

Contents

Editorial

New Open Days in 2020

Long Lasting sun protection performance

How to have a C factor in compliance with ISO 24443:2012 for difficult products

Editorial

For quite a very long time, in vitro tests for evaluation of the sun protection were only considered as a screening tool and especially for SPF (beyond recent standardization of in vitro UVA with ISO 24443 standard).

Nowadays, a new protocol, based on the use of two different substrates and also some specific equipment such as a robotic appliance, has been proposed to drive the in vitro SPF beyond the "screening" consideration.

Even if, some people STILL consider having their own way, own contention, own so-called expertise, etc. it has been demonstrated it is far from being efficient for all the products. But the new method has been evaluated having more or less the same reliability than the in vivo tests taking into account these improvements and equipment

Already, a lot of big companies all over the world, experienced with in vitro sunscreen testing, are now equipped with this robotic appliance to perform their in vitro test "in house" because they freed themselves from the financial aspect by the understanding that there is no other solution for reliability.

Nowadays, we can even hope now for an ISO method in a very next future.

Dominique Lutz, CEO Scientist Manager

HELIOSCREEN TEAM GATHERS TO WISH YOU ALL A HAPPY NEW YEAR FILLED WITH HAPPINESS AND SUCCESS!

Congress & Events

**in-cosmetics®
global**

Barcelona • 31 March – 2 April 2020

in-cosmetics global

Barcelona

31 March - 2 April 2020

Visit us

HelioScreen Labs

44, rue Léon Blum

60100 Creil

Phone: +33 (0)3 44 55 17 91

commercial@helioscreen.fr

«HelioNews» published by

HelioScreen Labs

Author, Editor & Design:

S. MIKSA

smiksa@helioscreen.fr

Publisher:

D. LUTZ

dltuz@helioscreen.fr



Be ready for 2020!

After its international success in 2016, our In Vitro Suncare Open Days come back!

For reminder, this event is dedicated to all professionals interested by visiting our laboratory specialized in In Vitro sun protection assessment and by learning more about sun care testing, including R&D managers and directors, formulation chemists, regulatory affairs personnel, retailers of sun care products...

With an agenda based on Theoretical and Practical within 1 day, our delegates discovered all fundamentals of sun protection tests to ensure reliable results and visited our company. Moreover, several equipments have been presented and In Vitro sunscreen tests have been performed. If you missed this event, you will be able to participate to this spectacular day during our next session.

The precise date for the 2020 edition will be disclosed soon and don't forget it's always **free of charge!**



LONG LASTING SUN PROTECTION PERFORMANCE

ABSTRACT

For their daily routine on the morning, some consumers are looking for products providing a sun protection during several hours even if some studies emphasized the decrease of the sun protection in time. The authors propose a new in vitro test to measure the Long Lasting effect of sunscreen products by an in vitro method.

INTRODUCTION

All worldwide experts, health agencies, cosmetic manufacturers, consumer associations, etc. involved in the sun protection field recommend to reapply sunscreen product frequently (at least every two hours and especially after swimming or sweating) and generously to reduce the skin damages under sun exposure. Moreover, some regulations ban mentions which do not incite for reapplication.

As an evidence, even if this recommendation is well understood for the beach sunscreen products (also called primary sunscreen product that is represented as being primarily to protect the skin from UV radiation), unfortunately, reapplication experience is sometimes negative because it is time consuming and boring. This appreciation and consideration should be similar for secondary sunscreen product (a product that is represented as having a primary function other than sun protection whilst providing some protection of the skin from UV radiation) such as make-up, foundation, anti-ageing, moisturizer, etc. However, when consumers don't plan to stay on the sun, most of the time they use these products (primary and/or secondary) mainly for their daily routine on the morning with no attention to reapply during all the day.

Therefore, some consumers are looking for products providing a sun protection during several hours even if some studies emphasized the decrease of the sun protection in time by UVA camera or SPF value analysis. Obviously, all claims such as the mention "Long Lasting", "Once-a-day", "8hr protect", and recently "Durable sunscreen", etc. should be based on a scientific proof. These proofs are generally obtained by an in vivo SPF assessment method considering a drying step longer (several hours compared to few minutes according to official method) before the UV exposure and redness reading. Nevertheless, this way of testing is biased for sunscreen products because, all day long, external factors challenge the sun protection such as the clothes, sand, sweat, sun light (considering photostability), etc. Moreover, these adapted methods are expensive and time consuming and brands may be interested to use in vitro methods to support these claims.

Finally, in this article, the authors tried to propose an in vitro method to measure the durability of the sun protection performance in time and considering the photostability too.

METHOD

Sunscreen products: For this study, 17 sunscreens were tested with different textures (emulsion, stick, foundation, oil, powder and alcoholic spray) and varying levels of protection ranging from SPF 6 to 50+.

Substrate selection: The roughness of test substrates has been shown to affect the reproducibility of UV in vitro tests. Thus, molded polymethyl methacrylate (PMMA) plates HD6 were used for the present study. The application area measured 47.5 mm x 47.5 mm, i.e., more than 22 cm², and only one face of the plates was rough. All surface topography parameters were controlled with an ad hoc profilometer and were in total compliance with the specifications described in the ISO 24443:2012 standard for in vitro UVA-PF determination.

Sunscreen application: Sunscreens were shaken to assure good homogenization, then applied to the PMMA substrates at a rate of 1.3 mg/cm² in nine areas using a 1-mL syringe. Immediately following, the sunscreen was spread using an automated device.

Automated spreading: The automated spreading device HD-SPREADMASTER used is composed of two parts. The first is a robotic arm, which performs precise and repeatable movements—particularly circular and linear strokes with controlled pressure. The second part is a tool with a hard surface that simulates the human finger. This combination perfectly imitates human spreading with better reproducibility, as was previously demonstrated. After spreading, samples were allowed to dry and settle for 15 min before the first measurement, during which the temperature of surface substrates and products were maintained at 25°C ± 1.0°C.

Solar simulator: Irradiation was realized in a calibrated testing device Ametek Suntest CPS+ simulating solar irradiance as similar as possible to the irradiance at ground level under a standard zenith sun and within the acceptance limits specified in the ISO 24443:2012 standard. Finally, samples were tested with a controlled testing temperature at 25°C.

Transmittance measurements: The evaluation of sun care product absorbance was performed using a spectrophotometer Labsphere UV-2000S. Before measurements, the transmittance analyzer was calibrated

according to the ISO 24443:2012 Annex A by wavelength accuracy linearity and dynamic test, using a calibrated reference standard to which UV filters were added. Furthermore, blank transmissions were created using PMMA plates covered with glycerin. Measurements of the test samples were taken in the UVA and UVB wavelength range, from 290 nm to 400 nm, in 1-nm increments.

Protocol: For each product, a measurement has been performed at t0 (15 min in reality), t2h, t4h and t8h considering that a typical day is about 8h for the photoprotection from the morning to the evening. Moreover, several UV exposure doses were applied to challenge the photostability of the product and representing 2h, 4h and 8h of UV exposure as used in outdoor situation during a standard day light irradiance.

Calcul: For each step, the in vitro SPF is calculated and the ratio with initial condition was controlled in order to assess the percentage of Long Lasting (%LongLasting) with:

$$\%LongLasting = \frac{(\text{in vitro SPF «after drying or UV exposure»} - 1)}{(\text{in vitro SPF « t0 or without UV exposure»} - 1)}$$

Selectivity: For the selectivity, the proposal is to consider a product «Long Lasting» if the protection is maintained at 95% compared to the initial value (t0) regarding the drying values and the photostability percentage at 2h, 4h and 8h.

RESULTS AND DISCUSSION

The **Table** here below presents the different results for the tested sunscreen products with a drying and photostability time of 2h, 4h and 8h. From these results, a product is considered as «Long Lasting» if the resistance percentage of drying time and photostability is more than 95% (in comparison to the t0 value).

Firstly, it is interesting to observe a rational decrease of the number of products with a “Long Lasting” performance

when the time increase with the following summary:

- About 1/2 of the products presents a Long Lasting after 2h,
- About 1/3 of the products presents a Long Lasting after 4h,
- About 1/4 of the products presents a Long Lasting after 8h.

Secondly, we can observe a certain continuity in the “Long Lasting” performance from 2h to 8h. In other terms, if the product is resistant at 8h, it is reasonable to interpolate the “Long Lasting” performance to 4h and to 2h.

Thirdly, the recommendation to frequently reapply sunscreen products every 2 hours is extremely important for the majority of sunscreen products in order to conserve a high level of photoprotection for consumers.

CONCLUSION

Even if the claim «Long Lasting» is most of the time not appropriate for a primary sunscreen product because it is leading to an overexposure to the sun with a product losing photoprotection in time, different brands already propose this claim to consumers. To be able to detect this protection level, an in vitro method was proposed considering the sun protection factor (SPF) at different time and including photostability factor.

From this method and applying a high level of selectivity in terms of resistance percentage (time and photostability) for consumer’s health, we can conclude that about 25% of products maintain their protection during all day (about 8 hours).

Finally, as an evidence, this proposal is a starting point and these results should be completed by in vivo analysis to ensure a higher security and include several other external factors from real life (sweat, sand, rub, etc.).

ACKNOWLEDGEMENT

The authors would like to thank Mrs Doriane DESPLAN for her support and the tests.

Table 1. Results of resistance percentage («Long Lasting») for Drying and Photostability at 2h, 4h and 8h

Product	Type	SPF t0	Drying t2h % Long Lasting	Exposure t2h % Long Lasting	2h Long Lasting	Drying t4h % Long Lasting	Exposure t4h % Long Lasting	4h Long Lasting	Drying t8h % Long Lasting	Exposure t8h % Long Lasting	8h Long Lasting
P1	Emulsion	13,2	97,2%	96,4%	YES	97,5%	98,9%	YES	96,1%	94,9%	NO
P2	Emulsion	32,9	99,5%	80,8%	NO	99,2%	72,4%	NO	100,1%	59,7%	NO
P3	Emulsion	39,0	75,1%	72,2%	NO	73,9%	68,2%	NO	74,2%	63,8%	NO
P4	Emulsion	42,6	143,9%	68,9%	NO	177,2%	59,2%	NO	206,7%	53,2%	NO
P5	Emulsion	25,0	95,7%	47,2%	NO	95,1%	37,6%	NO	93,6%	32,5%	NO
P6	Emulsion	29,7	97,1%	105,2%	YES	97,0%	103,6%	YES	94,1%	102,3%	NO
P7	Fondation	15,6	104,3%	105,8%	YES	111,5%	105,1%	YES	112,8%	96,7%	YES
P8	Fondation	10,9	139,0%	77,1%	NO	155,5%	61,3%	NO	164,4%	50,5%	NO
P9	Fondation	21,4	99,5%	67,8%	NO	98,4%	50,8%	NO	97,6%	36,2%	NO
P10	Oil	10,6	106,2%	122,5%	YES	106,8%	136,6%	YES	102,6%	144,0%	YES
P11	Oil	44,3	92,4%	90,9%	NO	93,4%	91,9%	NO	89,0%	81,9%	NO
P12	Oil	54,6	89,2%	90,7%	NO	88,0%	91,7%	NO	86,1%	109,9%	NO
P13	Powder	6,7	103,3%	99,4%	YES	103,6%	97,7%	YES	103,7%	97,0%	YES
P14	Alcoholic spray	93,1	98,4%	99,7%	YES	96,9%	99,4%	NO	94,8%	90,5%	NO
P15	Alcoholic spray	11,3	115,2%	95,3%	YES	126,7%	94,8%	NO	131,2%	99,4%	YES
P16	Alcoholic spray	18,3	60,7%	43,1%	NO	64,8%	46,7%	NO	73,3%	49,1%	NO
P17	Stick	45,7	100,4%	388,2%	YES	104,6%	334,8%	YES	105,5%	265,1%	YES

HOW TO HAVE A C FACTOR IN COMPLIANCE WITH ISO 24443:2012 FOR DIFFICULT PRODUCTS

In the current version of the ISO 24443:2012 standard for in vitro UVAPF assessment of a sunscreen product, the in vitro absorbance curve is adjusted in order to have an equivalence between the in vitro SPF and the measured in vivo SPF for reproducibility and accuracy reasons. For this purpose, a C factor is used and typically lies between 0.8 to 1.6.

Nowadays, with a long history of use and innovative products, the respect of this C factor may be difficult for some products. In order to help laboratories, here below, we present you several explanations and solutions to apply to be in compliance with the standard.

NOTE: as an evidence, when an item is not compulsory, it is better to follow the recommendation in first instance.

A. General explanations

- a. In vivo and/or the in vitro SPF value is not enough robust because (i) it was incorrectly assessed (protocol, appliances, consumables, key parameters, etc.) and/or (ii) the sun protection performance afforded by the product presents a level of variability.
- b. Other reasons can lead to impact the C factor such as (i) the laboratory shared the target SPF or the labelled value (instead of the measured in vivo SPF value), (ii) the in vivo test was obtained for the laboratory batch and the in vitro test is performed on the industrial batch, (iii) the in vivo test was performed on a first formula and the in vitro test is performed on a similar formula (with few modifications), (iv) the sample is different due to sampling impact (texture, UV filters distribution, packaging, etc.).

B. Technical solutions

a. APPLICATION

- i. in the current version, the testing process described that the “Finger cots should not be used to spread the product on the plate” but it is not forbidden. This C factor may be impacted if the test is performed with or without the finger cot.
- ii. in the current version, a spreading process is described but the gesture, pressure and/or duration are mentioned with the term “should” allowing another way if necessary. This C factor may be impacted if the test is performed with another gesture, pressure and/or duration.
- iii. in the current version, the drying time is at least equal to 30 min but a maximum is not indicated (even if, generally, no more than 60 min). This C factor may be impacted if the UV measurement is performed after 30min, 60min, 120min or more.

b. TEMPERATURE

- i. in the current version, the testing process allows a temperature between 25°C to 35°C (with the same temperature before and after UV exposure). This C factor may be impacted if the test is performed at 25°C, 30°C or 35°C.

c. UV MEASUREMENT

- i. in the current version, the part “One or more observations of absorbance may be made per plate and the mean value shall be determined for each plate” opens the possibility to have different number of localizations for UV measurement. Obviously, even if enough representative area of the surface should be measured for consistency, considering the intraplate variability, it may be possible to have an impact on the C factor by the use of different localizations (with exactly the same localization(s) before and after UV exposure).

From these examples, considered individually and/or together, they may help to solve the difficulty to respect the C factor range. Obviously, other solutions could be used to respect the C factor (such as substrate type, quantity, etc.) but they are not allowed in the current version of the ISO 24443:2012.