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Suncert News

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Approval of raw materials dedicated to sun protection

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Regulations continuously change and new worldwide harmonized methods are proposed to improve sun protection assessment. This is a fact and these evolutions take time to ensure reliable and relevant sun protection to consumers.

During this time, we also believe that raw materials claiming any advantage in sun protection should have a clear identification to help formulators during sunscreen development by saving time and money. For this reason, in page 2, we describe in details our new approval proposal for ingredients claiming:

- SPF booster - UVA booster,
- Water Resistance booster.

Beyond this new service and to continue to help you to develop better sunscreen products, in page 3, we present you different items dedicated to sun protection testing from our online store. Moreover, as the ISO standardisation process may be difficult to understand from an external point of view, we propose you to discover the different stages during standard development.

Therefore, in this new edition of our SUNCERT News, you are going to discover (i) the sun protection ingredients approval, (ii) items dedicated to sun protection testing, (iii) standard development steps, and (iii) the sunscreen regulation in Brazil.

Sébastien MIKSA, CEO

Audit and Monitoring of your sunscreen testing subcontractors

The respect of standards and methods is essential to the reliability of the results obtained during solar studies. Therefore, if you want to outsource your quality and technical audit of your service providers dedicated to sun protection testing or just to be accompanied, SUNCERT can be a support in this case.

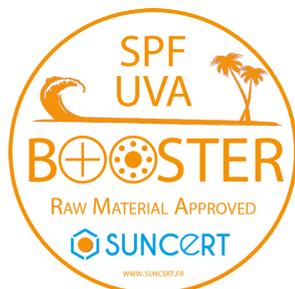
Feel free to contact us if you have any further questions

Approval for ingredients dedicated to sun protection

Read more on our website:
www.suncert.fr



In order to help you to select the best raw materials for your sunscreen products, SUNCERT is committed to certification of raw materials for a better sun protection. For this purpose, we developed with the feedback of different stakeholders two kinds of approval for ingredients claiming «SPF Booster», «UVA Booster» and «Water Booster» with the different requirements for each one here below.



A label that ensures a SPF and/or UVA booster effect

Today, high SPF and/or UVA are increasingly in demand with increased consumer awareness of the risks of exposure to harmful UV rays. To increase the value of SPF and/or UVA by avoiding the use of a significant amount of UV filters in the formula, sunscreen boosters (also called “SPF booster” or “UV booster”) have become popular to improve the effectiveness and add interesting properties for the skin. In addition, their effectiveness allows a normal level of use in formulations of 1 to 3% on an active basis.

Although they can significantly increase this SPF and/or UVA efficiency depending on the formulation and types of sunscreens used, UV boosters are not UV filters because they, alone, do not significantly contribute to SPF or UVA. To this end, a wide range of raw materials has been developed and it is difficult to clearly distinguish a good “SPF Booster”.

Therefore, SUNCERT offers to certify raw materials claiming an effect “SPF Booster”. For this, the following criteria shall be respected:

- I. Results, using a placebo and a dose effect, demonstrating:
 - improvement of the SPF and/or UVA of at least 20% and at a minimum of 5 points by using the ingredient at a minimum concentration (generally $\leq 2\%$),
- OR
- improvement of the SPF and/or UVA of at least 40% and at a minimum of 10 points by using the ingredient at a minimum concentration (generally $\leq 5\%$).
- II. The results with submission of the reports shall be evaluated in two different laboratories using:
 - In Vivo method (minimum 5 valid human volunteers).
- III. An absorbance curve demonstrating minimal absorbance of the ingredient in UV with information on E (1; 1) at λ_{max} .
- IV. A description of how this MP works.



A label that ensures a booster effect of the Water Resistance

Nowadays, sunscreen products are more and more efficient with an increased willingness of consumers to keep effective protection in all circumstances (swimming, sports, etc.) against harmful UV rays. Thus, some products are Water Resistant and generally boosters have become popular for improving this resistance to aqueous stress while adding properties of interest to the skin. In addition, their effectiveness allows a normal level of use in formulations of 1 to 3% on an active basis.

Although they can significantly increase this water resistance efficiency depending on the formulation and types of sunscreen used, a wide range of raw materials has been developed and it is difficult to make clear distinction between a true and a false “Water Resistance Booster”.

Therefore, SUNCERT proposes to certify the raw materials claiming a “Water Resistant Booster” effect. For this, the following criteria shall be respected:

- I. Results, using a placebo and a dose effect, demonstrating:
 - improvement of the Water Resistance of at least 10% and at a minimum of 5 points by using ingredient at the first concentration (generally $\leq 2\%$),
- OR
- improvement of the Water Resistance of at least 20% and at a minimum of 10 points by using ingredient at the second concentration (generally $\leq 5\%$).
- II. The results with submission of the reports shall be evaluated in two different laboratories using:
 - In Vivo method (minimum 5 valid human volunteers).
- III. An absorbance curve demonstrating minimal absorbance of the ingredient in UV with information on E (1; 1) at λ_{max} .
- IV. A description of how this MP works.

ISO standard development steps



The ISO process is extremely clear for standard development in terms of steps, rules and principles. The aim of this topic is not to present all details but to show an overview. As an evidence, the herein information are extracted from ISO website (www.iso.org) and ISO/IEC Directives, Part 1.

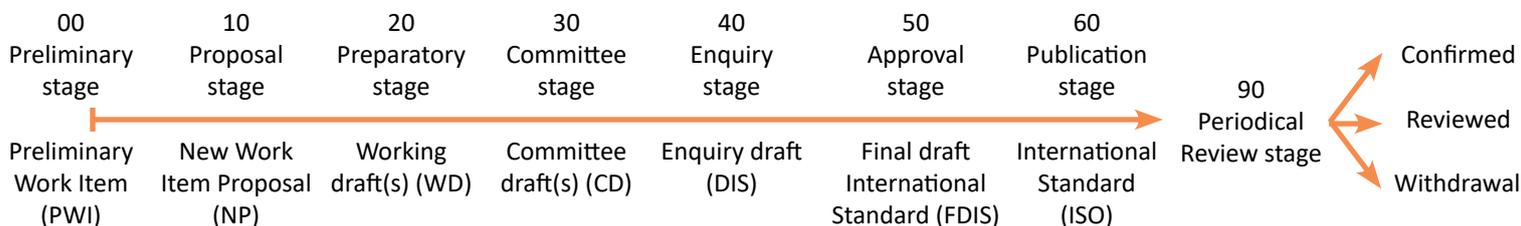
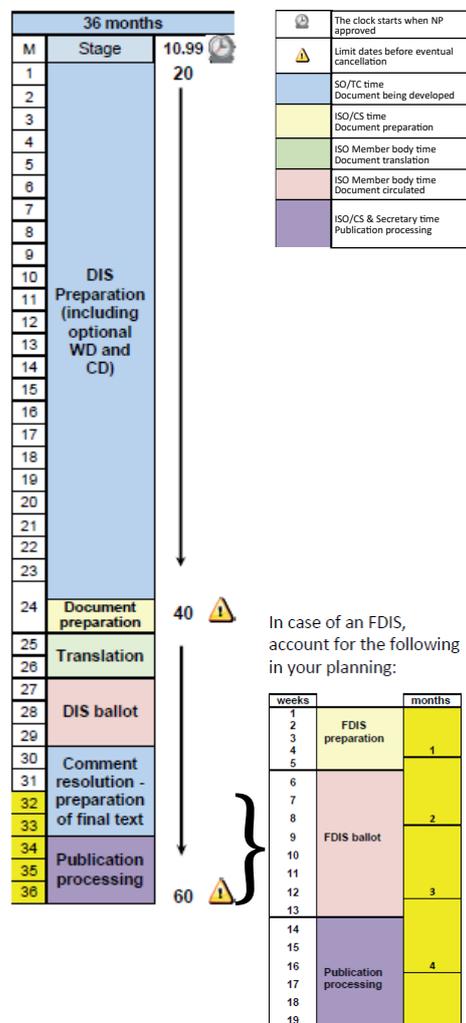
First, to remind, the formal definition from the International Organization for Standardization (ISO) is: « a document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context ». In other words, an International Standard is a document containing practical information and best practice based on an agreed way of doing something or a solution to a global problem.

Second, the key principles in standard development can be summarized in 4 points:

1. ISO standards respond to a need in the market,
2. ISO standards are based on global expert opinion worldwide,
3. ISO standards are developed with multi-stakeholders,
4. ISO standards are based on a consensus.

Third, the important distinction between standards and legislation is that standards are voluntary, whereas legislation is mandatory. When regulatory authorities use standards as a basis for legislation, only then do they become mandatory, and then only within the jurisdiction covered by the legislation. Most of the time in the cosmetic industry (including sunscreen field), standards are used as the reference.

Finally, from first proposal to final publication, developing a standard usually takes about 3 years (an example of a target date planner based on 36 months is presented on the right). Furthermore, here below the different stages with associated documents are summarized knowing that substages are available for each stage with: 00 - Registration ; 20 - Start of main action ; 60 - Completion of main action ; 90 - Decision.



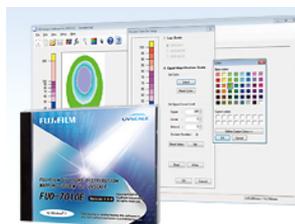
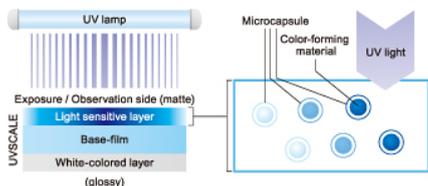
Items for sun protection testing



UV sensitive film - UVSCALE

Visualizes UV light amount distribution by color density.

One side of the base film has a UV light sensitive layer, with the opposite side having a white-colored layer. The light sensitive layer changes color according to the amount of UV light it receives, so the amount of light distributed on the exposed surface is easily seen by observing a light sensitive layer and white-colored layer are attached to the base. Since the color density of the white-colored layer corresponds to the amount of UV light received, the light amount distribution on the light receiving surface can easily be investigated.



Software FUD-7010E

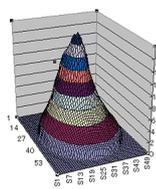
UV Light Distribution Mapping System with management by converting colors into numeric values with analysis system.

In this system, exclusive analysis software is used along with a usable scanner (sold separately). The system makes it possible to scan color of UV scales, convert it into UV light amount values, analyze UV light amount distribution, and save them.

Details and more articles available in our website:
www.suncert-shop.com



Graph on Excel generated from the data



Brazil: Sunscreen Regulations for Sun Protection methods and labeling



In Brazil, the sunscreen regulations are driven by the Brazilian Health Regulatory Agency (ANVISA).

ANVISA published in the Official Gazette of December 1, RDC 216/2016, which contemplates the definitions and technical requirements for cosmetics for tanning of the skin, in addition to establishing a specific labeling warning for tan activators / accelerators. According to the Agency's definition, sunscreen product ("bronzeador") is a cosmetic preparation designed to come in contact with the skin, with the sole or principal purpose of protecting it against UVB and UVA radiation, without preventing the tanning action of the sun. This kind of product is different than (i) a self-tanner ("bronzeador simulatório") which is a cosmetic to brown the skin by external application, regardless of exposure to sunlight, and (ii) an activator or accelerator of tanning ("ativador/acelerador de bronzeador") is intended to favor the tan by external application on the skin.

The procedures for legalization of these products with ANVISA remain unchanged and must comply with the requirements of the [RDC n°7/2015](#), in other words, sunscreens are subject to registration while Self-tanners and Activators or tanning accelerators are exempt. Moreover, in addition, sunscreens must also comply with the requirements of the [RDC n°30/2012](#) which is the approval of the [MERCOSUR/GMC/RES. N° 08/11 - REGLAMENTO TÉCNICO MERCOSUR SOBRE PROTECTORES SOLARES EN COSMÉTICOS](#) (available on the website www.mercosur.int), described here below.

I. Sunscreen: any cosmetic preparation intended to come into contact with the skin and lips, with the exclusive or main purpose of protecting it against UVB radiation and UVA, absorbing, dispersing or reflecting the radiation.

Multifunctional products: any cosmetic preparation intended to enter into contact with the skin and lips, the benefit of protection against UV radiation is not the main purpose, but is an additional benefit of the product.

II. The degree of protection has to be measured using the following methods or their updates.

Protection	Method
SPF	USFDA monograph – In Vivo SPF (2011) Cosmetics Europe 2006 - In Vivo SPF* ISO 24444:2010 – In Vivo SPF**
PFA	JCIA – In Vivo PPD 1995* Cosmetics Europe 2011 – In Vitro UVA & CW* ISO 24442:2011 – In Vivo UVA** ISO 24443:2012 – In Vitro UVA & CW**
Water Resistance	USFDA monograph – In Vivo Water Resistance 2011 Cosmetics Europe 2005 – In Vivo Water Resistance*

SPF: Sun Protection Factor – UVAPF: UVA Protection Factor – CW: Critical Wavelength

*Generally, products tested under older methods do not need to be retested and remain valid methods but trend to move towards ISO methods.

**Even if not clearly indicated, this method is "accepted".

III. The claims indicating UVB and UVA protection efficacy provided by sunscreen products can be made only if the protection equals or exceeds minimum levels as described in the table here below. For Water Resistance, please referred to the used method.

Additional non-mandatory information on the label	Labelled category (DCP)	Measured SPF	Minimum UVA-PF	Minimum CW
«Skin slightly sensitive to sunburn»	«Low protection»	6.0 – 14.9	1/3 of labelled SPF	370 nm
«Skin moderately sensitive to sunburn»	«Medium protection»	15.0 – 29.9		
«Skin very sensitive to sunburn»	«High protection»	30.0 – 50.0		
«Skin extremely sensitive to sunburn»	«Very high protection»	More than 50.0 and less than 100		

* Disclaimer: These documents, these tools, any answers or information provided herein by SUNCERT, does not constitute a legally binding obligation of SUNCERT. While the descriptions, designs, data and information contained herein are presented in good faith and believed to be accurate, it is provided for guidance only. No warranties of any kind, either express or implied, including warranties of merchantability or fitness for a particular purpose, are made regarding products described or designs, data or information set forth. Because many factors may affect the final value, we recommend that you perform a full inspection of the product to determine the suitability for your particular purpose prior to use.

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IV. In the main (primary and secondary) labeling of a sun protection product it is compulsory (i) to include the Designation of Protection Category (DCP for Designacion de la Categoria de Proteccion) concerning the protection offered by a product against UVB and UVA radiation and (ii) to indicate prominently the whole number of sun protection preceded by the symbol "FPS" or the words "sun protection factor".

V. Sunscreens should not contain statements on their label that imply the following characteristics:

- 100% protection against UV radiation or sunscreen effect,
- It is not necessary to repeat the application of the product in any case,
- Designations that induce total protection or blocking of solar radiation.

VI. The labeling of sunscreens should contain the following warnings and instructions for use:

- "The reapplication of the product is necessary to maintain its effectiveness";
- "Helps prevent sunburn";
- "For children under 6 months, consult the doctor";
- "This product does not offer any protection against insolation";
- "Avoid prolonged exposure of children to the sun";
- "Apply abundantly before exposure to the sun". When there is a time determined by the manufacturer or a waiting period (before exposure), it should also be stated on the label.
- "Reapply always, after intense sweating, swimming or bathing, towel drying and during sun exposure". When there is a time determined by the manufacturer for reapplication, it should also be stated on the label.
- "If the amount applied is not adequate, the level of protection will be significantly reduced".

VII. For Multifunctional products:

- Personal hygiene products, cosmetics and perfumes that contain sunscreens only for the protection of the formulation and do not claim activity as a sunscreen and do not mention a value of SPF do not need to comply with this Regulation.
- If product revendicates UV protection or SPF value, then the minimum tested SPF value should not be less than SPF 2 and the minimum tested UVA protection should be UVAPF 2.
- The labeling of multifunctional products should contain the following warning: "This product is not a sunscreen".