

IKW RECOMMENDATION ON THE EFFICACY AND CLAIMS RELATING TO SUNSCREENS

- taking into account the “Commission Recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto” -

These Recommendations are only applicable to sunscreens within the meaning of the definition included in the Recommendation of the EU Commission. Cosmetic products for skincare, which offer protection against UV radiation as a secondary benefit, can be labelled on a voluntary basis with the individual elements of this Recommendation provided that the corresponding criteria and methods of determination described in the Recommendation are complied with.

1. Method for the determination of UVB protection

The sun protection factor (SPF) should be determined in accordance with the “International Method for the Determination of the Sun Protection Factor” or preferably – as soon as such a method will be available – in accordance with an *in vitro* test method with correlating results.

The “International Method” was published – most recently in June 2006 – by Colipa.

2. Indication of the Sun Protection Factor (SPF)

(a) Result of the determination of the SPF according to the International Method

The SPF indicates the mean value from the individual determination in at least 10 and no more than 20 test subjects. In addition to the mean value, the confidence interval for a 95% probability is mentioned. An SPF determination is only valid if the confidence interval is below 17%.

Example: 10.6 ± 1.6 .

This means that the mean SPF of the corresponding sample test falls within the range of 9.0 – 12.2 with a probability of 95%.

If high SPFs are indicated, the possible variability of the SPF should in all cases be taken into consideration. Confirmatory measurements in different institutes are advisable in this case.

(b) Indication of the SPF and product categories

The mean SPF identified is rounded down to the next lower number in the SPF classification table (see below). This number represents the maximum SPF indication. SPF test results may not be rounded up to the next higher number in the SPF classification table.

The SPFs are restricted to the numbers expressly specified in the SPF classification table. Consequently, the lowest SPF of a sunscreen is 6 and the highest 50+ (corresponds to a measured SPF of more than 60).

The product categories and SPF numbers specified in the following table are to be indicated on the products:

Product category	SPF
Basis	6, 10
Medium	15, 20, 25
High	30, 50
Very high	50+

The SPF as well as the product category should be specified on the label of the product in a highly visible location. The product category should be identifiable at least as precisely as the SPF.

3. Method for the determination for the UVA protection

The UV-A protection should be determined in accordance with the *in vivo* PPD method or preferably in accordance with an *in vitro test* method with correlating results. Such a method was published by Colipa. See also the corresponding Colipa Recommendation No. 20.

4. Claim of UVA protection

Every sunscreen should have UVA protection which corresponds at least to one-third of the specified sun protection factor. The claim should be made by means of this symbol:



See also the corresponding Colipa Recommendation No. 21.

5. Determination of the critical wavelength

In addition to the determination of the SPF and the UVA protection in accordance with the above mentioned methods, the critical wavelength should be determined as well (370 nm).

6. Claims of sunscreens / Instructions on use and warnings

The claims should not give any indications which could incite consumers to have excessive sunbathing. There should, more particularly, not be any indications which suggests full protection of the products against UV radiation such as:

“Sunblock”, “Sunblocker”, “Full protection”, “Protection for the full day” or the similar.

Within the framework of the product descriptions, it should basically also be referred to the risks of excessive sun exposure.

The following instructions for use and / or warnings should be indicated in this or a similar form on all sunscreen packages (except for UV protection sticks for the lips).

1. Avoid intensive sun at noon
2. Apply before sunbathing
3. Apply repeatedly, in order to maintain sun protection, in particular after a stay in the water
4. Apply sunscreens generously. Low application amounts reduce the protective effect.
5. Protect babies and infants from direct sun exposure
6. Use protective clothing as well as sunscreens with a high sun protection factor (SPF of more than 25) for babies and infants
7. Even sunscreens with high sun protection factors do not provide full protection against UV radiation

7. Implementation

The companies should take these new Recommendations into account as soon as possible and no later than in the summer of 2009 all products should be provided with the new labelling elements. Some elements of the Recommendation of the EU Commission will already be identifiable on the market in the course of 2007.