HelioScreen

HelioNews

News about In Vitro Sun Protection Testing

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Congress & Events

Sun Protection Summit
27-28 April 2017, Brussels

Conference by S. MIKSA about «Replacement of In Vivo Methods by In Vitro Methods in Sun Protection Domain»

SunProtectionConference

Sun Protection Conference
6-7 June 2017, London

Conference by S. MIKSA about «Challenging the claimed SPF – The need to increase the number of testing laboratories for higher reliability»

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Editorial

Nothing is perfect in our word and especially testing sun products with both in vivo and in vitro methods. Few months after the big clash between consumer's institutes and representatives of the cosmetic industry about some results on measuring UVAPF values on marked products, it sounded interesting to analysis what could be the reasons for such a confrontation. When we state something as a true affirmation or results, we have to make sure our statement is not also arguable. Testing in vivo or in vivo is not perfect but in both cases we know quite a lot about the requirements and sometimes just have to follow the rules to get the best results as possible. I am really convinced it is far from being the case. The best would be to have several (even blinded) results from different laboratories on the same products with the supposed same methodologies before claim any results as a golden result. But there is a cost. So it could be a perennial debate without any end if both parties do take into account about the real need to have an approach with expertise, experience and of course humility.

Dominique Lutz, CEO Scientist Manager

Information or Speculation

Control of sunscreen products on the market

As each year, a new market survey was published in France by a consumers association last summer. In this study, 17 sunscreen products have been tested to evaluate the UVB and UVA protection level. On the one hand, the in vivo SPF value has been assessed according to the ISO 24444:2010 standard. On the other hand, the ISO 24443:2012 has been used to obtain the in vitro UVA-PF value. Based on this study demonstrating strange results with a low UVA protection level for 5 products, the consumers asssociation undertakes legal forces against these cosmetics manufacturers.

To respond to this attack, different cosmetic industry associations published letters against this study to explain that some choices during study have been wrongly taken. One of the major explanation against these wrong results was the use of the in vitro UVAPF method for some « new » and « mineral » products leading to highlight a confusion by both organizations about this fact.

Therefore, based on a logical approach, in case of any doubt regarding the efficacy of the sunscreen products, the prior condition before set up any action that will discredit or modify a method is to increase the confidence of study according to 5 points.

1. Validation of results with the same method (in vivo or in vitro)

Whatever the method used (even strictly respected), some variability could appear and the final results could be a little bit different allowing to accept or not a borderline product. That means that several measurements from different laboratories should be requested to confirm the sun protection claimed.
Therefore, from only one value (in vivo or in vitro), how to be sure about the variability of this result in the market survey...?

2. Validation of results with the other method (in vivo or in vitro)

In case of a strong difference is highlighted, it should be requested to check with the other method (in vivo or in vitro) if this danger for the consumers health is confirmed or not.
The reliability and the relevance of methods could be challenged considering the large number of products on the market and «new» products launch (including galenic form and high quantity of mineral UV filters). Indeed, development of the both methods have been based on few tested products and of course without the latest «new» products. In other words, even if the in vivo method is considered as the «gold» value for some persons, we should not forget that the in vivo method has been developped before the in vitro one.
Therefore, how to be sure that the in vivo method is relevant for all products in the world...?

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3. Details of the testing laboratory

An important part is the confidence on the laboratory which performs the tests for the survey. Indeed, on the current market, control based on standard compliance (excepted «sometimes» some «basic controls») is performed to check the reliability of the laboratory selected. In other words, none proof is avaiable to indicate if the used laboratory followed the rules except its «sincerity». That means that some deviation from the the standards could have a high impact on final results. The worst situation is to not disclose the testing laboratory name when it is requested (publicly or not).
Therefore, how to be sure that results from testing laboratory are reliable in a market survey...?

4. Details from the cosmetic manufacturers

On the market, serious cosmetics manufacturers performed a lot of tests to ensure to consumers the highest safety. Of course, these tests include claiming tests in compliance with regulations and standards. But it would be preferable to ask them how they obtained these claimed results instead of just consider that they lie.
Therefore, why the new results obtained in a market survey have to be considered as the «truth»? Just because of the «independancy» claiming...?

5. Opinions from several experts

Even if, only one experienced person in sun protection field has been contacted, the opinion from several experts is recommended to avoid some shortcoming for any public results or letters. Perhaps it has already been done but it is still impossible to check the reliability of the expert(s) who written articles or letters.
Therefore, how to know if the communicated information is relevant from both parts...?

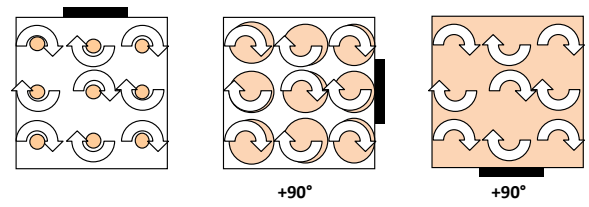
To conclude, we should take care about how a «result» could be used to make a buzz but also how an «answer» can feed this buzz and lead to take unconsidered actions.

How to use the Helioplate HD6 & SB6

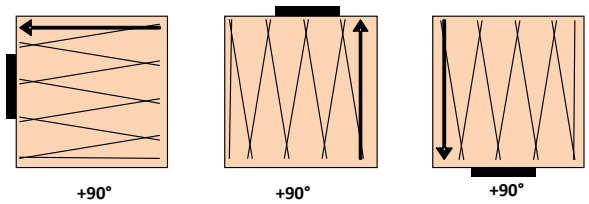
Often asked how to use our substrates, we described hereinbelow the general process for the Molded PMMA plates (Helioplate HD6) and the Sandblasted PMMA plates (Helioplate SB6).

Product is applied on the substrate by weight and to ensure the correct application rate, the pipette has to be weighed before and after product application. The rate is determined in such a way that the actual quantity of product left on the substrate before spreading is 1.3 mg/cm² for Helioplate HD6 and 1.2 mg/cm² for Helioplate SB6. Considering the plate size of 48 mm x 48 mm (size where the product is applied, not the total size), the quantity is thus equal to 29.95 mg for HD6 and 27.65 mg for SB6. The amount of sunscreen product is applied by using a pipette and distributed evenly over the whole roughened PMMA surface of the plate (50 x 50 mm) in the form of a large number of small drops of equal volume. Immediately after weighing, the sunscreen product is spread over the whole surface using a finger-cot «pre-saturated» with the product.

First, start the spreading by light circular strokes using a low pressure from the top left to the bottom right for recover all spots of product. Secondly, turn the plate at 90° and start again the spreading. Thirdly, replicate the same step. The spreading has to be completed as quickly as possible (less than 30 seconds by plate) for all replicates.



Then the sample was rubbed with linear strokes into the rough surface using a medium pressure from the top right to the bottom left. Turn the plate at 90° and start again the same spreading. Finally, replicate the same step. This phase also has to take 20 to 30 seconds by plate.



The sample thus obtained has to be settle for 30 minutes in the dark at room temperature (ideally 25°C ± 2°C) to ensure self-leveling of the formula.

Of course, according to the standards used, these parameters have to be changed to be in compliance.

New In Vitro assessment of Wet Skin factor of sun care porducts

Introduction

Nowadays, customers are conscious of the harmful effects caused by the solar radiations and more particularly caused by ultra-violet (UV). Indeed, an overexposure to UV leads to many damages like the apparition of sun burns, a premature skin ageing or the development of skin cancers. It explains why they desire sunscreen products claiming a good UV protection but now they also require personalized sun care products with resistance factors such as Water Resistance, Rub Resistance, Sand Resistance, Sweat Resistance or a Wet Skin application.

That is why our laboratory propose an innovative In Vitro tests allowing the assessment of the Wet Skin Application factor of sun care products. The present paper is a short version of the published method[1].

Results

First, the influence of key paramters regarding the wet skin application process have been investigated including the dampening, the substrate and the temperature (see **Figure 1**).

Dampening	The %COV is a little bit higher when the dampening is performed with a spray rather with a syringe. So, these two dampening modes have a slight influence on the %Wet. But, the spray wets the plates in a heterogeneous way and it's easier to control the quantity of water apply with a syringe.
Substrate	The %COV obtained for SB6 substrates is clearly higher compared to this obtained with the HD6 substrates. So, molded plates give results more reliable.
Temperature	The COV% is clearly lower when the temperature during the totality of the test is 25°C compared to 35°C.

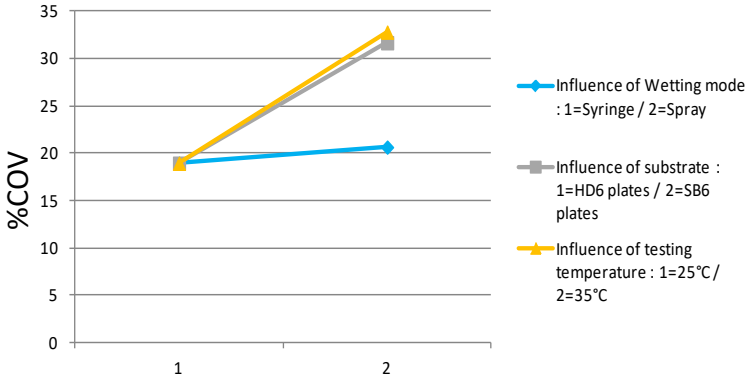


Figure 1: Mean %COV of testing products according to the wetting mode, substrate and testing temperature

In addition to the %Wet, the second criterion for a Wet Skin product is a homogeneous application without leaving white marks. This parameter isn't a necessity because it doesn't put in jeopardy consummers but it's a real advantage for customers who don't want white marks when they apply sunscreen product on wet skin. According to the **Figure 2**, on the left plate, it is a product leaving white marks on wet substrate and for the right plate it is not the case for another product in the same conditions.

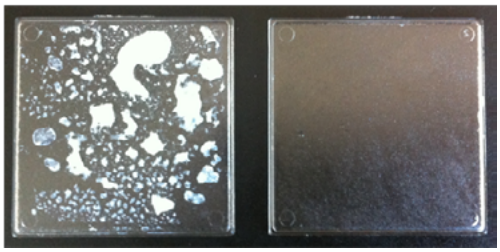


Figure 2: Comparison of spray residuals on wet substrate (sunscreen products leave white marks on the left plate, transparent film on the right plate)

Protocol for Wet Skin Application test

STEP 1

Conduct the calibration and the validation of keys parameters of the test equipement including blanck measurement.

STEP 2

0.05 mg/cm² of distilled water are applied in substrate by means of a syringe. Then, the water was manually and homogeneously spread.

STEP 3

Sunscreen product is applied on wet and dry PMMA substrates with an automatic syringe at 1.3 mg/cm² (3 replicates).

STEP 4

Sunscreen product is spread on wet and dry plates by means of automated spreading.
Drying step of 15 minutes in the dark.

STEP 5

Acquisition of In Vitro UV absorbance spectrum of the sun care product on wet and dry plates.

STEP 6

Calculation of the Wet Skin percentage:

$$\%Wet = \frac{SPFwet-1}{SPFdry-1} \times 100$$

Conclusion

The aim was to develop a standardized In Vitro method for the determination of Wet Skin factor of solar products. To optimize this method and to reduce the variability causes, several parameters have been tested to identify and master their influence on %Wet Skin. That is why, thanks to the results obtainend, the PMMA molded substrates, the dampening mode with a syringe and the testing temperature at 25°C were chosen allowing the best results with a low variability. It is a repetable and reproducible method.

[1] Wet Skin Factor for Sunscreens: In vitro Method to Substantiate Wet Skin Product Claims - E. Delamour, S. Miksa and D. Lutz, Cosmetics & Toiletries, July 2016

New In Vitro test for the assessment of the resistance of the sun protection in extreme conditions

Introduction

In this study, the aim is to develop a new In Vitro method to check that the sunscreen product tested preserves its UV protection in extreme conditions. Indeed, a modification of the UV protection of some products has been observed because of the variations of the temperature or the humidity [1;2]. Therefore, a method adapted to standards has been developped to assess the resistance of sunscreen products to extreme conditions to guarantee to consumers a protection against UV whatever the season or the place where they are.

Protocol & Method

In this study, 21 sunscreen products were tested using the experimental protocol (**Figure 1**) in 5 different conditions:

- 25°C and 55% of hygrometry (standard condition)
- 10°C and 30% of hygrometry (extreme condition n°1)
- 10°C and 80% of hygrometry (extreme condition n°2)
- 40°C and 30% of hygrometry (extreme condition n°3)
- 40°C and 30% of hygrometry (extreme condition n°4)

STEP 1

Calibration and validation of the test equipements including blanck measurement.

STEP 2

Application of sunscreen product on untreated roughened molded PMMA plates with a syringe at 1.3 mg/cm².

STEP 3

Spreading of sunscreen product on PMMA plates by means of an automated device.

STEP 4

Drying step of PMMA plates during 15 minutes in the dark at **different temperatures and hygrometry percentages**.

STEP 5

Acquisition of In Vitro UV absorbance spectrum of the product by means of a spectrometer on substrates dried at different conditions.

STEP 6

Calculation of the percentage of resistance to extreme conditions (%EC):

$$\%EC = \frac{SPF_{in\ extreme\ conditions} - 1}{SPF_{in\ standard\ conditions} - 1} \times 100$$

Figure 1. Experimental Protocol

Results

First of all, a sunscreen product is considered resistant when the %EC is superior to 75% for each extreme conditions tested. So according to the **Figure 2**, 13 products out of 21 don't resist to extreme conditions. Furthermore, products tested resist less to condition n°4 (40°C 80%) (10/21 products) compared to condition n°1 (10°C 30%) (4/21 products) for example. However, all of these conditions are necessary to claim Extreme Conditions Resistance. Indeed, it is especially the case for products P1, P17 and P20 which are non resistant because of only one condition.

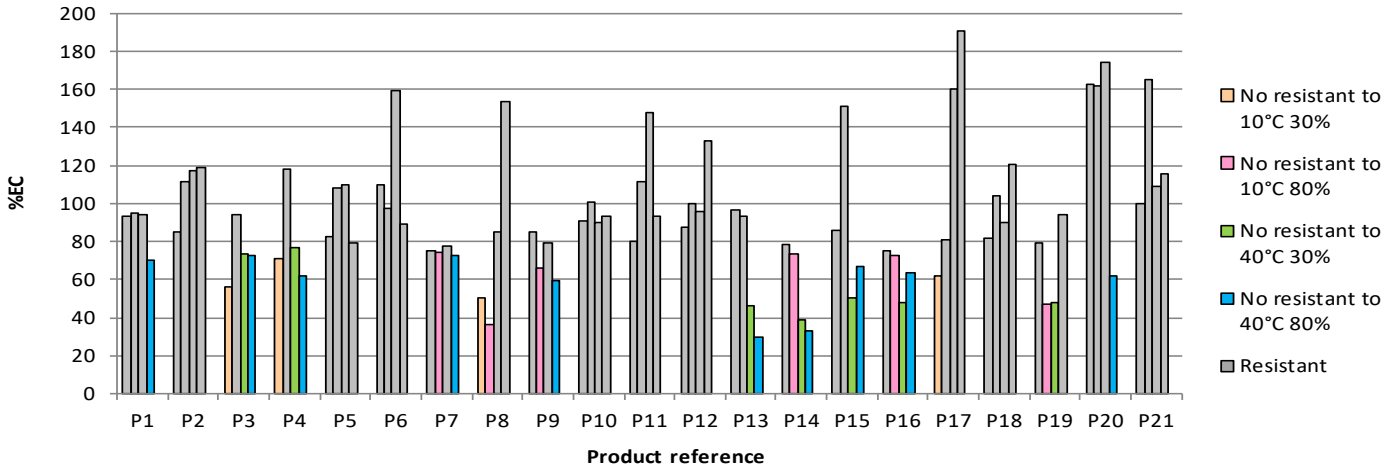


Figure 2. Graph representing the %EC for each tested products according to different extreme conditions

A method is considered repeatable and reproducible when the Percentage of Coefficient of Variation (%COV) is inferior to 20%. According to **Figure 3**, this criterion is respected. However, for extreme conditions n°2 (10°C 80%) and n°4 (40°C 80%) the %COV is always superior compared to the other conditions. Maybe it means that the high level of hygrometry lead to more variations in results. Finally, some products give results more variable (P4) than others (P10). So, the variability depends not only on the testing condition but on the tested product too.

Conclusion

This method allowing the assessment of Extreme Conditions Resistance of sunscreen products can be implemented in the laboratory. Indeed, this one is repeatable, reproducible and enough selective that means that at the end of the test not all tested products are considered resistant.

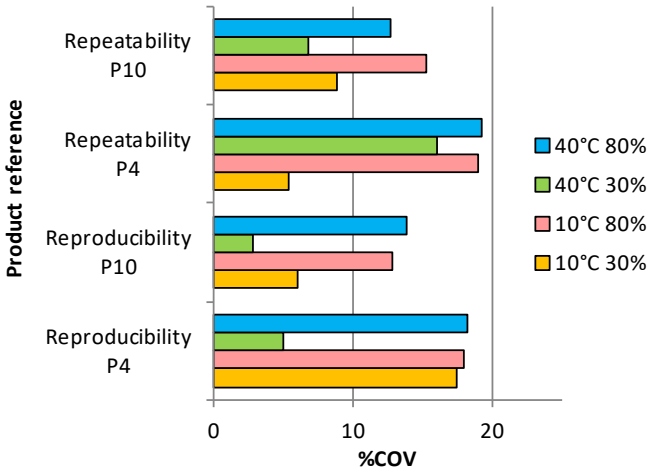


Figure 3. Graph representing the %COV for several products according to different extreme conditions to assess the repeatability and the reproducibility

[1] S. MIKSA, D. LUTZ and C. GUY, *UV Transmission Assessment: Influence of Temperature on Substrate Surface*, Cosmetics & Toiletries magazine, Vol. 128, No.7, Juillet 2013, p.484-494

[2] V. HUBICHE, P. LENNON, *Influence of climate on sensory properties of sunscreens*, 2015 Sunscreen Symposium, The Next Horizon of Sun Care Innovation & Global Regulatory Requirements