INNOVATIVE SKINCARE® EXTREME PROTECT SPF 30 SUN PROTECTION STUDY

MatTek Inc.

STUDY OBJECTIVE

EXTREME PROTECT SPF 30 was evaluated for its ability to protect the skin against damage from sun exposure according to both United States and international standards.

STUDY DESIGN

Methods used in this evaluation were: (1) SPF measurement method used by the FDA in the United States, (2) International SPF method used in countries other than the United States, (3) Colipa European method for evaluation of UVA protection, the UVA-PF method, (4) FDA rule requirements as of June 2011 for UVA protection claims of "broad spectrum UVA and UVB protection".

SIGNIFICANCE OF STUDY

Standard evaluation methods of solar protective ability of topical sunscreen products have been developed. These methods are scientifically verified and reproducible although they vary somewhat according to country or region. These measurements are published as an aid to consumers when comparing and purchasing sunscreen products claiming sun protection.

SPF measurements pertain to protection from solar rays in the UVB range only. UVB rays penetrate the most superficial layers of skin and are responsible for sunburn. UVB exposure also relates to the development of skin cancer. SPF measurements pertain to UVB exposure only and measure the time required for a standardized minimum amount of skin erythema (redness) to develop on UVB-exposed skin if the product is used compared to non-use of the product. For example, if the SPF is 10, then 10 times longer is required to develop the specified amount of erythema (redness) if the product is used compared to if it is not used on bare skin. Results are also reported in "confidence intervals" which gives mathematical assurance that the results are statistically reliable. In the United States, 20 subjects are required for evaluation. For the International method used outside the United States, 10 subjects are required for evaluation. All SPF measurements were "static" which do not involve water exposure.

UVA protection was also evaluated. UVA rays penetrate deeper into the skin and are causative in sun-related premature skin aging and the development of skin cancer. UVA rays damage DNA in the chromosomal genetic material within skin cells. In E.U. countries, the method for UVA evaluation is the UVA-PF or UVA-Protection Factor method. This is an in vitro method which has shown statistically reliable and reproducible correlation with the in vivo Persistent Pigment Darkening method. In the EU, 10 subjects are required for evaluation. To claim UVA protection and exhibit the UVA seal used in the E.U. on the package, the sunscreen's UVA-PF must measure greater than or equal to one-third of the sunscreen's SPF value. In June 2011, the FDA in the United States released its new sunscreen labeling rules. To carry the package label of "broad spectrum UVA and UVB protection" in the United States as of 2012, the sunscreen must have an SPF of 15 or higher. Sunscreens with an SPF in the range of 15 to 50 will be able to claim on the package that they protect against UVA damage, skin cancer and sun-related premature skin aging.

RESULTS AND CONCLUSIONS

The SPF measurements for EXTREME PROTECT SPF 30 are given below by country/region.

United States FDA SPF method—32.61 (mean)

International SPF method—32.9 (mean)

The UVA-Protection Factor measurement for EXTREME PROTECT SPF 30 is given below.

UVA-PF method—10.71 (mean)

These SPF results reported according to strict United States FDA and International standardized protocols are all within the label claims of SPF 30 for EXTREME PROTECT SPF 30.

Results for UVA protection according to E.U. Colipa standards substantiate package label claims of UVA protection in the E.U.

SPF results in the United States conform to the FDA requirements for package label claims of "broad spectrum UVA and UVB protection". Protection against skin cancer and sun-related premature aging may also be claimed on the package label in the United States.