



P1 / EDITORIAL

Note from the CEO of SUNCERT company.



P2 / CERTIFICATION

Gradual confidence levels of standards compliance for reliable sunscreen testing results.



P3 / METHODS

Key words and abbreviations in sun protection field



P4 / REGULATIONS

Focus on South Africa sunscreen regulations.

Suncert News



<< SN04

By



SN05

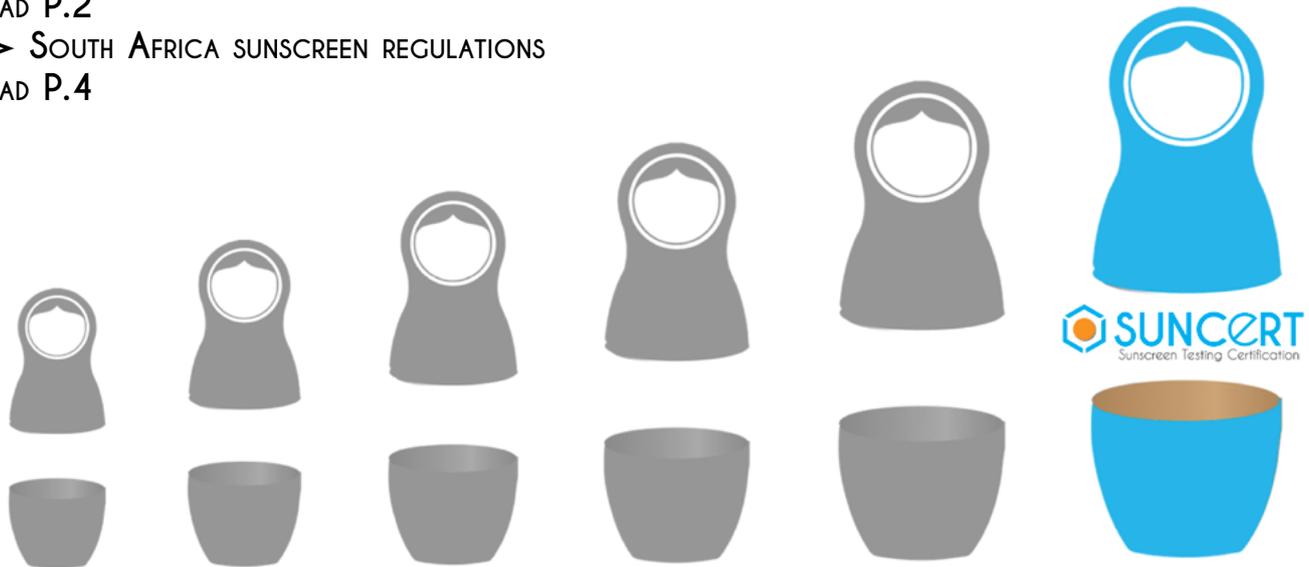
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>> **GRADUAL CONFIDENCE LEVELS OF STANDARDS COMPLIANCE FOR RELIABLE SUNSCREEN TESTING RESULTS**

READ P.2

>> **SOUTH AFRICA SUNSCREEN REGULATIONS**

READ P.4



Beyond the notation associated with feelings, appreciation of raw materials or other normal analysis, the main goal to perform in-market control of sunscreen products is to be able to check the UV performance effectiveness for consumers health. In other words, to have a second external control to confirm the UVB and UVA protection provided by product.

Unambiguously, this control has to be performed in total compliance with standards to avoid any deviation which could occur during testing and to have reliable harmonized results worldwide. Indeed, if tests don't strictly follow rules, laboratories will provide different "true" or "false" results and it is a danger.

Therefore, before to publish any results (by associations, health agencies...), two important points have to be respected to ensure reliable results:

- (1) use standardized tests,
- (2) use audited laboratories.

Regarding these agencies claiming to be totally



*The same story every year,
the same error every year*



independant and serving to protect consumers from cosmetic industries, I'm always "shocked" to observe that none prior audit and monitoring - of used laboratory during in-market control - have been performed by an external expert and independant auditor... The worst, sometime they explain that standards and regulations have been not followed...

Therefore, it seems difficult to believe these false counter analysis from these agencies... Unfortunately, consumers believe these false "scientific" papers...

In this new edition of our SUNCERT News, you are going to discover (i) the gradual confidence levels for reliable sunscreen testing results, (ii) sun protection terms and (iii) the South Africa sunscreens regulations.

Sébastien MIKSA, CEO

SUNCERT will be attending and presenting:

«Sunscreen Symposium»

in Florida on 14-16 September 2017 about:

«How worst practices in the field of sun protection testing could be solved by a sunscreen testing certification?»



Gradual confidence levels of standards compliance for reliable sunscreen testing results



Reliable sunscreen products are a major concern as the efficiency claiming has an impact on consumers' health compared to other product claiming esthetic performance. For this purpose, determination of this efficiency is crucial and different confidence levels in regards of standards compliance have been identified. Several cases are described^[1], starting from a new laboratory with a low confidence percentage to a sunscreen testing certified laboratory for the highest confidence percentage. As an evidence, this percentage is theoretical and some serious laboratories could reach higher percentage. Nevertheless, without a reliable monitoring and control by an external expert company, it sounds difficult to recognize them.

Inexperienced company

By means of the normalization of sun protection assessment methods, standardized processes are clearly described and each step are explained to ensure reliability. Therefore, it sounds easy to follow these methods and laboratories could be interested by performing this kind of test for different reasons. Nevertheless, some key points are complicated to understand and the respect of compulsory needs and recommendations could be unintentionally missed leading to high variability.

Expert company

In the sunscreen testing field, this kind of expertise is more or less linked to the rules understanding and compliance. In the current market, even if some of them are effectively experts, no further relevant controls are performed in a simple manner by an external third-party body to distinguish them. Moreover, as an evidence, even with a strong expertise, some deviations could appear without consistent quality and technical systems including a performance comparison.

Interlaboratory comparison

A proficiency testing (PT) program is an external quality control by interlaboratory comparison which can be especially created to evaluate the performance of analysis of laboratories.

Even if, this step is compulsory for a worldwide improvement of the performance and harmonization of the testing laboratories, it is clearly neither a control of quality system nor standards compliance information. In other words, (i) no further control is done relating to the quality and technical systems of the laboratory and (ii) no inspection is done to check, to monitor and to confirm the standards compliance.

Quality system

Considering the two last chapters as a pre-requisite, the quality system has to be valid to ensure reliable results but also for (i) general management, (ii) data management, (iii) quality process, (iv) document management. Indeed, by means of this general quality system inspection by a third-party body, it allows consistency, traceability, harmonization and confidence in all parts of the system to avoid some deviations.

Technical system

In addition to the general quality system, the technical provisions help to ensure that the organization performing sunscreen tests meets the requirements of standardized methods such as these field parts: facilities, staff, equipment, processes, etc. Nevertheless, by means of this global technical system, the competency of

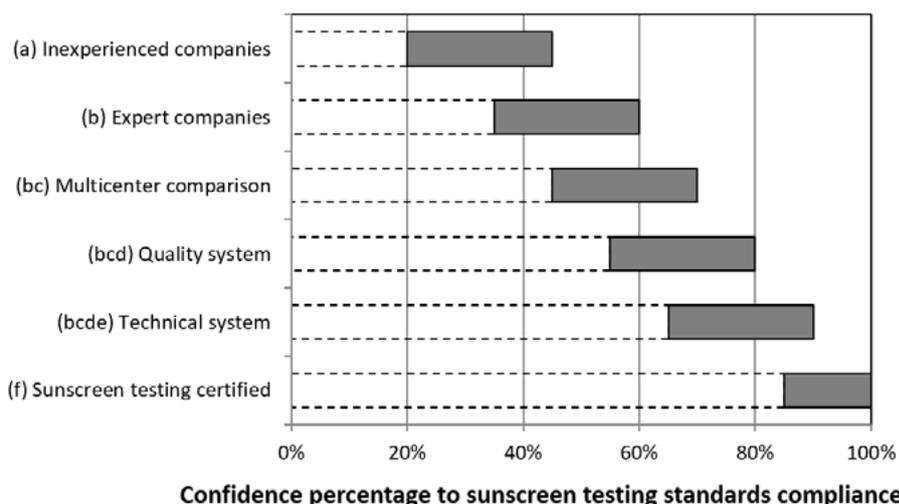
a company is challenged only in general testing field. Indeed, for the purpose of sunscreen testing field, the auditor should also well know the inspected subjects to obtain a reliable confidence in this particular field with a real inspection of sunscreen testing parts.

Sunscreen testing certification

To summarize the different previous levels, the company should be expert, participating in multicenter comparison, having a quality and technical system dedicated to sun protection field. To reduce these deviations, a complementary monitoring of laboratories is often performed but it represents time and money consuming for all involved companies (cosmetic manufacturers, consumer associations, health authorities, etc.). Therefore, it seems important to have a unique and simple sign under a sunscreen testing certification to prove the reliability of sun protection results for all actors. One of the solutions is to audit or to certify the competency and the total standards compliance by an independent and expert organization involved in sunscreen testing. For this purpose, this inspection should include the checking of the quality and technical system, the testing performance and the respect of all key parameters from standards in sunscreen testing field.

CONCLUSION

Regarding each level, the (a) inexperienced companies, (b) expert companies, (bc) expert companies participating in multicenter comparison, (bcd) expert companies participating in multicenter comparison with recognized quality system, (bcde) expert companies participating in multicenter comparison with recognized quality and technical system and (f) sunscreen testing certified companies have a theoretical percentage of confidence of standards compliance respectively about 20 - 45%, 35 - 60%, 45 - 70%, 55 - 80%; 65 - 90% and 85 - 100%. As an evidence, this is a worldwide average case and it cannot represent each laboratory.



Key words and abbreviations in sun protection field



In the context of the sun protection field, some key words are often used to detail the level of obligation:

“shall” indicates a requirement

“should” indicates a recommendation

“may” is used to indicate that something is permitted

“can” is used to indicate that something is possible

“requirement” is defined as an “expression in the content of a document conveying objectively verifiable criteria to be fulfilled and from which no deviation is permitted if compliance with the document is to be claimed.”,

“recommendation” is defined as an “expression in the content of a document conveying a suggested possible choice or course of action deemed to be particularly suitable without necessarily mentioning or excluding others.”

In complement, for sunscreen products in European Union, different level of documents are used:

“regulation” is a binding legislative act and must be applied in its entirety across the EU,	“recommendation” is not binding and suggest a line of action without imposing any legal obligation on those to whom it is addressed,	“directive” is a legislative act that sets out a goal that all EU countries must achieve (it is up to the individual countries to decide how),	“decision” is binding on those to whom it is addressed (e.g. an EU country or an individual company) and is directly applicable,	“opinion” is not binding and is an instrument that allows the institutions to make a statement in a non-binding fashion.
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Obviously, it seems extremely difficult to have a worldwide list of all actors, words and acronyms. The hereinbelow list presents some of them from European and international area:

Organisations:

EU - European Union
CE - Cosmetics Europe
CEN - European Committee for Standardization
EC - European Commission
ISO - International Organization for Standardization
CIE - International Commission on Illumination
SCCS - Scientific Committee for Consumer Safety
ECAH - European Chemicals Agency
EFSA - European Food Safety Authority
ECVAM - European Centre for the Validation of Alternative Methods
OECD - Organisation for Economic Cooperation and Development
PEMSAC - Platform of European Market Surveillance Authorities for Cosmetics
EDQM - European Directorate for Quality of Medicines and Healthcare
OCCLs - Official Cosmetics Control Laboratories
UAEPME - European Association of Craft, Small and Medium-Sized Enterprises
JRC - Joint Research Centre
DG SANCO - Directorate-General for Health and Consumers
DG GROW - Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
COS - Working Group on Cosmetic Products
ET - Expert Team
TC - Technical Committee
WG - Working Group

Documents:

TS - Technical Specifications
PAS - Publicly Available Specifications
IWA - International Workshop Agreements
TR - Technical Report
DTR - Draft Technical Report
TS - Technical Specification
DTS - Draft Technical Specification
PWI - Preliminary Work Item
NP or NWIP - New Proposal / New Work Item Proposal

AWI - Approved new Work Item
WD - Working Draft
CD - Committee Draft
FCD - Final Committee Draft
DIS - Draft International Standard
FDIS - Final Draft International Standard
PRF - Proof of a new International Standard
IS - International Standard

Sun protection key words:

SPF - Sun Protection Factor
UVAPF or PFA - UVA Protection Factor
CW - Critical Wavelength
PA - Protection grade of UVA
UV - Ultraviolet (290 - 400 nm) with UVB (290 - 320 nm), UVA-II (320 - 340 nm) and UVA I (340 - 400 nm)
IR - Infrared (700 - 3000 nm) with IR-A (700 - 1400 nm) and IR-B (1400 - 3000 nm)
ITA° - Individual Typology Angle
PMMA - Polymethyl methacrylate
T(λ) - Transmittance
A(λ) or Abs - Absorbance
I(λ) - Irradiance spectrum
E(λ) - Erythema action spectrum
P(λ) - PPD action spectrum
MED - Minimum Erythema Dose
%RCEE - Percentage Relative Cumulative Erythema Effectiveness
UV-SSR - UV Solar Simulator Radiation
PPD - Persistent Pigment Darkening
MPPDD or MPPD - Minimal Persistent Pigment Darkening Dose
WR - Water Resistance
%WRR - Percentage of water resistance
SD - Standard Deviation
SEM - Standard Error of the Mean
CI - Confidence Interval
COV or CV - Coefficient of Variation

South Africa: Sunscreen Regulations

For Sun Protection methods and labeling



In South Africa, the cosmetic industry is regulated by a self-regulatory system.

The major document to be used for sunscreen product field is the **SANS 1557:2014 South African National Standard**. It specifies requirements for primary and secondary sunscreen products, suitable for topical use, for the protection of human skin against the adverse effects of solar UVA and UVB rays, and provides a basis for the evaluation of sunscreen products in accordance with performance criteria. It

also specifies requirements for the advertising and labelling of sunscreen products.

Furthermore, the Advertising Standards Authority in South Africa (ASA) provides, in complement to **general cosmetic**, the code of practice for sunscreen products in the **Appendix B**. This Code is supplemented by individual codes which are determined by the various member organizations or negotiated with governmental institutions.

In complement to this previous The Code of Advertising Practice (ASA) with a specific part dedicated to sunscreen field, the sunscreen product shall comply with the relevant general cosmetic statutory requirements, **SANS 98 - Ingredient labelling of cosmetic products**, **SANS 1937 - Cosmetics products - Quantity and marking**, and the **CTFA Cosmetic Compendium**.

I. Concerning product manufacture, sunscreen product shall be manufactured in accordance with the GMP requirements as specified in the CTFA Cosmetic Compendium. Moreover, proof of claimed results shall be available and remain valid for the product sold (until any changes in formulation, raw material source or method of manufacture for that specific product are introduced). Finally, only UV filters and maximum approved concentration listed in annex B of SANS 1557 standard shall be used in the product.

Classification of protection	Labelled SPF	Measured SPF	Minimum UVAPF*	Minimum CW*	Minimum Water Resistance**
Low	6	6.0 - 9.9	1/3 of labelled SPF	370 nm	Mean %UWR - d ≥ 50%
	10	10.0 - 14.9			
Medium	15	15.0 - 19.9			
	20	20.0 - 24.9			
	25	25.0 - 29.9			
High	30	30.0 - 39.9			
	40	40.0 - 49.9			
	50	50 - 59.9			
Very high	50+	≥ 60.0			

*If UVA protection is claimed

**Only if the product claims this allegation and is valid for Water Resistant or Very Water Resistant claim.

Protection	Method
SPF	ISO 24444 - In Vivo SPF (or any other equivalent SPF Test method)
UVAPF	ISO 24442 - In Vivo UVA (or any other equivalent UVA Test method) ISO 24443 - In Vitro UVA & CW (or any other equivalent UVA Test method)
Water Resistance	SANS 1557:2014

SPF: Sun Protection Factor - UVAPF: UVA Protection Factor - CW: Critical Wavelength

II. 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.

III. The degree of protection has to be measured using the following methods or their updates.

IV. If UVA protection is claimed, the UVA logo symbol for the labelling of sunscreen products shall be used if claimed on primary and secondary container and shall not have any specific dimensions.

V. When appropriate, "Water resistant" or "very water resistant" claims (primary and secondary containers) shall be accompanied by the following: "re-apply after perspiring, swimming or towel drying".

VI. A sunscreen product shall not claim (i) Block-out or similar claims to imply 100% protection from UV radiation, (ii) All day protection and extended protection claims, (iii) Sweat resistance claims, and (iv) Waterproof claims. If a UV protection claims or sun protection is claimed or implied, products shall bear the SPF number tested under previous method.

*Disclaimer: This is an unofficial translation provided by SUNCERT as an informational service to assist non-Chinese companies. This document should only be used as an information and in case of any discrepancy between the English and Chinese versions the original Chinese version shall prevail.

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