

COMMISSION RECOMMENDATION

of 22 September 2006

on the efficacy of sunscreen products and the claims made relating thereto

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(Text with EEA relevance)

(2006/647/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular the second indent of Article 211 thereof,

Whereas:

(1) Sunscreen products are cosmetic products within the meaning of Article 1(1) of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products ⁽¹⁾.

(2) Under the first paragraph of Article 2 of Directive 76/768/EEC, cosmetic products placed on the Community market must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling and any instructions for its use.

(3) Article 6(3) of Directive 76/768/EEC obliges Member States to take all measures necessary to ensure that, in the labelling, putting up for sale and advertising of cosmetic products, text, names, trade marks, pictures and figurative or other signs are not used to imply that these products have characteristics which they do not have.

(4) Moreover, under Article 7a of Directive 76/768/EEC, the manufacturer or his agent or the person to whose order a cosmetic product is manufactured or the person responsible for placing an imported cosmetic product on the Community market must, for control purposes, keep information on the proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product, readily accessible to the competent authorities of the Member State concerned.

(5) In order to contribute to a high level of health protection, guidance should be given as to the impli-

cations of the provisions laid down in Article 6(3) of Directive 76/768/EEC for claims made in respect of the efficacy of sunscreen products.

(6) While industry has already made certain efforts in this respect, it is appropriate to set out examples of claims which should not be made in relation to sunscreen products, precautions that should be observed, and usage instructions that should be recommended for some of the characteristics claimed.

(7) It is also appropriate to address certain other aspects relating to claims made for sunscreen products and the efficacy of such products, namely the minimum efficacy of a sunscreen product in order to ensure a high level of protection of public health and how the labelling of sunscreen products can be kept simple and comprehensible in order to assist the consumer in choosing the appropriate product.

(8) Sun radiation consists *inter alia* of (shorter) ultraviolet B radiation ('UVB radiation') and of (longer) ultraviolet A radiation ('UVA radiation'). The inflammation of the skin ('sun burn') and the resulting reddening of the skin (*erythema*) is mainly caused by UVB radiation. As to the cancer risk, although UVB radiation is the main contributor, the risk generated through UVA radiation cannot be neglected. Furthermore, UVA radiation is cause of premature ageing of the skin. Research also suggests that excessive exposure to UVB radiation as well as UVA radiation impacts on the body's immune system.

(9) Sunscreen products can be effective in preventing sunburn. Scientific findings also suggest that sunscreen products can prevent the damage linked to photo-ageing and that they can protect against induced photo-immunosuppression. Epidemiological studies show that the use of sunscreen products may prevent some types of skin carcinoma.

(10) In order to have these preventive characteristics, sunscreen products need to protect against both UVB and UVA radiation. Therefore, although the sun protection factor refers only to protection against the radiation which causes *erythema* (mainly UVB radiation), sunscreen products should contain both UVB and UVA protection.

⁽¹⁾ OJ L 262, 27.9.1976, p. 169. Directive as last amended by Commission Directive 2006/65/EC (OJ L 198, 20.7.2006, p. 11).

- (11) Even sunscreen products which are very effective and which address both UVB and UVA radiation cannot guarantee full protection against health risks from ultra-violet (UV) radiation. No sunscreen product can filter all UV radiation. Moreover, there is, to date, no conclusive scientific evidence that the use of sunscreen products prevents melanoma. Consequently, sunscreen products should not claim or create the impression that they provide total protection from the risks deriving from over-exposure to UV radiation.
- (12) This holds particularly true for sun exposure of babies and young children. As exposure to sun during childhood is an important contributor to the development of skin cancer at a later age, sunscreen products should not give the impression that they provide sufficient protection for babies and young children.
- (13) Mistaken perceptions of the characteristics of sunscreen products should be addressed through appropriate warnings.
- (14) Based on several studies, the International Agency for Research on Cancer of the World Health Organisation has emphasised the importance of the link between the correct application of sunscreen products and the efficacy of the sun protection factor claimed. In particular, frequent re-application of sunscreen products is crucial. Moreover, in order to reach the protection level indicated by the sun protection factor, sunscreen products have to be applied in quantities similar to the ones used for testing, i.e. 2 mg/cm², which equals 6 teaspoons of lotion (approx. 36 grams) for the body of one average adult person. This quantity is higher than that usually applied by the consumers. Applying a smaller quantity of sunscreen product leads to a disproportionate reduction in protection. For example, if the quantity applied is reduced by half, protection may fall by as much as two-thirds.
- (15) Sunscreen products should be sufficiently effective against UVB and UVA radiation to ensure a high protection of public health. To this end, a sunscreen product should provide a minimum UVB and UVA protection. An increased sun protection factor (i.e. mainly UVB protection) should include an increase in the UVA protection as well. Therefore, the protection against UVA and UVB radiation should be related. Scientific findings show that certain biological damage to the skin can be prevented and reduced if the ratio of the protection factor measured in the persistent pigment darkening test (i.e. addressing mainly UVA radiation) is at least 1/3 of the factor measured by the sun protection factor testing method (i.e. addressing mainly UVB radiation). Moreover, in order to ensure a broad protection, dermatologists recommend a critical wavelength of at least 370 nm.
- (16) In order to ensure reproducibility and comparability of the recommended minimum protection against UVB radiation, the *International Sun Protection Factor Test Method (2006)* as updated in 2006 by the European, Japanese, American and South African industry should be used. In order to assess the minimum protection against UVA radiation, the persistent-pigment darkening method as applied by the Japanese industry and modified by the French health agency *Agence française de sécurité sanitaire des produits de santé — Afssaps* as well as the critical wavelength test should be used. These testing methods have been submitted to the European Committee for Standardisation (CEN) in order to establish European standards in this field ⁽¹⁾.
- (17) While these testing methods should be used as reference methods, preference should be given to *in vitro* testing methods delivering equivalent results, as *in vivo* methods raise ethical concerns. Industry should increase efforts to develop *in vitro* testing methods for the protection against both UVB and UVA radiation.
- (18) Claims concerning the efficacy of sunscreen products should be simple, meaningful and based on identical criteria in order to help the consumer to compare products and to choose the right product for a given exposure and skin type.
- (19) There is in particular a need for a uniform claim on UVA protection in order to facilitate the choice of the consumer for a product protecting against both UVB and UVA radiation.
- (20) A wide variety of numbers used on labels for indicating the sun protection factor does not support the aim of making claims that are simple and meaningful. The increase in protection from one number to the next is negligible, particularly in the high range. Moreover, the increase in protection is only linear in the case of sunburn, that is to say, a product with sun protection factor 30 protects twice as well from sunburn as product with a sun protection factor of 15. However, a product with sun protection factor 15 absorbs 93 % of UVB radiation, and a product with sun protection factor 30 absorbs 97 % of UVB radiation. Finally, sun protection factors above 50 do not substantially increase the protection from UV radiation. Therefore, the range of labelled sun protection factors can be made smaller without reducing the choice of different strengths for the consumer.
- ⁽¹⁾ Standardisation mandate addressed to CEN on methods for testing efficacy of sunscreen products, Mandate M/389, 12 July 2006.

- (21) Labelling using one out of four categories ('low', 'medium', 'high' and 'very high'), provides for a simpler and more meaningful indication of the efficacy of sunscreen products than a variety of different numbers. Therefore, the category should be labelled at least as prominently as the sun protection factor.
- (22) Consumers should be informed about the risks stemming from excessive sun exposure. Moreover, consumers need guidance as to the appropriate sunscreen product in terms of its efficacy taking into consideration the degree of sun exposure and the skin type,
- (c) 'UVB radiation' means sun radiation in the spectrum 290-320 nm;
- (d) 'UVA radiation' means sun radiation in the spectrum 320-400 nm;
- (e) 'critical wavelength' means the wavelength for which the section under the integrated optical density curve starting at 290 nm is equal to 90 % of the integrated section between 290 to 400 nm;

HEREBY RECOMMENDS:

SECTION 1

SUBJECT MATTER AND DEFINITIONS

1. This Recommendation gives guidance on the following:

- (a) in Section 2, on the application of Article 6(3) of Directive 76/768/EEC in relation to some of the characteristics of sunscreen products and the claims made as regards their efficacy;

- (b) in Sections 3, 4 and 5, on the minimum efficacy of sunscreen products in terms of ensuring a high level of protection against UVB and UVA radiation and on the simple and comprehensible labelling of sunscreen products in order to facilitate the choice of the appropriate product for the consumer.

2. For the purposes of this Recommendation, the following definitions apply:

- (a) 'sunscreen product' means any preparation (such as creams, oils, gels, sprays) intended to be placed in contact with the human skin with a view exclusively or mainly to protecting it from UV radiation by absorbing, scattering or reflecting radiation;
- (b) 'claim' means any statement regarding the characteristics of a sunscreen product in the form of text, names, trade marks, pictures and figurative or other signs used in the labelling, putting up for sale and advertising of sunscreen products;

- (f) 'minimum *erythema* dose' means the quantity of *erythema*-effective energy;

- (g) 'sun protection factor' means the ratio of minimum *erythema* dose on skin protected by a sunscreen product to the minimum *erythema* dose on the same unprotected skin;

- (h) 'UVA protection factor' means the ratio of the minimum UVA dose necessary to induce a persistent pigment darkening on the skin protected by a sunscreen product to the minimal UVA dose necessary to induce the minimal darkening effect on the same unprotected skin.

SECTION 2

UVA/UVB PROTECTION, CLAIMS, PRECAUTIONS FOR USE, USAGE INSTRUCTIONS

3. The characteristics and claims referred to in points 4 to 8 should be considered for the purposes of complying with Article 6(3) of Directive 76/768/EEC.

4. Sunscreen products should protect against both UVB and UVA radiation.

5. No claim should be made that implies the following characteristics:

- (a) 100 % protection from UV radiation (such as 'sunblock', 'sunblocker' or 'total protection');

- (b) no need to re-apply the product under any circumstances (such as 'all day prevention').

6. Sunscreen products should display warnings indicating that they do not provide 100 % protection and advice on precautions to be observed in addition to their use. This may include warnings such as:
- (a) 'Do not stay too long in the sun, even while using a sunscreen product';
 - (b) 'Keep babies and young children out of direct sunlight';
 - (c) 'Over-exposure to the sun is a serious health threat'.
7. Sunscreen products should carry instructions for use that will ensure that the claim made for the effectiveness of the product can be achieved. This may include instructions such as:
- (a) 'Apply the sunscreen product before exposure';
 - (b) 'Re-apply frequently to maintain protection, especially after perspiring, swimming or towelling'.
8. Sunscreen products should carry instructions for use to ensure that a sufficient quantity is applied on the skin to achieve the effectiveness claimed for the product. This may be done, for example, by indicating the quantity required through a pictogram, an illustration or a measurement device. Sunscreen products should carry an explanation of the risks involved in applying a reduced quantity, such as, 'Warning: reducing this quantity will lower the level of protection significantly'.
10. The minimum degree of protection provided by sunscreen products should be as follows:
- (a) a UVB protection of sun protection factor 6 as obtained in application of the *International Sun Protection Factor Test Method (2006)* or an equivalent degree of protection obtained with any *in vitro* method;
 - (b) a UVA protection of UVA protection factor of 1/3 of the sun protection factor, as obtained in application of the *persistent pigment darkening method* as modified by the French health agency *Agence française de sécurité sanitaire des produits de santé – Afssaps* or an equivalent degree of protection obtained with any *in vitro* method;
 - (c) a critical wavelength of 370 nm, as obtained in application of the critical wavelength testing method.

SECTION 4

SIMPLE AND MEANINGFUL CLAIMS OF EFFICACY

11. Claims indicating the efficacy of sunscreen products should be simple, unambiguous and meaningful and based on standardised, reproducible criteria.
12. Claims indicating UVB and UVA protection should be made only if the protection equals or exceeds the levels set out under point 10.
13. The efficacy of sunscreen products should be indicated on the label by reference to categories such as 'low', 'medium', 'high' and 'very high'. Each category should be equivalent to a standardised degree of protection against UVB and UVA radiation.
14. The variety of numbers used on labels for indicating the sun protection factors should be restricted in order to facilitate the comparison between different products without reducing the choice for the consumer. The following range of sun protection factors for each category and the respective labelling is recommended:
9. Sunscreen products should provide for a minimum degree of protection against UVB and UVA radiation. The degree of protection should be measured using standardised, reproducible testing methods and take photo-degradation into account. Preference should be given to *in vitro* testing methods.

SECTION 3

MINIMUM EFFICACY

Labelled category	Labelled sun protection factor	Measured sun protection factor (measured in accordance with the principles recommended in point 10 (a))	Recommended minimum UVA protection factor (measured in accordance with principles recommended in point 10 (b))	Recommended minimum critical wavelength (measured in accordance with principles recommended in point 10 (c))
'Low protection'	'6'	6-9,9	1/3 of labelled sun protection factor	370 nm
	'10'	10-14,9		
'Medium protection'	'15'	15-19,9		
	'20'	20-24,9		
	'25'	25-29,9		
'High protection'	'30'	30-49,9		
	'50'	50-59,9		
'Very high protection'	'50 +'	60 ≤		

15. The category of sunscreen products should be indicated on the label at least as prominently as the sun protection factor.

SECTION 5

CONSUMER INFORMATION

16. Consumers should be informed about the risks associated with excessive exposure to UV radiation and of the category of sunscreen products required for a certain degree of sun exposure and a certain type of skin. This may be done, for example, through information on national web-sites, leaflets or press releases.

SECTION 6

ADDRESSEES

17. This Recommendation is addressed to the Member States.

Done at Brussels, 22 September 2006.

For the Commission
Günter VERHEUGEN
Vice-President