Suncert News

<< SN03 / By SUNCERT Sunscreen Testing Certification / SN04 / EDITION APRIL 2017

SUNCERT
SUNSCREEN TESTING CERTIFICATION

BIPEA
PROVIDER OF PROFICIENCY TESTING PROGRAMS

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The sun protection field is continuously moving for higher and higher reliability such as methods with strict rules, products with higher technology, regulations with enhanced security, consummers with higher awareness, etc. Our aim is to help you to pass all these change with serenity.

BIPEA and SUNCERT: a partnership for the quality of sunscreen products analysis!
BIPEA (provider of proficiency testing schemes) and SUNCERT decided to work closely in the field of sunscreen products. These two organizations are involved in the quality of laboratories performing analysis in solar products, by helping them to improve the reliability of sun protection values. The beginning of an exciting partnership... This edition of SUNCERT contains a presentation of the BIPEA.

Second, to continue its role to improve sunscreen testing confidence, SUNCERT also started an additional program named "Certified Sunscreen Testing Partner" with the goal to list the different serious actors dedicated to the equipment, consummable and service for testing field. This program is also explained in the next page of the present newsletter.

> "A Trusted Partners list allowing to increase the confidence in the different suppliers of appliances, services, consumables..."

Third, the revision of the international ISO 24444:2010 for in vivo SPF assessment is in progress and we present you the potential modifications to anticipate this change as far as possible.

Fourth, the new China sunscreen regulations is in force since 1 Dec 2016 and we propose you to discover the different aspects of these documents.

Therefore, in this new edition of our SUNCERT News, you are going to discover (i) the presentation of BIPEA's mission, (ii) our Certified Sunscreen Testing Partner system, (iii) the future revision of the ISO 24444:2010 and (iv) the China sunscreens regulations.

Sébastien MIKSA, CEO

SUNCERT will be attending and presenting at:

«Sun Protection Summit»
in Brussels on 27-28 April 2017

«The Challenges of the EU Cosmetic Regulation: Practical Advice for the Industry»
in Manchester on 11 July 2017

BIPEA
as a proficiency testing Schemes provider

BIPEA
PROVIDER OF PROFICIENCY TESTING PROGRAMS

Who is BIPEA ?
BIPEA is an International non-profit organization, ISO 17043 accredited for the organization of proficiency testing (PT) programs. With over 40 year's experience, BIPEA provides more than 130 regular PT programs in the fields of food, environment, cosmetics and gathers near 2000 laboratories worldwide.

What is a proficiency testing program ?
A PT program is an external quality control, very well appreciated by laboratories. It can be used to:
1. Characterized a material,
2. Develop and validate a new method,
3. Evaluate the analytical performance of a laboratory.

In the field of sunscreen products test, the first two points have already been verified using standardized methods. Concerning the last point, a proficiency test, also called interlaboratory comparison, can be specially designed to evaluate the performance of analysis of laboratories.

The principle is simple: laboratories participating to BIPEA PT program receive a homogeneous sample. They analyze it and submit their results to BIPEA, who guarantee the confidentiality of the participants and their results. BIPEA statistical department makes a statistical treatment and publish an interlaboratory comparisons report, in which each participant can identify himself through a confidential code. Thus, they can check the accuracy of their results analysis by comparing their results to the assigned value calculated with a robust algorithm.

What are the benefits for laboratories who perform analysis in sunscreen products?
This external quality assessment is useful for analytical laboratories because it they can:
- evaluate their analytical performance,
- demonstrate the accuracy of their analyzes to their clients and stakeholders,
- identify the drifts and biases arising from their analytical processes.

BIPEA organizes the most important interlaboratory comparisons dedicated to sunscreen products testing worldwide. They currently include participants from 10 countries.

The PT programs proposed by BIPEA are mentioned below:

Programs	Parameters	Round per year	Sample per round
60 - Sunscreen products: SPF in vivo	SPF, water resistance	2	2
63 - Sunscreen products: UVA in vivo	In vivo UVA	1	2
64 - Sunscreen products: UVA in vitro	In vitro UVA	2	3

Conclusion: BIPEA - SUNCERT: a true complementarity
As part of laboratory quality control, taking part in PT program is necessary for the performance improvement and harmonization of testing laboratories, at a global scale.
However, it does not replace internal quality control or an assessment of compliance with standards: this is the role of SUNCERT.

Certified Partners
For equipment, consumables and services

Beyond the certification of the competence of laboratories which assess the sun protection of cosmetic products, it is important to have confidence in the conformity of equipment, consumables and services provided by suppliers according to standards and methods.

As an independent agency regarding these suppliers, SUNCERT provides a "Certified Partner" list in which products and services meet the different international standards in the sun protection field.

For this, each product (equipment - consumables) and service (calibrations - interlaboratory campaigns) shall meet complete technical specifications extracted from the standards and methods including a mandatory annual documentary inspection. In addition, the certificate of each batch of these products and services has to be also checked through the transmission of the information to SUNCERT to ensure sustainability of compliance.

Future Revision of the standard ISO 24444:2010 for in vivo SPF assessment

All ISO standards are systematically reviewed every five years in order to establish if a revision is required to keep it current and relevant for the marketplace. Consensus is the key element in the revision of a standard: to balance the different expectations of stakeholders from professionals, associations, countries, etc. from a technical, practical, economic and political point of view.

For ISO 24444 allowing the assessment of the in vivo SPF, the process was initiated in 2016 since a revision was considered necessary and asked by a great majority of professionnels specialized in this field. A dedicated technical committee has therefore been set up to formalize the objectives of the revision resulting from the comments of all the actors concerned. Finally, the approval of these objectives is subject to a vote among ISO members.

Concerning this future revision, the main potentially revised elements, extracted from conferences with the granted permission of authors [1-2], are described hereinbelow:

- Realization of a video showing all steps of the methodology, especially for application gesture of the tested product on the back of volunteers,
- Inclusion of human volunteers based only on ITA° to ensure better MEDu determination (**Fig. 1**),
- Definition of a range of MED determination:
Funnel MEDi = f(ITA°) based on collected data (**Fig. 2**),
- Application and visualisation of the spreading and of the migration of tested products: Wood lamp and standardized pictures (**Fig. 3**),
- Revision of the MED definition and evaluation with the image analysis possibility (**Fig. 4**),
- Setting up new standards for SPF 30 and 50 (to define),
- Harmonization of the MED unit (J/cm^2),
- Application of powders: When a pre-treatment is used, product should not be transformed into a paste.

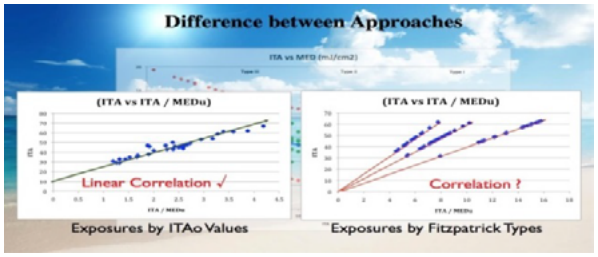

Figure 1. MEDu determination based on ITA°

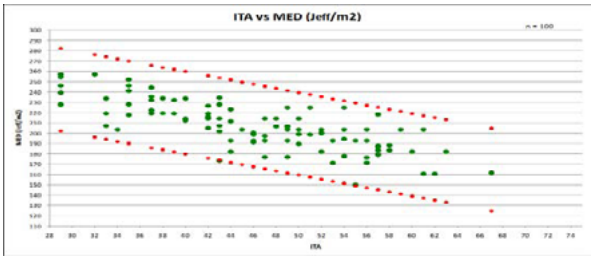

Figure 2. Funnel MEDi = f (ITA°)

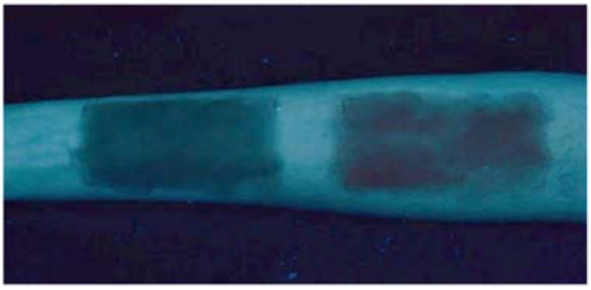

Figure 3. Image of tested products with a Wood lamp

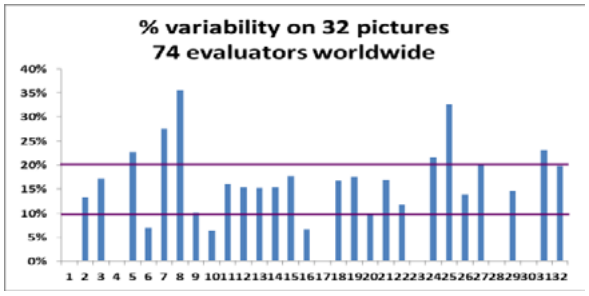

Figure 4. MED Definition with image analysis possibility

Obviously, plenty of minor revisions would be accepted such as:

- Establishemenf of a frequency for solar simulator calibration: at least once every 12 months or after 1000 hours (TBD) of lamp running time,
- Evaluation of the products in the prone position to prevent the samples which may flow from failing-off the testing surface,
- Definition of the pressure used during application gesture,
- Definition of the grading scale of erythema response for MED reading,
- Inclusion of additional information in the test report,
- Addition of an expiration date and storage conditions for manufactured standard products,
- Etc.

All those recommendations and modifications are still under discussion and will be discussed at further ISO plenary meeting.

In parallel, the other standards ISO 24442 (in vivo UVAPF) and ISO 24443 (in vitro UVAPF) will be also subject to a vote to consider if a revision is necessary or not.

[1] John Staton, SPF - Real or Imagined, 29th IFSCC Congress, Oct. 30 - Nov. 2, 2016, Florida
[2] TRICAUD Caroline, The new in-vivo methods: update and perspectives, CosmeticDays 1-2 December 2016, Marseille, COSMED

China: Suncreen Regulations For Sun Protection methods and labeling

In China, the sunscreen regulation is driven by the health authority body China Food and Drug Administration (CFDA). In complement to the "Regulatory Guide for Cosmetics" published in 2013 and dedicated to the administrative approval for domestic and imported special-use cosmetics, to align the China regulation with the international level, the CFDA published a notice concerning the "labelling requirements for the efficacy of sunblock (No. 107 of 2016)" and notice on the implementation of "Technical Safety Standard for Cosmetics (TSSC) (No. 268 of 2016)" (click on the file in the bottom of the different pages). According to these two last announcements, TSSC and the labelling requirements of sunblock have both been officially implemented on the 1st Dec. 2016.
The aim of the present text is to provide the main information contained in these different published documents which are only dedicated to the sun protection (in other words, several other aspects have to be followed but are not cited here).

I. UV filters

The "Chapter 4 - Physical and Chemical Testing Methods" in the TSSC presents the list of authorized UV filters with their concentration on p. 120-122 with the note that the total amount of the substance used in sunscreen cosmetics should not exceed 25%. Furthermore, the UV filters analysis methods are available in the TSSC on p. 432 to 451.

II. Application documents - Testing report

In the list of application documents to provide, the "Testing report issued by CFDA-accredited testing institutions, related dossier or Sun Protected Factor testing report (SPF, PFA or PA, Broadspectrum) issued by overseas laboratories" has to be included. Any submission of testing report shall meet at least the following requirements:

1. Chinese legal units of measurement shall be used,
2. All foreign languages (excl. overseas addresses, URLs, registered trademarks, patent names, SPF, PFA or PA, UVA, UVB, etc., which must be in foreign language) should be translated into standard Chinese, the translated test shall be attached to the corresponding foreign materials,
3. Submission of original documents [or the copies (incl. translation documents) confirmed and issued by Industry Association, Chinese Embassy (consulate) and notary offices of the country (region) where the laboratory is located],
4. Testing reports issued by licensing test institutions should include the following information: (a) Product name consistent with the name of the test samples (or a certificate proving this correspondence); (b) The testing application form; (c) Notice of acceptance for test; (d) Package inserts; (e) Health & Safety testing report (microbiology, hygienic chemistry, toxicology); (f) SPF, PFA or PA testing reports,
5. For the provision of sun protection (SPF, PFA or PA, Broadspectrum) testing report issued by overseas laboratories, the following information shall be submitted: (a) The qualification certificate if the laboratories are accredited laboratories; (b) The certificate for the compliance with "Good Clinical Practices" (GCP) or "Good Laboratory Practice" (GLP) if the laboratories are not accredited; (c) Other laboratory qualification documents.

III. Labelling requirements of sunscreen product

1&2. The following table summarizes the labelling system:

Table 1. Range of SPF.

Measured SPF	Labelled SPF
< 2	Cannot claim sunscreen product
2 - 50	Actual value
> 50	SPF 50+

Table 2. Range of PFA.

Measured PFA	Labelled PA
< 2	Cannot claim UVA protection
2 to < 4	PA+
4 to < 8	PA++
8 to < 16	PA+++
≥ 16	PA++++

3. In the case of the sun protection cosmetic would like to claim waterproof effect, it shall meet following requirements: SPF value is reduced by less than 50% after shower in the waterproof capacity test, and both the SPF values before and after shower shall be signed on the label or only the SPF value after shower shall be indicated (only revealing SPF value before shower is not acceptable).
4. Enterprises can conduct initial applications or alteration applications on the basis of notice request since the notice was released. Alternation shall be completed for approved sun protection cosmetics before the 30th June 2017.
5. In case the level of sun protection effect is changed, the enterprise shall submit original sun protection effect testing report. If the sun protection effect test has been re-conducted, the new testing report, the original testing report and the alteration reason shall be submitted.

IV. Testing requirements

Tests of SPF, water resistance performance, Critical Wavelength, PFA of sunscreen product shall be conducted in terms of testing methods on TSSC. If necessary, these tests can refer to relevant testing methods published by International Standard Organization (ISO). Therefore, in the TSSC, the part relating to the sun protection is described hereinbelow:

- Chapter 4 - Physical and Chemical Testing Methods

1.9. Cosmetics - Anti - UVA instrumentation method - Test in vitro of protection against UVA (p. 191)
[Ed: The method here below is not in compliance with international ISO method]
"Application of product using a syringe or pumping method on 3M film or single-sided abrasive polymethyl methacrylate (PMMA) plate. The actual amount of each board should be between 1.8 mg/cm² - 2.2 mg/cm². After the product is spread using a latex medical finger coated with sample to obtain a uniform surface. The sample is allowed to stand at room temperature (20°C to 30°C), 40% to 60% relative humidity for 20 min. Finally, the UV analyzer equipment is used to measure the absorbance curve of each sample with no less than 4 points and at least with two or more plates for determination. The Critical Wavelength equation is used and product identified as Broad Spectrum if λc ≥ 370 nm."

- Chapter 8 - Human body efficacy evaluation testing method

1. General principles (p. 545)
2. Determination Methods of Sun Protection Factor (SPF) (p. 546)
"ISO 24444:2010 and United States Food and Drug Administration (FDA) on sunscreen products SPF test method (Testing Procedure, Federal Register, 21 CFR. Parts 201 and 310, 2011)"
3. Determination Methods of Water Resistant Performance (p. 552)
"The United States Food and Drug Administration (FDA) of sunscreen products SPF test method (Sunscreen Water Resistant Testing Procedure, Federal Register / Vol 64, No 98/1999)"
4. Determination Methods for PFA of Sunscreen Cosmetics (p. 554)
"ISO 24442:2011"

*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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Publisher: Sébastien MIKSA

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