



Cosmetics Europe Recommendation No 25

Use of appropriate validated methods for evaluating sun product protection

Sunscreen products play an essential role in preventing short- and long term damage to human skin caused by exposure to UV radiation. In order to inform and protect consumers, several organisations (test magazines, consumer organizations, scientific workgroups etc.) may test sunscreen products from the market for their efficacy and publish the results. However, it is important that the testing is performed according to validated methods to ensure accurate results.

Testing sun protection effectiveness is a very complex task, and although different methods are used, some of them may not give reliable results. To ensure valid, reproducible and comparable results, it is crucial to use appropriate validated and standardised test methods. Cosmetics Europe has invested considerable effort in developing test methods that can be used as standard methods to determine Sun Protection Factor, UVA-protection and water resistance. These published methods have been validated by ring tests, which are proven to give reproducible results relevant for consumers. Recently, the majority of these published methods have been standardised by the International Standardisation Organisation (ISO) and published by the European Standardisation Organisation (CEN). These standard methods have been acknowledged by the European Commission as EU reference methods. The vast majority of the manufacturing companies are using these methods to qualify their products and to define the consumer information to be displayed on the label.

From time to time some consumer associations, journals and even market control authorities still choose to use other unproven, non-validated methods that are inappropriate for comparative testing. Their results are sometimes numerically different to the results from using the standard, validated methods used by the manufacturers. Referring to results of these tests is ultimately confusing for consumers and undermines the common understanding that is built by using the standard labeling rules and testing methods. It is of utmost importance that consumers are given a consistent message and

can understand what level of protection (i.e. what SPF number) they should use for their skin.

Cosmetics Europe strongly recommends using always the methods cited below when testing SPF, UVA or water resistance of sunscreens:

Sun Protection Factor (SPF): The Standard EN ISO 24444:2010 Cosmetics - Sun protection test methods - *In vivo* determination of the sun protection factor (SPF).

This standard test method replaces the earlier reference method (International Sun Protection Factor Test Method (2006) as updated in 2006 by the European, Japanese, American and South African industry) as specified in the EU recommendation from 2006. Although the EN ISO test method is now considered as the reference method within the EU, the above cited International Test Method remains a valid test method. Sunscreens tested with the International Test Method do not have to be re-tested.

There is currently no *in-vitro* method that is proven to give reliable and meaningful test results for SPF, therefore no *in vitro* method should be used for consumer information purposes.

UVA protection: The Standard EN ISO 24443:2012 Cosmetics – Sun protection test methods – *In vitro* determination of sunscreen UVA photoprotection.

This standard has been published by CEN (June 2012) and replaces the earlier reference method (Colipa Guidelines - Method for *in vitro* Determination of UVA protection, 2011). The EN ISO test method is now considered as the reference method within the EU. Cosmetics Europe therefore recommends cosmetic manufacturers to use this standard to determine the UVA Protection Factor and the Critical Wavelength..

Earlier test results obtained by using the above cited Colipa Test Method remain valid and can be considered as equivalent to the EN ISO test results. It is not necessary to re-test these products.

The Standard EN ISO 24442:2011 Cosmetics - Sun protection test methods - *In vivo* determination of sunscreen UVA protection which replaces the persistent pigment darkening method published by the Japanese industry in 1995 for *in vivo* determination of UVA protection as specified in the EU Recommendation (2006) can be also used to test products.

For UVA protection testing, preference is given to the standardised *in vitro* test method which avoids the need for *in vivo* testing while delivering equivalent results.

Water resistance: Cosmetics Europe published the "(Colipa) Guidelines for Evaluating Sun Product Water Resistance, 2005" and this method is widely accepted and used by manufacturers to qualify their products.

There is currently no *in-vitro* method that is proven to give reliable and meaningful test results for water resistance, therefore no *in vitro* method should be used for consumer information purposes.

Cosmetics Europe continues to actively contribute to the development of validated methods for sun protection efficacy measurement in order to enhance consumer information about the efficacy of sunscreen products. Using the validated testing methods recommended by Cosmetics Europe enables consumers to have confidence in the SPF and UVAPF ratings and therefore the efficacy of their sun protection products.
