



**P1 / EDITORIAL**

Note from the CEO of SUNCERT company.



**P2 / CERTIFICATION**

- Organizations which can be sunscreen testing certified.  
- Technical sunscreen audits.  
- SUNCERT Tool - A new service.



**P3 / METHODS**

Controlled testing for reliable sun protection.



**P4 / REGULATIONS**

Focus on Australian sunscreen regulations.

# Suncert News



<< SN02

By



SN03

EDITION DECEMBER 2016

>> "ARE YOU SUNSCREEN TESTING CERTIFIED?"

>> TECHNICAL SUNSCREEN AUDITS

>> DISCOVER THE NEW SUNCERT TOOL

READ P.2



Who never heard that norms are not followed or wrongly understand?

Who never heard that some testing laboratories don't correctly perform sunscreen tests?

Who never heard that some organizations, testing market products, don't share any details on methods used but claim their independency, their impartiality and that they are the only ones to hold the truth?

Sun protection testing is a complex and a sensitive field. Indeed, during testing, only one key parameter not respected can significantly change the final value. Therefore, without an external control of the testing competence by an expert company, it seems difficult to obtain reliable results. It is true that is ambiguous for a company to be both judge and jury for any certification or label by remaining independant and impartial.

Is there is a way to improve the confidence in the sunscreen testing company and to avoid confusing situations? Yes, by means of a simple question:



**Are you sunscreen testing certified?**



I'm convinced that this question will be more and more requested in the next years by the cosmetic manufacturers, the privat label manufacturers, the health authorities, etc.

In this third edition of our SUNCERT News, you are going to discover (i) the different organizations which can be sunscreen testing certified, (ii) the presentation of the SUNCERT Tool, (iii) the different key requirements for reliable UV protection and (iv) the Australian sunscreens regulations.

**To conclude, I wish you a Merry Christmas and Happy New Year!**

**Sébastien MIKSA, CEO**

# The different organizations which can be sunscreen testing certified by SUNCERT



“Are you sunscreen testing certified?”. A simple and a powerful question to keep in mind each time an UV protection result is presented. In this way, the sunscreen testing certification can be obtained, used, required or requested to prove the reliability of sun protection results according to different company categories presented here below:



**1** You are a sunscreen testing laboratory, a service supplier, a contract research organization (CRO), etc.



**2** You are a cosmetic manufacturer, a raw material supplier, a OEM/ODM, a private label manufacturer, etc.



**3** You are a consumer association, an university, a health authority agency, etc.

You wondered if you are a potential candidate to be certified? Before starting any certification process, a gap analysis and diagnosis of the current situation with the requirements of reference methods could be performed by a certification agency such as SUNCERT.

## Support of SUNCERT during the technical sunscreen audits



Beyond the certification, SUNCERT could also provide a support during solar audits of companies.

This technical audit brings a thorough analysis of the structure and of the competence of audited people in achieving sun protection assessment tests.

Indeed, with our recognized expertise and our knowledge in the sun protection assessment, we provide advice and support to strengthen the monitoring / technical audits of your service suppliers, a company that is in judicial process further to the publication of some results, etc.

Following the technical audit, in addition to the technical evaluation grid, we deliver a decision table to drive corrections and changes to do. This report summarizes one by one each validated points and recognized critical points including associated advice for each case.

## SUNCERT Tool A new service proposed



Depending on your level of membership, SUNCERT proposes different tools to help you in the development and the evaluation of your sunscreen products.



### Confidence of In Vivo SPF value to reach the SPF target

The SUNCERT « In Vivo SPF Confidence Tool » is a tool enabling the estimation of the confidence probability of the In Vivo SPF obtained during the screening tests on few volunteers to reach the SPF target based on a statistical approach. According to results obtained, this tool helps to determine if In Vivo tests and so the development of the product can continue or if the formulation has to be adjusted before continuing the project.

Item	Value
Target SPF (S)	
Average measured in vivo SPF (S <sub>0</sub> )	
Standard Deviation (SD) of measured in vivo SPF (SD <sub>0</sub> )	
Number of test conditions (N) (S <sub>0</sub> > S)	
Probability to reach target SPF	
Recommended SPF value	
Recommended SPF standard deviation	

### Comparison of two In Vivo SPF values

The SUNCERT « In Vivo SPF Comparison Tool » is a tool enabling the comparison of two In Vivo SPF values. This tool helps to determine if two In Vivo SPF values are significantly different or not based on a statistical approach.

Item	Product A	Product B
Average measured in vivo SPF (S <sub>0</sub> )		
Standard Deviation (SD) of measured in vivo SPF (SD <sub>0</sub> )		
Number of test conditions (N) (S <sub>0</sub> > S)		
Confidence Interval (CI) of Confidence Average		
Significant difference		

If you have any tool proposal, comments or suggestions, please feel free to contact us to share this information. We will check the feasibility of it and if it is possible we will implement on our website.

# Controlled testing For reliable sun protection



To obtain reliable UV protection afforded by sunscreen products for consumers' health, different key requirements have to be respected including technology, compliance, labelling, assessment methods and control. Concerning the latest necessity, the guarantee of confidence in services and organizations involved in sun protection testing could be easily challenged without enhanced control. Indeed, sunscreen testing is a complex field requiring a high technical expertise and a strong quality system checked by a third-party. After summarising the key requirements which have already been explored, this review (partially extracted from a recent article<sup>[1]</sup>) focuses on the certification of sunscreen testing for the improvement of UV protection.

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## Four basis key requirements for reliable UV protection

### Technology

Sunscreen technology is the starting point influencing the efficacy of UV protection and can be basically summarized as two criteria:

- the intrinsic performance in providing UV protection (depends on the UV filter system used),
- the distribution of the product onto the skin (depends on the level of uniform distribution).

### Compliance

The compliance influences sun protection when product is used and can be basically summarized as three criteria:

- the real quantity applied and how far consumers try to achieve a uniform layer compared with laboratories,
- the development of cosmetically elegant and pleasing formulations leading to encourage consumers to use and reuse them correctly,
- to inform and educate consumers with strong preventive messages in photoprotection campaigns.

### Labelling

To have safe products with reliable UV protection, it is important to follow up-dated standards and label criteria:

- the Sun Protection Factor (SPF) expressing mainly UVB protection with a consensus more or less shared,
- the UVA protection is still confusing for consumers due to the large variability of labelling such as the UVA logo, Broad Spectrum, PA+ system or the Boots 5-star rating,
- the additional claims such as Water Resistance, Infrared protection, Photostability, etc.

### Assessment

A reliable assessment of the sunscreen performance is also crucial for the magnitude (quantity) as for the breadth (quality) of the UV protection spectrum according to standardised:

- in vivo (based on biological response) methods (see [SUNCERT News 1](#)),
- in vitro (based on analytical response) methods (see [SUNCERT News 2](#)).

To conclude this part, fulfilling the four basis key requirements, described above, should improve the reliability of sunscreen products in terms of sun protection. Nevertheless, it is impossible to check in a simple manner if the sun protection values are well assessed and if they are in compliance with standardised methods, as no more control of testing laboratories' performance is proposed.

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## The fifth key requirement for reliable UV protection

For reliable UV protection, the fifth key requirement is based on the control of sunscreen tests on several points by means of external audits by a third party, totally independent and expert in the sunscreen testing field. Indeed, improving the reliability of sun protection results would be helpful for all actors in the sunscreen field, such as cosmetic manufacturers, raw material suppliers, market regulators, etc.

First of all, for ethical and political reasons, it allows better consumer safety, it could avoid any loss of credibility for the brand image and it protects cosmetic manufacturers in case of control. Second, for economical and practical reasons, it allows saving money and time at the different stages of sunscreen development such as the screening of raw materials, the formulation to reach the targeted sun protection, the claiming for regulatory purposes, the controls from different organisations after the commercialisation of the product.

### **Sun protection testing - General**

The quality system should be more or less adaptable for any company/laboratory with a mastery of (i) organisational part (management commitment, responsibilities, resources, etc.), (ii) information part (content of documents, approval and diffusion, registration and confidentiality, etc.), (iii) quality part (internal audits, nonconformities, continuous improvement, etc.) and (iv) technical system (facilities, staff, equipments, process, etc.).

### **Sun protection testing - Technical**

The technical provisions help to ensure that the organisation, performing the sunscreen testing, meets the requirements of standardised methods. For this purpose, several factors are required and can be subjected to inspection as shortly presented in the list herein after but not limited to the (i) Testing zone, (ii) Environment, (iii) Application, (iv) Spreading, (v) UV exposure, (vi) Measurements, (vii) Test validation, (viii) Report, (ix) Traceability.

### **Sun protection testing - Performance**

In addition, the skill also has to be validated in order to provide worldwide consistency of results regarding sun protection performance. To meet this need, unknown products should be regularly tested (such as participation in interlaboratory comparison). In case of deviance from target and average values, the laboratory has to set up actions (training, process modifications, double-check, etc.) to obtain reliable results closer to the other laboratories.

Clearly, this fifth key requirement is one of the last steps for the improvement of reliable sunscreen products. Indeed, the control of the strict respect of norms, in terms of general quality system and mainly in terms of sun protection assessment, allows the improvement of confidence in results to save time and money for all actors involved in sunscreen products (raw material, finished product, laboratories, etc.). Furthermore, all key requirements are related to each other and all different stakeholders should request this kind of specific recognition in sun protection for ethical, political, economical and practical reasons.

# Australia: sunscreen regulations

## For Sun Protection methods and labeling



Australia is one of the country leader in terms of sun protection awareness with strict regulatory requirements. As in Europe with strong recommendations (see [SUNCERT News 1](#)) or in the USA with compulsory rules to follow (see [SUNCERT News 2](#)), all sunscreen products supplied in Australia shall respect some rules.

The Australian Regulatory Guidelines for Sunscreens (ARGS) have been developed by the Australian Government Departement of Health - Therapeutic Goods Administration (TGA) to provide guidance and to assist in the understanding of the Australian sunscreen regulations (see <https://www.tga.gov.au/book/export/html/5307>).

These guidelines contain information such as (i) listing, exemption and registration of therapeutic sunscreens, (ii) the responsibility of sponsors to report adverse reactions and advertisements following the use of therapeutic sunscreens, (iii) labelling, (iv) stability testing, (v) manufacture and quality control, (vi) permitted and new ingredients.

In the present issue, some important rules for the Australian sunscreen market are described here below:

I. The TGA regulates some sunscreens as therapeutic goods which are required to be included in the Australian Register of Therapeutic Goods (ARTG) and the labeling must be in compliance with (i) the Labeling Order (Therapeutic Goods Order No. 69), (ii) the Therapeutic Goods Advertising Code and (iii) the AS/NZS 2604:2012 standard.

II. Sunscreens are required to be manufactured in accordance with the principles of Good Manufacturing Practice (GMP).

III. Sunscreens must comply with the AS/NZS 2604:2012 standard with:

a. Two different kind of sunscreen product are used in Australian standard through (i) Primary sunscreens - products used primarily for protection from UV radiation (e.g. Beach products) - and (ii) Secondary sunscreens - products for which the primary usage purpose is not as a sunscreen (e.g. cosmetics such as Skin Care, Color or Lip). According to the type of sunscreen, the classification follows the table here below:

SPF	Labelled SPF	Category description	Broad spectrum		
			Primary	Secondary	
				Skin care	Colour/Lip
1-3	Not allowed	Not allowed	Not allowed	Not allowed	Not allowed
4-14	4, 6, 8, 10	Low	Compulsory	Compulsory	Optional
15-29	15, 20, 25	Medium or moderate	Compulsory	Compulsory	Optional
30-59	30, 40, 50	High	Compulsory	Compulsory	Compulsory
60 or higher	50+	Very high	Compulsory	Compulsory	Compulsory

b. This previous classification table includes (i) the determination of the *in vivo* SPF through the ISO 24444:2010 standard, (ii) an assessment of the level of UVA and UVB protection by means of the *in vitro* UVAPF and the *in vitro* Critical Wavelength through the ISO 24443:2012 standard with Broad Spectrum pass/fail displaying (according to UVAPF/SPF labeled ratio  $\geq 1/3$  and 370 nm limit) and (iii) the *in vivo* Water-Resistance statement (with tested SPF after immersion displayed) regarding the immersion time used following the here below table:

Tested SPF after immersion	Maximum water resistance claimable
At least 4 but less than 8	No claim
At least 8 but less than 15	40 min
At least 15 but less than 30	2 h
At least 30 or above	4 h

As for the previous SUNCERT News issues, we also added some proposals for a possible future revision:

I. For products considered as Secondary sunscreens, the UVB and UVA protection requirements should be required whatever is the value of SPF as for the Primary sunscreens.

II. Due to the potential variability of the used method and of the product, several In Vivo SPF values should be used for SPF claiming.

III. 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.

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