

INDUSTRY INITIATIVES ON SUN PROTECTION

Sun protection is an important area of activity for The European Cosmetic, Toiletry and Perfumery Association (Colipa). The industry association has a tradition of voluntary initiatives on product testing and labelling in this field, driven by the responsible attitude of its member companies. So although harmonisation of testing and labelling of sun protection has always been outside the scope of the EU Cosmetics Directive 76/768/EEC¹, as early as 1976, Colipa realised that there was a need to develop and actively promote industry standards on testing, labelling and consumer education.

Colipa's overall objectives are to provide advice and support to consumers based on a dialogue between the authorities and industry. These contribute to a stable framework in which to operate and generate trust.

Colipa has successfully worked on agreed industry practices for the substantiation of efficacy claims (Testing) and harmonised consumer information on how to choose and use sunscreens correctly (Labelling).

TESTING

The agreed industry practices for the substantiation of efficacy claims (Testing) cover test and measurement protocols, calculation and interpretation of results and quality and compliance criteria.

Sun protection factor

The first standard method for SPF determination and labelling was the Proposed Monograph 1978 issued by the US Food and Drug Agency (FDA). This was followed in 1984 by the German DIN 67501 norm which was applied elsewhere in Europe. These two standards differed in respect to the type of ultraviolet (UV) source used (xenon arc lamp or natural sunlight and mercury lamp, respectively) and the rate of product application to the skin (2.0 and 1.5mg.cm⁻²) which led to some discrepancies in the measured protection factors.

Other countries followed the FDA by issuing similar standards: the Standards Association of Australia (SAA) in 1986 (latest version 1998 in association with the New Zealand Standards Association)² which included both SPF and water resistance testing, the Japanese Cosmetic Industry Association (JCIA) in 1991 (latest version 1999) and the South African Bureau of Standard (SABS) in 1992 (latest version 2002). The original FDA Monograph is now in a 1999³ version but implementation is postponed until specific methods for UVA testing and labelling can be introduced.

Colipa has worked hard to improve methods for the evaluation of sun protection efficacy. It introduced innovative techniques to characterise and specify the emission spectrum of the UV source and to select skin types

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colorimetrically in its European SPF Guidelines (1994)⁴. Two high SPF standard reference products were proposed to meet the demand for testing newly developed high SPF sun protection products. The Austrian Önorm (1998)⁵ and a revised DIN standard (1999)⁶ were aligned with the 1994 Colipa Guideline. Korea, Columbia, Mercosur (the customs union between Brazil, Argentina, Uruguay, Paraguay and Venezuela) and the People's Republic of China adopted methods referring to FDA or Colipa standards.

The development of standardised sun protection factor (SPF) testing was thus accompanied by improvements in science and methodology and growing acceptance of the concept of SPF which measures mainly UVB protection.

However, SPF determination between different methods is variable according to: selection of volunteers (number, phototype), test area, number and size of test sites, products (quantity applied, application procedure), solar simulation (lamp type, light quantity, light quality), evaluation of unprotected and protected minimal erythral dose (MED_u and MED_p), and statistics.

A major achievement by Colipa was to ensure the reproducibility and comparability of SPF determination. This was done through the introduction of a standardised test protocol setting tight specifications for these variables, a video demonstration of product application technique and a 'Guideline for Monitoring of UV Light Sources'. These advances were consolidated in the first International SPF Test Method adopted in 2003 by cosmetic industries in the European Union, Japan and South Africa, joined by the US Cosmetic, Toiletry, and Fragrance Association (CTFA US) for the latest version in 2006⁸. Australia and China expressed an interest in harmonisation with this method. The European Commission applied used it as the basis for its 'Recommendation on the efficacy of sunscreen products and the claims made relating thereto' (2006)⁹. Seeking further international harmonisation, Colipa, has become a Liaison Member of the International Standards Organization (ISO) Technical Committee 217, Working Group 7 on Methods to Assess Efficacy of Sun Protection Products.

Water resistance

A Water Resistance Method was issued by Colipa in 2005¹⁰. It is based on the principle of comparison of the SPF for a sunscreen product after a defined period of immersion in water with the original (static) SPF determined according to the International SPF Test Method. It defined the immersion equipment and conditions to be used: Spa pool, Jacuzzi or bath tub, water quality and temperature and immersion wet-dry sequence standardised.

Definitions for 'water resistance' were also set: 'water resistant' if after 2 baths of 20 minutes the remaining SPF efficacy is $\geq 50\%$ + IC 90% ; 'very water resistant' if after 4 baths of 20 minutes the remaining SPF efficacy is $\geq 50\%$ + IC 90%.

UVA protection

Whilst sun protection products have long protected against erythema mainly caused by UVB radiation, research indicating that UVA radiation has harmful

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effects (such as premature ageing of the skin)¹¹ led Colipa to develop a Method for the *in vitro* Determination of UVA Protection Provided by Sunscreen Products¹². It has been validated against the *in vivo* Persistent Pigment Darkening (PPD) method¹³ currently in use and published in 2007. The importance of this method is that it provides the means for ensuring uniform claims on UVA protection in order to make it easier for the consumer to choose for a product protecting against both UVB and UVA radiation. The European Commission gives preference to *in vitro* testing methods delivering equivalent results⁹, as *in vivo* methods raise ethical concerns. ISO WG 7 is currently reviewing *in vivo* and *in vitro* methods of UVA testing and Colipa will contribute full information on its *in vitro* UVA test method.

Photostability

Since UV active formulations such as sun protection products may start to break down when they are exposed to light¹⁴, a test of photostability is required. Colipa issued Guidelines on Photostability Testing of UV Filters in Sunscreen Formulations in 2004¹⁵. These are based on an *in vitro* procedure for determining the photostability of UV filters alone and within sunscreen formulations. A simple and reliable *in vitro* model enables the concentration of UV filters to be determined analytically before and after exposure to controlled doses of UV radiation from a standard source.

Scientific evidence that the final test protocols give reproducible results and a demonstration of their accuracy by ring studies has been published (UV filters)¹⁶.

LABELLING

Colipa's approach to labelling reflects the Consensus position of the American Academy of Dermatology (2001)¹⁷ that SPF should be the primary consideration for sunscreen potency. The industry association is aware that sunscreens need to be correctly applied in order reach the protection level indicated by the SPF¹⁸, particularly in sufficient quantities and with frequent re-application¹⁹. Therefore Colipa has sought to harmonise consumer information on how to use sunscreens correctly (Labelling), whilst making recommendations to industry on placing clear usage instructions on sun products (2004)²⁰. It has also advocated clear labelling of the key parameters of sun protection and fully supported individual Company initiatives on consumer education, including joint programmes with authorities and dermatologists.

Sun protection factor

Colipa's objective was to simplify the existing sun protection labelling system in order to avoid confusion and to give consumers clear and meaningful information. In 2002 it issued recommendations²¹ for restricting the proliferation of labelled SPF values by limiting them to a few categories of protection. This enables the consumer to compare different products without reducing choice. It also provides additional relevant information to consumers in a harmonised manner which does not lead to confusion with existing SPF labelling. Colipa also actively discouraged the use of the word 'unblock+

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since no sunscreen product can filter all UV radiation nor provide total protection from the risks of over-exposure to UV radiation.

The following labelled categories and their corresponding range of sun protection factors have since been adopted, with slight changes, by the European Commission in its Recommendation on the efficacy of sunscreen products and the claims made relating thereto⁹.

Colipa		European Commission	
Labelled category	Labelled sun protection factor (SPF)	Labelled category	Labelled sun protection factor (SPF)
Low	2 4 6	Low protection	6 10
Medium	8 10 12	Medium protection	15 20 25
High	15 20 25	High protection	30 50
Very high	30 40 50	Very high protection	50+
Ultra	50+	-	-

UVA protection

Consistent with Colipa's approach to UVB protection, the industry association considers that the SPF is also the key efficacy parameter for the consumer for UVA protection labelling. Although SPF is primarily an indicator of UVB protection, sun protection products need to be effective against both UVB and UVA radiation in order to adequately protect the skin. Therefore Colipa proposed that the UVA protection of a product should be in relation to the SPF (i.e. UVB protection) to ensure consistent protection over the whole UV spectrum. According to Colipa, UVA related claims should be supported by a minimum ratio of the protection factor measured for UVA of at least 1/3 of the SPF labelled for UVB radiation. This ratio has also been included in the European Commission's Recommendation on the efficacy of sunscreen products and the claims made relating thereto.

UVA logo

Colipa has developed a labelling scheme for sunscreen products that meet the European Commission's Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto of having a UVA protection factor of at least 1/3 that of the sun protection factor. This makes it easier for the consumer to choose a product protecting against both UVB and UVA radiation.

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Colipa recommends that on-pack indication of compliance with the EC recommendation should be done through the letters "UVA" printed in a simple circular shape.²² The diameter of the logo should not exceed the height of the SPF. The logo will progressively appear on products in the market.

Instructions to consumers

Colipa has pioneered usage instructions that improve consumer awareness of the necessity and means to protect themselves (and particularly children) against the sun. The industry association's recommendation is that all sun protection products carry clear advice to consumers to avoid intensive midday sun, to apply sun protection products in sufficient quantity before exposure to the sun (protection may not reach the labelled SPF if a smaller amount is used) and to reapply frequently. Children's products are to carry additional advice to keep babies and young children out of direct sunlight, to wear protective clothing and to use very high SPF sunscreens (higher than 25 or high protection).

Consumer education

Programmes to educate the consumer in responsible behaviour towards sun protection include both harmonisation of product usage instructions carried out by Colipa at industry level and the provision of brochures and website (for example, explaining to parents how to use sun protection for their children) carried out by individual companies at corporate level.

CONCLUSION

Colipa has a history of commitment to sun protection and has led the way in developing and promoting industry standards on testing, labelling and consumer education. It is actively engaged in harmonisation of these across the industry and at an international level.

Thanks to Colipa, standardised test protocols are on hand today for SPF measurement, water resistance measurement, photostability measurement and there is a method for UVA protection measurement.

Colipa is also largely responsible for the fact that the vast majority of sun products sold in Europe are labelled not only correctly but informatively too. It has led the way in harmonising the labelling in current use for UVB Protection (SPF), UVA protection and Water resistance.

¹ EU Cosmetics Directive 76/768/EEC

² Australian/New Zealand Standard: Sunscreen products . Evaluation and classification. AS/NZS 2604:1998

- ³ Department of Health and Human Services, FDA, USA: Sunscreen drug products for over-the-counter human use. Final Monograph. Federal Register. 64/98, 276866-27693, May 21, 1999 (provisional)
- ⁴ COLIPA SPF test method. Ref 94/289. 1994
- ⁵ Önorm: Sunscreen products . Laboratory testing of sun protection factors (SPF). Önorm S 1130, 1998
- ⁶ Deutsches Institut für Normung (DIN): Experimental evaluation of erythema protection of external sunscreen products for the human skin. Revision of DIN 67501, 9/1999
- ⁷ COLIPA Guideline for Monitoring of UV Light Sources. 2007
- ⁸ COLIPA International Sun Protection Factor (SPF) Test Method. May 2006
- ⁹ European Commission Recommendation on the efficacy of sunscreen products and the claims made relating thereto. OJ L 265/39, 26.9.2006.
- ¹⁰ COLIPA Guidelines for evaluating sun product water resistance. 2005
- ¹¹ Stanfield J, Stewart S, Krochmal L. UVA protection factors. In the Biological effects of UVA radiation (F Urbach & R Gange, Editors, Praeger Publ NY), 469-479, 1986
- ¹² COLIPA: Method for the *in vitro* Determination of UVA Protection Provided by Sunscreen Products.2007a
- ¹³ Japan Cosmetic Industry Association. Measurements Standards for UVA Protection efficacy Nov 15, 1995
- ¹⁴ Deflandre A, Lang G. Photostability assessment of sunscreens. Benzylidene camphor and dibenzoylmethane derivatives, Int J Cosmet Sci 1988;10, 53-52
- ¹⁵ COLIPA Guidelines on Photostability Testing of UV Filters in Sunscreen Formulations. 2004
- ¹⁶ Berset G, Gonzenbach H, Christ R, Martin R, Deflandre A, Mascotto R, Jolley JDR, Lowell W, Pelzer R, Stiemt T. Int. J. Cos. Scien 1996; 18(4), 167.
- ¹⁷ Lim HW et al Academy of Dermatology consensus conference on UVA protection of sunscreens JAAD, 2,505-508, 2001
- ¹⁸ Stenberg C, Karkö O. Sunscreen application and its importance for the sun protection factor. Arch Dermatol 121,1400-1402, 1985
- ¹⁹ Diffey B. When should sunscreen be reapplied? J Am Acad Dermatol. 45, 882-885. 2001
- ²⁰ Colipa recommendation N°13 Important usage instructions labelling of sun products 2004
- ²¹ COLIPA Recommendation N°11 SPF classification/Upper limit June 2002
- ²² COLIPA Recommendation N°21 Labelling of sunscreen products with UVA protection claim