

Evaluating the variability in effective protection against ultraviolet A (UVA) radiation-induced pigmentation provided by mineral sunscreens

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Introduction, Objectives, and Methods

Introduction

- Sun Protection Factor (SPF) is widely recognized as an index of the protection against ultraviolet B (UVB). However, SPF rating does not provide explicit information on the magnitude of protection against ultraviolet A (UVA), which penetrates deeper into the skin and causes pigmentary, photoaging, photocarcinogenic, and immunomodulatory effects.
- Mineral sunscreens, even those providing broad-spectrum protection, may offer different levels of UVA protection. Sunscreens with higher levels of zinc oxide (ZnO) generally have superior in vitro UVA absorbance, but the clinical relevance in terms of UVA-induced pigmentation is not well understood.

Objectives

- To clinically evaluate US mineral sunscreens for protection against UVA radiation-induced pigmentation in vivo per ISO24442:2022 and in vitro per ISO24443:2021.^{1,2}
- To compare critical photoprotection attributes of different sunscreen product types that make up the US mineral sunscreen category.

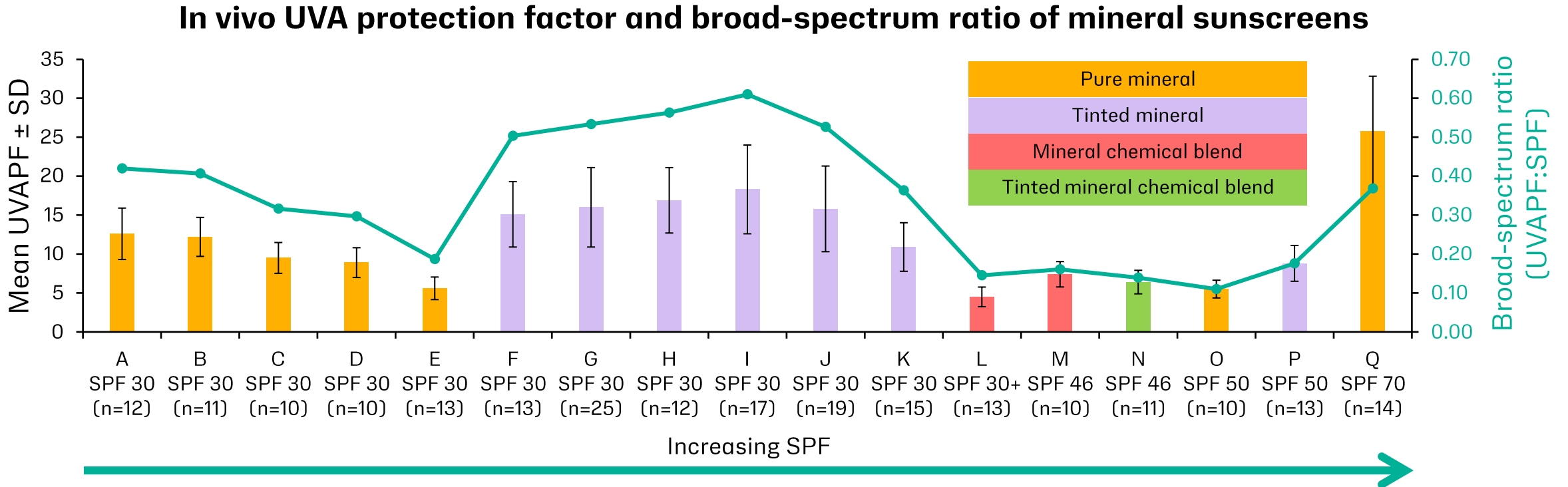
Methods

- A single-center, randomized, evaluator-blind, self-controlled clinical study was conducted to evaluate the UVA Protection Factor (UVAPF) per the method (ISO24442:2022) described by the International Organization for Standardization (ISO) for evaluating the UVAPF of sunscreen products using the persistent pigmentation darkening response of skin.
- Per ISO24442:2022, sufficient healthy male/female participants, 18-70 years of age, with Fitzpatrick skin type II to IV were enrolled to receive at least 10 valid test results for each investigational product.
- Eighteen broad-spectrum mineral sunscreens ranging from SPF 30 to 70 were evaluated. Eight sunscreens were further evaluated in vitro (per ISO24443:2021) to compare photoprotection attributes of pure mineral, mineral chemical blend, tinted mineral, and tinted mineral chemical blend sunscreens.

1. International Organization for Standardization. (2022). Cosmetics – Sun protection test methods – In vivo determination of sunscreen UVA protection (ISO Standard No. 24442:2022). 2. International Organization for Standardization. (2022). Cosmetics – Determination of sunscreen UVA photoprotection in vitro (ISO Standard No. 24443:2021, corrected version 2022-02).

Results –

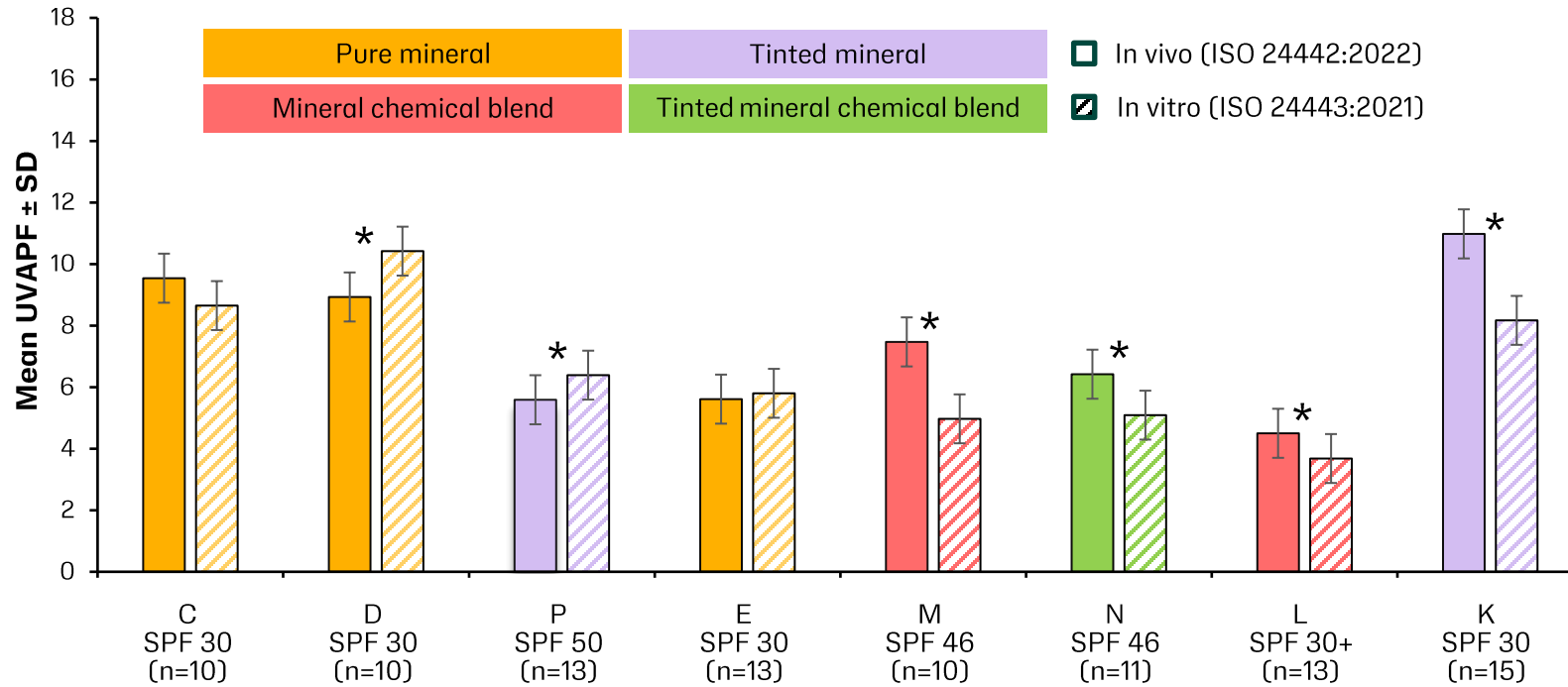
Large variability in UVA protection across broad-spectrum mineral sunscreens



- Not all “broad-spectrum” mineral sunscreens have the same broad-spectrum protection as indicated by the UVAPF:SPF ratio, which ranged from 0.11 to 0.61. The EU regulates broad spectrum via a ratio of at least 0.33.
- The addition of tint improved the UVA protection of the pure mineral sunscreens, but interestingly, it had the opposite effect for the mineral chemical blend sunscreen.
- High SPF mineral sunscreens had lower UVA protection and “broad spectrum” except for sunscreen Q, which was the only high SPF mineral sunscreen with a broad-spectrum ratio of over 0.33.

Results – Mineral chemical blend sunscreens exhibited the lowest in vitro UVAPF and critical wavelength

In vivo and in vitro UVA protection factor comparison of mineral sunscreens



*Denotes statically significant difference (p<0.05).

- Comparisons between ISO24442:2022 and ISO24443:2021 indicated a statistically significant difference for sunscreens D, P, M, N, L, and K.
- Mineral chemical blend sunscreens with and without tint (M, N, L) demonstrated the lowest in vitro UVA protection of the sunscreens tested.
- Mineral chemical blend sunscreens with and without tint (M, N, L) showed the lowest critical wavelengths and the biggest shift post irradiation, indicating lack of photostability.

Sunscreen critical wavelength			
Product	Labeled SPF	Mean critical wavelength	
		Pre-UV exposure	Post-UV exposure
C	30	376.05	376.15
D	30	371.70	371.95
P	50	371.35	371.10
E	30	373.00	373.00
M	46	365.10	368.00
N	46	366.10	368.90
L	31	366.40	368.45
K	30	378.05	377.00

Conclusions

- Key photoprotection attributes including UVA protection and photostability were observed to vary greatly across pure mineral, tinted mineral, mineral chemical blend, and tinted mineral chemical blend products that make up the US mineral sunscreen categories.
- Mineral sunscreens demonstrated high UVAPF variability across the entire SPF range with clinically obtained UVAPF to SPF ratios ranging from 0.11 to 0.61, despite all being labeled “broad spectrum”.
- The addition of tint improves UVAPF for pure mineral sunscreens; however, the opposite effect is observed for mineral chemical blend sunscreens.
- Products with SPF 30-40 exhibited UVAPFs of 4.5-18.3; products with SPF 41-50 exhibited UVAPFs 5.5-8.8; while the product with the highest SPF of 70 provided the highest observed UVAPF of 25.8.
- High SPF along with high UVAPF for sunscreen Q confirms that balanced protection is achievable, indicating the importance of formulation design to maximize efficacy of UV actives.
- Mineral chemical blend sunscreen demonstrated the weakest UVA protection and photostability.
- Superior broad-spectrum protection in practice does not end with formula efficacy, but it also depends on the formula aesthetics. Further research is needed to optimize the balance between the two.