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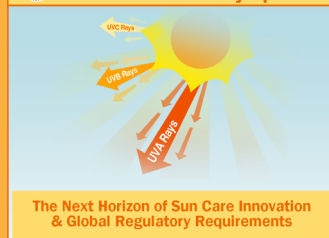
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Continuig Education Course by  
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**Vist our booth**

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### Editorial

The way to get at last an official SPF method all over the world or may be just in some continents is very long and hard. The most complicated will not be to solve the technical problems about reproducibility or reliability but to change the minds about perception of In Vivo testing. I already mentioned it in a lecture during the Jean-Paul Marty Skin & Light days 2 years ago. On a technical point of view, our laboratory has proposed a new method which has been demonstrated to be correlated with In Vivo results... as far as possible. Because if we consider the proper variability of the In Vivo method whom nobody wanted to mention previously, we cannot have better results than the ones presented in the last ISO meeting!

You can take it for sure we will have a method soon or late but next step is now the acceptance from the industry itself. As a matter of fact some existing results could now be challenged with quite good arguments. I am still convinced it is better for the industry to prepare the next step towards In Vitro than wait for the change under the pressure. More and more the variability of In Vivo method is mentioned as another reason than ethical problem to change quickly our way to evaluate sun protection afforded by cosmetics.

The following problem when we will have at least a validated official In Vitro method will be to get it fully accepted and applied because the In Vivo method offers some comfort for the industry as they can deal with the higher results which can be found in such or such laboratory. Unfortunately, it will be also the case for In Vitro if institutes will not follow the rules with ad hoc equipment's required to get reliability.

Dominique Lutz, CEO Scientist Manager

## Shortcoming in UV protection for USA's sunscreen products?

### INTRODUCTION

Nowadays, it is well known that beyond UVB protection, the UVA protection is also important and sunscreens must provide a total protection. Whatever the kind of product, we can state the sunscreen's efficacy will be brought from two criterions, the UV protection performance and the distribution onto the skin. Indeed, the first will depend on the UV filters selection-combination and homogeneous distribution into the formulae. The second will depend on the thickness and homogenous repartition after product's spreading which must allow the fewest thin layers as possible as well as any area without product. These parts are the compulsory requirements in order to achieve sun protection performance.

Thus, the aim of this study is to determine if the USA sunscreen products have a chance to ensure to consumers the protection against UVB and UVA based on the UV filters combination into formula. In order to estimate the UV protection performance of formulations, the most convenient approach towards this goal is computational simulation<sup>[1-2]</sup>. Indeed, this approach has been privileged compared to the In Vivo method due to ethical and reliable issues but also compared to the In Vivo and In Vitro methods due to practical and economical

reasons regarding the large number of product checked. Anyhow, even if the reliability of the simulator for UV performance checking could be challenged on very few products, it can be considered as reliable from a statistical point of view on a large number of products (a total of 1,037 sunscreens analyzed).

### METHODS

As previously explained regarding the use of simulation, in this paper, we used one of the most well known in silico model for calculation (BASF sunscreen simulator<sup>[3]</sup>) from the combination of the algorithm used with in vitro measurements and the approach employed with in vivo determination both tuned to produce results as close as possible to experimental in vivo and in vitro data. Beyond the percentage of UV filters into formula required for the simulation, such simulation uses the following element already recorded in the software:

- a database with UV spectra of the relevant UV filters
- a mathematical description of the irregularity profile of the sunscreen film on the skin
- changes in UV filter concentration due to photoinstabilities
- formulation influences (e.g. UV filter distribution)

Finally, the UV filters percentage details have been obtained through the EWG's Guide to Sunscreens 2015<sup>[4]</sup> with a data base on 1,764 sunscreen products but only the 1,037 products with only organic UV filters have been analyzed. The percentages have been incorporated into the simulator and from these simulations, different results have been extracted as recommended by the FDA final Rule 2011 with (i) the SPF value and (ii) the CW (Critical Wavelength) but also (iii) the UVA-PF value in order to determine the UVA-PF/SPF labeled ratio as recommended by European Recommendation 2006 (i.e. ratio should be higher than 1/3).

From these results, the SPF claimed and simulated will be compared and the UVB/UVA protection will be checked. In the example here below with the product A (SPF labeled 30) and B (SPF labeled 50+), we explained the process step by step allowing to obtain the different values required for analysis.

- **Step 1.** The UV filters percentage has been obtained through EWG's Sunscreen Guide 2015 (see **Table 1**).

Table 1. UV filters into product A and B

UV filter	% into product A	% into product B
Avobenzon	2.0%	3.0%
Homosalate	-	10.0%
Octocrylene	-	6.0%
Oxybenzone	3.0%	-
Octinoxate	7.0%	-
<b>Total</b>	<b>12.0%</b>	<b>19.0%</b>

- **Step 2.** The UV filters percentage has been introduced into the BASF sunscreen simulator.

- **Step 3.** The results have been exported for SPF, UVA-PF and CW analysis (see **Table 2**).

Table 2. UV protection results

UV protection	Values product A	Values product B
SPF labeled	30	50+
SPF calculated	17.5	17.0
UVA-PF calculated	4.2	7.4
CW(nm) calculated	360	375

## RESULTS & DISCUSSION

Using the different steps previously explained, the all samples have been analysed (i.e. 1,037 products). The results have been summarized in the graph here below. Nevertheless, 44 sunscreen products presented an UV filters percentage higher than authorized in the USA and have not been included in the present analysis (thus 993 products remaining).

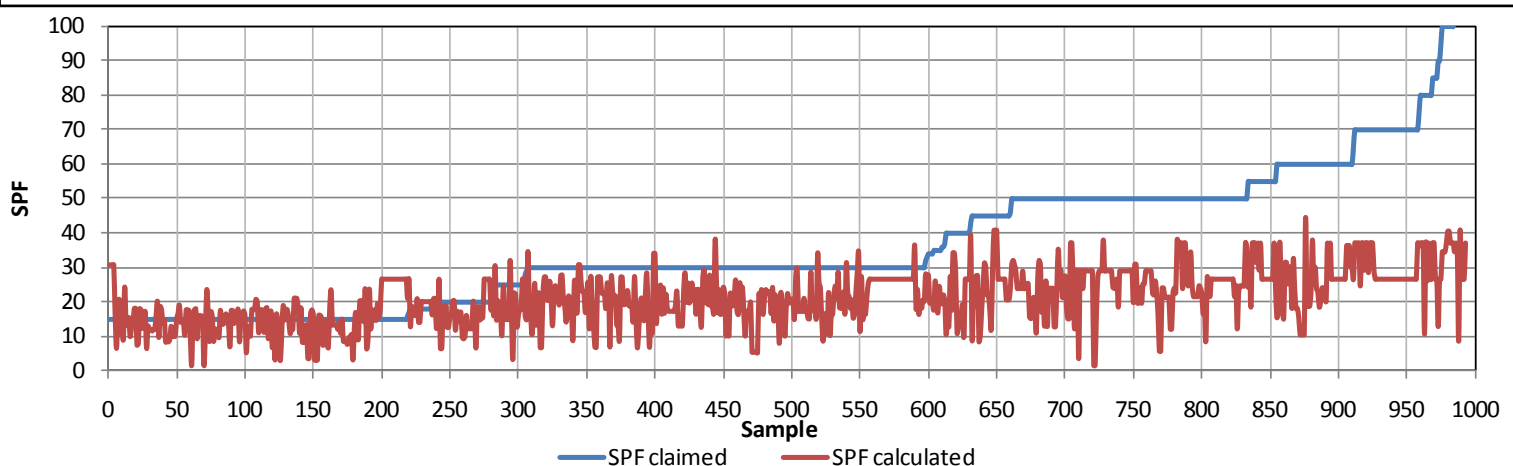


Figure 1. Distribution of SPF label vs. SPF calculated

### a) SPF label vs. SPF calculated

In a first step, the **Figure 1** presents the comparison between the SPF label on the packaging and the SPF calculated for the all products. By comparing each SPF claimed vs. SPF simulated, it is possible to conclude that the SPF simulated (red line) is strictly lower than the SPF claimed (blue line) for **86%** of products in the worst case! Moreover, approximately **67%** of products have a SPF simulated lower than 25% of the SPF claimed! Furthermore, the difference between the both SPF (i.e., simulated and claimed) seems to be higher proportionally to the SPF.

In other words, even if the simulation could have sometimes some biases (e.g., galenic influence), it seems that in general SPF labeled from a lot of USA sunscreen products overestimate the real UV protection for consumers health!

### b) Ratio UVA-PF / SPF labeled

According to the **Figure 2**, it seems that about **48%** of products sold in the USA don't reach the minimum of UVA protection recommended in Europe (UVA-PF  $\geq 1/3$  SPF label)! This warning information is in contradiction with the affirmation within the FDA final Rule 2011:

«[...] We also agree with the submissions requesting that UVA protection should be proportional to the SPF value. We are requiring such proportionality in the broad spectrum test described in this document. Because of this proportionality, there is no longer a need for a separate UVA rating. Instead of a rating, we are requiring a "broad spectrum" statement on the PDP if a product has a critical wavelength equal to or greater than 370 nm. This pass/fail "broad spectrum" statement is consistent with the recommendations in the submissions citing the recommendations of the European Commission.[...]».

In other words, the importance of UVA-PF assessment should be reconsidered for consumers health.

### c) Broadspectrum analysis

According to this same FDA final Rule 2011, the pass/fail «broad spectrum» statement is based on a critical wavelength  $\geq 370$  nm which seems reliable. In case of no respect of this limit, the product could be sell on the market with only a warning message. But is it really enough for the consumer health when about **52%** of products analyzed in the present paper presents a CW simulated lower than 370 nm (see **Figure 3**)?!

In other words, the importance of a compulsory minimum of CW equal to at least 370 nm should be also reconsidered for consumers health.

## CONCLUSION

First, regarding the UVB protection, it is surprising that on the 1,037 sunscreen products analyzed, **67%** (i.e., **663** samples) has a SPF simulated lower to the SPF claimed with a difference > 25%! In other terms, the SPF labeled from a lot of USA sunscreen products overestimate the real UV protection for consumers health!

Second, as already demonstrated in the previous HelioNews 17, a lot of sunscreens sold in the USA (i.e., **48%** representing **467** samples) has relatively low effective protection against UVA following European Recommendations (i.e. UVA-PF/SPF labeled < 1/3) but also a lot of products i.e. **52%** representing **521** samples presents a CW < 370 nm as recommended in the FDA monograph 2011!

This fact based on a large number of products leads to conclude that perhaps different factors could influence the SPF labeled. Indeed, beyond the well-known variability of the In Vivo method, the current debates challenge the real protection of the product if the factor erythema is only delayed due to ingredient (such as anti-inflammatory) instead of a real improvement of the UV protection. As it is the case with the In Vitro method, this health concern is avoided by using the simulator which avoid any biological effect issue. This fact raises the difficulty to have a correlation between a biological and analytical method (i.e. In Vivo and In Vitro) not only based on UV protection performance...

Furthermore, to provide more effective UVA protection for consumers, it is recommended that the USA regulatory evolves according to the European Recommendations with the compulsory determination of the UVA-PF /SPF labeled > 1/3 and a CW ≥ 370 nm (or at least only a CW ≥ 375 nm as explained in the pervious HelioNews 17).

To conclude, in general the USA's sunscreen products seem presented a health risk for consumers due to the over-estimation of the SPF labeled obtained by the In Vivo method and the poor UVA protection. That means beyond ethical, practical and economical reasons, In Vitro method should be preferred compared to In Vivo one in order to avoid biases (variability and undesirable biological effects without real UV protection). Finally, it seems that several products have presented UV filters concentration outside the valid boundaries authorized in USA.

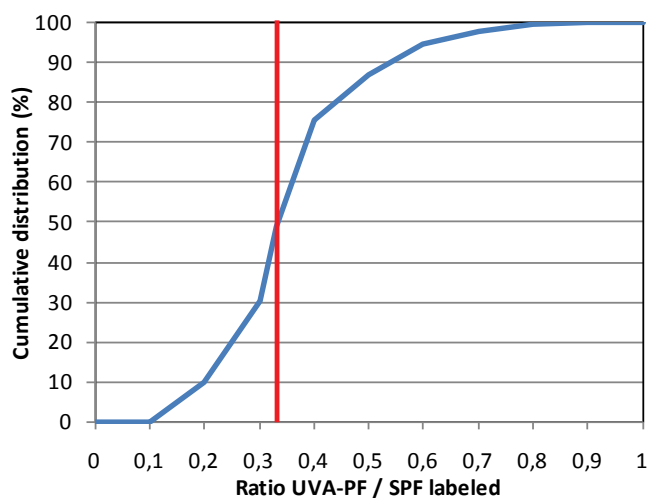


Figure 2. Cumulative distribution of ratio UVA-PF / SPF labeled

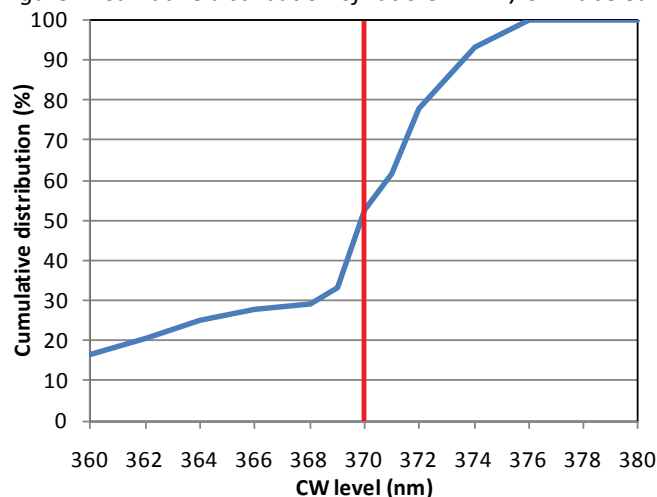


Figure 3. Cumulative distribution of CW

## Sun Care industry

As men and women throughout the world rush out to enjoy the warmer summer weather, there is an obvious trend towards using appropriate protective and preventative measures. For this goal, sun care products are used with the well-known SPF (Sun Protection Factor) for UVB protection with increased emphasis on UV-A protection whilst maintaining overall broad spectrum activity. Due to the increasing global awareness regarding the impact and damage by the sun's harmful rays, the sun care market is one of the fastest growing categories of skin care.

In 2015, the global sun care market in the world is estimated to a retail value of about 11.9 billion U.S. dollars including its sun protection products, aftersun and self-tanning segments respectively representing 80%, 10% and 10% of the market. The graph here below (see **Figure 4**) depicts the value of the sun care market in the world from 2010 to 2015 (estimation), by segment of region.

Thus, it can be observed that the sun care market in Western Europe seems stagnate with only 5% of progression in 5 years since 2010 compared to the North America with a progression of 20% (from 2010 to 2015). Furthermore, Asia Pacific with Latin America will together account for 50% of the sun care category's global revenue in few years with

respectively a progression of about 40% and 70% in 5 years since 2010.

Nevertheless, even if a lot of opportunities abound in the global sun care market, companies should (a) educate as well as (b) innovate to bolster sales.

Concerning the first purpose (i.e. (a)), a thirds of parents only worry about sun protection in summer months but forget to use sun care product all days in order to avoid skin damages due to UVB and UVA. Beyond these points, improvement of sun protection for consumer leads to propose by cosmetics manufacturers, health authorities, and consumer associations... plenty of recommendations and information of several types: labelling, conditions of use, measurement methodologies of protections values, specific tests of security and stability.

For the second purpose (i.e. (b)), during NPD (New Product Development), different trends sights have to be used in a global approach in order to propose innovative product for consumer with a total of 8 trends as presented here below. Obviously, for each trend, different sub-trends and sub-trend crossover could be followed leading to a complex map for the tomorrow's consumer brand landscape<sup>[5]</sup>.

1. Health & Wellness
2. Easy & Affordable
3. Individualism & Expression
4. Sensory & Indulgence
5. Sustainability & Ethics
6. Smart & Connected
7. Comfort & Uncertainty
8. Evolving Landscapes

Regarding especially sun care product innovation, additionally, consumers want to help their skin better deal with sunlight in general (i.e. not just sunscreen) and with innovative sensory products. Thus, the most relevant trends for success focus on:

- Protection (trend 1): care and cure
- Convenience (trend 2): novel application
- Adapted solutions (trend 3): personal product

To conclude, with an already large share of the cosmetics market, the sun care market still has a bright sunny days ahead and may continue to surprise us in future.

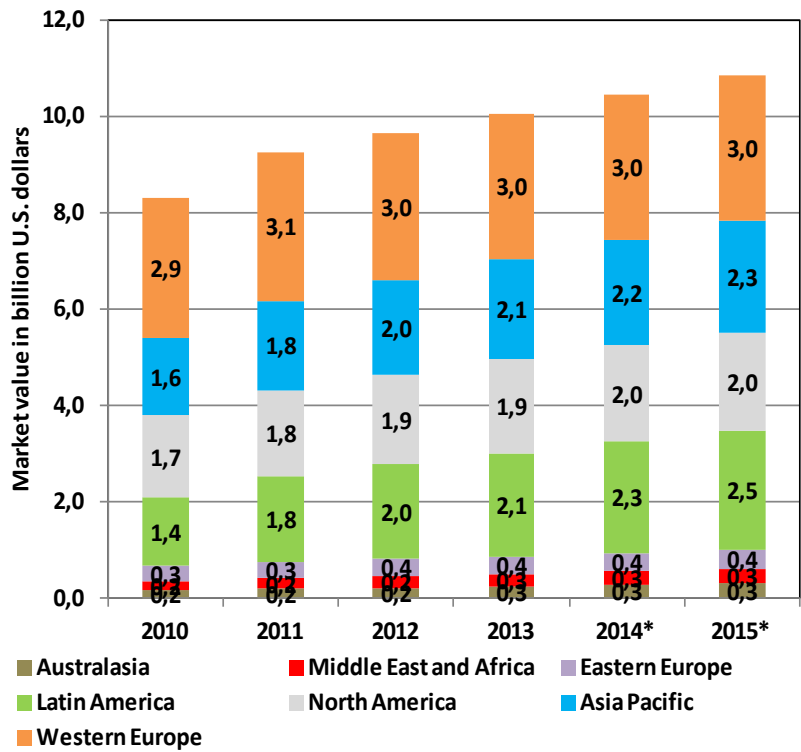


Figure 4. Global sun care market value in the world

**5-6 OCTOBER 2015**  
HelioScreen Laboratory, France

**SAVE THE NEW DATE!**  
**APRIL, 15<sup>th</sup> 2016**

Due to its international success, we propose a new date for the In Vitro Suncare Open Days more suitable and always Free of charge!

En raison de son succès international, nous proposons une nouvelle date plus appropriée pour les Journées Portes-Ouvertes et toujours entièrement gratuites!

**IN VITRO SUNCARE**  
OPEN DAYS 2016  
JOURNÉES PORTES-OUVERTES 2016

**HelioScreen**  
In Vitro sunscreen testing solutions

## Save the new date for the In Vitro Suncare Open Days!

Thank you for your interest in our [In Vitro Suncare Open Days](#) and your registration.

Nevertheless, due to its international success, we propose a new date for this big event more suitable close to in-cosmetics Paris 2016!

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...

Save the new date on [April, 15th 2016](#) and don't forget it's always **free of charge!**

Want to have additional information or to book your place?

Please click [here](#) or on the image on the left or visit our website at [www.helioscreen.fr](http://www.helioscreen.fr) in order to complete the registration form (one registration form by person).

## Scientifics articles and notes

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