International Journal of Research in Dermatology
Gala M et al. Int J Res Dermatol. 2026 Jul;12(4):324-330
https://www.ijord.com

DOI: https://dx.doi.org/10.18203/issn.2455-4529.IntJResDermatol20261933

Original Research Article

Evaluation of skin irritation and skin sensitization potential of Venusia sunscreen using human repeat insult patch test

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Received: 30 March 2026
Accepted: 05 June 2026

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ABSTRACT

Background: Sunscreens are widely used for daily photoprotection, making evaluation of their dermatological safety essential. This study aimed to assess skin irritation and sensitization (hypoallergenic) potential of Venusia Sun Unseen (sunscreen) in healthy human participants.
Methods: This single-centre, evaluator-blinded study using human repeat insult patch test (HRIPT). It was conducted in three phases: induction (21 days), rest (14 days) and challenge phase (4 days), with skin reactions in the induction and challenge phases graded using the Draize scale and International Contact Dermatitis Research Group (ICDRG) scale, respectively. Test product and a negative control (0.9% isotonic saline) were applied occlusively on the back of participants using patch chambers.
Results: Out of 220 participants, 218 completed the study (mean age 38.8 years; 94.5% female). Among them, 64.2% had normal skin and 35.8% had sensitive skin. Venusia Sun Unseen was classified as non-irritant, with a mean cumulative Draize score of 0.21 (induction phase). Negative control showed a score of 0, confirming the absence of irritation. ICDRG assessments demonstrated predominantly negative responses with test product, with 176 participants exhibiting no reaction at 48 hours and any doubtful or weak reactions resolving by 96 hours (challenge phase). It showed no strong positive reactions at any time point, while negative control showed negative responses throughout the study. No adverse events (AEs) or serious AEs were reported.
Conclusions: Venusia Sun Unseen was found to be non-irritant and hypoallergenic, with no clinically significant irritation or sensitization observed. It was well-tolerated, supporting its routine use for photoprotection.

Keywords: Human repeat insult patch test, Hypo allergenic, Skin irritation, Skin sensitization, Sunscreen

INTRODUCTION

Sunscreens are a cornerstone of photoprotection and have been widely recommended since their first commercialization in the United States in 1928.[1,2] They reduce manifestations of photoaging, including wrinkling and sagging and lower the risk of actinic keratosis and photocarcinogenesis.[3] Modern sunscreens are formulated to provide broad-spectrum ultraviolet (UV) A and UVB protection, while also shielding the skin from visible light, infrared radiation and environmental pollution, which drives continued innovation in photoprotective agents, formulations and delivery systems.[1,4] Globally, sunscreen use is widespread and increasing. Surveys indicate facial application of sunscreen as the most frequently adopted sun-protective measure, reported by 60% of individuals.[5] A cross-sectional study involving around 50,000 individuals from 20 countries found Asia reporting one of the highest sunscreen usage prevalences (25.08%).[5,6] In India, the primary reason for sunscreen use was the prevention of tanning, reported by 73% of males and 82% of females.[3] Most individuals strongly believed that sunscreens protect against UV radiation (84%), sun damage (85%) and sunburn (77%) and

preferred formulations that are non-sticky, minimally irritating, less allergenic and have minimal acne aggravation.[3] Regulatory agencies, including the Food and Drug Administration, approve broad-spectrum sunscreens with a sun protection factor (SPF) of 15 or higher for the prevention of sunburn, photo-induced pigmentation, premature aging and skin carcinoma.[3,7,8] The American Academy of Dermatology recommends regular use of sunscreen with an SPF of 30 or higher for all skin types.[9]

However, with the increasing use of sunscreens in recent years, reactions such as allergic contact dermatitis, photo-irritation, photo-allergenicity and photo-toxicity remain major concerns for assessing the tolerability of topical sunscreens.[10] Therefore, it is important to evaluate the irritation and sensitization potential of sunscreens to ensure their safe and optimal use. Thus, the present study aims to evaluate the skin irritation and skin sensitization potential (allergenicity) of the Venusia Sun Unseen using the HRIPT technique.

METHODS

Study design

This was a single-centre, evaluator-blinded study conducted at C.L.A.I.M.S. Pvt. Ltd., Mumbai, Maharashtra, India, to evaluate the skin irritation and skin sensitization potential (allergenicity) of Venusia Sun Unseen, using the HRIPT technique. The test product and control were coded and labeled by C.L.A.I.M.S. Pvt. Ltd. to ensure that the evaluator remained blinded to product allocation throughout the study, thereby minimizing assessment bias.

Ethical approval

The study received approval from the Independent Ethics Committee of C.L.A.I.M.S. Pvt. Ltd. (ECR/245/Indt/MH/2015/RR-22; Approval date: April 30, 2025) and was conducted in compliance with the Protocol, Bureau of Indian Standards guidelines (IS 4011:2018, Third Revision, July 2018), Indian Council of Medical Research guidelines (2017), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use E6 (R3) Guideline for Good Clinical Practice (2016), Good Clinical Laboratory Practice and the Declaration of Helsinki (Brazil, October 2013). The study was registered with the CTRI (CTRI/2025/05/087310). The study's potential risks and benefits were explained before screening, queries were addressed and informed consent was obtained from all participants.

Study population

The study enrolled men and women aged 18–65 years with apparently healthy skin at the test area and Fitzpatrick skin types III (Tans after initial burn), IV (Burns minimally, tans easily) and V (Rarely burns, tans darkly easily). At least 50 participants with sensitive skin, as determined by the lactic acid sting test described in a previous study, were included. Participants were instructed to avoid intense UV exposure, water contact (e.g., swimming) and activities causing sweating (e.g., exercise or sauna), at the test site during the study.[11] Participants who were pregnant or lactating, had scars, excessive terminal hair or tattoos on the study area or presented with dermatological infections or pathologies at the test site were excluded. Individuals with a history of hypersensitivity or allergy to cosmetic products, raw materials or hair dyes or those with clinically significant systemic or cutaneous diseases that might interfere with study outcomes, recent use within one month of systemic or topical medical treatments, participating in other food, cosmetic or therapeutic studies were also excluded from the study.

Study procedure

This study was conducted between 23 June 2025 and 2 August 2025 to evaluate a test product, Venusia Sun Unseen, along with a negative control, 0.9% isotonic saline solution. The study was carried out in two sequential batches and comprised three distinct phases: the Induction Phase, Rest Phase and Challenge Phase. At baseline (Visit 1), eligible participants were enrolled and patch test materials were prepared for application. Approximately 0.04 g of the test product and filter papers containing approximately 0.04 mL of the negative control were placed in separate wells of patch chambers and applied occlusively on the participants' backs by trained Clinical Research Associate.

Induction phase

The induction phase was conducted over approximately three weeks. During this phase, patches containing the test product and negative control were applied nine times on alternate days starting from Visit 1 (V1, V3, V5, V7, V9, V11, V13, V15, V17). Each patch application was followed by patch removal on the subsequent visit, conducted on alternate days starting at Visit 2 (V2, V4, V6, V8, V10, V12, V14, V16, V18). Clinical evaluation of the patch application sites was performed on alternate days starting at Visit 3 (V3, V5, V7, V9, V11, V13, V15, V17, V19). Skin reactions were examined, graded and scored using the Draize scale.

Rest phase

No patch applications were performed during this phase, which lasted approximately 14 days. This phase allowed for resolution of any transient skin responses prior to challenge testing.

Challenge phase

During the challenge phase, a single 24 hours occlusive patch containing the test product and negative control

was applied to new sites on the participants' backs at V20. The patches were removed after 24 hours V21. The application procedure was similar to that used during the induction phase. Subsequent clinical evaluations of skin reactions were performed at 48 hours (V22), 72 hours (V23) and 96 hours (V24) post-removal using the ICDRG scale (Figure 1).

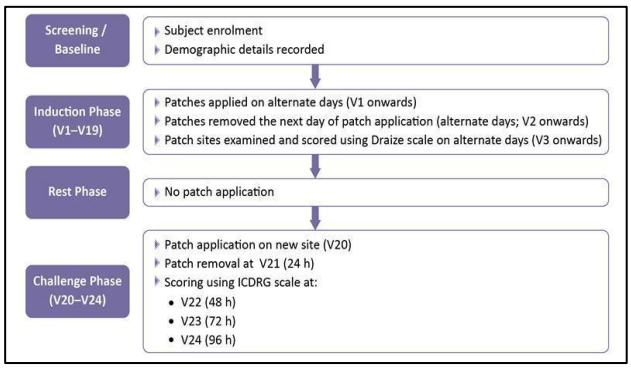


Figure 1: Study design and assessment flow.

Study assessment

Reactions observed during the Induction Phase were assessed using the Draize scoring system. Skin responses at the test site were evaluated and scored for erythema, dryness and wrinkling (A), as well as for oedema (O), each on a scale of 0 to 4 (Table 1). During the Challenge Phase, reactions were evaluated and scored according to the ICDRG scale, where reaction intensity represented by symbols from negative (−) to strongly positive (+++). Irritant reactions (IR) were recorded separately, including responses such as soap effect, vesicles, blisters or necrosis (Table 2).

Table 1: Scoring of induction phase reactions using Draize scale.

Score	Reaction	
	Erythema/dryness/wrinkles	Oedema
0	No reaction	No reaction
1	Very slight erythema/dryness with shiny appearance	Very slight oedema
2	Slight erythema/dryness/wrinkles	Slight oedema
3	Moderate erythema/dryness/wrinkles	Moderate oedema
4	Severe erythema/wrinkles/scales	Severe oedema

For each sample (test product and negative control), the mean irritation score was calculated using the equation:

Mean irritation score=total score (A+O) for each sample/Total number of subjects.

In accordance with the IS 4011:2018, methods of test for safety evaluation of cosmetics (third revision) guidelines, a mean score value up to 2.0/8.0 was classified as non-irritant; >2.0/8.0 to 4.0/8.0 as mildly irritant; and >4.0/8.0 as irritant.

Table 2: Scoring of challenge reactions/ rechallenge phase will be carried out as per ICDRG scale.

Symbol	Morphology	Interpretation
-	No reaction	Negative reaction
?	Erythema only, No infiltration	Doubtful reaction
+	Erythema, infiltration, possibly discrete papules	Weak positive
++	Erythema, infiltration, papules, vesicles	Strong positive
+++	Erythema, infiltration, confluent vesicles	Extreme positive
IR	Different types of reactions (soap effect, vesicles, blister, necrosis)	Irritant

Adverse events

All AEs and serious AEs (SAEs) were recorded and assessed by the PI for their potential relationship to the study product.

Sample size

As per the IS 4011:2018 methods of test for safety evaluation of cosmetics (third revision) guidelines, 200 complete cases were required for the study.[12] In consideration of potential participant dropouts, 220 participants were enrolled.

Statistical analysis

No formal statistical analysis was conducted. Data were recorded and presented in tabular form for descriptive interpretation.

RESULTS

Between June 23 and August 02, 2025, a total of 220 participants were enrolled. Of these, 218 completed both the induction and challenge phases, while two dropped out due to loss to follow-up. Therefore, the final analysis included 218 participants.

Demographic characteristics

The study population had a mean age of 38.8 years and was predominantly female (94.5%). Most participants had normal skin (64.2%) in the nasolabial area, while a notable proportion had sensitive skin (35.8%). Key baseline characteristics of the study population are presented in Table 3.

Table 3: Demographic and baseline characteristics of study participants (n=218).

Characteristic	Value
Age (in years)	
Mean	38.84
SD	10.32
Range	18-65
Gender N (%)	
Males	12 (5.5)
Females	206 (94.5)
Skin N (%)	
Sensitive skin	78 (35.8)
Normal skin	140 (64.2)

Product assessment score

In the induction phase, the mean cumulative score for A and O for Venusia Sun Unseen was 0.21. Based on the criteria defined in the IS 4011:2018 (Third Revision) guidelines, this score falls within the non-irritant range, while the negative control (0.9% isotonic saline) recorded a score of 0.00, indicating absence of irritation (Figure 2).

During the challenge phase, ICDRG scoring showed that at 48 hours, 80.74% of participants exhibited no reaction, 18.8% had doubtful reactions and only 0.46% showed a weak positive reaction. None of the participants exhibited strong positive reactions. At 72 hours, 97.7% of participants demonstrated negative reactions, while 2.3% showed doubtful responses. By 96 hours, all participants exhibited negative reactions, indicating complete resolution of earlier findings. The negative control (0.9% isotonic saline solution) showed negative reactions at all time points (Figure 3). A photographic representation of two participants with normal and sensitive skin, illustrating patch application and scoring for both the induction and challenge phases (Figure 4).

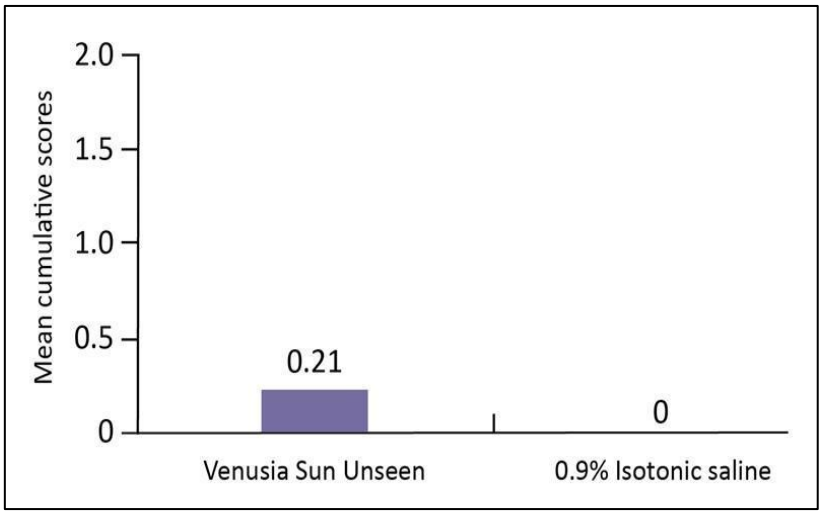


Figure 2: Mean cumulative Draize scores for the induction phase for test product and negative control.

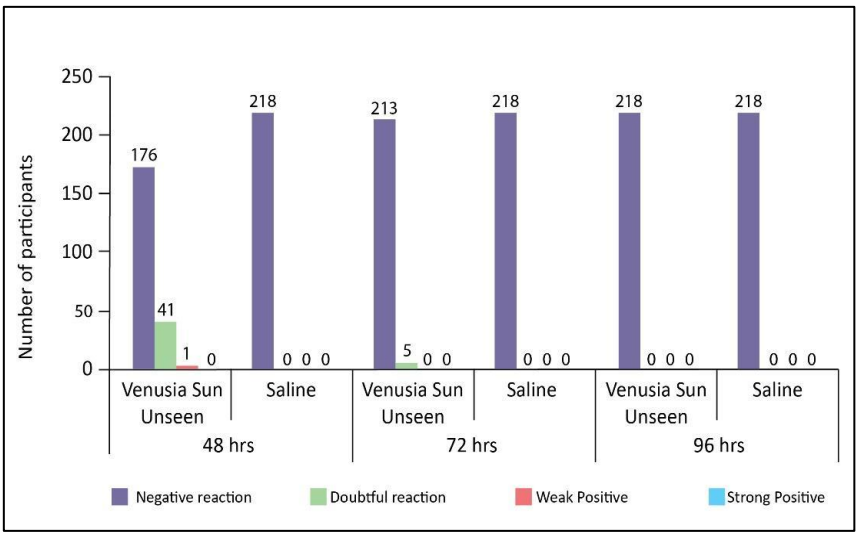


Figure 3: ICDRG skin reaction scores for the challenge phase for test product and negative control.

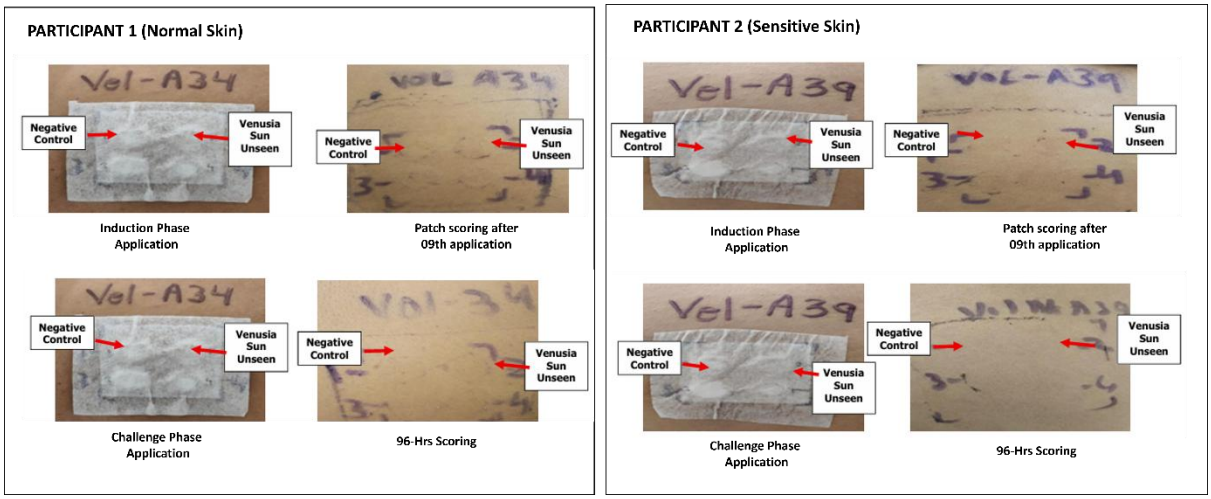


Figure 4: Participants with normal and sensitive skin, showing application and scoring for both the induction and challenge phases.

Adverse events

No AEs and SAEs were reported throughout the study.

DISCUSSION

Broad-spectrum sunscreen formulations that block both UVB and UVA radiation are critical for preventing photodamage from prolonged sun exposure, particularly in photosensitive individuals.[10,13] However, despite increased use, certain sunscreen agents have been linked to allergic contact dermatitis and photodermatitis, underscoring the need for careful evaluation of acute and subacute reactions such as photo-irritation, photo-allergenicity and photo-toxicity.[10] Additionally, potential skin penetration of UV filters raises concerns regarding systemic absorption, emphasizing the importance of assessing dermal tolerability.[13,14] Given these considerations, assessment of skin irritation and sensitization potential represents a critical component of the safety evaluation of sunscreen formulations intended for regular use.

Accordingly, the present study evaluated the skin irritation and sensitization potential (allergenicity) of Venusia Sun Unseen using HRIPT in 218 participants with normal and sensitive skin. The HRIPT is a widely recognized and reliable method for evaluating such responses in human subjects, as it is specifically designed to simulate repeated or exaggerated exposure and to detect both primary irritant reactions and delayed immunological sensitization.[15,16] HRIPT involves repeated applications of the test product under occlusion to maximize skin contact and detect cumulative irritation during the induction phase, followed by application at a separate site during the challenge phase to assess sensitization potential.[15,16] Cutaneous responses are typically characterized by erythema, edema, vesicles, papules or pruritus and persistent reactions at both induction and challenge sites are indicative of sensitization.[15,16] By providing confirmatory human data, HRIPT validates whether products remain compatible with the skin and are unlikely to induce irritation or sensitization under conditions of repeated or exaggerated exposure.[15,16]

In this current study, Venusia Sun Unseen demonstrated excellent dermal tolerability under repeated occlusive application across participants with normal and sensitive skin types. Overall, Venusia Sun Unseen was non-irritant, with only a small proportion of participants exhibiting minimal, transient skin reactions and no adverse events reported, confirming its hypoallergenic nature and safety under repeated dermal application. The results are consistent with a dermal irritation study of cosmetic and personal care formulations containing natural ingredients. In that study, a sunscreen lotion showed a mean score of 0 at both 30 minutes and 24 hours post patch removal, while a sunscreen spray demonstrated a mean score of 0.4 at 24 hours, both categorized as non-irritant and well-tolerated across diverse skin types including oily, mixed, dry, normal and sensitive skin.[17] The comparable dermal tolerability outcomes indicate that Venusia Sun Unseen exhibits a safety profile similar to sunscreen formulations with natural ingredients, reinforcing its suitability for use in individuals including sensitive skin as a safe and well tolerated sunscreen formulation.

Consumer perception and real-world experience play an important role in sunscreen adherence and the overall effectiveness of photoprotection. A one-year study of broad-spectrum sunscreen applied daily demonstrated visible improvements in skin texture, clarity and pigmentation, indicating that it potentially helps in reversing photodamage while preventing further UV-related harm.[18] These findings suggest that positive user experiences encourage daily use, enhancing both safety and photoprotection. Consistent with these observations, the present study demonstrate that Venusia Sun Unseen Sunscreen is a non-irritant and non-sensitizing product

which are key attributes for regular use. Its favorable safety profile, combined with well-characterized, photostable UV filters and a skin-compatible formulation, is likely to enhance consumer acceptance and support continued use, in individuals with normal and sensitive skin.

The study's strengths include the use of the validated HRIPT and standardized scoring systems (Draize and ICDRG scales), providing reliable evaluation of skin irritation and sensitization. A large sample size of 218 participants, including both normal and sensitive skin, enhances the generalizability of findings, while evaluator blinding minimizes bias and ensures protocol adherence. The inclusion of a negative control further supports the validity of the results. Limitations include its single-centre design, lack of randomization and short-term occlusive testing, which may not fully reflect real-world use. Additionally, the product was tested only on the back of participants, limiting assessment of regional differences in skin response. Further studies are needed to confirm safety across diverse populations.

CONCLUSION

Venusia Sun Unseen sunscreen demonstrated non-irritant and hypoallergenic properties when evaluated using the HRIPT. It did not produce any clinically relevant irritation or sensitization responses following repeated occlusive applications in participants with normal and sensitive skin. Venusia Sun Unseen showed good dermal compatibility and was well-tolerated, with no AEs observed. These findings indicate its suitability for routine topical use, including individuals with sensitive skin and support its use as a daily sunscreen formulation for effective photoprotection.

ACKNOWLEDGEMENTS

The authors thank NeoCrest Life Sciences Consulting Private Limited for providing medical writing assistance for this manuscript. The authors also thank the study participants, principal investigators, and site (Site name: C.L.A.I.M.S. Pvt. Ltd) staff.

Funding: Dr. Reddy's Laboratories Ltd., Hyderabad, Telangana, India
Conflict of interest: All authors are employees of Dr. Reddy's Laboratories Ltd.
Ethical approval: The research/study was approved by the Independent Ethics Committee of C.L.A.I.M.S., registration number: ECR/245/Indt/MH/2015/RR-22, Dated April 30, 2025

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Cite this article as: Gala M, Creado S, Muchhala S, Dhanaki G, Sanghavi A, Kotak B. Evaluation of skin irritation and skin sensitization potential of Venusia sunscreen using human repeat insult patch test. Int J Res Dermatol 2026;12:324-30.