Sun protection factor: meaning and controversies *

Fator de proteção solar: significado e controvérsia

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Abstract: The Sun Protection Factor (SPF) is the most important data to quantify the effectiveness of a sunscreen, being universally accepted. The method is based on determining the minimum erythematous dose (MED), defined as the smallest amount of energy required for triggering the erythema, in areas of protected and unprotected skin. The SPF value is then calculated as the ratio between the MED of protected and unprotected skin. The first publication of a method for determining the SPF was presented in 1978 by the U.S. FDA agency, followed by other publications of FDA and other international regulatory agencies. Although considered the reference method for quantification of sunscreen efficacy of topical products, there are controversies in literature about the method for determining the SPF and the implications of the real conditions of use in the protection achieved in practice by users.
Keywords: Dermatology; Solar radiation; Sunscreening agents

Resumo: O Fator de Proteção Solar (FPS) é o principal dado para quantificação da eficácia fotoprotetora de um filtro solar, sendo universalmente aceito. Seu método é baseado na determinação da Dose Eritematosa Mínima (DEM), definida como sendo a menor quantidade de energia necessária para o desencadeamento de eritema, em áreas de pele protegidas e não protegidas pelo produto em estudo. O valor do FPS é, então, calculado como a razão numérica entre a DEM da pele protegida e a da pele não protegida. A primeira publicação demonstrando um método para determinação do valor do FPS foi apresentada em 1978 pela agência norte-americana FDA, seguida por outras publicações do próprio FDA e de outras agências regulatórias internacionais. Apesar de ser considerado o método referência para quantificação da eficácia fotoprotetora de produtos tópicos, existem controvérsias na literatura acerca do método para determinação do FPS e sobre as implicações das reais condições de uso na proteção atingida na prática pelos usuários.
Palavras-chave: Dermatologia; Queimadura solar; Protetores de raios solares

INTRODUCTION

It has always been part of human nature to protect the skin against sunburn through the use of clothes and accessories or simply by avoiding sun exposure. The first scientific reports on the attempted use of photoprotective agents emerged in the late XIX century, with substances of very limited effect. [1]

In 1891, Friedrich Hammer [1] published the first monograph on photobiology, in which he discussed the use of different products in the prevention of sunburn (1891 apud Roelandts, [1] 2007, p.5).

In 1928, the first sunscreen becomes commercially available in the United States of America

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- an emulsion containing benzyl salicylate and benzyl cinnamate. [2] In subsequent years, however, little attention was given to photoprotective agents, and their use was very limited.

During World War II, due to the need for adequate photoprotection of American soldiers in battle fronts in the tropics, red petrolatum was used as a standard protective substance. [1]

In 1943, para-aminobenzoic acid (PABA) was patented as the first sunscreen established, indicating a new stage of photoprotection. [2]

However, it was only during the 1970s that the popularity of sunscreens increased with the incorporation of different UVB filters in creams and lotions. [3]

The use of UVA filters effectively began in 1979, but only the introduction of inorganic particles of titanium dioxide in 1989 and of zinc oxide in 1992 led to more effective protection in the UVA range [2].

The classic definition of a sunscreen, according to Pathak[4], is a product designed to block the sun and protect or shelter viable skin cells against the potentially harmful effects of ultraviolet radiation such as sunburn and skin cancer.

According to current concepts, topical photoprotectors or sunblocks (or sunscreens), are substances applied to the skin in different presentations which contain in their formulation ingredients capable of interfering with sun radiation, reducing its harmful effects. [5]

Ultraviolet (UV) filters are the ingredients present in sunscreens that have the ability to interact with incident radiation through three (3) basic mechanisms: reflection, dispersion and absorption, as shown in Figure 1. [6]

UV filters can be divided into inorganic (physical) or organic (chemical) filters, depending on their physico-chemical properties. [7]

Inorganic filters are metal oxide particles capable of reflecting or dispersing incident radiation through an optical mechanism. Its main representatives are zinc oxide (ZnO) and titanium dioxide (TiO_2), usually used in combination with organic filters. The main characteristics of inorganic filters are their low skin permeability and their high photostability, that is, their ability to maintain photoprotection even after long periods of sunlight. [7]

Organic filters are molecules that interfere with incident radiation through the mechanism of absorption, when the filter acts as an exogenous chromophore by absorbing a *photon* of energy and evolving to the excited state of the molecule. Upon returning to the stable state (unexcited), the release of energy occurs at a longer wavelength, either in the range of visible light (as fluorescence) or in the range of infrared radiation (as heat). The process can be repeated numerous times by a mechanism called resonance. Depending on their capacity to absorb shorter or longer wavelengths, organic filters can be subclassified into UVA filters, UVB filters and filters for broad-spectrum protection (UVA and UVB). [9]

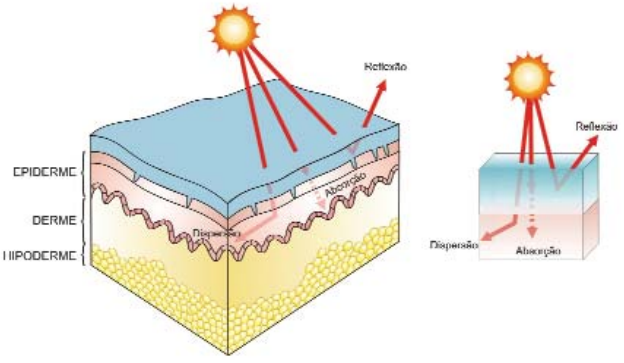


FIGURE 1: Mechanisms of interaction of sunscreens with sun radiation
Adapted source: Schalka [6]

The U.S. legislation (FDA 99) [10] classifies sunscreens as nonprescription medication and lists sixteen (16) substances approved as UV filters, allowed for use in photoprotectors.

In Brazil, the National Health Surveillance Agency (ANVISA) [11] defines sunscreens as cosmetic products and presents a list of permitted ultraviolet filters, containing thirty-eight (38) active ingredients.

The development and use of topical photoprotectors have always been related to the prevention of the acute effects of sun radiation, especially sunburn. [4]

It was not until after the 1980s, with studies demonstrating the role of UV rays in the development of skin cancer, that the sunscreen came to be understood not only as an agent against sunburn, but also as an important element in preventing chronic actinic damage, particularly in relation to the development of skin cancer. [4]

Different studies have shown that the sunscreen has a protective effect against chronic actinic damage.

Regular use of sunscreens can reduce the number of actinic keratoses. [12,13]

According to Green, [14] only squamous cell carcinoma, and not basal cell carcinoma, can be prevented by the regular use of sunscreens.

Vainio, [15] in a recent publication, concluded that the daily use of photoprotectors reduces the risk of squamous cell carcinoma development.

Fourtanier [16] presented a work conducted with rats in which he demonstrated the superiority of broad-spectrum sunscreens in comparison to others

that are not broad spectrum, in the protection against DNA damage and in the prevention of photocarcinogenesis, delaying tumor development.

The use of sunscreens has been reported as capable of preventing the development of skin cancer triggered by UV by decreasing the formation of cyclobutane-pyrimidine dimers, as well as preventing other immunological effects induced by UV rays, such as the suppression of contact hypersensitivity [7].

A study conducted by Hayag, [17] in 1997 concluded that the application of a sunscreen with SPF 30 before sun exposure can prevent the decrease of Langerhans cells in the irradiated site and reduce UV-induced suppression in contact hypersensitivity to dinitrochlorobenzene (DNCB).

With regard to the use of sunscreens and the risk of developing melanoma, the literature still shows some controversy.

Huncharek and Kupelnick [18] published a meta-analysis of eleven studies showing that the use of photoprotectors has only a small advantage in decreasing the risk of developing melanoma.

Rigel, [19] however, in a review of only the most recently published articles in which only sunscreens with a high SPF were used, concluded that that the use of these products seems to offer a clear protective effect against the risk of melanoma.

In 2005 Diffey [20] presented a review of the subject, in which the author concluded that recent improvements in the effectiveness of modern sunscreens will offer additional protection against melanoma. But this result will not be seen in the coming decades .

In view of all this, and also with the perception of the deleterious effect of UVA radiation on different photodermatoses, on the development of skin cancers, and on photoaging and photoimmunosuppression, new UV filters have been developed, with greater photoprotective capacity in the UVB band and broader absorption spectrum in UVA and UVB. This leads to a leap in photoprotective efficacy, particularly in the Sun Protection Factor (SPF) value [20].

The average SPF value of products used in Europe in 1984 was from four (4) to six (6), progressing to 6 to 10 in 1987 and to about 15 in 1997, showing the recent evolution of photoprotectors. [20]

According to the International Agency for Research on Cancer (IARC), [21] despite insufficient evidence that sunscreens have a protective effect against BCC and melanoma, and only limited evidence that they prevent SCC, the use of the sunscreen should be considered as part of a complete photoprotection regimen.

For better photoprotective efficiency, the sunscreen should present in its composition ultraviolet filters with an absorption spectrum in the range of UVA and UVB rays and be photostable. Moreover, for an ideal protective effect, the product should form a homogeneous film, capable of delivering its ingredients on a regular basis throughout the skin surface. [9]

SUN PROTECTION FACTOR - HISTORICAL ASPECTS

The first report on the evaluation of the protective efficacy of sunscreens was done by Friedrich Ellinger in 1934 [22] in which the author determined the minimal erythemal dose (MED) for protected and unprotected skin, using both forearms and a mercury lamp. He proposed a coefficient of protection that decreased in value to the extent that protection increased.

In 1956, Rudolf Schulze [23] evaluated commercially available sunscreens by calculating a protection factor, later called "Schulze Factor". The author divided the exposure time required for the induction of erythema on sunscreen-protected skin by the time required for the production of erythema on unprotected skin, using incremental doses of radiation emitted by lamps with a radiation spectrum closer to sunlight. The *Schulze* method has been used for decades in European countries, as a reference in the evaluation of sunscreens.

It was only in 1974 that the term Sun Protection Factor (SPF) was introduced by Greiter [24], being only a new name for the already known "Schulze method."

The Sun Protection Factor, proposed by Greiter, quickly became popular and used worldwide. However, due to the lack of standardization of the method, the numerical values found and used in sunscreens varied considerably, not rendering it reliable. [25]

In 1978, the North-American regulatory agency (FDA) proposed the first normatization to determine the Sun Protection Factor (SPF) [26].

SUN PROTECTION FACTOR - CONCEPT AND INTERNATIONAL METHODS

The Sun Protection Factor can be defined, as proposed by the FDA in 1978, [26] as the numerical ratio between the minimal erythemal dose (MED) of sunscreen-protected skin, applied in the amount of 2 mg / cm ^{2} and the Minimal Erythemal dose of unprotected skin, a mathematical relation that can be represented by the following equation:

FPS = MED (protected skin) / MED (unprotected skin)

To determine the FPS value, a group of 10 to 20 volunteers (according to the reference method), with skin phototypes I-III (Fitzpatrick classification) [27], is selected and subjected to increasing doses of ultraviolet radiation emitted by an artificial light source called solar simulator, in areas of unprotected and sunscreen-protected skin in the amount of 2 mg/cm2. After about 16 to 24 hours of exposure, the reading of the MED in both areas is done and their ratio is calculated (Fig. 2). The mean values found for the group of volunteers is the SPF of the product.

After the publication of the method by the FDA in 1978, new methods were proposed by international regulatory agencies.

The German agency Deutches Institut für Normung (DIN) presented a new version of the method in 1984, called DIN 67501, at that time used throughout Europe. [25] Methodological differences between them were large and mainly referred to the emitting source of ultraviolet (Xenon Arc lamp for the FDA Methodology and natural light or Mercury lamp for DIN) and the amount of sunscreen applied (2.0 mg / cm ^{2} for the FDA methodology and 1.5 mg / cm ^{2} for DIN). [25]

All the following publications maintained the methodological concepts described in the monograph presented by the FDA in 1978, that is, xenon arc lamp as the emitting source and the amount of 2.0 mg / cm ^{2} as the standard amount of sunscreen to be applied.

After the first publication in 1978, [26] the FDA produced its proposal of a final monograph in 1993 [28] and, finally, the final monograph in 1999. [10] Currently a new methodological revision proposed by the FDA at the end of 2007 is under discussion. [29]

In addition to the FDA action, other institutions and international regulatory agencies have produced technical monographs describing the procedures necessary for conducting a clinical trial to assess sunscreen efficacy by determining the Sun Protection Factor [25].

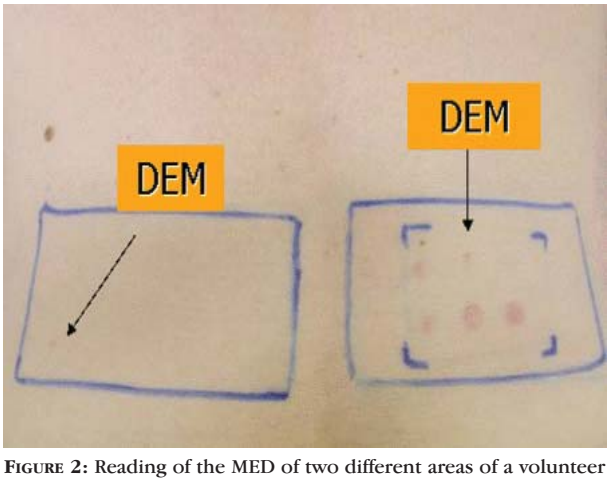


Figure 2: Reading of the MED of two different areas of a volunteer

The European community, through the European Cosmetic, Toiletry and Fragrance Association *(Comité de Liason des Associations et Européenes de Industrie et de la Parfumerie* - COLIPA) developed its first version of a monograph in 1994. [30]

In 2003 the method called *International Sun Protection Factor Test Method* (ISPF) was presented jointly by the European (COLIPA), Japanese (JCIA) and South African (CTFA-SA) associations, [31] followed by a subsequent revision in 2006, with the introduction of Cosmetic, Toiletry and Fragrance Association of the United States (CTFA-USA). [32]

The North American (FDA) and European (COLIPA or international) methodologies have become a reference for determining the Sun Protection Factor (SPF) in different countries, among them Brazil, which through Resolution RDC 237 issued by the National Health Surveillance Agency (ANVISA) in 2002 [11] determines that any product denominated sunscreen should present studies showing its photoprotective effectiveness (SPF determination test) through one of two international methodologies: FDA 1993 Methodology [28] or COLIPA 1994 [30] or even through one of their updates.

Table 1 shows all the publications about methods for determining the FPS that have been presented by authorities since 1978. [25]

Because these are the most currently employed methods in Brazil and other countries in the world, Table 2 shows the main methodological characteristics and the main differences of the methods for determining the FPS published by the FDA 1999 (standard method in North America) and the International *Sun Protection Factor Method* (ISPF) 2006 [32] (standard method in the EU and Japan).

Despite the methodological differences shown in Table 2, studies on FPS conducted by the two different methods mentioned (FDA method and International method) yield similar results. In practice, we understand that the two methods produce equivalent SPF values.

FPS - Controversies

The Sun Protection Factor quantifies the protection that a product is able to offer in terms of exposure time in relation to sunburn when compared to unprotected exposure. [10] Therefore, if a particular sunscreen has SPF 30, this means in practice that a sun exposure 30 times greater is necessary to produce erythema, compared to the situation in which this

Table 1: Chronological evolution of the main methods for determining the SPF

Year	Institution or Regulatory Authotrity	Territory
1978	Food and Drug Administration (FDA)	United States
1983	Standards Association of Australia (SAA)	Australia
1985	Deutches Institut für Normung (DIN)	Germany
1991	Commission Internationale De L'Eclairage (CIE)	International
1992	Japanese Cosmetic Industry Association (JCIA)	Japan
1993	FDA - Review	United States
1994	European Cosmetic and Toiletries Association (COLIPA)	Europe
1998	Australia Standards / New Zealand Standards (AS / NZS) - Review	Australia & New Zealand
1999	FDA - Review	United States
2003	International Sun Protection Factor Method (COLIPA / JCIA / CTFA - SA)	Europe, Japan and South Africa
2006	International Sun Protection Factor Method - Review (COLIPA / JCIA / CTFA - AS / CTFA - USA)	Europe, Japan, South Africa and USA
2007/2008	FDA - Review	United States

Adapted source: Brown [24]

user would not be photoprotected.

For us to calculate the length of protection with the use of sunscreen, we would need to know the time of exposure needed for the production of erythema without such protection for that individual. This time, however, suffers a strong influence of personal and environmental factors such as individual erythematogenic response (for which the phototype is an attempt at classification), the ultraviolet index (UVI) of that particular day (remembering that the UVI is an estimate for the solar noon), time of day, the index of exposure of that region of the body (eg, the face has an index of 0.3, ie, it receives only about 30% of the total radiation) and soil type (considering that the reflection index varies from soil to soil and is not estimated by UVI). For these reasons, the tendency is not to use the FPS value to determine time of sun exposure, but instead the level of protection.

Developed over thirty years, the Sun Protection Factor (SPF) is the most accepted method for evaluating the photoprotective efficacy of sunscreens, being universally considered as the main information in the labeling of sunscreens. Still, there are controversies regarding the method and its applicability in real conditions of use.

Because it uses a biological marker with individual variable response, such as erythema, the SPF is a method that can vary in its results.

According to Sayre, [33] the critical points for the SPF method to be reproducible, essential to the reliability of results, are the artificial source of ultraviolet radiation (currently standardized by the use of xenon-arc lamp) and the amount of product applied to the back of the volunteer.

In 1992 COLIPA put together a task force composed of scientists in the field of photoprotection and organized an inter-laboratory validation for the evaluation of Sun Protection Factor. [30] The evaluation was conducted at different stages: at first, six (6) European laboratories received four different sunscreens to determine their FPS. S The results showed a variation in the SPF value from 18.2% to 37%, the latter referring to a sunscreen made only with inorganic filters. We identified the following critical points of the method:

- Amount and manner of application of the sunscreen
- Spectrum and UV radiation flux of the emitting source
- Reading of the minimal erythemal dose.

Two other inter-laboratory evaluations were subsequently conducted [30] in order to produce greater control of the parameters described above. In the end, based on a conclusion of the study, the key parameters of the method, which should be ideally controlled, are the amount and form of application of the product.

The definition of the amount of 2 mg/cm ^{2} of product application, presented by the FDA in 1978 and later maintained by revisions of the FDA, COLIPA, and the International Method, is based on the observation that lower amounts reduce the homogeneity of the protective film on the skin as a result of irregularities of the skin surface. [34]

The skin surface is uneven, consisting of ridges and bumps that may have greater or lesser amplitude depending on the region of the body. [35]

Figure 3 schematically shows the skin surface. [36]

According to Brown and Diffey [34], although there is wide variation among individuals, the average

Table 2: Comparison of methods for determination of SPF: FDA 19999 and International SPF test method[31]
Adapted source: Schalka [6]

Methodology	FDA 1999	International SPF Method 2006 CTFA, COLIPA JCIA
Light Source	Solar Simulator with Xenon Arc Lamp	Solar Simulator with Xenon Arc Lamp
Volunteers	Maximum of 25 included ≥ 20 for valid data	Maximum of 20 included ≥ 10 for valid data
Phototypes of volunteers (Fitzpatrick)	I-III	I-III
Region of Application	Lower back	Lower back
Standard Product	HMS 8%	P1, P2, P3 or P7 (SPF <20) P2 or P3 (SPF > 20)
Amount of application	2 mg / cm 2 or 2 μL / cm 2 (grav. esp.= 1)	2 mg / cm 2 ± 2.5%
Waiting Period	≥ 15 min.	15 to 30 min.
Progression of Doses	SPF <8: 0.64X, 0.80X, 0.90X, 1.00X, 1.10X, 1.25x, 1.56X ≤ 15 ≤ 8 SPF: 0.69X, 0.83x, 0.91X, 1.00X, 1.09X, 1.20X, 1.44X SPF> 15: 0.76X, 0.87X, 0.93X, 1.00X, 1.07X, 1.15x, 1.32X	SPF ≤ 25: 25% SPF> 25: 12%
Reading of MED	22-24 hr	16-24 hr
Determination of final SPF	Mean SPF value of the group - CI95%	Mean SPF value of the Group
Statistical criteria for acceptance /		CI 95% within the interval ± 17% of mean FPS

volume for a given product to cover all the "ridges" present on the skin surface, corresponding to one (1) cm^2 , would be between 1 to 2 μl . In this case, any topical product, assuming a density of 1 g/cm^3 , would not cover the "top" of the epidermal ridges to the minimum of 1 mg/cm^2. Thus, according to the authors, the amount of 2 mg/cm ^{2} would be necessary for the sunscreen to offer a minimum of 1 mm of coverage of the tops of the epidermal ridges (Figure 4). [6]

However, although recommended, sunscreen users do not apply the amount of 2 mg/cm ^{2} when exposed to the sun for leisure or work activities.

Several studies published in the literature [36-41] show that the amount of sunscreen applied by users varies from 0.39 to 1.3 mg/cm ^{2} , much less than the amount applied in the laboratory test to determine the SPF, as recommended by internationally accepted methods . [10,.32]

The interference of the applied amount in the level of protection offered by sunscreens was evaluated by different authors. [36,38,42,43] The findings of these studies, particularly with regard to the evaluation of the interference pattern of the amount applied in determining the SPF value, are contradictory.

A recent study published by Schalka S, Reis VMS and Cuce LC [44] evaluated the interference of the applied amount of two photoprotectors (SPF values 15 and 30, respectively) in determining the SPF value, according to the methodology proposed by the FDA in 1999 [10] and concluded that there is an exponential relationship between the amount applied and the change in value of the SPF.

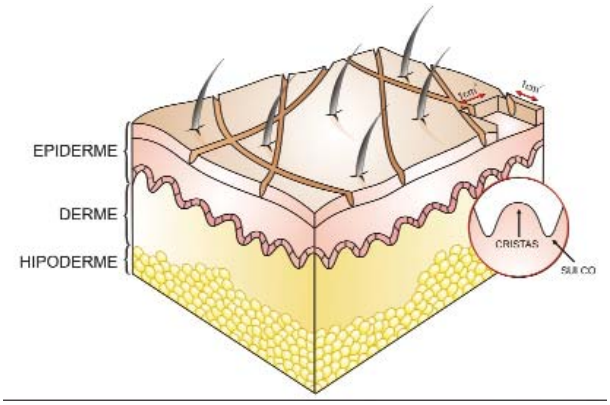


Figure 3: Schematic representation of the irregularities of the epidermal surface
Adapted source: Schalka[6]

The authors were able to develop a mathematical equation capable of estimating the protection achieved in practice by the volunteer, based on labeling data of SPF and the amount applied.

The main controversy, however, refers to the value of SPF being limited at 30, as suggested by the FDA in 1993. [28]

This proposal was based on a previously published study by Groves, [45] in which the authors showed through mathematical analysis and spectrophotometry that the absorbance value of a given sunscreen may be related to the inverse of the SPF value, as expressed by the following equation:

A = 1 - 1/FPS

Where A = Absorbance of the product

When this equation is applied, we can develop a relationship curve between absorbance and SPF, as shown in Graph 1.

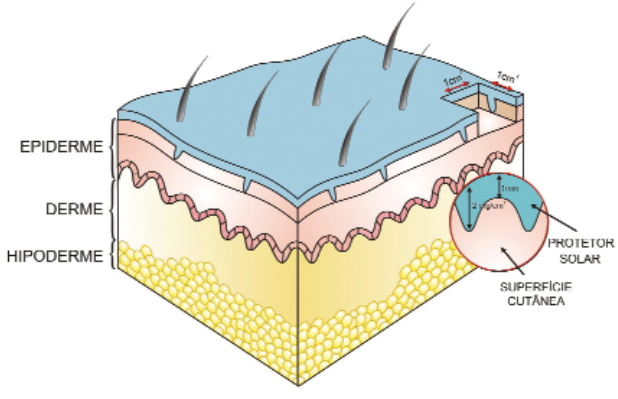


Figura 4: Schematic representation of the amount of 2 mg/cm 2, needed to provide a minimum thickness of 1mm of sunscreen in the the epidermal ridges
Adapted source: Schalka[6]

As we can see, the proportional gain of absorbance compared to an increase in the SPF value is reduced dramatically when the SPF value is above 30.

This rationale led the FDA to publish in its proposed final monograph in 1993 [28] a decision to limit SPF values at 30, a concept that has been widely circulated.

However, the issue is still controversial.

Osterwalder and Herzog, [46] in a recent article published, show that the proposed mathematical reasoning could be done in reverse, by analyzing how much energy passes through the sunscreen (transmittance) instead of how much energy is absorbed by it (absorbance) where:

T = 1 -A

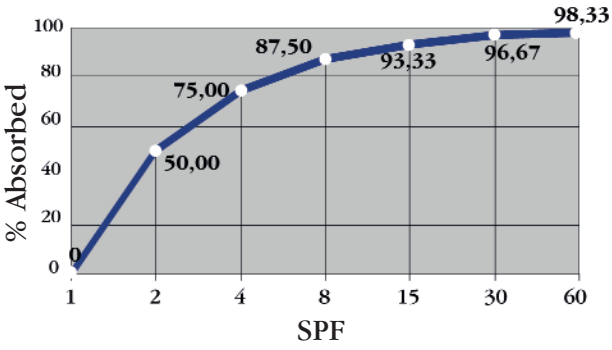
By applying this reasoning, we find that the amount of energy that passes through the sunscreen with SPF 60 (and therefore, affects the skin) would be half of that transmitted by a sunscreen with SPF 30. Thus, the protection offered by the product with SPF 60 would be double that offered by the product with SPF 30, as seen in graph 2.

Another point to consider is associated with the biological marker related to the protective effect. We know that the SPF measures the protection against sunburn, so the protection effect (in terms of percentage of absorption or transmission), as described above, refers exclusively to protect against the production of erythema. We cannot state, by this reasoning, what the percentage of protection against the development of skin cancer is or even discuss the effects of UVA radiation.

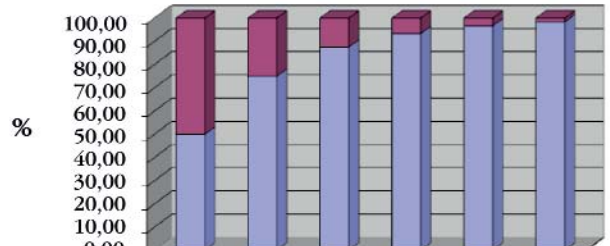
Finally, we must consider the relationship between the applied amount of sunscreen and SPF. As discussed above, the amount of the product applied is the main factor of interference in the SPF of a given sunscreen. [44] Therefore, if the amount of the sunscreen applied is inadequate, as in most cases, the protection achieved by the user is lower than that shown in the product label, and the relationship between absorbance and FPS, as proposed by Groves, [45] is no longer valid.

All these factors were considered by the FDA in its proposal to amend the final monograph on photoprotectors, presented in 2007 [29] and not yet completed to date. In this document, the U.S. regulatory agency recommends raising the threshold value for SPF to 50 +, reconsidering the observations made in 1993.

Questions regarding proper use of sunscreens, as an essential factor in the effectiveness of the product, have been highlighted in the international literature. Recent publications. [46.47] reinforce the need



Graph 1: Relationship between absorbance and SPF value



	2	4	8	15	30	60
Transmitância	50,00%	25,00%	12,50%	6,67%	3,33%	1,67%
Absorbância	50,00%	75,00%	87,50%	93,33%	96,67%	98,33%

Graph 2: Relationship between absorbance and transmittance x SPF

for greater attention to compliance with the most appropriate use of the photoprotector, including the application of the correct amount and periodic reapplication.

As Osterwalder and Herzog [46] comment in their review article on the subject: *"The best photoprotector may offer insufficient protection only if it is not applied uniformly, if it is applied in insufficient amount or if it is simply not applied."*

Table 3: Categories of sunscreens based on the value of the FPS

Protection Level	SPF Value
Maximum	> 50
High	30-50
Medium	15-30
Low	2-15

Thus, as stated earlier, the SPF value should no longer be considered in absolute terms, such as additional exposure time before the formation of erythema.

The most up-to-date concept in terms of photoprotection is to consider the SPF value in a range of protection, as proposed by the FDA in 2007 [29] and presented in Table 3.

A more appropriate interpretation is that the SPF value, in numerical terms, should be relative, as a result of the actual circumstances of product use. Therefore, in practice, the use of a sunscreen with SPF 30 or 35 makes no difference if, for example, it is not applied properly.

CONCLUSION

The Sun Protection Factor is still the main information about the photoprotective efficacy of a sunscreen, but its interpretation should not be based solely on its numeric value, but must also consider the proper way to use the product in terms of applied amount and regularity of reapplication.

Finally, in choosing a photoprotective agent, in addition to the SPF, data on the substantivity (water resistance), UVA protection and photostability should be considered for adequate protection. ❑

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