DEUTSCHE GESELLSCHAFT FÜR WISSENSCHAFTLICHE
UND ANGEWANDTE KOSMETIK E.V.

Gegr. 1957

Multicenter methodology comparison of the FDA and ISO standard for measurement of in vitro UVA protection of sunscreen products

By: Bielfeldt, S.; Klette, E.; Rohr, M.; Herzog, B.; Grumelard, J.; Hanay, C.; Heinrich, U; Hansen, P.; Kockott, D.; Lademann, J.; Mendrok-Edinger, C.; Peters, S.; Rudolph, T.; Schlaeger, T.; Tronnier, H.; Wiechers, S.; Zastrow, L.; Pfluecker, F.

Journal of Photochemistry and Photobiology, B: Biology (2018), 189, 185-192

In vitro std. methods are available and accepted worldwide to assess UVA protection of sunscreen products. Though, harmonisation of methods has made progress in the last decade, still two differing methods - one by FDA the other by ISO - are in use. In a multicentre study including 9 centers in Germany, 4 different com. sunscreen products were assessed using both methods to discover their similarities and differences. UVA protection factor and Crit. Wavelength were detected at various substrate type (sandblasted vs. molded PMMA plates), at different surface roughness of the plates as well as at different product application dose using two different irradn. spectra. Results: The strongest influence on UVA protection factor results from the surface roughness of the plates. Depending on the roughness (accepted range of 2 to 7 µm in the FDA method) a variability in the UVA protection factor of up to 25% was obsd., while the much narrower definition of plate roughness by ISO (4.5 to 5.2 µm) had no relevant influence on the test results. Sandblasted plates in our assessment led to higher UVA protection factors and produced less scattered results compared to molded plates. These differences were not pronounced. Application dose and spectra of the irradn. source were of negligible influence on UVA protection factor results for the investigated UV-filter combinations. The UVA protection factor which is the endpoint of the ISO method was found to be a parameter with a high potential to differentiate among different test products. The endpoint of the FDA method - the Crit. Wavelength - was found to be an unambitious endpoint. Insensitivity to all described modifications of the method was obsd. All investigated products performed similar and passed the Crit. Wavelength criteria independent of method and parameters.