

COMMISSION RECOMMENDATION

of XXX

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

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

1. Sun protection products are recognised as cosmetic products within the meaning of Article 2 1.(a) of the Regulation (EC) No 1223/2009 on cosmetics products.
2. Whilst their common function is to protect the skin from harmful effects of ultraviolet (UV) radiation, the intended use scenario of different sun protection products can range from intermittent, deliberate, high intensity UV exposure (e.g., holidays, outdoor work or recreational activities) to unavoidable, regular, low intensity UV exposure (e.g., daily activities).
3. The sun protection function can be the exclusive or main cosmetic function of the product (often referred to as 'primary sun protection products'; e.g., beach sunscreen) or be present as a secondary benefit (often referred to as 'secondary sun protection products'; e.g., makeup or skincare with sun protection).
4. Sun protection products within the meaning of this Recommendation do not include products where UV protection is not intended to protect the skin (e.g. photoprotection of hair or photoprotection of the product itself).
5. Under the first paragraph of Article 3 of Regulation (EC) No 1223/2009, cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular, of the following:

(a) presentation including conformity with Directive 87/357/EEC;

(b) labelling;

(c) instructions for use and disposal;

(d) any other indication or information provided by the responsible person defined in Article 4.

1. Under the first paragraph of Article 22 of Regulation (EC) No 1223/2009, Member States shall monitor compliance with this Regulation via in-market controls of the cosmetic products made available on the market. They shall perform appropriate checks of cosmetic products and checks on the economic operators on an adequate scale, through the product information file (PIF) and, where appropriate, physical and laboratory checks on the basis of adequate samples.
2. In addition, Article 20 (1) of Regulation (EC) No 1223/2009 stipulates that in the making available on the market and advertising of cosmetic products, text, names, trademarks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have.
3. Moreover, under Article 11 (1) and (3) of Regulation (EC) No 1223/2009 , when a cosmetic product is placed on the market, the responsible person shall keep a product information file for it and shall make the product information file readily accessible in electronic or other format at his address indicated on the label to the competent authority of the Member State in which the file is kept.
4. In order to contribute to a high level of health protection, guidance should be given in respect of the efficacy of sun protection products as regards the provisions laid down in Article 20(1)(3) of Regulation (EC) No 1223/2009 and in Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products.
5. While industry has already made significant efforts in this respect, it is appropriate to set out examples of claims which should not be made in relation to sun protection products, precautions that should be observed, and usage instructions that should be recommended for some of the characteristics claimed.
6. It is also appropriate to address certain other aspects relating to claims made for sun protection products and the efficacy of such products, namely the minimum efficacy of a sun protection product in order to ensure a high level of protection of public health and how the labelling of sun protection products can be kept simple and comprehensible in order to assist the consumer in choosing the appropriate product.
7. The ‘ultraviolet’ (UV) portion of the sun’s energy comprises both of shorter-wavelength ultraviolet B radiation (‘UVB radiation’) and longer-wavelength ultraviolet A radiation (‘UVA radiation’). ‘Sun burn’ (delayed visible redness or ‘erythema’) is caused by both UVA and UVB radiation, although UVB wavelengths are up to 10,000 times more effective in doing so. Increased risk of non-melanoma skin cancers (e.g., basal cell / squamous cell carcinoma; now known as keratinocyte cancers) and ‘photoaging’ (i.e., premature skin ageing) is strongly associated with the total lifetime dose of individuals to both UVB radiation (through a shared mechanism with erythema induction) and UVA radiation (through oxidative stress). Increased risk of malignant melanoma cancer is strongly linked with blistering sunburn and chronic UV exposure, although the precise mechanism remains less clear.
8. Epidemiological and longitudinal studies provide compelling evidence that use of broad-spectrum sun protection (protecting against both UVB and UVA wavelengths) are effective in significantly reducing the risk of sunburn, skin cancer and photoaging.
9. In order to have these preventive characteristics sun protection products need to protect against both UVB and UVA radiation. Therefore, although the sun protection factor refers only to protection against the radiation which cause erythema (mainly UVB radiation), sun protection products should contain adequate protection against both UVB and UVA radiation.
10. Even high sun protection factor (SPF), broad-spectrum sun protection products (with adequately balanced UVA-PF / SPF ratio) cannot guarantee full protection against all risks to human health from acute / chronic exposure to solar UV radiation. This is due to both technical limitations in achieving a complete attenuation of all UV wavelengths by the UV filters used in cosmetic products and also due to the limitations of compliance with and application of such products by end-users.
11. Consequently, sun protection products should neither claim nor create the impression that they provide total protection from risk associated with over-exposure to UV radiation.
12. This is true particularly for babies and / or young children (where UV exposure in childhood is a known risk for skin cancer later in life). Consequently, sun protection products should neither claim nor create the impression that they provide total protection to babies and / or young children from future risk associated with over-exposure to UV radiation.
13. Such mistaken perceptions of the characteristics of sun protection products should be addressed through appropriate warnings.
14. Based on several studies, the International Agency for Research on Cancer of the World Health Organisation (IARC) has emphasised the importance of the link between the correct application of a sun protection product and its efficacy. In particular, frequent re-application of sun protection products can be crucial in specific instances.
15. In order to reach the protection level indicated by the sun protection category, sun protection products must be applied in generous quantities, because applying lower quantities of sun protection product leads to a disproportionate reduction in protection.
16. Moreover, after application of sun protection products, the initial protection level might decrease over time due to biological (e.g., sweating) or physical reasons (e.g., swimming or towelling). Therefore, in specific intended use scenarios, water resistant sun protection products may be needed.
17. Scientific findings show that, in order to reduce risk of certain biological damage to the skin and ensure a high level of public health, sun protection products should be sufficiently effective against UVB and UVA radiation. To this end, any sun protection product should provide a broad and balanced protection against UVB and UVA radiation, considering:

- a minimum ratio of 1/3 (UVA protection factor / sun protection factor) reflecting the relative contribution of the two wavebands to the action spectra for UV damage.

- a critical wavelength of at least 370 nm.

1. Certain skin conditions may further benefit from sun protection products with reinforced protection against UVA radiation. Current research shows this to be the case in particular for: sun intolerant skin, hyperpigmentation disorders, melanin-rich skin.
2. In order to ensure reproducibility and comparability of the assessment of the recommended minimum protection levels, international standard methods (i.e., ISO / CEN methods) should be used to determine:

- protection against UVB

- protection against UVA

- critical wavelength

- water resistance

1. While all ISO/CEN methods can be used as reference methods, when applicable, preference should be given to *in vitro* testing methods to minimise exposure of volunteers to UV radiation.
2. Claims concerning the efficacy of sun protection products should be made in compliance with Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products. In particular, claims concerning the efficacy of sun protection products should be simple, meaningful and based on identical criteria in order to help the consumer to compare products and to choose easily the right product for skin type and intended sun exposure.
3. Given that all sun protection products should have a balanced minimum protection for both UVA and UVB, specific claims on UVA protection levels would be confusing for consumers and therefore should not be made. However, products with a reinforced UVA protection as mentioned above should be easily recognisable by consumer through a simple and harmonised logo and a verbal descriptor of skin conditions concerned.
4. Labelling using one out of four categories (‘low’, ‘medium’, ‘high’ and ‘very high’), that inherently cover UVA and UVB protection, provides for a simpler and more meaningful indication of the efficacy of sun protection products than a variety of different numbers subject to various misinterpretations. Therefore, categories should be the most prominent indicator of UV protection labelled on the sun protection product.

[+ Potential visual representation to be discussed]

Given that SPF numbers are still mandatory on the main display in some regions of the world, it can be necessary to maintain for some transition time this indicator as supplementary information on products that are marketed in the EU and internationally. However, SPF number should be presented less prominently than the category and not on the main display panel when possible.

1. Consumers should be informed about the risks stemming from excessive sun exposure through education campaigns by national authorities and industry, including dermatology community, this may be done, for example, through off pack alternatives including digital communication, websites, leaflets or press releases.
2. Moreover, consumers need guidance on the choice of the appropriate sun protection product for their skin type and intended sun exposure. In particular, consumers should easily recognise sun protection products suitable for intermittent, deliberate, high intensity UV exposure (e.g., holidays, outdoor work/ recreational activities) through a harmonised logo.

HEREBY RECOMMENDS:

SECTION 1

**SUBJECT MATTER AND DEFINITIONS**

1. This Recommendation gives guidance on the following:

(a) in Section 2, on the application of the Regulation (EU) No 655/2013 and of Art. 20 of the Regulation (EC) No 1223/2009, in relation to some of the characteristics of sun protection products and the claims made as regards their efficacy;

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

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

(a) ‘Sun protection product’ means a cosmetics products intended to be placed in contact with the human skin with a view to protecting it from solar spectrum radiation by absorbing, scattering, or reflecting radiation.

The intended use scenario of different sun protection products can range from intermittent, deliberate, high intensity UV exposure (e.g., holidays, outdoor work or recreational activities) to unavoidable, regular, low intensity UV exposure (e.g., daily activities).

The sun protection function can be the exclusive or main cosmetic function of the product (often referred to as 'primary sun protection products'; e.g., beach sunscreen) or be present as a secondary benefit (often referred to as 'secondary sun protection products'; e.g., makeup with sun protection).

(b) ‘claim’ means any statement regarding the characteristics of a sun protection product in the form of text, names, trademarks, pictures and figurative or other signs used in the labelling, putting up for sale and advertising of sun protection products;

(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;

(f) ‘minimum erythemal dose’ means the quantity of erythema-effective energy;

(g) ‘sun protection factor’ means the ratio of minimum erythemal dose on skin protected by a sunscreen product to the minimum erythemal 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;

(i) 'water resistance' means the comparison of the sun protection factor (SPF) of a sun protection product after a period of immersion in water with the static SPF without immersion in water.

SECTION 2

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

3. The characteristics and claims referred to in points 4 to 7 should be considered for the purposes of complying with the provisions laid down in Article 20(1) of Regulation (EC) No 1223/2009 and in Regulation (EU) No 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products.

4. Sun protection 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’, ‘sun blocker’ or ‘total protection’);

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

6. Sun protection products that consumers may use for intermittent, deliberate, high intensity UV exposure (e.g. holidays, recreational activities, outdoor work) should display warnings indicating that they do not provide 100 % protection and advise on precaution 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 sun protection product’;

b) ‘Keep babies and young children out of direct sunlight’\*;

c) ‘Over-exposure to the sun is a serious health threat’,

*Note\*: For products that can be reasonably foreseen to be used on babies and young children.*

Unless justified by the nature and presentation of the product [example to be added], sun protection products intended for unavoidable, regular, low intensity UV exposure (e.g. daycare products with sun protection) should display warnings indicating that they are not intended for intermittent, deliberate, high intensity UV exposure. This may include warning such as:

a) ‘When exposed to intense or lasting sun exposure use an appropriate sun protection product’

b) ‘Over-exposure to the sun is a serious health threat’

7. Sun protection products should carry instructions for use that will ensure that the claim made for the UV protection of the product can be achieved.

Unless justified by the nature and presentation of the product (e.g., make up), sun protection product should carry instructions for use to ensure that a sufficient quantity is applied on the skin. This may include instructions such as:

a) ‘Apply the product uniformly and generously before sun exposure'

b) ‘Re-apply frequently to maintain protection, especially after sweating, swimming or towelling’\*

*Note \*: indication all parameters (sweating, swimming, or towelling) might not be necessary depending on the nature of the sun protection product.*

SECTION 3

**MINIMUM EFFICACY**

8. The degree of sun protection should be measured using International Standardised ISO/CEN, reproducible testing methods and take photo-degradation into account. When applicable, preference should be given to in-vitro testing.

9. Sun protection products should provide for a minimum and balanced degree of protection against UVB and UVA radiation as defined in the table of Article 14.

SECTION 4

**SIMPLE AND MEANINGFUL CLAIMS OF EFFICACY**

10. Claims indicating the efficacy of sun protection products should be simple, unambiguous, and meaningful and based on standardised, reproducible criteria.

11. Claims indicating sun protection should be made only if the protection equals or exceeds the levels set out under point 10. Furthermore, the logo ['A' in Annex I] should be only labelled if the product is intended for intermittent, deliberate, high intensity UV exposure (e.g., holidays, outdoor work/ recreational activities) and the product is water resistant, except, when not applicable (e.g., winter activities).

12. The efficacy of sun protection products should be indicated on the label by reference to categories: ‘low’, ‘medium’, ‘high’ or ‘very high’. Each category should follow the requirements set up in the table mentioned in Art 14 of this document.

[+ Potential visual representation to be discussed]

Given that all sun protection products must have a balanced minimum protection for both UVA and UVB, specific claims on UVA protection levels would be confusing for consumers and therefore should not be made. However, products with a reinforced UVA protection as mentioned above may label the logo ['B' in Annex I] if the product follows the corresponding requirements set in Article 14.

13. Minimum recommended protection levels to ensure adequate protection against UVA and UVB radiation.

14. The category of sun protection products (i.e.: ‘low’, ‘medium’, ‘high’ and ‘very high’) should be the most prominent indicator of UV protection labelled on the sun protection product.

[+ Potential visual representation to be discussed]

Given that SPF numbers are still mandatory on the main display in some regions of the world, it can be necessary to maintain for some transition time this indicator as supplementary information on products that are marketed in the EU and internationally. However, SPF number should be presented less prominently than the category and not on the main display panel when possible.

SECTION 5

**CONSUMER INFORMATION**

16. Consumers should be informed about the risks associated with over exposure to UV radiation and of the category of sun protection products required for a certain degree of sun exposure and a certain type of skin. This may be done, for example, through off pack alternatives including digital communication, websites, leaflets or press releases.

This Recommendation is addressed to the Member States.

[…]

Done at Brussels,

 For the Commission

 […]
 Member of the Commission