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Original Research Article

Evaluating the non-comedogenic profile of Venusia Sun Unseen: a prospective, double-blind, randomized and controlled study

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ABSTRACT

Background: The comedogenic potential of topical sunscreens is an important consideration for both skin safety and long-term adherence to photoprotective regimens. This study aimed to evaluate the comedogenicity of Venusia Sun Unseen sunscreen under occluded conditions, compared with positive and negative controls.
Methods: A prospective, randomized, double-blind, positive- and negative-controlled, two-cohort parallel-group study was conducted involving 30 healthy adults aged 18 to 55 years with prominent follicular orifices on the upper back. The test sunscreen (Venusia Sun Unseen) was evaluated against coconut oil as the positive (comedogenic) control, and glycerine as the negative (non-comedogenic) control. Products were applied under occlusive patch chambers on three designated sites on the upper back. Follicular biopsies were obtained before and after 12 alternate-day applications over a 4-week period. Microcomedones were graded on a four-point scale using light microscopy. Statistical comparisons were performed using the Mann–Whitney U test.
Results: The method was validated as the positive control showed significantly higher mean comedone grades (2.07±0.84) than the negative control (0.76±0.58; p=0.001). The test product, Venusia Sun Unseen, demonstrated a significantly lower mean comedone grade (0.86±0.95) compared to the positive control (p=0.001), indicating non-comedogenicity. No adverse events related to the test or control products were reported.
Conclusions: Venusia Sun Unseen sunscreen is non-comedogenic and safe when applied topically under occluded conditions.

Keywords: Comedegenicity, Non-comedogenic sunscreen, Microcomedones, Cosmetic safety

INTRODUCTION

Sunscreens are topical formulations designed to protect the skin from the harmful effects of ultraviolet (UV) radiation, which is a well-established risk factor for skin aging, sunburns, and skin cancers including melanoma.[1,2] While significant research has focused on the photostability, skin penetration, and potential cytotoxicity of various UV filters, less attention has been paid to their effects on skin pore health, particularly in relation to comedogenesis.[3,4] Sunscreen is as an essential adjunct in the management of many dermatologic conditions. Broad-spectrum sunscreens are considered a key component of therapy for melasma and postinflammatory hyperpigmentation, where regular use helps prevent exacerbation and supports pigment lightening.[5-7]

In acne vulgaris, expert groups recommend daily use of non-comedogenic sunscreens and moisturizers, particularly in patients receiving topical retinoids or systemic antibiotics, to reduce photosensitivity, maintain barrier function, and minimize post-inflammatory hyperpigmentation.[8] High-SPF, broad-spectrum sunscreens are also routinely advised for photosensitive

disorders and pigmentary diseases such as vitiligo, to prevent sunburn of depigmented areas and to reduce long-term photodamage.[9]

Comedogenicity is a key parameter in evaluating the suitability of dermatological formulations. Comedogenicity refers to the potential of a substance or product to cause comedones, which are clogged hair follicles leading to blackheads or whiteheads. High comedogenicity in skincare or cosmetic products can result in acne development, particularly in individuals prone to oily or acne-prone skin.[10,11] The outcome of using comedogenic products includes inflammation, increased sebum production, and potential worsening of acne severity.[11] Certain cosmetic ingredients have been demonstrated to induce comedones by occluding hair follicles and stimulating inflammatory processes within the pilosebaceous unit.[12] Given that sunscreens are often applied daily and may contain organic and particulate UV filters alongside various emollients, it is essential to assess whether these complex formulations contribute to comedogenic reactions. As consumer demand grows for formulations that not only protect but also support skin health without exacerbating acne-prone conditions11, rigorous evaluation of comedogenicity in sunscreen products is warranted.

The present study was designed to evaluate the comedogenic potential of a topical sunscreen (Venusia Sun Unseen) in healthy adults using a standardized occluded patch test model with cyanoacrylate follicular biopsy.[13] We aimed to compare microcomedone formation induced by the test product against both positive control (coconut oil) and negative control (glycerin), thereby validating the methodology and determining whether Venusia Sun Unseen meets the criterion of non-comedogenicity under controlled conditions of repeated occlusive application.

METHODS

Study design and setting

This was a prospective, randomized, double-blind, positive- and negative-controlled, two-cohort parallel-group study conducted between July-2025, and August-2025, at C.L.A.I.M.S. Private Limited, Mumbai, India. The objective was to evaluate the comedogenic potential of a topical sunscreen (Venusia Sun Unseen) when applied to the skin under an occluded patch, in comparison with positive and negative controls.

Participants

Eligible participants were healthy men and women aged 18 to 55 years with visibly prominent follicular orifices on the upper back and apparently healthy skin at the test area. Participants were required to avoid excessive ultraviolet exposure (sunlight or artificial sources), water contact (e.g., swimming), or activities that induced sweating, such as exercise or sauna, for the duration of patch application. All volunteers agreed to wear loose cotton clothing during the study.

Individuals were excluded if they had occupations involving frequent water exposure or physical exertion leading to perspiration; if they were pregnant or lactating; or if the investigator believed that compliance would be inadequate. Individuals with scars, tattoos, or any dermatologic pathology known hypersensitivity to cosmetic products or raw materials were excluded. Participants with clinically significant systemic or cutaneous conditions likely to interfere with study outcomes, those receiving systemic, hormonal, or topical medications within the preceding three months, or those who had participated in another clinical study within 30 days before screening were also excluded.

Test products and control

The test product, Venusia Sun Unseen, was evaluated alongside coconut oil as the positive control and glycerine as the negative control. All materials were tested, coded, and randomized in blocks by an independent third party.[14,15]

Test sites and product application

Applications were performed on the upper back. Three test sites (each 3×3 cm^2) were demarcated using a standardized template, with one site allocated to each condition: the test product, positive control, and negative control.

Baseline follicular biopsies were obtained from all three sites before product application. For each biopsy, 1–2 drops of cyanoacrylate adhesive were placed on a microscope slide, which was then gently applied to the marked area. The adhesive was allowed to set for 30–60 seconds. The slide was carefully removed, yielding a follicular biopsy specimen.

Approximately 2 hours after baseline biopsy collection, products were applied according to the randomization schedule. Although each site measured 3×3 cm^2, applications were occluded using 2×2 cm^2 patch chambers placed centrally within the marked area.

A standardized dose of approximately 0.025 g of the test product and 0.025 ml of each control was applied to the respective sites and covered with the patch chambers. Patch application and removal were repeated a total of 12 times over the study period.

Assessment schedule

At day 1, participants underwent screening, enrolment, baseline follicular biopsy, and the first patch application (approximately two hours after biopsy). Patches were removed after 24 hours (day 2), with assessments for adverse events and concomitant medications. At 48 hours

(day 3), patches were reapplied to the same sites. This alternate-day cycle was repeated 12 times, corresponding to three weekly applications on Monday, Wednesday, and Friday; no applications or removals were conducted on Sundays.

On the final study day, approximately two hours after patch removal, follicular biopsies were repeated at all three sites. In a subset of ten participants, standardized photographs were obtained to document the presence of comedones.

Outcome measures

The primary outcome was the comedogenic potential of the test product compared with controls, assessed based on microcomedone grading under light microscopy. Microcomedones were graded using a four-point scale (Table 1). Adverse events were also observed and recorded.

Table 1: Scale for microcomedone grading.

Scale	Grading
0	Non comedogenic
1	Small microcomedones
2	Moderately sized microcomedones over most of the field
3	Large globoid microcomedones over the entire field

Statistical analysis

All microscopic scores were averaged per test site, and statistical analyses were performed using statistical package for the social sciences (SPSS) version 30.0. All the p-values are reported based on a two-sided significance test, and all the statistical tests were interpreted at 95% level of significance.

Comparisons included mean comedone grades of positive control versus negative control for method validation, and comparison of mean comedone grades between the test product and positive control. The Mann–Whitney U test was used for group comparisons. No formal sample size calculation was undertaken prior to study initiation.

RESULTS

The demographic and clinical characteristics of the study participants are summarized in Table 1.

Method validation: positive versus negative control

The mean comedone grade for glycerine was significantly lower than that of coconut oil, validating glycerine as a non-comedogenic negative control and coconut oil as a reliable comedogenic positive control. (Figure 1 and Table 2).

Test product versus positive control

The test product (Venusia Sun Unseen) demonstrated a statistically significantly lower mean comedone grade compared with the positive control, indicating that Venusia Sun Unseen is non-comedogenic when applied topically under occluded conditions (Table 2). The mean comedone grades of positive control (coconut oil), negative control (glycerine) and test product (Venusia Sun Unseen) is represented in Figure 2.

Table 2: Statistical comparison of mean comedone grades-positive control (coconut oil), negative control (glycerine) (for method validation) and test product - Venusia Sun Unseen.

Products	Mean comedone grades ($\bar{X}$±SD) (N=29)
Positive control (coconut oil)	2.07±0.84
Negative control (glycerine)	0.76±0.58
Test product (Venusia Sun Unseen)	0.86±0.95

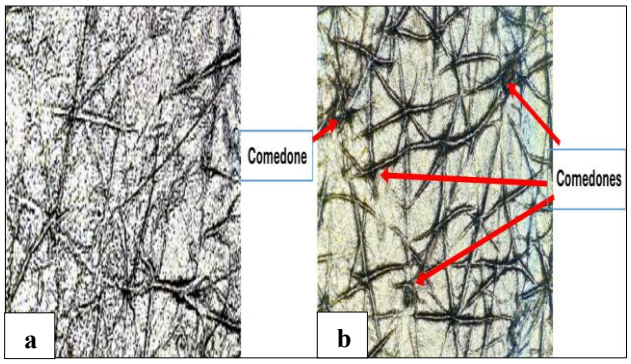

Figure 1: Control groups showing skin response: (a) negative control using glycerine, demonstrating a grade 0 reaction; and (b) positive control using coconut oil.

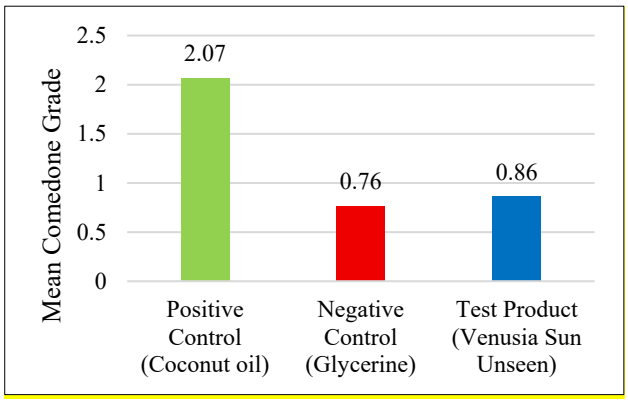

Figure 2: Mean comedone grades of positive control (coconut oil), negative control (glycerine) and test product (Venusia Sun Unseen).

Safety and tolerability

No adverse events related to the test product or control materials were reported during the study period. One participant experienced an accidental head injury while using Venusia Sunscreen. The event was assessed as unlikely to be related to the study product and was classified as moderate in severity. The condition resolved following dressing of the wound. The participant was discontinued from the study, and the event was not considered a serious adverse event (SAE).

DISCUSSION

The present study employed a cyanoacrylate follicular biopsy technique under occluded patch conditions to assess the comedogenic potential of the test sunscreen in a controlled human model.[13,16,17] A key strength of the present study was the inclusion of both positive and negative controls within the study design, enabling simultaneous validation of the assay methodology and evaluation of the test product. The high comedogenicity of coconut oil is consistent with prior findings that certain lipophilic substances, including natural oils, can induce comedone formation due to follicular occlusion and sebum alteration.[18] This is similar to what has been described in studies examining comedogenic agents such as squalene monohydroperoxide.[12] Conversely, glycerine, a humectant known for its moisturizing properties without occlusive effects, maintained a low comedone grade consistent with its non-comedogenic profile.[19]

The test product (Venusia Sun Unseen) produced a mean comedone grade of 0.86±0.95, which was statistically significantly lower than the positive control (coconut oil; p=0.001). Notably, the comedone grade for Venusia Sun Unseen was comparable to that of the negative control (glycerin: 0.76±0.58), suggesting that the test formulation is non-comedogenic under the occlusive patch application conditions employed in this study.

This finding is clinically relevant given the widespread perception among consumers that sunscreen products are inherently "pore-clogging" or acneogenic.[10] This perception-driven non-adherence represents a significant clinical problem. Thus, demonstrating that the test product is non-comedogenic has important implications for dermatologic practice and patient adherence.

The study was conducted under controlled laboratory conditions with occluded patch application, which represents an intentionally stringent testing scenario. Occlusion creates a microenvironment of elevated temperature, humidity, and sebum retention that can amplify any comedogenic potential compared to non-occluded use.[20] Therefore, the non-comedogenic potential demonstrated under these rigorous conditions suggests that Venusia Sun Unseen can be non-comedogenic even under typical real-world use patterns involving non-occluded facial application.

Safety and tolerability outcomes in this study show that there were no treatment-related adverse events, indicating that the test sunscreen was well tolerated under repeated occlusive application. The absence of cutaneous reactions or treatment-related discontinuations further supports the favourable safety and tolerability profile of Venusia sunscreen in healthy adults under the study conditions. The study's strict inclusion criteria, exclusion of participants with dermatological conditions or recent systemic treatments, and controlled application conditions, reduces confounding effects and supports the observed safety findings.

This favourable safety profile is particularly relevant from a consumer perspective, as long-term daily use of sunscreen is recommended for prevention of photoaging and skin cancer with safety demonstrated in long-duration studies.[21,22] For individuals with acne-prone or sensitive skin, non-comedogenic, well-tolerated sunscreens are strongly recommended to maintain adherence to both acne therapy and photoprotection, since irritation or perceived "pore clogging" often leads to discontinuation of use.[23] The absence of adverse events and the demonstrated non-comedogenic profile in this study therefore support the potential suitability of this formulation for sustained, real-world daily use.

Limitations

Limitations include the relatively small sample size and the short duration inherent to patch testing, which may not capture longer-term effects associated with chronic use. However, the intensive occlusive challenge employed in this protocol can be considered more stringent than typical daily use, and thus provides a conservative estimate of comedogenic potential. The study population consisted of healthy participants with prominent follicular orifices on the upper back. While this design is standard for comedogenicity testing, it is important to note that follicular morphology, sebum composition, and comedone susceptibility may vary between anatomical sites and among individuals.[13,16,17] The generalizability of these findings to clinical populations with active acne vulgaris, although biologically plausible, has not been directly tested in the present investigation. Future studies in acne-prone populations would further strengthen claims regarding its suitability.

CONCLUSION

In conclusion, this study provides evidence for the non-comedogenic nature of Venusia Sun Unseen sunscreen under occluded conditions, demonstrating statistically significant and clinically relevant safety compared to a known comedogenic agent.

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