Hybrid Diffuse Reflectance Spectroscopy: Non-Erythemal in vivo Testing of Sun Protection Factor.

Abstract

Background/Aims: In order to define a label sun protection factor (SPF) of topically applied sunscreens, in vivo test methods like ISO 24444, FDA guideline, or the Australian standard are used worldwide. The basis of all these methods is provoking an erythemal skin reaction by UV irradiation to find the level of unprotected and protected minimal erythemal doses (MED). In vitro methods replacing the human skin by any kind of non-human material are still not available. Thus, offering the new hybrid diffuse reflectance spectroscopy (HDRS) technique that is able to stay on an in vivo level for SPF testing but meanwhile neglecting the UV-dose-related erythemal skin reaction is a perfect combination to take care of sun protection and any ethical concerns in SPF testing nowadays.

Methods: HDRS is a combination of in vivo diffuse reflectance spectroscopy (DRS) measurements on the skin and in vitro transmission measurements of a sunscreen on a roughened polymethylmethacrylate plate. By this technique, the in vivo behavior of the investigated sunscreen on the skin is measured as well as the UVB absorption, which is still non-visible in the reflectance technique. In order to establish an alternative method for in vivo SPF testing, a huge number of sunscreens (80 samples) was measured by HDRS and compared to the worldwide accepted standard ISO 24444. The variety of sunscreens measured reflects a wide range of different types of formulations as well as a wide range of SPFs (5–120) to validate this new alternative SPF testing procedure.

Results: The applied quantity of product as well as skin color dependencies of signal generation are shown to support any basic correlation of DRS signal generation and sun protection expectations. Far-reaching statistical data analyses show an excellent link of the new non-erythemally driven HDRS-SPF technique and ISO 24444 results. In the same way, HDRS-UVA-PF results can be correlated with UVA-PF values calculated from ISO 24443.

Conclusion: Due to the elimination of any erythemal relevant UVB and UVA doses, absolutely no skin reaction occurs. Consequently there is no need to define a MED any more. For the first time an alternative way to SPF is shown without any ethical concerns of SPF testing in vivo and/or any restriction of SPF testing in vitro. Regardless of the type of formulation or the level of protection, an excellent correlation of SPFHDRS and SPF24444 for sunscreen
labeling could be found. By this new alternative non-erythemal technique, not only SPF values can be measured, but also UVA-PF values can be calculated with an excellent correlation to ISO 24443 from the same set of data. For the first time a robust alternative test method of SPF- and UVA-PF values is described, taking into account the interaction of sunscreen formulation and skin.

Citation