Suncert News

<< SN06 / By SUNCERT Sunscreen Testing Certification / SN07 / EDITION JANUARY 2019

Solar irradiance in sun protection methods

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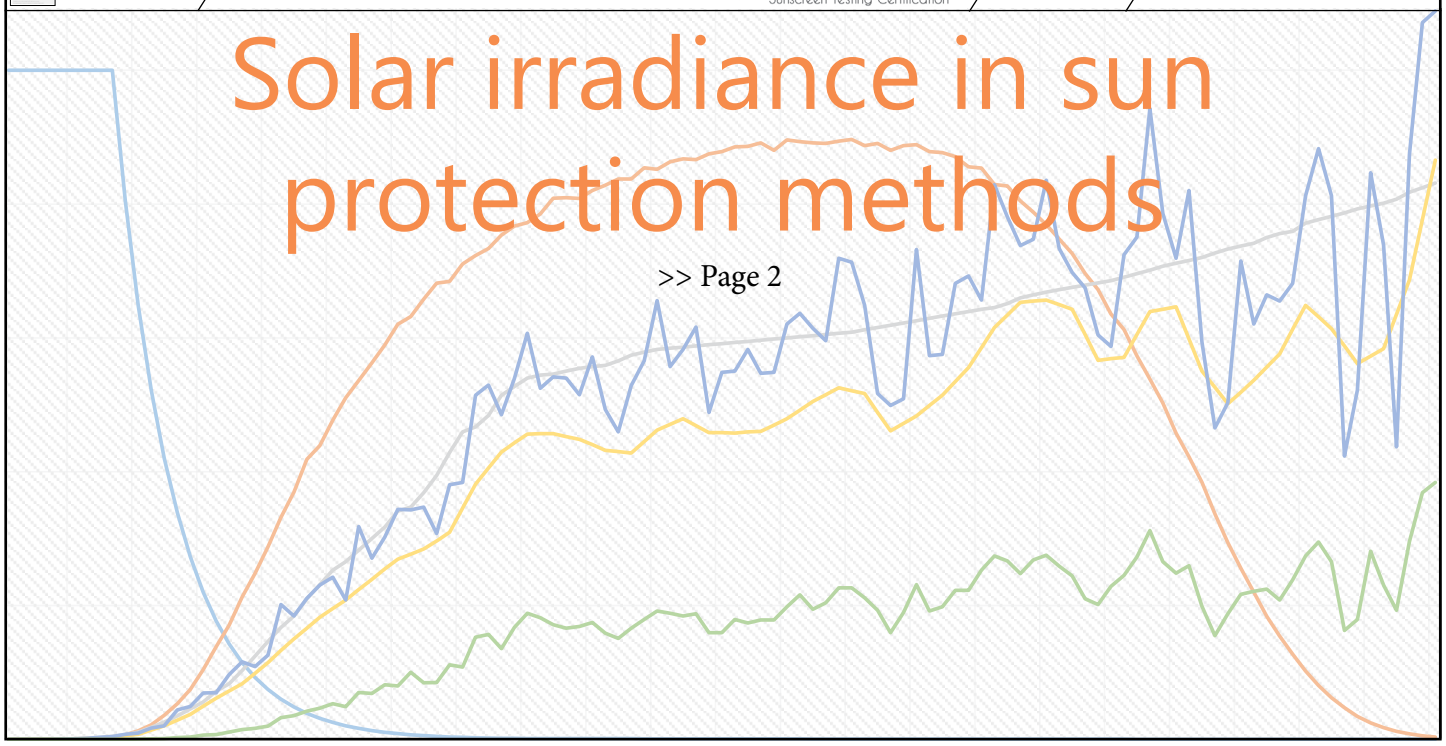


Regulations continuously change and new worldwide harmonized methods are proposed to improve sun protection assessment. This is a fact and these evolutions take time to ensure reliable and relevant sun protection to consumers.

To help different actors in sun protection testing field to discover reliable consumables, appliances and software, we are pleased to propose you a new website called Suncert-Shop.

In complement, as it could be confusing, we describe the different solar irradiance used in the current methods and in development (see page 2).

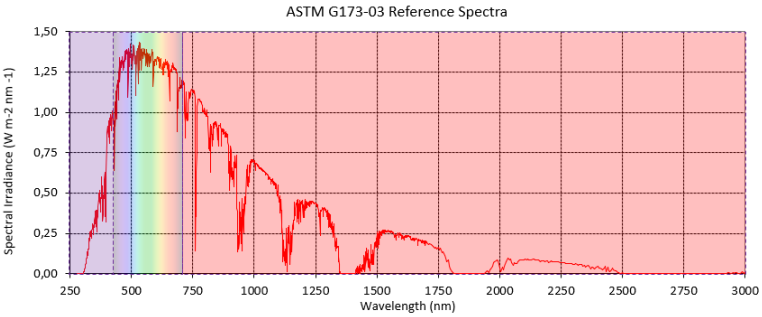
Beyond this new service and to continue to help you to develop better sunscreen products, in page 3, we propose new free online tools such as SPF or UVA protection label guidance but also regulatory sheets on different countries, audit and monitoring service, software dedicated to sunscreen testing, etc.

Therefore, in this new edition of our SUNCERT News, you are going to discover (i) the solar irradiances, (ii) new free online tools and (iii) the sunscreen regulation in Russia.

Sébastien MIKSA, CEO

Solar irradiance in sun protection methods

Solar irradiance is defined as the power per unit area in the wavelength range and expressed as W.m-2.nm-1 (real sun light is presented in the right graph). In sun protection testing field, UVB range is defined from 290-320 nm and UVA range from 320-400 nm (with UVA-I from 340-400 nm and UVA-II from 320-340 nm).



A solar simulator (also called artificial sun) is a device that provides a controllable indoor illumination used for testing different materials and devices. Generally, the specifications from IEC 60904-9, ASTM E927 & JIS C8912 standards are used according to the control of three dimensions (1) spectral content, (2) spatial uniformity and (3) temporal stability. Each dimension is classified in one of three classes: A, B, or C as presented in the right table.

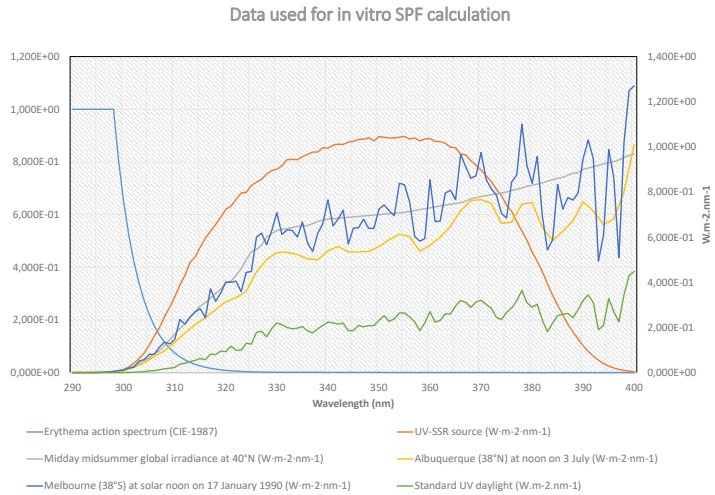
Classification	Spectral Match to sun air mass (%total irradiance for each interval)	Irradiance Spatial Non-Uniformity	Temporal Instability
Class A	0.75–1.25	2%	2%
Class B	0.6–1.4	5%	5%
Class C	0.4–2.0	10%	10%

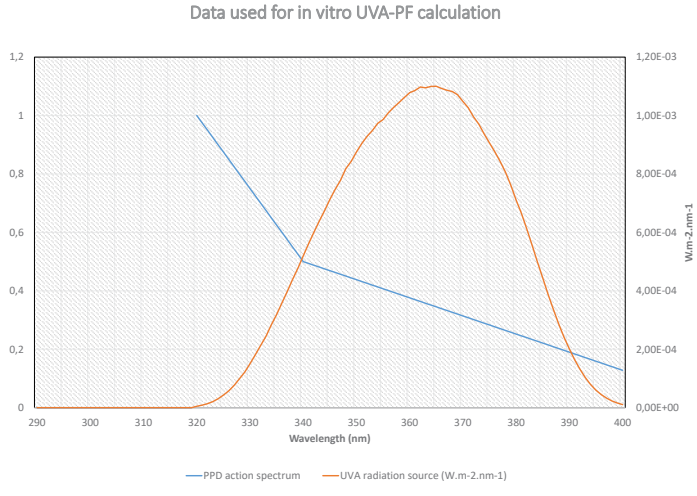
In the several worldwide in vivo and in vitro sun protection assessment methods (current and under development), another specifications are used. Nevertheless, the aim of this chapter is not to describe the different specifications in terms of radiometric proportion, %RCEE, exposure conditions, etc. (available in different norms) but only to present a global view according to the method (see table here below).

Method	Value	UV spectrum		Biological specturm
		Calculation	UV exposure	
ISO 24442:2011	In vivo UVAPF	-	UVA	-
ISO 24443:2012	In vitro UVAPF & In vitro CW	SSR	Similar to SUN	E (for SPF) & P (for UVAPF)
ISO 24444:2010	In vivo SPF	-	SSR	-
ISO 23675*	In vitro SPF multi-substrates	SUNmid	SSR	E
ISO 23698*	In vivo/In vitro HDRS-SPF	SSR	Similar to SUN	E
FDA 2011	In vivo SPF & In vitro CW	-	SSR	-
Boots Star Rating System 2011	In vitro UVA:UVB ratio	-	SUN	-

*Method under development in ISO process.
SPF : Sun Protection Factor | UVAPF : UVA Protection Factor | CW : Critical Wavelength | HDRS : Hybrid Diffuse Reflectance Spectroscopy
SSR : Solar Simulated Radiation source in vivo SPF institute (W·m-2·nm-1) | SUN : Irradiance similar to real sun light | SUNmid : Midday midsummer global irradiance at 40°N (W·m-2·nm-1) | SUNalb : Albuquerque (38°N) at noon on 3 July (W·m-2·nm-1) | SUNmel : Melbourne (38°S) at solar noon on 17 January 1990 (W·m-2·nm-1)
E : Erythema action spectrum (CIE-1987) | P : Persistent Pigment Darkening (PPD) action spectrum

Finally, the different solar irradiances used for UV exposure and/or calculation are globally presented in the graph here below (for SPF and UVA).





Suncert Tool

By SUNCERT

New free online tools

Following our previous Suncert News with the introduction of online tools to help you to devevelop and evaluate your sunscreen products, we have the pleasure to include new tools and all of them are totally free of charge. Here below, discover our six online tools.

In Vivo SPF Confidence

Probability of reaching the target SPF value during the in vivo screening phase

https://www.suncert.fr/en/pro-home/suncert-tool-en/in-vivo-spf-confidence-en/

The challenge

During development of a sunscreen product, estimating the probability of reaching the target SPF value during the in vivo screening phase on a small number of volunteers is often difficult and we do not have an objective tool to take a decision.

In Vivo SPF Comparison

Determine if both products are equivalent in in vivo UVB protection

https://www.suncert.fr/en/pro-home/suncert-tool-en/in-vivo-spf-comparison-en/

The challenge

During development of a sunscreen product or for a quick verification of the efficacy of a new product or batch, an in vivo screening of the SPF is often used with a small number of volunteers and we do not have an objective tool to take a decision in terms of equivalence on UVB protection.

SPF label regulatory

Determine the level of SPF you can claim depending on the country

https://www.suncert.fr/en/pro-home/suncert-tool-en/spf-label-regulatory-en/

The challenge

During develpment of a sunscreen product for the market, the question arises quickly about the possible claim of the level of SPF protection depending on the marketing area. In addition, a margin of safety is sometimes interesting to protect the consumer.

UVA label regulatory

Determine the level of UVA protection you can claim depending on the country

https://www.suncert.fr/en/pro-home/suncert-tool-en/uva-label-regulatory-en/

The challenge

During develpment of a sunscreen product for the market, the question arises quickly about the possible claim of the level of UVA protection depending on the marketing area.

UV index relation to erythema

Time of appearance of erythema as a function of exposure, skin and sunscreen

https://www.suncert.fr/en/pro-home/suncert-tool-en/uvindex-sunburn-spf-en/

The challenge

During a solar exposure, the probability of occurrence of a sunburn is directly related to many factors (UV Index, Phototype, Sun protection, etc.) and the consideration of the use of a Solar product is sometimes difficult to estimate.

SPF In Vivo veritas

Estimate the potential sun protection that could obtain the consumer

https://www.suncert.fr/en/pro-home/suncert-tool-en/spf-in-vivo-veritas-en/

The challenge

When using a sunscreen product by the consumer, the sun protection actually provided by the product can be mitigated if the application is poorly controlled and dosed or if the product itself has a spreading variability. It is therefore difficult to quantify the final SPF that the consumer could potentially have

*You need to be registred to have access to these online tools.

Russia: Suncreen Regulations for Sun Protection methods and labeling

The Eurasian Customs Union (EACU) is a customs union which consists of all the Member states of the Eurasian Economic Union (EAEU) including Russia, Belarus, Kazakhstan, Armenia and Kyrgyzstan.
On July 20th, 1998, the Ministry of Health Act N 217 text was adopted by order of the Ministry of Public Health of the Russian Federation. This text concerns requirements on hygienic assessments of cosmetic products. It regulates the hygienic assessment of products, goods and production facilities, as well as the logo confirming that products passed hygienic assessment. Beyond this text, the Gosstandart P 51391-99 was adopted in 1999 by the Russian Committee on Standardization Metrology and Certification. It defines the general labelling requirements for perfumes and cosmetic products.
Finally, the Technical Regulation CU TR 009/2011 on safety of perfumes and cosmetic products was adopted into the Customs Union between Russia, Belarus and Kazakhstan by decree n° 799 of Customs Union Commission and came into force on July 2012. This regulation tends to be similar to the EU (Regulation (EC) 1223/2009) than previous legal requirements. The authority responsible for application and verification of the CU TR 009/2011 application in Russia is RosPotrebnadzor, the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing, acting under the Ministry of Health. Thus, according to these rules, the important parts are described herein below.

I. Sunscreens are classified as cosmetic products according to the Technical Regulation and are not subjected to registration, only a notification before product entry in the Customs Union is mandatory. Nevertheless, all the cosmetic products are required to have a Declaration of Conformity according to the GOST standards (State Standards of the Soviet Union).

II. Declaration of Conformity to Technical Regulations (DOC TR) is asked by customs and on the commercialization / utilization place on the soil of the Russian Federation. The DOC TR shall be registered with an organism authorized in the TR system, based on proofs of conformity presented by the declarant. DOC obtainment is authorized solely by Russian legal entities (distributor, importer or official representatives of foreign manufacturers). In addition, each declarant must possess its own declaration of conformity issued in its name. The DOC TR can be realized on the behalf of the manufacturer if documents elements are provided (K-BIS, delivery contract) from its importer. In this case, the manufacturer can completely control the compliance process and use the results of the conformity assessment for several importers.
The following documents are needed for obtain the Declaration of Conformity: (i) List of ingredients et concentrations, (ii) Copy of physicochemical and organoleptic characteristic's products, certified conform by the applicant, (iii) Tests protocols or tests reports or acts of hygiene expertise or conclusions of an accredited laboratory, (iv) Label sample, (v) GMP certification, (vi) Documents proving product claims.
In the case of products modifications, State certification and Declaration of Conformity are no longer valid.

III. Labelling of cosmetic products are regulated in the law for the Protection of Consumers and are established in the regulatory text Gosstandart n°51121-97 in the section for industrial products. Since April 2016, cosmetic products coming from outside the Customs Union have the obligation to be labelled according to the Russian requirements before customs clearance. The labelling information must be written in Russian and contain different data (please read the our Technical Sheet available in our website for complete details).
If the cosmetic products are accompanied with further information, the products are marked with a symbol of an open book. Concerning claims, there is no legislative texts or official guidelines regulating sunscreens products. However, claims must be proven by evaluations and its documents have to be send for the Declaration of Conformity.

IV. The conformity marking "EAC" (for EurAsian Conformity) of the Customs Union is made up of initials. It means product is certified in conformity with the essential health and safety requirements of the Technical Regulation TR TC 09/2011. It gives access to free circulation on all the territory of the Customs Union.

The initials of conformity EAC is also affixed visibly on products or/and documents accompanying its.

V. For the sunscreen products, the labelling guidelines are similar to the EU guidelines and the following information must be added to the previous ones:

- SPF (with a scale of maximum of 50+),
- UVA protection according to the UVA logo circle or the PA+ to PA+++ (respectively for UVAPF 2-4; 4-8 and ≥ 8) with broad-spectrum feature,
- Water resistance (80 minutes and the minimal percentage for the "wash-off" criteria is 50%).

VI. In order to ensure the determination of sunscreens products efficacy, Russia and the other countries belonging to the Customs Union integrated to the Technical Regulation 009/2011 ISO norms as GOST standard (as described in different documents DOC 1 - DOC 2 - N°46 - N°110 - N°273). The following norms are mandatory.

Protection	Method
UVB	GOST in vivo ISO 24444-2013 – In Vivo SPF
UVA	- GOST in vivo ISO 24442-2016 – In Vivo UVAPF (implemented in July, 1st 2019) - JCIA 1995 – In Vivo UVAPF - GOST in vitro ISO 24443-2016 – In vitro UVAPF and CW (implemented in July, 1st 2019)
Water Resistance	- FDA monograph 2011 – In Vivo Water Resistance - Colipa 2005 Guidelines for Evaluating sun Protect Water Resistance

SPF: Sun Protection Factor – PFA or UVAPF: UVA Protection Factor

In complement, the norm GOST EN 16344-2016, transposed from the norm NF EN 16344:2013, will be implemented in the Customs in 2019. It will frame the method to analyze and detect UV filters in cosmetic products, as well as the determination of 10 UV filters by the HLPC instrumental method.

VI. As in other countries, the cosmetic, sunscreen including, shall fulfill other requirements:

a. Stability evaluation determined by the methods described in the norm GOST 29188.3-91 of the TR TC 009/2011,
b. Product and safety data shall be contained in the DOC TR with tests realized in a laboratory accredited by the Russian authorities,
c. Regulatory requirements for ingredients and nanoparticles are very similar to the EU list,
d. Animal testing is still accepted but, in 2016, the State Duma (Federal Assembly) introduced to ban animal testing for cosmetics and ingredients and this proposition is currently examined,
e. Russia doesn't have a cosmetovigilance system,
f. GMP requirements.

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