Suncert News

You are involved in sun protection field?

You want to have reliable sunscreen testing results?

>>A SHORT VIDEO INTRODUCING SUNCERT.
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After several months from the creation of SUNCERT for sunscreen testing certification, the majority of laboratories have been informed about this new service. Moreover, we received several requests from testing laboratories in order to be certified under the SUNCERT certification.

> "Everyone can define itself as an expert in sunscreen testing field but not all laboratories can obtain the SUNCERT certification."

Even if, a lot of competent and serious companies are interested by this certification, some others didn't unterstand (or perhaps didn't want) this compulsory need for a reliable sun protection for consumer's health. They mentionned that they have already been "certified", "recognized" or "approved" by other organizations or just explained they just explained that they are "experts". Nevertheless, everyone can define itself as an expert in sunscreen testing field but not all laboratories can obtain the SUNCERT certification.
Indeed, beyond these general "recognitions" or "expertise", when we asked them more technical details relating to sun protection testing, the answers are unbelievable (from my point of view)... Indeed, as for *in vivo* or *in vitro* methods, some of them don't calibrate their solar simulator and/or their radiometer, don't respect the human volunteers criteria selection and/or technical substrate specifications, don't apply the right amount of product or they don't follow the entire procedure...

Anyhow, we will continue to explain, help and certify all testing laboratories to be in compliance with the rules. In this case we will contribute to the improvement of reliable sun protection testing all over the world.

In this second edition of our SUNCERT News, you are going to (i) discover our policy statement on the independence and impartiality of SUNCERT, (ii) have an overview of *in vitro* methods and (iii) learn about the USA sunscreens regulations.

Sébastien MIKSA, CEO

Policy statement on the independence and impartiality of SUNCERT

The sunscreen testing certification of cosmetic or pharmaceutical products has the overall goal to give confidence to all stakeholders. Indeed, the system and the methods have to meet the requirements of the standards whether normative, regulatory or accepted by a community of interests.

The value of the certification is related to the competence of the certification body and its evaluators but also its impartiality and its independence of all third parties involved in the operation of its certification system. Therefore, as a certification body, SUNCERT has to take actions (at its disposal) to ensure the integrity of the certification. Obviously, SUNCERT undertakes to follow this policy and to ensure compliance by any person involved in the certification process. The different points are described herein below:

1 Our simplified joint-stock company and the composition of our capital (private persons) ensure our perfect independence towards a third party whatever it is and mainly companies which could be certified.

2 Maintaining our independence and ensuring the objectivity of our certification decisions is a daily concern in the exercise of our profession as certification body. Therefore, if a situation presents a conflict of interest and if we cannot do the necessary to reduce the risk, then the service is denied.

3 The inspector mandated by SUNCERT will and has to refuse any payment outside of established prices, gift, commission or other even non-monetary benefits, for himself or his family, by customers or any another persons, which could doubt his independence in carrying out the audit.

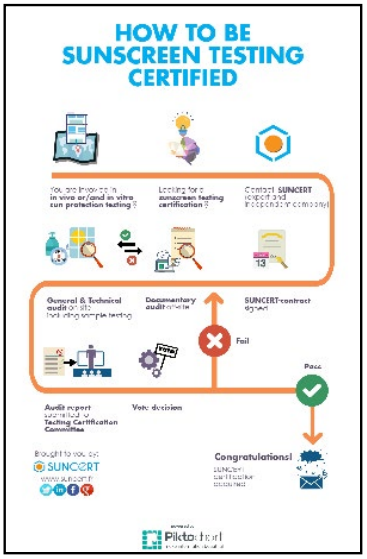
4 To ensure our independence, we prohibit to establish financial partnerships (not related to ensure standards compliance) with companies which supply services in the field of evaluation of sun protection.

5 Our Testing Certification Committee, composed of independent members and representing different stakeholders of the certification (including the methods of sun protection assessment), ensures the impartiality of our operations and certification decisions.

Concerning the Testing Certification Committee which is composed of limited members choson on voluntary basis, it is the decision making body in the award of the SUNCERT certificate and it will take actions collectively, anonymously and confidentially.
To ensure its role of watchfulness, the Testing Certification Committee periodically analyzes elements provided by SUNCERT under anonymous audit report. Following consultation, each member individually submits their opinions and the decision is obtained by the majority of votes.

Beyond this policy statement on the independence and impartiality of SUNCERT, the references documents (**SUNCERT-GEN** and **SUNCERT-TEC**) are mainly based on sun protection testing methods which are already harmonized and standardized. In other words, even if it is required, SUNCERT has not and will not promote any methods, consumables or materials for commercial interests except for technical and compliance interests.

As a conclusion of this policy, the infographic here after presents the certification process including the involvment of the Testing Certification Committee.



In vitro Methods For Sun Protection Assessment

The reliable assessment of sun protection factors is crucial. Indeed, they are the guarantee of the level of protection of sunscreen products. This determination is performed under rigorous conditions with the desire to have a global harmonization of methods and regulation.

Nowadays, beyond *in vivo* methods, *in vitro* methods are also worldwide used for claiming purpose according to ISO 24443:2012, FDA monograph 2011, Cosmetics Europe 20011 and Boots Star Rating System 2011.

Regarding the *in vitro* methods, the simplified illustration is presented in **Figure 1**, the detailled timetable is described in the **Table I** and the terms is given in **Table II**.

• Typically, the UVA-PF, CW and UVA:UVB ratio are measured on specific roughned substrates (checked by using a profilometer) by strictly applying 0.75, 1.0 or 1.3 mg/cm2 (according to method) of a sunscreen formula. After a controlled spreading, the sample is allowed to dry during at least 15 or 30 minutes.

• The first UV absorbance measurement is then performed for the different plates by means of a spectrophotometer (UV analyzer) to calculate the sun protection factors for UV dose exposure calculation (if required).

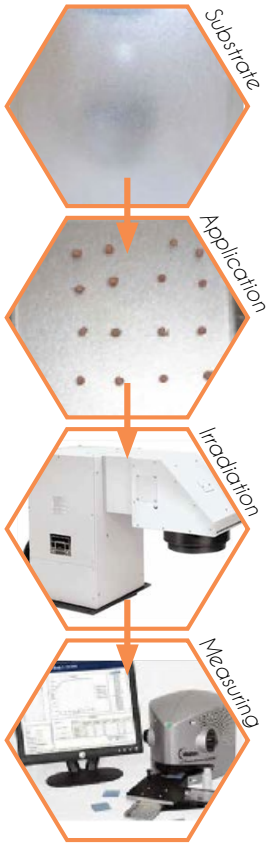
• After that, samples are exposed to UV light from a calibrated solar simulator delivering (UV source checked by using a spectroradiometer) under a precise dose (checked by using a radiometer) and a second UV absorbance measurement is then performed.

• The UVA-PF, CW or UVA:UVB ratio are finally calculated from the UV absorbance curve for UVA protection determination and label based on the average of 4 to 10 valid substrates under statistics criteria for acceptance.

As an evidence, in order to ensure reliable and reproducible results for consumer's health, some key parameters shall be strictly followed and certified such as:

- Appliances calibration,
- General procedure,
- Substrates selection,
- Amount, application and spreading,
- UV exposure condition,
- UV analyzer,
- Calculation software.

Figure 1. Simplified in vitro process methods



Images from: E. QUESTEL. Evaluation des différents indices solaires : méthodes in vivo. Keratin [20] 2014

Table II. Termes

UV (ultraviolet): electromagnetic radiation with wavelength UVB (290 nm to 320 nm), UVA-II (320 nm to 340 nm) and UVA I (340 nm to 400 nm).

SPF (Sun Protection Factor): level of protection of a sample against erythema-inducing radiation calculated with spectral modelling.

UVA-PF (UVA Protection Factor): level of protection of a sample against UVA radiation including persistent pigment response calculated with spectral modelling.

CW (Critical Wavelength): Wavelength where the area under the absorbance spectrum from 290nm to λc is 90% of the integral of the absorbance spectrum from 290nm to 400nm.

UVA:UVB ratio (Boots Star rating system): ratio of the mean UVA absorbance to the mean UVB absorbance, both defined by the area (per unit wavelength) of the respective UV portion from the same curve.

Profilometer: instrument used to measure the surface profile characteristics of a materrial (i.e. the substrate).

Solar simulator: instrument used to produce a continuous spectral distribution of UV radiation.

Spectrophotometer: instrument used to measure absorbance (or transmission) properties of a sample at each wavelength.

Spectroradiometer: instrument used to measure spectral irradiance (intensity in W/unit area/nm) of a light source

Radiometer: instrument used to measure broad band irradiance (intensity in W/unit area) of a light source.

Table I. Programme détaillé des méthodes in vitro (FPUVA, LOC & Ratio UVA:UVB)

	Etape	Tps 1	Tps 2	Tps 3
UVA-PF, Critical Wavelength or Boots Star Rating System	Calibration of appliances (solar simulator, spectrophotometer, balance...)	x		
	Control of temperature during the whole process	x		
	Selection of substrate according to technical specification	x		
	Application of the product	x		
	Spreading under strict conditions (pressure, speed, time...) including drying time	x		
	First measurement of UV absorbance of all plates	x		
	Calcul of the sun protection factors for UV exposure dose calculation (if required)		x	
	UV exposition under precise dose (checked by using a radiometer) and conditions control		x	
	Second measurement of UV absorbance of all plates			x
	Calculation of the sun protection factors of product (UVA-PF, CW, Star ratio...)			x

USA suncreen regulations
For Sun Protection methods and labeling

The ISO (International Organization for Standardization) aims to harmonize all over the world the methods for higher reliability in technical terms such as the sun protection testing field. For this purpose, different norms are proposed for the UVB and UVA protection assessment through the ISO 24444 (in vivo SPF), ISO 24442 (in vivo UVAPF), ISO 24443 (in vitro UVAPF and CW), soon the ISO 16217 (in vivo Water Resistance procedure) and ISO 18861 (Water Resistance calculation) and in the future the *in vivo* SPF...

Nevertheless, even if an harmonization in terms of methods and labeling is highly required, some countries persist to impose different methods and claim in their own market. This is mainly the case in the USA (United States of America) with the FDA (Food and Drug Administration) final monograph 2011.

Thus, in the present review, the important parts are described herein below:

I. The 2011 sunscreen final rule applies to OTC (over-the counter) sunscreen drug products that (i) are marketed without approved drug applications (without NDAs - new drug application - or ANDAs - abbreviated new drug application) and (ii) contain any of the following active ingredients, alone or in combination: aminobenzoic acid (PABA), avobenzone, cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, oxybenzone, padimate O, sulisobenzone, titanium dioxide, trolamine salicylate, zinc oxide.

II. The proposed principal display panel (PDP) labeling includes (i) the determination of the in vivo SPF with numerical SPF value displaying (i.e. no section), (ii) an assessment of the level of UVA and UVB protection by means of the in vitro Critical Wavelength test with Broad Spectrum pass/fail (with 370nm limit) displaying and (iii) the in vivo Water-Resistance statement regarding the immersion time used with 40 or 80 minutes (in this case with SPF after immersion value displayed).

III. For sunscreen drug products, different directions and warnings must be displayed. A special warning has to be displayed if the Broad Spectrum Test not pass or if the SPF value is less than 15.

IV. Only methods proposed and described in the FDA final monograh 2011 can be used (i.e. no ISO methods, etc.). to asses the performance of sun protection products.

V. Labeling of OTC sunscreen drug products subject to the 2011 sunscreen final rule must be submitted to the FDA as required by the drug listing provisions.

As for the European Recommendations presented in our last SUNCERT News issue (SN01), it seems appropriate to replace the current final monograph by an update version or by the use of ISO rules taking into account scientific progress since 2011. Therefore, we also added some proposals for a possible future revision:

I. To adopt ISO testing methods for in vivo SPF, in vivo Water Resistance (procedure) and in vitro CW assessment.

II. To ensure consumer's health, the sun protection performance of sunscreen products should be assessed regarding their stability through different factors (Light, Temperature, Time, Package, etc.) and between each batch.

III. To follow the international trend regarding a higher relevant UVA protection required for consumers' health, it should be required (i) an UVAPF at least equals to 1/3 of the SPF labeled with a CW ≥ 370 nm or (ii) a CW at least equals to 375 nm (instead of current 370 nm limit).

IV. To set an upper limit for labeled SPF values at "50+" permitting sunscreen products with SPF test results above 50 to be labeled with a "50+" value instead of the specific value (see citation 76FR35672).

V. Beyond the FDA approval, the claims indicating UVB and UVA protection effectiveness should be assessed by laboratories having a sunscreen testing certification delivered by an independent and expert company.

Finally, even if it seems logical, we should never forget that the sun protection indices are only a relative scale to classify the protective capabilities between different products, used as a reference mark for consumer guidance and without attempting to represent the conditions of use in real life.

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