ORIGINAL ARTICLE

Comparison of ultraviolet A light protection standards in the United States and European Union through in vitro measurements of commercially available sunscreens

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Background: The importance of adequate ultraviolet A light (UVA) protection has become apparent in recent years. The United States and Europe have different standards for assessing UVA protection in sunscreen products.

Objective: We sought to measure the in vitro critical wavelength (CW) and UVA protection factor (PF) of commercially available US sunscreen products and see if they meet standards set by the United States and the European Union.

Methods: Twenty sunscreen products with sun protection factors ranging from 15 to 100+ were analyzed. Two in vitro UVA protection tests were conducted in accordance with the 2011 US Food and Drug Administration final rule and the 2012 International Organization for Standardization method for sunscreen effectiveness testing.

Results: The CW of the tested sunscreens ranged from 367 to 382 nm, and the UVA PF of the products ranged from 6.1 to 32. Nineteen of 20 sunscreens (95%) met the US requirement of CW >370 nm. Eleven of 20 sunscreens (55%) met the EU desired ratio of UVA PF/SPF > 1:3.

Limitations: The study only evaluated a small number of sunscreen products.

Conclusion: The majority of tested sunscreens offered adequate UVA protection according to US Food and Drug Administration guidelines for broad-spectrum status, but almost half of the sunscreens tested did not pass standards set in the European Union. (J Am Acad Dermatol http://dx.doi.org/10.1016/j.jaad.2017.01.017.)

Key words: critical wavelength; photoprotection; sunscreen; ultraviolet A; UVA protection; UVA protection factor.

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The detrimental effects of chronic and excessive ultraviolet (UV) radiation exposure have been well studied and linked to the development of sunburn, skin cancer, immunosuppression, and photoaging.[1-4] Current photoprotection strategies include sun avoidance, wearing protective clothing, and sunscreen application. In the United States and Europe, the application of sunscreen is the most common photoprotective behavior practiced by the public.[5]

The use of sunscreen affords a variety of benefits, including decreasing the number of nevi in children,[6,7] preventing the development of actinic keratosis,[8,9] squamous cell carcinoma,[10-12] melanoma,[13] and reducing the signs of photoaging.[14,15] Currently, the only numeric measure of sunscreen efficacy in the United States is sun protection factor (SPF), which is based on an in vivo test that measures protection against sunburn or erythema induced primarily by ultraviolet B light (UVB; 290-320 nm) and ultraviolet A2 light (UVA2; 320-340 nm). The SPF value offers little information regarding protection against UVA1 light (340-400 nm).

In June of 2011, the US Food and Drug Administration (FDA) issued a final ruling on the labeling and effectiveness testing of sunscreen products in the United States.[16] In the ruling, the FDA adopted the in vitro critical wavelength (CW) as a measure of assessing UVA or broad-spectrum protection.[17] CW is defined as the wavelength at which 90% of the total area under the absorbance curve resides, with the absorption measures across the UV spectrum ranging from 290 to 400 nm. Specifically, the FDA has ruled that only products with CW ≥370 nm can be labeled as having "broad-spectrum" protection.

Although sunscreens with broad-spectrum status under current US regulations offer a pass or fail standard for UVA protection (an in vitro CW of ≥370 nm), the balance of UVA protection to UVB protection (SPF) is more lenient in contrast with Europe, which has adopted the International Organization for Standardization method 24443[18] for measuring UVA protection. Regulatory guidelines in the European Union recommend a minimum UVA protection factor (UVA PF) to SPF ratio of at least 1:3 for all marketed sunscreen products.[19]

In this study, we determined the in vitro CW and UVA PF of 20 sunscreen products commercially available in the United States and assessed their level of UVA protection by determining the ratio of UVA PF/SPF to see if they meet standards set by the United States and European Union.

CAPSULE SUMMARY

- The United States and European Union have different standards for assessing ultraviolet A light protection in sunscreen products.
- Most commercially available US sunscreens meet ultraviolet A light protection standards in the United States, but almost half do not meet EU standards.
- US sunscreens with higher sun protection factor may require more stringent standards to afford better ultraviolet A light protection. Sunscreen alone may not provide adequate ultraviolet A light protection.

METHODS

Product selection

Twenty sunscreen products were selected because of their sales volume, SPF values, and accessibility. All products tested were labeled as broad-spectrum in addition to their SPF value. All the sunscreens were purchased at a brick and mortar CVS store in San Francisco, California, and Winston-Salem, North Carolina. The products were packaged and labeled only by code numbers before analysis.

In vitro UVA protection tests

Two in vitro UVA protection tests, specifically the critical wavelength and UVA protection factor, were conducted in accordance to the testing protocols outlined in the 2011 US FDA Final Rule[16] and 2012 International Organization for Standardization 24443 method,[18] respectively.

For determination of the CW, sunscreen products were applied at 0.75 mg/cm^2 to 3 polymethylmethacrylate (PMMA) plates with a roughness value of 6 μm (HD-6; Helioscreen, Creil, France). The plates were then irradiated with a full-spectrum UV dose of 4 minimal erythema doses (800 effective J/m^2) using a 1000-W xenon arc solar simulator (LS1000-4S-001; Solar Light Co, Philadelphia, PA). The UV transmittance of the irradiated plates was measured from 290 to 400 nm using a spectroradiometer equipped with an integrating sphere (Optronic Laboratories OL756; Gooch & Housego, Orlando, FL). Absorbance spectra for UV doses corresponding to the requirements of the test methods were obtained and used to calculate CW.

For the determination of the UVA PF, PMMA plates with a roughness value of 6 μm (SD-6; Helioscreen) were used. Each sunscreen product