

TAM4-1

Applying the proposed FDA sunscreens rule – an in vitro and in silico assessment of the UVA protection of eight US sunscreens

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On 27 August 2008 the US Food and Drug Administration (FDA) published a “proposed rule” on sunscreens. The objective of the current study is to evaluate the UVA protection part by comparing the proposed in vitro method to the existing Boots method, the basis of the new rule, and the COLIPA guideline which assesses the UVA-Protection Factor (UVA-PF) in vitro. For this comparison eight popular US sunscreens with various degrees of UVA protection UVA-PF and different SPF values were selected. In silico calculations are based on the absorption properties of the sunscreen actives combined with a model of the sunscreen film on the skin. In the in vitro experiments sunscreen products were applied to roughened polymethylmethacrylate (PMMA) plates according to the Colipa guideline. We observed good agreement of the UVA indices between the in vitro measurements and in silico calculations and also a good correlation between the new proposed in vitro UVAI/UV ratio and the established in vitro criteria in Europe from Boots and the European Commission. Achieving three stars in both the new FDA rule as well as the Boots labelling system is required to fulfil the European UVA-PF/SPF > 1/3 pass/fail criterion. Only few US sunscreens currently fulfil this standard and none achieves more than 3 stars. Based on in silico experiments, existing European sunscreens that achieve 5 Boots’ star can be expected to also meet the “Highest” FDA 4 star category. For this to happen new sunscreen actives have to be approved in the USA.