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Original Research Article

Evaluation of a sunscreen for phototoxic and photo-irritant potential via photo patch testing

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ABSTRACT

Background: Evaluation of the potential of Venusia Sun Unseen Sunscreen to induce phototoxicity (photo irritation) in adult participants, using a photo patch test technique.
Methods: This is a monocentric, non-randomised, single-application study to evaluate the potential of the Venusia sun unseen sunscreen to induce phototoxicity in adult participants, using a photo patch test technique. Two treatment sites were tested on the back of each subject and the grading was done for erythema/dryness/wrinkles (A) and oedema (O) reactions on the Draize scale. At both sites ~0.04 g of the test sunscreen was applied occlusively (T1 and T2) at visit 1. One additional site (C1) in the adjoining skin was exposed to ultraviolet (UV) light for the same period to act as a control (no product was applied on this site) for the UV exposure. At 24 hrs, T1 and C1 were UV-exposed and T1 reapplied; T2 stayed occlusive. All sites were scored at 48 hrs, with recovery confirmed at 1 week.
Results: The study included 26 healthy male and female participants aged 18-65 years. At 48 hrs, mean combined phototoxicity scores (A + O) were low across sites: 0.04 at control (C1), 0.75 at UV-exposed test site (T1), and 0.96 at unexposed test site (T2). No study-related adverse events (AEs) or intolerances were reported.
Conclusions: Venusia sun unseen sunscreen is well tolerated and suitable for long-term daily use, including in individuals with sensitive skin. Regular application helps reduce cumulative UV damage and lowers the risk of skin cancers.

Keywords: Venusia Sun Unseen Sunscreen, Draize scale, Photo-patch test, Phototoxicity, Skin safety

INTRODUCTION

Sunlight exposure is recognized for its physiological benefits, including mood modulation, cutaneous improvement in disorders such as rickets, psoriasis, eczema, and vitiligo, and its essential role in endogenous vitamin D synthesis. Nevertheless, cumulative evidence highlights the detrimental consequences of excessive UV exposure. As the primary environmental interface, the skin is continuously subjected to oxidative stress generated by solar UV radiation and a wide spectrum of environmental pollutants, including vehicular emissions, cigarette smoke, halogenated hydrocarbons, heavy metals, and ozone. Functioning as the body's foremost protective barrier, it plays a critical role in mitigating and responding to these external biochemical and oxidative challenges.[1] Solar UV consists of ~90-95% UVA (320-400 nm) and 5-10% UVB (280-320 nm), while UVC is absorbed by the ozone layer. Acute UV effects include erythema, oedema, sunburn, and photo immunosuppression; chronic effects include photoaging and carcinogenesis. UVA penetrates the dermis, generating reactive oxygen species that indirectly damage DNA, while UVB is absorbed in the epidermis and directly induces DNA mutations. These photolesions disrupt replication and repair, leading to characteristic

UV signature mutations.[2] UVA plays a significant role in immediate pigment darkening by oxidizing and polymerizing melanin precursors. Both UVA and UVB contribute to delayed tanning.[3] Whereas UVB irradiation predominantly elicits acute cutaneous responses, UVA is chiefly implicated in long-term photodamage driven by oxidative stress, resulting in collagen breakdown and premature skin aging. UVA-induced generation of reactive oxygen species (ROS) activates key transcription factors, including activator protein-1 (AP-1) and transforming growth factor-β (TGF-β) thereby amplifying molecular pathways that accelerate skin aging.[4]

Sunscreens shield the skin from UV radiation and must meet safety requirements such as skin tolerability, user customization, and sustainability, all of which are presently significant and will only become more so in the future.[5] In order to counteract UV-induced skin aging, erythema, wrinkles, and mutagenesis, modern sunscreen lotions frequently include additional active chemicals. These include exogenous DNA repair enzymes such as photolyase and traditional antioxidants like ascorbic acid, which, when applied topically, restore DNA integrity.[6] Many consumers with sensitive skin avoid sunscreens due to fear of irritation. Validating non-irritancy is critical to encourage long-term adherence and consumer trust.[7] While SPF and broad-spectrum coverage are essential, dermatologists also consider skin tolerability before recommending a sunscreen, especially for patients with chronic or sensitive skin conditions.[8] The American Academy of Dermatology (AAD) advises using water-resistant sunscreen with broad-spectrum protection, including UVA and UVB coverage, and at least SPF 30 for optimal safety.[9] For effective photoprotection, regulatory authorities such as the FDA advise applying sunscreen at a density of 2 mg/cm², which corresponds to approximately 35 mL per full-body application for an average adult with a body surface area of 1.73 m^2.[10]

Exposure to UV or visible light in the presence of certain medications or topical agents can lead to phototoxic or photoallergic reactions. These substances act as photosensitizers, mainly absorbing UVA and visible light and generating reactive species that damage skin cells. Phototoxic reactions are common, predictable, and resemble severe sunburn with redness, swelling, and later pigmentation. Photoallergic reactions are rare, immune-mediated, and present as itchy, eczematous dermatitis.[11]

Phototoxicity, as mentioned above, is an immediate reaction in which specific wavelengths of light activate photosensitising compounds in the skin. As these molecules return to their stable state, they release energy that generates free radicals, especially oxygen, which then damages cellular proteins, lipids, and nucleic acids. This oxidative injury produces a response similar to severe sunburn. The exact mechanisms vary, and the triggering wavelength depends on the photosensitizer's absorption profile.[12] Clinically, symptoms begin within hours of exposure, presenting as erythema and oedema that peak over the next several hours to days, and may later progress to hyperpigmentation and peeling as the skin recovers. UVB-induced sunburn is a typical phototoxic response, primarily resulting from photon absorption by DNA, leading to direct cellular injury. UVA can also produce erythema, but it more prominently stimulates pigment production, resulting in tanning or darkening rather than marked redness. A sunscreen proven to not trigger such reactions may hence be preferred for daily use. [11]

The present study was conducted to determine the phototoxicity potential of the test sunscreen formulation (Venusia sun unseen sunscreen). Phototoxic potential was evaluated in healthy adult volunteers using a standardized photopatch testing methodology, which enables controlled assessment of cutaneous responses following defined UV irradiation. This validated technique provides a robust framework for detecting photo-irritant reactions by comparing irradiated and non-irradiated sites. The study design ensures a rigorous appraisal of the formulation's dermatological safety profile under UV exposure, thereby supporting its suitability for routine and sustained use. The study addresses real-world decision-making helping to establish evidence for products that may be suitable for sensitive skin and supporting consumer willingness to use sunscreen consistently.[13]

METHODS

Study design

This is a Monocentric, non-randomised, single-application study to evaluate the potential of the test product (sunscreen) to induce phototoxicity in adult participants, using a photo patch test technique. The study was carried out at Clinical Aesthetics and Investigative Management Service Private Limited (C.L.A.I.M.S. Pvt. Ltd), located at 27 MIDC Commercial Premises, 5th Floor, 17th Road, MIDC, Andheri East, Mumbai 400093. It was carried out between 19 June 2025 to 28 June 2025 under the supervision of the principal investigator, and the study documents were reviewed, and the trial was approved on 04/06/2025 by the Independent Ethics Committee, C.L.A.I.M.S. Private Limited. The study was conducted in accordance with the approved protocol, BIS guidelines {IS 4011: 2018 methods of test for safety evaluation of cosmetics (Third revision) guidelines}, ICMR guidelines (2017), ICH E6 (R3) Good Clinical Practice (2016), Good Clinical Laboratory Practices (GCLP), the Declaration of Helsinki (2013), and other applicable regulatory requirements.

This study included 26 normal healthy participants (men and women) aged 18- 65 years, having apparently healthy skin on the test area, and Fitzpatrick skin types III, IV and V were recruited. All participants were required to avoid intense UV exposure and activities leading to excessive sweating or water contact (e.g., swimming, exercise, and

sauna) during the course of the trial. Participants were not on any medical treatment, either systemic or topical, which may interfere with the performance of the study. Pregnant or lactating women, individuals with scars, excessive terminal hair or tattoos on the studied area, dermatological infection/pathology on the level of the studied area, or chronic illness that could influence the outcome of the study were excluded. The study was designed to evaluate the potential of the test sunscreen product to induce phototoxic (photo-irritant) reactions in healthy adult participants, utilising the standardized photo patch test technique.

Treatment and follow-ups

The test product was Venusia sun unseen sunscreen 0.04g (B. No TR2571A). The active ingredients were Vitamin C, E and F, Octinoxate, Octocrylene, Octisalate, Uvinul A Plus, Tinosorb S.

It was applied using an occlusive patch and chambers on the backs of participants. 2 test sites-T1 and T2 (2×2 cm^2) were marked on the back of the participants. 0.04 g of the test product was applied occlusively on marked test sites on the back of each participant, by clinical research associates under the supervision of the Investigator at 0 hr. After 24 hr, one of the patches in the pair (T1) was removed and the skin at the test site was exposed to appropriate sources of UV light (UVA 5 J/cm^2). The site was occluded again. The other patch in the pair (T2) was left undisturbed. One additional site (C1) in the adjoining skin was exposed to UV light for the same period to act as a control (no product was applied on this site) for the UV exposure. After a further period of 24 hrs, both patches are removed.

Phototoxicity (photoirritation) scoring criteria

Scoring of the test area was done using the Draize scale, which evaluates erythema/dryness/wrinkles and oedema on separate 0-4 scales. Erythema/dryness/wrinkles=(A), oedema=O, erythema/dryness/wrinkles +oedema=A+O

Table 1: Scoring criteria for erythema, dryness, wrinkles, and oedema.

Score for erythema/dryness/wrinkles	Score of oedema
0=No reaction	0=No reaction
1=Very slight erythema/dryness with shiny appearance	1=Very slight oedema
2=Slight erythema/dryness/wrinkles	2=Slight oedema
3=Moderate erythema/dryness/wrinkles	3=Moderate oedema
4=Severe erythema/wrinkles/scales	4=Severe oedema

Safety evaluation

Participants were monitored for AEs throughout the study.

Table 2: Criteria for phototoxicity classification according to mean score thresholds.

Mean score	Classification
Up to 2.0/8.0	Non-photo irritant
>2.0/8.0 to 4.0/8.0	Mildly photo irritant
>4.0/8.0	Photo irritant

Statistical analysis

Data analysis was carried out and conclusions drawn as per IS 4011: 2018 methods of test for safety evaluation of cosmetics (Third revision) guidelines.

If there is no reaction (irritation) at site of patch-T2 (not exposed to light), but the site of the exposed patch-T1 (exposed to UV light) shows evidence of the skin irritation, then test product can be considered as a photo irritant.

The skin area taken as control-C1 and exposed only to UV light should also not develop any skin irritation for the results to be valid.

RESULTS

Participants

A total of 26 participants were included in the study. For 2 participants the control site (without product application) showed an unexplained score of 2. Hence, data for these 2 participants were not considered for analysis and a dataset of 24 participants was analysed.

Table 3: Demographic and other baseline characteristics.

Parameters	N
Total no. of participants	24
Age (in years)	18-65
Mean	29.71
SD	9.43
Range	18.00-46.00 years

Table 4: Phototoxicity (Photo irritation) scores of test product (Unexposed and exposed to UV).

Product/site	Sample size	Mean score (A+O) exposed UV	Mean score (A+O) unexposed UV	Irritancy assessment
Test product (Venusia sun unseen sunscreen)	24	0.75	0.96	Non-irritant/non-phototoxic
Control site	24	0.04	-	Non-irritant/non-phototoxic

Protocol deviation

There were no protocol deviations for this study.

Demographic details

The age of the participants varied from 18 years to 65 years with average age being 29.71 years. There were 13 men and 11 women in the study

Phototoxicity (Photo irritation) score of Venusia sun unseen sunscreen for the unexposed site was 0.96 and the exposed site was 0.75. The scores at both exposed and unexposed sites were below 2.0. Such low values, well below the clinical irritancy threshold, confirm that Venusia sun unseen sunscreen is non-phototoxic/non-photo irritant and may be suitable for daily application (Figure 1).

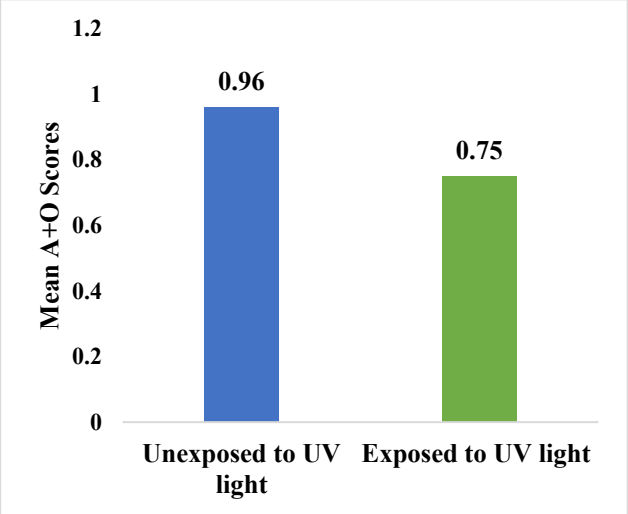

Figure 1: Phototoxicity (photoirritation) scores of Venusia sun unseen sunscreen (Unexposed and exposed to UV).

The graph shows that Venusia sun unseen sunscreen demonstrated no phototoxic response. The mean Phototoxicity (photoirritation) score was 0.96 on the unexposed site and 0.75 on the UV-exposed site, both indicating minimal irritation.

Importantly, UV exposure did not increase the irritation score, confirming the product's photostability and good dermal tolerability.

AEs

There were no study-related AEs or intolerances observed during the study.

DISCUSSION

Repeated unprotected exposure to UV radiation (UVR) may lead to skin photodamage and skin cancer. Both UV A (UVA) and UV B (UVB) are involved in these events.[14]

UV B (280-320 nm) affects mostly the epidermis and is the primary cause of erythema. UVA (320-400 nm), instead, penetrates deeper into the dermis and is the main culprit in photoaging.[15] Sunscreens are a cornerstone of dermatological care, helping prevent photoaging, pigmentary disorders, photodermatoses, and photocarcinogenesis. Despite their widespread availability, they remain underused, particularly by individuals with sensitive or chronic skin conditions, owing to concerns about irritation or intolerance.

Sunscreens can provide protection against sunburn while still permitting endogenous vitamin D production. Formulations with a high UVA protection factor (UVA-PF) allow substantially greater vitamin D synthesis than those with a low UVA-PF, as they inherently permit greater transmission of UVB radiation, which is essential for cutaneous vitamin D formation.[16] Therefore, demonstrating both broad-spectrum efficacy and safety against phototoxic reactions is critical to ensure consumer satisfaction and compliance while also garnering dermatologist confidence.

Current dermatological guidelines from organizations like AAD emphasize a balanced approach to sunscreen use that prioritizes broad-spectrum protection, high sun protection factor (SPF), and tolerability to ensure consistent use, especially in high-risk populations.[17] However, many formulations have not been systematically evaluated for phototoxicity, limiting their suitability for patients requiring daily, long-term use.[18]

Venusia sun unseen sunscreen demonstrated phototoxicity (photoirritation) scores, measured on Draize scale, of 0.96 (unexposed) and 0.75 (UV-exposed), which were well below the 2.0 irritancy threshold. These values confirm that the product does not elicit phototoxic or photoirritant reactions, even under controlled UV exposure. The slightly lower score at the

exposed site may suggest a protective effect of the formulation, reinforcing its value beyond simple UV filtering alone. Importantly, the absence of AEs strengthens the case for the good tolerability of the product, possibly making it suitable for users with sensitive skin, patients with chronic dermatoses, and individuals undergoing dermatological treatments, where the risk of irritation often impedes adherence.

The main ingredients of venusia sun unseen sunscreen were vitamin C, E and F, Octinoxate, Octocrylene, Octisalate, Uvinul A Plus, Tinosorb S. Vitamins C and E, along with their stabilized derivatives, are frequently incorporated into modern dermo-cosmetic formulations due to their well-established antioxidant, photoprotective, and skin-repairing properties. Their inclusion in the Venusia Sun Unseen Sunscreen supports enhanced protection against UV-induced oxidative stress and may contribute to improved skin barrier resilience and overall photostability of the formulation.[19] The integration of antioxidants with sunscreen agents is well-established, as these compounds exhibit synergistic activity in quenching UV-induced reactive oxygen species, thereby augmenting cutaneous photoprotection and contributing to both the prevention and potential attenuation of photoaging-related structural damage.[20,21] Octocrylene, an organic UV filter from the cinnamate class known for its strong absorption of short-wavelength UVA and UVB radiation, is included to enhance broad-spectrum photoprotection and contribute to the overall stability and efficacy of the formulation.[22] Octinoxate is frequently incorporated into advanced sunscreen formulations to enhance UVB protection and to help stabilize other photolabile UV filters by absorbing specific UVB wavelengths. It contributes to broad-spectrum efficacy and supports the overall photostability of the formulation.[23] Octisalate (OS) is a commonly used organic UVB filter that enhances protection against sun-induced erythema by efficiently absorbing mid-range UVB wavelengths, it strengthens the formulation's UVB coverage, improves photostability, and supports the overall synergistic performance of the sunscreen's multi-filter system.[24] Uvinul A Plus is a highly effective UVA filter with peak absorption in the long-wave UVA range, providing robust protection against UVA-induced photoaging. Unlike several traditional filters, it exhibits excellent photostability, allowing it to maintain its protective capacity even under prolonged UV exposure. Skin-tolerance assessments have shown that Uvinul A Plus is generally well tolerated, with a low likelihood of irritation or sensitization.[25] Importantly, current evidence does not indicate any impact on hormonal pathways. Its enhances the formulation's UVA coverage and contributes to long-lasting, stable photoprotection.[26] Tinosorb S, one of the UV filters incorporated in the Venusia sun unseen sunscreen formulation, demonstrates broad-spectrum photoprotective properties, effectively stabilizing and enhancing the performance of other UV filters under UV exposure.[27]

Routine daily use of sunscreen is widely recommended by AAD association for all individuals, regardless of demographic factors. As per the AAD, high-number SPF does not allow individuals to spend additional time outdoors without reapplication. As many individuals only apply about 20-50% of the amount of sunscreen needed to achieve the amount of SPF on the label, application of high-SPF sunscreens helps to compensate for this under-application. Sunscreen should be reapplied approximately every two hours when outdoors, even on cloudy days, and after swimming or sweating. Broad-spectrum sunscreens with SPF 30 or higher (along with wearing protective clothing, hats, and sunglasses) have been recommended by American Cancer Society (ACS) for their proven efficacy in protecting against UV-induced skin damage, aging, and cancer.[9,28] Clinical and histological data demonstrate that daily sunscreen reduces UV-induced skin damage compared with intermittent use of higher-SPF products, highlighting the importance of consistent everyday application rather than occasional high-SPF use.[29] A one-year evaluation of daily facial application of a broad-spectrum sunscreen demonstrated a 40-52% improvement in skin texture and pigmentation scores. All participants exhibited enhanced skin clarity and smoothness, indicating that consistent daily use not only prevents photoaging but can also produce measurable and visible improvements in existing photodamage.[30] It also helps to maintain an even skin tone, reduces mottled pigmentation, and improves texture, which are key cosmetic outcomes valued by users.[31] The application of sunscreen generously to all exposed skin should be done 15-30 minutes before going outdoors. Reapplication is needed after activities that may remove sunscreen, such as swimming, towelling off, heavy sweating, or rubbing the skin.[32]

By validating safety through a standardized photopatch test, this study provides relevant evidence, reassuring consumers who seek reliable, daily irritation-free sun protection.

Strengths and limitations

The study demonstrates strong methodological robustness through the use of duplicated application sites, controlled UVA exposure, and an independent UV-only control area, enabling precise differentiation between intrinsic irritancy and phototoxic responses. The quantitative scoring of erythema, dryness, wrinkles, and oedema using a standardized visual assessment scale generated consistent low-grade reactions across participants. Additionally, photographic documentation of representative cases supports the objectivity of clinical observations, collectively strengthening the validity of the conclusion that the test product exhibits no phototoxic potential.

The limitations of this study include the modest sample size, single-center design, and short-term assessment focused on acute reactions under occlusive conditions. Broader, multicenter trials with extended follow-up and

repeated applications would further establish the safety profile across diverse populations. Despite these limitations, the study provides a strong basis for presenting Venusia Sun Unseen Sunscreen as a consumer-relevant option that demonstrates safety with minimal risk of photo irritation.

CONCLUSION

Venusia sun unseen sunscreen was confirmed to be non-phototoxic (non-photoirritant), with Phototoxicity (photoirritant) scores well below clinically significant thresholds in both UV-exposed and unexposed conditions. These findings highlight that the product is well-tolerated, with no signs of erythema, oedema, or irritation. This strong safety profile allows dermatologists to recommend it confidently for long-term, daily use. Its gentle, non-irritating formulation makes it suitable even for individuals with sensitive or chronic skin conditions. Overall, Venusia Sun Unseen Sunscreen demonstrates both regulatory compliance and dependable real-world performance.

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