SUNCERT News

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New Sunscreen Testing Certification

The evolution of sunscreen products and their role and use are necessary for effective sun protection.

With worldwide cultural differences and cultural evolution, consumers awareness relating to UV damages allows reducing UV exposure and to increase the use of sun protection ways. Obviously, a good UV protection from the product is also required and for reaching this goal, several key requirements have been identified such as the technology including UV filters and formulation, measurement methods, regulations and testing laboratories competences.

Therefore, it seems logical to harmonize and control all these key requirements as they will impact the consumer's health. Nevertheless, even if an authorized list of UV filters, developed standardized methods and published compulsory regulations are already available, no more control of testing laboratories performance is proposed.

Unfortunately, some other alternatives recognitions have been wrongly used such as ISO 9001 certified, ISO 17025 certified, FDA approved, TGA approved... but all of them are not relevant and sufficient in sunscreen testing field. Beyond this fact, it is well known that some laboratories didn't, don't and won't follow the rules if no official certification is proposed and requested by all actors. In other words, even if an institute could claim competent itself, no relevant signs can reveal and certified the compliance to rules and quality level.

> "This new certification will allow to recognize the competence of laboratories for sun protection testing."

Thus, it was so logical for me to have a certification for suncreen testing comptence that is why I decided to create and propose you for the first time an innovative, independent and expert company dedicated and involved in this task: the SUNCERT organization for sunscreen testing certification.

Finally, in complement to inform all our subscribers about sunscreen testing field through Methods, Regulations, News about SUNCERT..., a special newsletter has been created and will be disctributed several times per year. This is the goal of SUNCERT News and of this first issue.

Sébastien MIKSA, CEO

Sunscreen Testing Certification For Reliable Sun Protection

This certification via the SUNCERT certificate is the result of a simple observation. The lack of an official sunscreen testing certification, the difficulty to recognize the conformity of sunscreen assessment according to standards without external control, the need to support organizations focusing on compliance with rules... are some examples that can be highlighted.

1. Certified methods

To protect effectively and reliably consumers, the key is to certify that allegations concerning the sun protection were determined in accordance with the standards.

Thus, several indices of protection via *in vivo* and *in vitro* methods can be certified according to standardized methods (see **Table I**).

Table I. List of certified methods

Index	Standard
In vivo SPF	ISO 24444
In vivo UVA-PF	ISO 24442
In vitro UVA-PF / In vitro CW	ISO 24443
In vivo SPF / In vivo WR In vitro CW	FDA monograph 2011 21 CFR Parts 201, 310, and 352
In vivo SPF	Cosmetics Europe 2006
In vivo WR	Cosmetics Europe 2005
In vitro UVA-PF / In vitro CW	Cosmetics Europe 2011
In vivo UVA-PF	JCIA 1999
In vivo SPF / In vivo WR In vitro UVA-PF / In vitro CW	AS/NZS 2604:2012
In vitro UVA:UVB ratio	Boots Star Rating System 2011

2. Certification process

Many factors, which will be subjected during audits, determine the accuracy and the reliability of testing of a laboratory. Such factors may include elements from:

- quality system,
- human factors,
- installations and working conditions,
- validation of standardized methods,
- equipment and calibration,
- traceability of measuring,
- general procedures.

> “This new certification offers plenty of benefits for the business success such as the expertise comparison between laboratories, the assurance of reliability for your customers, the improvement of the organization’s brand name...”

For this purpose, the certification is organized by cycles of 3 years (full cycle) allowing to appreciate in its entirety if the system can ensure and guarantee that the selected sunscreen tests are compliant. All nonconformities which are general or technical, minor or major, documentary or applicative entail corrective and preventive actions.

Contract

- General information
- Audit’s agenda
- Audit engagement letter

Year 1

Step 1

- Documentary audit **off-site**
- Edition of an acceptability report

Step 2

- General & Technical audit **on site**
- Certification decision

Year 2

Step 3

- General & Technical audit **off-site** and/or **on site**
- Certification decision

Year 3

Step 4

- General & Technical audit **off-site** and/or **on site**
- Certification decision

Finally the SUNCERT certificate is based on three separate documents available on the website or on request. As soon as one or several organizations request a certification, a contract is established between the organization(s) and SUNCERT.

SUNCERT-PRO

Information regarding the certification process.

SUNCERT-GEN

General and technical requirements.

SUNCERT-TEC

Technical specifications and operational procedures.

SUNCERT-CONTRACT

Contract for the certification.

In vivo Methods For Sun Protection Assessment

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

Nowadays, even if *in vitro* methods are preferred when available, *in vivo* methods are still worldwide used for claiming purpose according to ISO 24444:2010, ISO 24442:2011, FDA monograph 2011, AS/NZS 2604:2012, JCIA 1995, Cosmetics Europe 2006 and Cosmetics Europe 2005.

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

Typically, the SPF and UVA-PF are measured on specific human volunteers by strictly applying 2 mg/cm^2 of a sunscreen formula to an area of the mid-back and allowed to dry during 15-30 minutes. After that, a serie of several increasing doses of UV radiation, from a calibrated UV source simulating different sunlight parts, are administered to protected skin sites with the sunscreen and unprotected skin sites. After a specified time (16 to 24 hours for SPF and 2 to 24 hours for UVA-PF), the irradiated skin sites are examined by qualified operator to determine the biological effect. The SPF or the UVA-PF is the lowest dose of UV radiation that caused respectively mild sunburn or persipent pigment in the sunscreen-treated area divided by the lowest dose of UV radiation that caused the same biological effet in the area without sunscreen. Finally, the label SPF and UVA-PF of a sunscreen formula are based on the average for 10 to 20 valid volunteers under statistics criteria for acceptance. By the way, for Water Resistance (WR) methods, immersion steps are added and different ways of claiming can be used based on an absolute or a relative value (i.e. respectively from only SPFw or from %WRR).

Obviously, in order to ensure reliable and reproducible results for consumers' health, several key parameters should be strictly followed and certified such as:

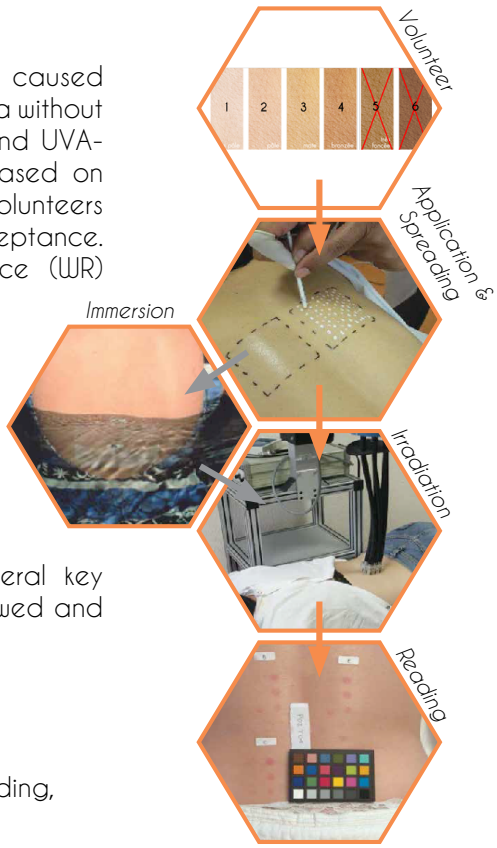
- Appliances calibration,
- General procedures,
- Volunteers selection,
- Amount, application and spreading,
- UV exposure conditions,
- Biologicial effects reading.

And in addition for Water Resistance:

- Immersion procedures,
- Water specifications,
- Immersion devices.

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

Figure 1. Simplified in vivo process methods



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

Table II. Detailled timetable of in vivo methods (SPF, UVA-PF & WR)

	Step	Time 1	Time2	Time3
SPF or UVA-PF	Calibration of appliances	x		
	Consent, History and Previous treatments of volunteers	x		
	Phototype and/or ITA° determination of volunteers	x		
	MED or MPPDD of subject estimation	x		
	Test sites determination of volunteers	x		
	UV exposure of unprotected test site	x		
	Application of product to be tested including drying time	x		
	UV exposure of protected test site	x		
	Biological effects determination (MEDnp & MEDp or MPPDDnp & MPPDDp)		x	
	Calcul of sun protection factors of product (SPF or UVA-PF)		x	
Water Resistance	Application of product to be immerged including drying time		x	
	Immersion step including drying time (with necessary repeatition)		x	
	UV exposure of immerged protected test site		x	
	UV exposure of immerged unprotected test site		x	
	Biological effects determination (MEDnpw and MEDpw)			x
	Calcul of sun protection factors of product (SPFw) and/or %WRR			x

Table III. Terms

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).

Phototype: Fitzpatrick classification ranging from a level of I to VI according to individual reaction of the skin under sunlight exposure.

ITA (Individual Typology Angle): colorimetric value characterizing the skin color of the subject.

MED (Minimum Erythema Dose): smaller dose of UV for which there is appearance of the first visible erythema, unambiguous, with regular edges.

SPF (Sun Protection Factor): Average for all subjects of the ratio of the MED on skin protected by the product (MEDp) on MED on unprotected skin (MEDnp) of the same subject.

MPPDD (Minimal Persistent Pigmentation Darkening Dose): smaller dose of UVA for which there is appearance of the first visible persistent pigmentation darkening, unambiguous, with regular edges.

UVA-PF (UVA Protection Factor): Average for all subjects of the ratio of the MPPDD on skin protected by the product (MPPDDp) on MPPDD on unprotected skin (MPPDDnp) of the same subject.

SPFw (Wet Sun Protection Factor): Average for all subjects of the ratio of the MEDp on wet skin (MEDpw) on MEDn on unprotected wet skin (DEMnpw) of the same subject.

%WRR (Percentage of Water Resistance): Average for all subjects of percentage of the report of individual SPFw (SPFiw) less 1 to the individual SPF (SPFi) less 1 of the same subject.

European Recommendations
The Future is Soon

In Europe, the sunscreen labelling is leaded by the "COMMISSION RECOMMENDATION of 22 september 2006 on the efficacy of sunscreen products and the claims made relating thereto (2006/647/EC)". As an evidence, recommendations differ from regulations, directives, decisions and opinions as they are not binding acts for Member States. Even without legal force, they have political weight and "have to" be followed. Thus according to these EU recommendations, the important parts are desccribed herein below.

I. A "sunscreen product" is a cosmetic product as a preparation intended to be safely placed in contact with human skin with a view exclusively or mainly to protecting it from UV radiation by absorbing, scattering or reflecting radiation.

II. The responsible person must, for control purposes, keep information on the proof of the effect claimed for the cosmetic product, where justified by the nature of the effect or product, readily accessible to the competent authorities of the EU Member State concerned which are obliged to take all measures necessary to ensure these information.

III. The sunscreen products should (i) protect against UVB and UVA radiations, (ii) no claim (through text, name, trade mark, picture, figurative or other sign) implying that those products have characteristics or functions which they do not have and (iii) display warning indicating and advice on precautions to be observed relating to their use.

IV. The degree of protection should be measured using standardised, reproducible testing methods and take photo-degradation into account. Preference should be given to *in vitro* testing methods delivering equivalent results, as *in vivo* methods raise ethical concerns.

V. The claims indicating UVB and UVA protection efficacy provided by sunscreen products should be made only if the protection equals or exceeds minimum levels (**Table IV**).

Table IV. Range of sun protection factors.

Labelled category	Labelled SPF	Measured SPF	Minimum UVA-PF	Minimum CW
«Low protection»	6	6 - 9,9	1/3 of labelled SPF	370 nm
	10	10 - 14,9		
«Medium protection»	15	15 - 19,9		
	20	20 - 24,9		
	25	25 - 29,9		
«High protection»	30	30 - 49,9		
	50	50 - 59,9		
«Very high protection»	50 +	≥ 60		

As an evidence, to ensure a high protection for consumers, it seems appropriate to replace the current recommendations by an update version taking into account scientific progress since 2006. Therefore, we also added some ways of improvement for the future revision of these recommendations. Herein below, some proposals:

I. Change the title of these Recommendations in order to have a binding legislative act (such as Regulations, Directives or other acts).

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. The claims indicating UVB and UVA protection efficacy should be assessed by a certified testing organization under a sunscreen testing certification, through a standard or a label from an independent and expert company.

IV. An international symbol displayed on the sunscreen product should be used to inform a minimum UVA-PF ≥ 1/3 of the labeled SPF and a CW ≥ 370 nm.

UVA

V. Additional claiming (e.g. Water Resistance, Sweat Resistance, Wet Skin Application, Infra-Red protection...) relating to sun protection should be assessed using standardised methods when available or using validated methods which are (i) published with an international dimension, (ii) freely accessible (technical report, texts, scientific journals...) and (iii) based on a large number of products for the estimation of robustness, accuracy, selectivity, repeatability and reproducibility.

VI. For ethical concerns, even if *in vivo* methods exist for the same sun protection factor, only the standardized *in vitro* methods shall be used when available delivering equivalent results and expressed in mandatory terms.

VII. A product that is represented as having a primary function other than sun protection whilst providing some protection of the skin from ultraviolet radiation (i.e. Secondary sunscreen product such as makeup products...) should fulfill the same requirements than a primary sunscreen (e.g. a product that is represented as being primarily to protect the skin from ultraviolet radiation).

To conclude, even if, no international harmonization relating to the labeling has been adopted yet, the European Recommendations rest the unique reference for sunscreen market in EU.

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