

Suncert News

<< SN05By  **SUNCERT**
Sunscreen Testing CertificationSN06EDITION MAY 2018

SunData

**Exploitation of your
sun protection results**

SPF / UVAPF / CW / UVA:UVB RATIO

SunTable

**Traceability of your
sun protection studies**

Product / Result / Equipment / Report






considered.

Nevertheless, both cases could present issues:

- external software is often linked to one appliance and none possibility to be flexible.
- internal software could include some errors leading to « wrong » results for standard methods. Furthermore, these softwares couldn't include other kind of calculation (photostability, water resistance, etc.).

For these reasons, SUNCERT developped its own system named SunSystem including the SunData and SunTable softwares (both based on Excel format).

Therefore, in this new edition of our SUNCERT News, you are going to discover (i) the SunData and SunTable softwares and (ii) the sunscreen regulation in Japan.

Sébastien MIKSA, CEO

SunSystem, solutions adapted to the evaluation of the sun protection.

Simple products and comply with sunscreen regulations.

Automated and secure data exchange between applications and reports.

An accompanying offer to support your assessment of sun protection through our tools.

SunData

A software to help your data analysis



SunData, a simple and comprehensive software to drive your assessment of sun protection and to exploit your results.

- You operate your sun protection results accurately and in compliance with standards.
- You determine the statistical criteria to confirm the validity of your sun protection studies with respect to the reference systems.
- You convert your data easily and access the elements used to calculate your values.
- You visualize your data (graphics, acceptance criteria, results, etc.).

Its content is described here below:

Access to the SunData general structure

-  - Access to the SunData system allowing the addition of functionalities.
-  - Securely access your data using a username and password with access history.
-  - Grant access rights to different applications depending on the user.
-  - Enjoy a system that guarantees the integrity of your calculations.
-  - Easily export your data in PDF or Excel form summarizing your information.
-  - Automatic transmission of information between SunData and SunTable (requires acquisition of SunTable).
-  - Manual entry (compatible for any appliance) or automatic import of your data from Labsphere UV-2000S.
-  - Integrated unit converter (mPE, Absorbance, %T, mW/cm², W/m², J/cm² ...).
-  - User manual made available to fully use the applications.

Module: IN VITRO

-  - Calculation of **UVAPF**, **Critical Wavelength** and **UVA:UVB ratio** values including correction factors, irradiation doses, validation criteria, etc. according to **ISO 24443:2012**, **FDA monograph 2011** and **Boots Star Rating System 2011**.
-  - Certificate of conformity of calculations with validation data.

Option: IN VITRO plugins

-  - Implementation of complementary plugins based on publications:
 - Photostability (1 - 2 irradiation steps),
 - Comparison (based on the shape of the absorbance curve, intrinsic variability and level of protection),
 - Resistance percentage (compatibility with water, sweat, sand, rub...)
 - Etc.

Option: Developer*

-  - Provision of the unlock codes of tabs as well as access to the VBA code.

-  *Warning: In advanced mode, we advise you to have programming knowledge to avoid mishandling as none after sales service is provided. This option is only available if all plugins have been purchased.

Option: Installation

-  - We support you in setting up the system and demonstrating the use of the system.

Option: Assistance 6 months

-  - To prevent mishandling of the software, we give you an original version on request without charge.

-  - For answers to technical or functional questions about the use of the system via e-mail and TeamViewer support.

-  - To take advantage of updates (slight improvements or corrections) and upgrades (major improvements).

Compatibility

The SunData application is compatible with all versions of Excel for Windows from Excel 2013 versions (xlsx format) and not compatible with Mac, LibreOffice / OpenOffice.

SunTable

A software to help your data treatment



SunTable, a simple and comprehensive software to control your evaluation of sun protection.

- You manage all your sunscreen testing activity by means of the traceability of your products, your results, your equipment and your contacts.
- You follow your sun protection studies efficiently thanks to the export to your Microsoft Outlook calendar.
- You control your equipment in accordance with sunscreen testing rules.
- You publish reports very simply and securely through Microsoft Word merge mailing.

Its content is described here below:

Access to the SunTable general structure

-  - Access to the SunTable system allowing the addition of functionalities.
-  - Securely access your data using a username and password with access history.
-  - Grant access rights to different applications depending on the user.
-  - Enjoy a system that guarantees the integrity of your data.
-  - Easily export your data in PDF or Excel form summarizing your information.
-  - Automatic transmission of information between SunData and SunTable (requires acquisition of SunData).
-  - Automatically add reminders to your Microsoft Outlook calendar.
-  - Edit your reports automatically via the Microsoft Word mail merge (requires acquisition of the reports separately).
-  - Traceability chart of your products, your results, your equipment and your contacts.
-  - User manual made available to fully use the applications.
-  - Calculation of control related to equipment (Spectrophotometer, Substrate, Reference Product, Solar Simulator, etc.) according to the different standards.
-  - Certificate of conformity of calculations with validation data.

Suncert Tool

- Comparison of two In Vivo SPF values
- Confidence of In Vivo SPF value to reach the SPF target

Option: IN VITRO reports



- Complementary standard reports:
 - ISO 24443:2012,
 - FDA monograph 2011,
 - Boots Star Rating System 2011,
 - Etc.

Option: Developer*



- Provision of the unlock codes of tabs as well as access to the VBA code.



*Warning: In advanced mode, we advise you to have programming knowledge to avoid mishandling as none after sales service is provided.

Option: Installation



- We support you in setting up the system and demonstrating the use of the system.

Option: Assistance 6 months



- To prevent mishandling of the software, we give you an original version on request without charge.



- For answers to technical or functional questions about the use of the system via e-mail and TeamViewer support.



- To take advantage of updates (slight improvements or corrections) and upgrades (major improvements).

Compatibility

The SunData application is compatible with all versions of Excel for Windows from Excel 2013 versions (xlsx format) and not compatible with Mac, LibreOffice / OpenOffice.

Japan: Sunscreen Regulations For Sun Protection methods and labeling



In Japan, cosmetics are regulated by the Ministry of Health, Labour and Welfare (MHLW) under the Pharmaceutical Affairs Law (PAL). For legal purposes, beauty products are divided into quasi-drugs and cosmetics. Cosmetics refer to articles with mild action on the human body, which are intended to be applied to the human body through rubbing, sprinkling or other methods, aiming to clean, beautify and increase the attractiveness, alter the appearance or to keep the skin or hair in good condition. For cosmetics, this includes 6 different categories where sunscreen products have the category of "Special purpose cosmetics".

Furthermore, the standardization process is coordinated by the [Japanese Industrial Standards Committee \(JISC\)](#) and published through [Japanese Standards Association \(JSA\)](#). Japanese Industrial Standards (JIS) specifies the standards used for industrial activities in Japan. By the way, the Japanese Cosmetic Industry Association (JCIA) published different documents to inform about [UVB-UVA labelling and accepted testing methods](#) but also to inform about [UV protection in general](#).

The aim of the present text is to provide the main information contained in the different published documents only dedicated to the sun protection (in other words, several other aspects have to be followed but not cited here).

I. Sunscreen products require approval of their formulations, ingredients, use levels and functionalities, in addition to stability testing and a certificate showing no animal-derived materials were used. Below is the link to the "[Standards for cosmetics \(Ministry of Health and Welfare Notification No.331 of 2000\)](#)" containing positive lists and negative lists of ingredients for cosmetics. Concerning UV absorbers, the limitation on inclusion is referred to the appendix 4.

II. A company that intends to market or import cosmetics products must obtain a license for marketing cosmetics on a commercial basis ("keshohin seizoh hanbaigyo no kyoka") from the appropriate local government offices for each business office location. For the company that intends to manufacture cosmetics, a license for manufacturing cosmetics ("keshohin seizogyo no kyoka") must be obtained for each manufacturing location. There are no official or mandatory good manufacturing practice (GMP) in Japan, although the JCIA has published voluntary technical guidelines for manufacturing and quality control.

To obtain a license for marketing cosmetics on a commercial basis, an applicant company is required to comply with GQP (Good Quality Practice) and GVP (Good Vigilance Practice) in terms of quality control and post-marketing safety management.

III. Testing requirements: Tests of SPF and PFA of sunscreen product shall be conducted in terms of testing ISO methods. The table here below summarizes the accepted methods as described in the JCIA's documents for [UVB protection](#) and [UVA protection](#):

Protection	Method
SPF	ISO 24444 - In Vivo SPF
PFA	ISO 24442 - In Vivo UVA

SPF: Sun Protection Factor - PFA or UVAPF: UVA Protection Factor

IV. Labelling requirements of sunscreen product with UVB and UVA protection compulsory.

1. The following table summarizes the labelling system for UVB protection as described in the JCIA's document for [UVB labelling](#):

Measured SPF	Labelled SPF
< 2	Cannot claim sunscreen product
2 - 50	Actual value with an integer rounded down to the decimal point of SPF
> 50.0 and Lower CI95% < 51.0	SPF 50
> 50.0 and Lower CI95% > 51.0	SPF 50+

2. The following table summarizes the labelling system for UVA protection as described in the JCIA's document for [UVA labelling](#):

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

3. According to PAL, the container, packaging, or package inserts of cosmetics be labeled expressed in the Japanese language with the specified items to ensure appropriate usage, handling, quality, and to clarify liability. Labeling with false or potentially misleading expressions, and unapproved claims of effect -efficacy in labeling are prohibited. The items that should be indicated for cosmetics are as follows:

a. Product name by type, b. Brand name, c. Name and address of primary distributor, d. Content (weight or capacity), e. Country of origin, f. Manufacturing number or code, g. List of ingredients as required by the MHLW, h. Expiration date, for a cosmetic designated by the MHLW, i. Precautions on usage or storage, for a cosmetic stipulated under the Enforcement Regulation, j. Information contact.

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