

- e) Provide data relative to the differential "wash-off" of ingredients during water immersion or sweating (i.e., differential changes to-UVB and/or UVA absorption).

Comment

To the best of our knowledge there is no evidence to support the hypothesis that the UV filters, either UVB, UVA or both may be differentially effected by water immersion. However, it is recognized that "water proof" or "water resistance" is an important product attribute for many consumers. Presently, the agency has a robust method to establish such claims for sunscreen products. Thus, we believe the current testing approach used to support waterproof claims is applicable to the product and there is no basis for considering waveband specific.

It is our view that the substantivity of a sunscreen product matrix together with the physicochemical properties of UV filters determine whether a waterproof claim is applicable. For example, in the formulation of a "water proof" sunscreen, the use of water soluble UV filters would, in general, be avoided due to their greater propensity to "wash off", thereby reducing product efficacy.

If water soluble UV filters are not used, then the formulator is left with UV filters that are oil soluble or particulates (i.e., metal oxides). More specifically, the currently approved long wave UVA filters are either particulates (TiO₂ or ZnO) or oil soluble (avobenzone). These UV filters would generally be in the same "phase" (i.e., oil phase) of a formula which is the same compartment where UVB/UVA II filters would be. Thus, it is logical that a test for waterproof using the current method would be sufficient to establish the claim independent of UV filter since there is no basis to consider differential wash off of filters occupying the same compartment in the formula.

It is possible that *in vitro* substrate spectrophotometry could be used to assess water proof claims of sunscreen products. This has been done for a small number of products¹⁶. In one study, the water resistance of 10 sunscreen products and three daily use products containing UV filters was assessed using substrate spectroradiometry. Sunscreen product was applied to the substrate, human epidermis, at 2 mg/cm² and the absorption spectra measured. The substrate was then subjected to 4, 20 minute immersions in a water bath. After each immersion, the epidermis was allowed to dry and the absorbance of the sunscreen product measured. The authors found that products which claimed to be "water resistant" or "waterproof" had significantly better substantivity than products which made no claim concerning water resistance. Because there was no difference in products claiming to be "water proof" versus "water resistance" in this study, the authors suggest that it is unnecessary to differentiate between these and that consumers would benefit from a simple label. Regardless, the data presented in this paper demonstrate that substrate spectroradiometry could be adapted to test for water resistance of sunscreen products throughout the entire UV spectrum.

In a second study, 4 sunscreen products were assessed using substrate spectrophotometry¹⁷. The conduct of this study was similar to that described above. Sunscreen products were applied to excised human epidermis and the absorption spectra

¹⁶ Stokes, RP, Diffey, BL (1999) The water resistance of sunscreen and day-care products. *Br J Dermatol.* 140:259-63.

¹⁷ Stokes, RP, Diffey, BL, Dawson, LC, Barton, SP (1998) A novel *in vitro* technique for measuring the water resistance of sunscreens *Intl J Cosmet Sci* 20:235-40.

obtained before and after 2, 20 minute immersions in a water bath with water constantly agitated. Importantly, this study determined the ratio of UVA/UVB to determine whether water immersion changed the absorption spectrum of a product by preferentially removing certain active ingredient. It was found that exposure to water did not product a significant change in the UVA/UVB absorbance ratio of any of the sunscreens.

In both studies described above, there was no evidence of a differential wash off of UV filters. This implies that sunscreen substantivity is a whole product attribute that is not UV filter specific.

Thus, although *in vitro* determination of "waterproof" of sunscreen products may be used, additional work would need to be performed. More important, there is no evidence of a differential wash off and, as such, it is recommended that the current method remain as the means of establishing this claim.