advantages.

5. Conclusion

The developed formulation demonstrated a stable profile and multifunctional benefits, including effective sweat and odor control, skin care properties, and support for the balance of the axillary microbiota. It exhibited significant deodorant and antiperspirant efficacy up to 72 hours post-application when compared to untreated control sites. Additionally, a statistically significant reduction in axillary erythema and skin dryness was observed, alongside an increase in skin hydration levels.

Modulation of the axillary microbiota was also noted, characterized by an increase in *Staphylococcus epidermidis* and the maintenance of *Staphylococcus aureus* and *Corynebacterium xerosis* populations. The present findings indicate that this formulation not only preserves microbiota homeostasis but also could contribute to improved skin condition, particularly in reducing irritation and dryness.

Altogether, this study supports the development of an antiperspirant formulation with expanded performance, achieved through a rational formulation strategy based on the incorporation of skin care technologies. The multifunctionality observed - without compromising efficacy, safety, or stability - demonstrates that it is possible to create antiperspirant products that go beyond basic functionality, delivering additional skin benefits while maintaining compatibility with the axillary microbiome.

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