

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. Definition

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. 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".

IV. 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		

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".

VIII. For any further information, the following table presents the different actors in Brazil.

Trade association representing the cosmetic products industry	Representing at international standardization level	Regulations/Health agency
Brazilian Association of the Cosmetic Toiletry and Fragrance Industry (ABIHPEC)	Associação Brasileira de Normas Técnicas (ABNT)	Brazilian Health Regulatory Agency (ANVISA)
https://abihpec.org.br/	www.abnt.org.br/	http://portal.anvisa.gov.br/
 ABIHPEC Associação Brasileira da Indústria de Higiene Pessoal, Perfumaria e Cosméticos	 ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS	 ANVISA Agência Nacional de Vigilância Sanitária