HelioScreen

HelioNews

News about In Vitro Sun Protection Testing

HN 2018 N°25

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Editorial

The perennial debate about the reliability of in vitro "new" or existing methods is far from being over and this is now, at last, a debate about reliability of in vivo methods.
Considering that any new or alternative method has to be correlated to the in vivo results, this is a critical issue due to the "reliability" of this last one!

As proposed in this issue, we should not consider any result (from any one including "specialists", "experts", etc.) if repeatability and reproducibility have not been previously demonstrated by applying the same rules.

As we are involved in the development of reliable in vitro methods, it has been demonstrated, published and checked with the collaboration of the most international laboratories, that it is IMPOSSIBLE to get reliable results if you don't follow all key parameters – including use an automatic spreading machine to perform the test.

Very slowly, the international organizations take in care both the quite poor reliability for the goal we have to reach (in vivo value) and the need of repeatability and reproducibility of the new proposed method. It is a long and expensive road with the need not only to change our way of proceeding the test but also our way of thinking.

Dominique Lutz, CEO Scientist Manager

Congress & Events

in-cosmetics global
17-19 April 2018, Amsterdam

Conference by S. MIKSA - Day 1- Workshops Room 1 - Suncare protection - The skin and the electromagnetic spectrum - about «**New in vitro method to assess if your sunscreens are infra-ready?**»

2nd Anti Ageing Sun Protection Summit
14-15 May 2018, Prague

Conference by S. MIKSA about «**Assessing a New In Vitro Method for Blue Light protection**»

HelioScreen Labs
44, rue Léon Blum
60100 Creil
Phone: +33 (0)3 44 24 33 29
administration@helioscreen.fr

«HelioNews» published by HelioScreen Labs
Editor & Design:
S. MIKSA
smiksa@helioscreen.fr
Publisher:
D. LUTZ
dlutz@helioscreen.fr

In Vitro Sun Protection Testing Repeatability vs. Reproducibility

Introduction

Any methods shall be reliable and relevant. In other words, concerning sun protection assessment field:

- in vivo methods shall be Reproducible and Relevant in terms of real UV protection for consumer,
- in vitro methods shall be Reproducible and Relevant in terms of real UV protection for consumer.

Both methods have the same two goals (hopefully) with a prior condition which is the Reproducibility, in other words, to obtain the same result (and the level) whatever the laboratories all over the world. Nevertheless, concerning in vitro methods, often people misuses Repeatability and Reproducibility.

Indeed, in our in vitro sunscreen testing field, the variability can be expressed as:

- (i) intra-plate variability (within the same plate by measuring several spots),
- (ii) inter-plate variability (between different plates by using the average for each individual plate),
- (iii) intra-laboratory variability (within the same laboratory by using several full studies),
- (iv) inter-laboratory variability (between different laboratories by using the average for each individual full study in the different laboratories).

In reality for the sunscreen testing field, at final, the most important point to ensure that a method is reproducible and to have a chance to be harmonized (obviously, a lot of totally different products and several laboratories shall be tested) is the **(iv) inter-laboratory variability**.

To simplify the checking of this inter-laboratory variability, the in vitro sunscreen testing method can be divided in to 7 key parameters:

- Environement (humidity, temperature and light can be easily controled)
- Substrate(s) (topographic parameters can be ensured by using the ad hoc plates)
- Quantity (can be easily controled)
- **Spreading (a specific protocol?)**
- UV irradiation (can be ensured by using an ad hoc solar simulator)
- UV analyzer (can be ensured by using an ad hoc appliance)
- Calculation (can be ensured by using an ad hoc software)

Therefore, if we try to summarize these points, we have to check the **operators variability**.

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RESULTS

Operators: 8 different operators from different companies (trained to perform in vitro sunscreen testing) tested the different products.

Substrate: In order to assure the higher reproducibility of other parameters, the Helioplate HD6 substrate was used.

Product: 36 sunscreens covering various formulations were chosen.

Transmittance measurements: The Labsphere UV-2000S was used to measure the UV transmittance through the thin product layer.

Procedure: We applied product in order to have a rate of 1.3 mg/cm². The product was spread on the whole surface by a specific protocol which guaranteed the lowest variability for human spreading (such as described into the ISO 24443:2012 standard). After the drying step, each plate was measured (3 plates per product). During the whole process (application, spreading and drying), the temperature was constant (25°C) and controlled by means of the HD-THERMASTER.

Results of in vitro SPF were presented into **Figure 1** and of in vitro Critical Wavelength (CW) into **Figure 2**. Without any doubts, such variability will never allow to have a reproducible and reliable in vitro SPF harmonized method. As few examples:

- Figure 1 with P07, we can observe an in vitro SPF between 28.5 to 258.2. In other words following 2006 EU Recommandation, a SPF claimed between 25 - 50+
- Figure 2 with P10, we can observe an in vitro CW between 369 to 372 nm. In other words following 2006 EU Recommandation, an UVA compliant or not compliant to 370 nm limit.

CONCLUSION

To be able to «Repeat» our own same result is the «basis» and, fortunately, all operators reach this condition if they control few key parameters. Nevertheless, to claim that its own process method is «reliable» because it is «repeatable» is unrelevant because this is the «basis».

Indeed, as soon as another operators/laboratories will test the same product, you can be sure that you won't find the same result in general. Data presented into **Figure 1** and **Figure 2** confirmed and demonstrated unambiguously that human spreading doesn't allow a reproducible in vitro method.

Therefore, for instance, if we are unable to reproduce our findings, we have to ask ourselves why, and to investigate further. That is what HelioScreen had done 5 years ago after more than 15 years of in vitro sunscreen testing practices, and that is the reason why we developed the **automated sunscreen spreading HD-SPREADMASTER**.

(Read our full article, for in vitro SPF: [1] In Vitro UV Testing—Robot vs. Human Spreading for Repeatable, Reproducible Results - S. Miksa, D. Lutz and C. Guy, Cosmetics & Toiletries, October 2013

Read our article, for in vitro Critical Wavelength: [2] Man vs machine - S. Miksa, D. Lutz and C. Guy, SPC magazine, April 2016)

Acknowledgements: The authors would like to thank all participants of this study from Chanel Parfum Beauté–Pantin; Yves Rocher–Issy les Moulineaux; Clarins–Pontoise ; Pierre Fabre–Castres ; Sisley–Saint Ouen l'Aumône; Parfums Christian Dior–Saint-Jean-de-Braye ; and L'Oréal–Chevilly-Larue.

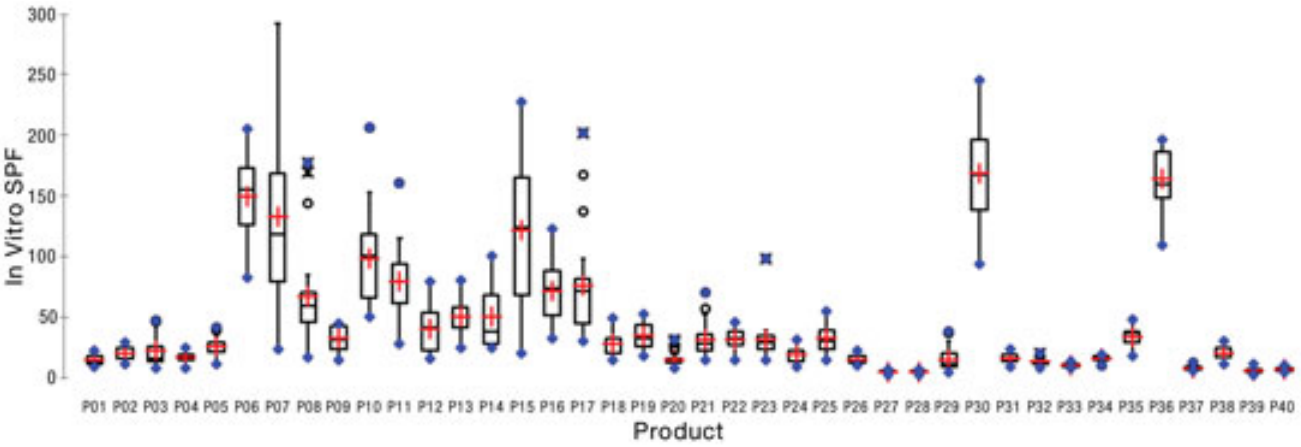


Figure 1. Results of in vitro SPF variability according to manual spreading from eigth operators

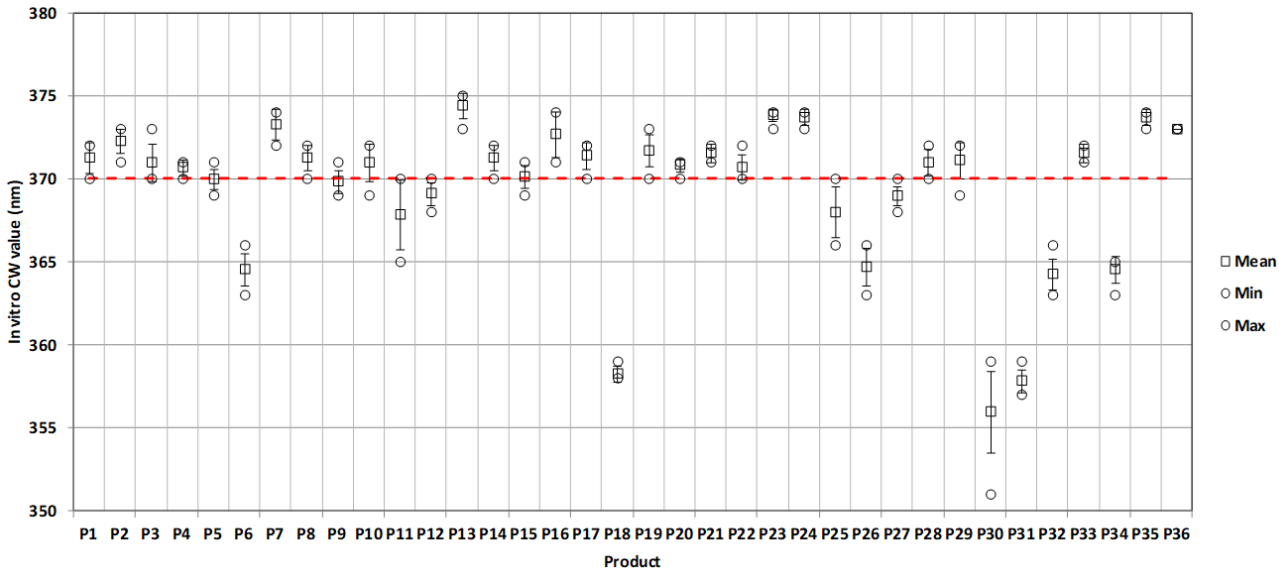


Figure 2. Results of in vitro CW variability according to manual spreading from eigth operators

Are your sunscreens infra-ready?

New In Vitro Method Puts Data Behind the Claims

Introduction

Considering more and more sun care products are claiming infrared (IR) protection, it is important to standardize the parameters by which they are evaluated.

Indeed, since IR-A and IR-B are the most implicated in skin damage, IR protection factors should be comparable between products and provide the balance of UV, visible and IR protection within a single product.

Therefore, by testing a large number of products, an innovative in vitro method was developped to assess the IR protection provided by sun care products.

Material and method

- To develop this method, 25 products from different companies were tested. These ones include different levels of protection, ranging between SPF 6 and 50+.
- For the described tests, substrates used were molded polymethyl methacrylate (PMMA) plates (Helioplate HD6, HelioScreen) and a quantity of 1.3 mg/cm² was applied.
- Immediately after the application, products were spread by means of an automated device (HD-SPREADMASTER, HelioScreen).
- After a drying step, a solar simulator (Model LS1000-4S-009, Solar Light Company, Inc.) was used to expose samples to 800 J/m²-eff that is equivalent to 4 Minimal Erythema Doses (MEDs).
- Finally, to obtain the UV spectrum, measurements were performed from 290 nm to 400 nm using a UV spectrophotometer (UV-2000S, Labsphere, Inc.) and for Infra-red spectrum, measurements were performed from 380 nm to 2,500 nm using an IR Visible spectrophotometer (V-770 UV-Visible/NIR Spectrophotometer, Jasco) and value adjusted (see Graph 1).

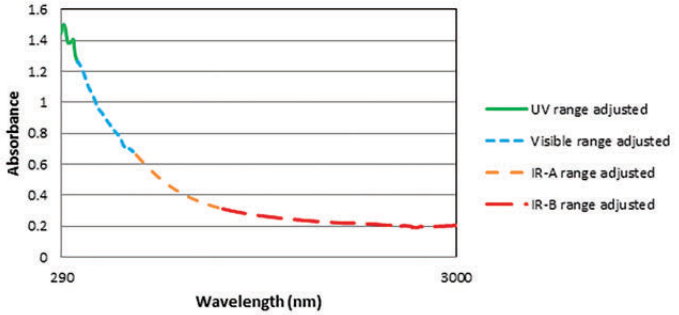
Results and discussion

To ensure any method is credible and can distinguish products between them, it must demonstrate reasonable selectivity. For this method, an 80-90% level of selectivity was set and the limits for each IR protection factor were calculated as following, by taking the integrating sphere into account:

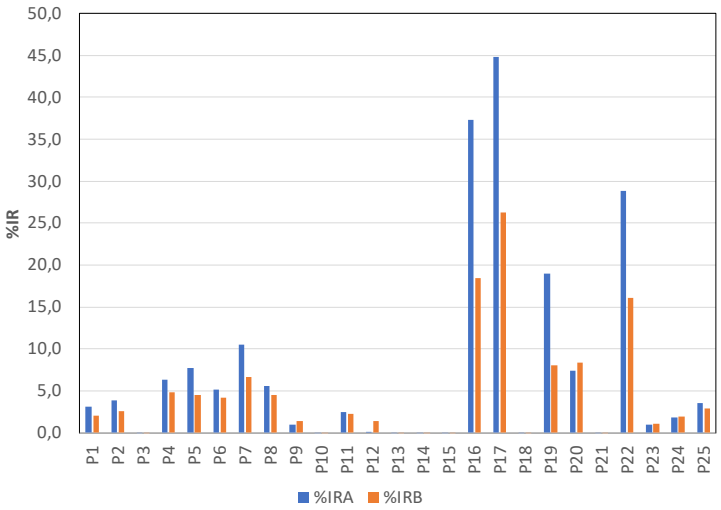
%IR ≥ 10%; %IRA ≥ 12.5%; and %IRB ≥ 10%

IR-CW ≥ 1200 nm; IRA-CW ≥ 900 nm; and IRB-CW ≥ 1200 nm

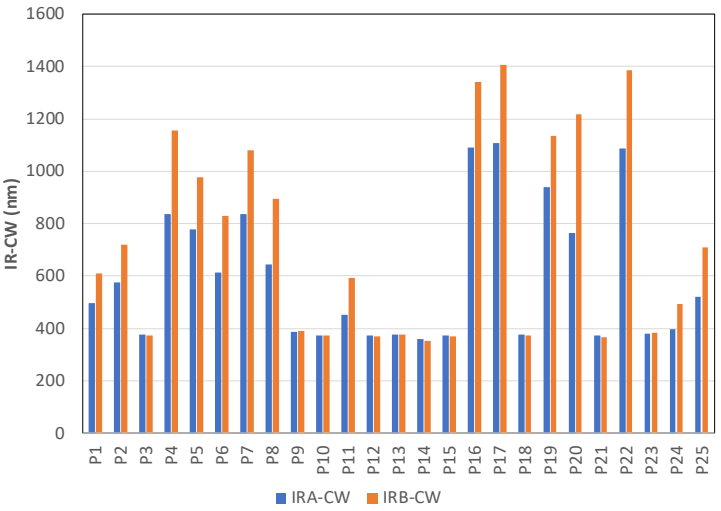
According to these parameters, only four products of the 25 tested—i.e., P16, P17, P20 and P22—demonstrated IR protection efficacy (see Graph 2 and Graph 3). Adjustments to the chosen criteria could improve these results, although it is important to consider some key variables may affect these results. The fixed limits could indeed be overly selective; the panel of test products may only include a few products with real IR protection; or all the selected products may provide IR protection but in terms of biological effects rather than absorbance.



Graph 1. Example of absorbance spectrum of product after adjustments



Graph 2. Results obtained for %IRA and %IRB in Infra-red study



Graph 3. Results obtained for IRA-CW and IRB-CW in Infra-red study

Conclusion

This study shows the development of an innovative in vitro method to assess the IR protection provided by sun care products. According to the final absorbance curve using different substrates and adjustments, the %IR and the IR-CW can be calculated to obtain the final IR protection value for each product.

To be credible and selective enough, an 80-90% selectivity limit was set among all the tested products. This resulted in just four of the 25 sunscreens tested, i.e., a 84% selectivity, exhibiting results to substantiate claims for IR protection. In fact, using an integrating sphere, this method showed test products exhibited IR protection when their %IR was greater or equal to 10% (%IRA ≥ 12.5% and %IRB ≥ 10%), and the IR-CW was greater or equal to 1,200 nm (IRA-CW ≥ 900 nm and IRB-CW ≥ 1200 nm). If one of these criteria (%IR and IR-CW) were not met, the product was not deemed to demonstrate IR protection. Furthermore, IRA or IRB protection could be separately claimed if both criteria (%IRA and IRA-CW or %IRB and IRB-CW, respectively) were met.

Read the complete article:

E Delamour, S Miksa and D Lutz, Are your sunscreens Infra-ready? New in vitro method puts data behind the claims, Cosmetics & Toiletries 132(9) (Oct 2017) pp 54-67

Are you ready to protect yourself from Blue Light?

New In Vitro method allowing the Blue Light Protection assessment of sunscreens

Introduction

The source of the blue light can be natural when the sun rays travel through the atmosphere but it can be artificial too. Indeed, digital and electronics devices use LED technology to improve brightness and clarity but this kind of technology emits strong blue light radiation. Blue Light belongs to visible range and has the shortest wavelengths (between 380 nm to 500 nm) producing the highest energy wavelengths. That is why, Blue Light is also called High Energy Visible (HEV) wavelengths.

Some scientists such as Tatiana Giacinti, Alberto Munoz, etc. explained that: «Long-term exposure to Blue Light, causes cells-to produce reactive oxygen species (free radicals) which are responsible for premature skin aging and skin photo-aging». They added: «In the long run, this damage induces similar physiological responses in the skin to UV exposure; leading to cytotoxicity in human cells, which translate to the typical signs of premature skin aging such as loss of elasticity, dryness and fine lines».

Therefore, in this present work, the authors focus on the development of a new In Vitro method allowing the assessment of the Blue Light protection of sunscreens.

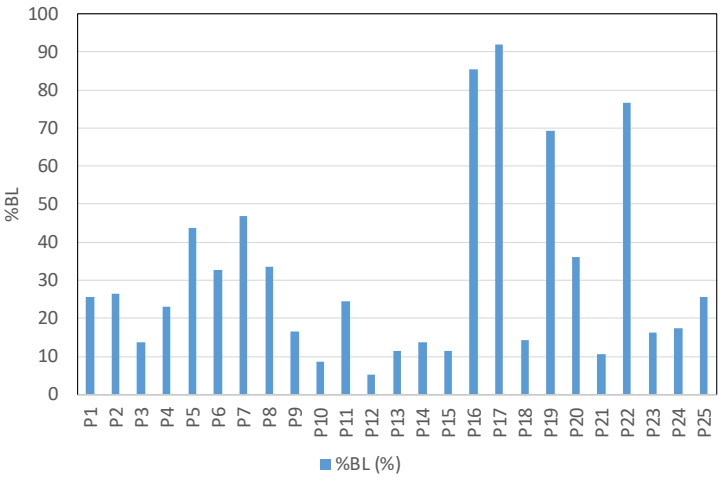
Material and method

- To develop this method, 25 products from different companies were tested. These ones include different levels of protection, ranging between SPF 6 and 50+.
- For the described tests, substrates used were molded polymethyl methacrylate (PMMA) plates (Helioplate HD6, HelioScreen) and a quantity of 1.3 mg/cm² was applied.
- Immediately after the application, products were spread by means of an automated device (HD-SPREADMASTER, HelioScreen).
- After a drying step, a solar simulator (Model LS1000-4S-009, Solar Light Company, Inc.) was used to expose samples to 800 J/m²-eff that is equivalent to 4 Minimal Erythema Doses (MEDs).
- Finally, to obtain the UV spectrum, measurements were performed from 290 nm to 400 nm using a UV spectrophotometer (UV-2000S, Labsphere, Inc.) and for Blue Light spectrum, measurements were performed from 380 nm to 500 nm using a Visible spectrophotometer (V-770 UV-Visible/NIR Spectrophotometer, Jasco).

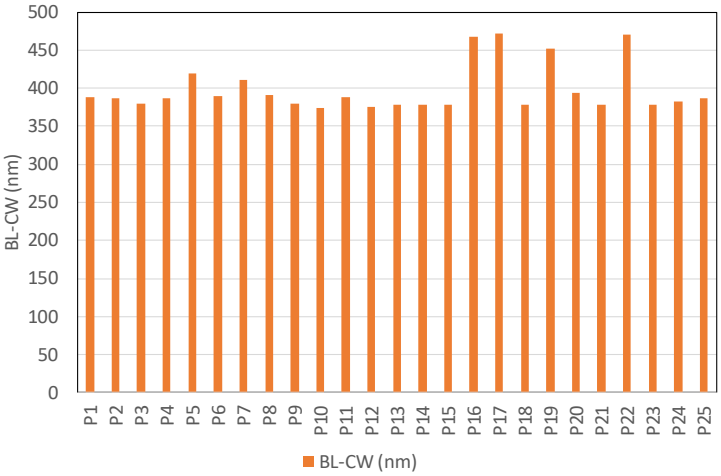
Results and discussion

Based on the adjusted spectrum, two Blue Light protection factors can be calculated. The first one corresponding to the percent of Blue Light radiations stopped by the product (%BL), it provides an indication regarding the level of sun protection to compare products between them. The second factor is the critical wavelength extended to Blue Light range (BL-CW). This one is in complement and provides an indication of the balance between the UV and the Blue Light protection.

Based on results presented in **Graph 1** and **Graph 2**, to ensure that a method is credible and is able to distinguish products, it must have a reasonable selectivity. It means that all



Graph 1. Results obtained for %BL in Blue Light study



Graph 2. Results obtained for BL-CW in Blue Light study

tested products cannot be considered positive to the test or the contrary. For this method, a 70-80% level of selectivity was selected and the limits for Blue Light protection factors were defined as follows:

%BL ≥ 35% and BL-CW ≥ 385 nm

Conclusion

According to these study results, **7 products of the 25 tested are considered as having a Blue light protection** that corresponds to a selectivity of 72% which is in compliance with the degree set.

Furthermore, products containing colored component have in most cases positive results for Blue Light protection. This seems to indicate that pigments may improve Blue Light protection in physical terms. On the other hand, this study also highlights the fact that In Vivo SPF values have no influence on the Blue Light protection factors.

Read the complete article:
E Delamour, S Miksa and D Lutz, Are you ready to protect yourself from Blue Light? New In Vitro method allowing the Blue Light Protection assessment of sunscreens, EURO COSMETICS 10-2017 (Oct 2017) pp 22-26