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## Congress & Events



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## Editorial

Already 15 years old. Indeed very few people trusted this company when I created... As well as In Vitro methods. We are very proud to have been a forerunner and still now quite a leader in innovation and concrete proposals to go towards the reliability of the In Vitro methods, not only in our laboratories but within the standard with our proposal with the ISO committee. At least when we consider the past and our beliefs considering our papers in these last 15 year's issues of HelioNews, we realize we stated long time ago what some people seems to discover just now. Clearly things are really different since we started the laboratory but only the last years allow having a hope for an harmonization with acceptable methods.

Clearly our expectation is not only to go further on the knowledge of compulsory rules to follow but also to make people (industrials and authorities) clearly following these rules. With the development of the In Vitro method and with the first ISO 24443 standard, it has been a great opportunity for many institutes to make new business. The paradox is that most of the time they do not care about the rules or recent improvements unless benefits are demonstrated by publications or international works. Most of the customers still consider the price as the first requirement. In other continent such ASIA where we start a new adventure, I realize they still proceed as done when we started HelioScreen (named before Helioscience for 8 years...) and nobody, included authorities who must guarantee public health and protection really worry about...

The more I am progressing in the mastering of these methods and confident with the results, the more I believe it will take time to have them understood, accepted and followed by all the laboratories. We have to be optimistic because things will change slowly. This is why we are confident for the future of our company.

Dominique Lutz, CEO Scientist Manager

## I. 15 years anniversary

### I.a. HelioScreen

HelioScreen is the specialist for more than 15 years of the In Vitro evaluation of sun protection products, it offers you a complete range of tests, consumables and services. Sun protection has clearly evolved (products, methods, requirement...) since first use for consumer safety but we stay the forerunner in this field. For the 15 years anniversary of the company, discover or re-discover the interesting history of a company involved in the In Vitro sunscreen testing summarized in 15 key dates. (see next page).

### I.b. HelioNews

As a pionner in the In Vitro sunscreen testing, the first HelioNews (HN0) has been published in 1999 in USA. After 15 years, we are glad to published the 18<sup>th</sup> issue in 2014!

For this anniversary, the first issues published in French have been translated in English and each one published. Discover or re-discover the «News about In Vito Sun Protection Testing» (HelioNews) and take an overview about these interesting following issues here below (click on the name for the link):

1999	HN0
2007	HN1 - <a href="#">In Vivo / In Vitro</a> : a wedding of convenience HN2 - <a href="#">HELIOPLATE®HD</a> : A new substrate for reliable In Vitro evaluation HN3 - A new In Vitro method for <a href="#">Water Resistance</a> HN4 - A new service proposed: help for <a href="#">formulation</a>
2008	HN5 - <a href="#">Quality control</a> of solar products: An innovative and interesting method HN6 - Sun protection in <a href="#">fabrics</a> . When the SPF becomes UPF
2009	HN7 - Helioplate: The <a href="#">secrets of industrial</a> manufacturing HN8 - <a href="#">Reference spectrum</a> : A challenge for the SPF calculation HN9 - Reference spectrum: A stake for <a href="#">calculation of the SPF</a>
2010	HN10 - <a href="#">Photo stability</a> and pre irradiation HN11 - Improvement of <a href="#">interface plate/product</a> , a key for SPF evaluation
2011	HN12 - FDA New Rule: Border line products in <a href="#">broadpectrum claiming</a> HN13 - <a href="#">ISO 24443</a> : Rules change requirements for In Vitro Testing
2012	HN14 - <a href="#">In Vitro Photo-Protection</a> Assessment of Sunscreen Products HN15 - <a href="#">Critical Wavelength</a> assessment - A false friend in reliability
2013	HN16 - <a href="#">Robot</a> delivers industry from flop in sun protection evaluation HN17 - <a href="#">Fundamentals</a> of In Vitro sunscreen testing methods
2014	HN18 - <a href="#">Worldwide regulation</a> for sun protection



## IN VITRO UV TESTS HISTORY

- ISO In Vitro SPF works on **robotic spreading** - 2014
- Comparison method** publication for quality control - 2013
- Publication of In Vitro UVA-PF **ISO 24443:2012 standard** - 2012
- Publication of the final **FDA monograph** - 2012
- Methods amendment for **Cosmetics Europe In Vitro UVA** & UVA:UVB Boots Star rating system - 2011
- Creation of **ISO expert group** for In Vitro SPF - 2011
- Start of **International groups ISO** sun protection evaluation method - 2008
- Publication of In Vitro UVA-PF **Cosmetics Europe method** - 2007
- Publication of the **European recommendations** - 2006
- ANSM** committee on sun protection - 2003
- Critical Wavelength index** - 1994
- UVA:UVB Boots Star rating system** - 1991
- 1<sup>st</sup> description of the **In Vitro method** - 1989
- Creation of the **SPF index** - 1962
- 1<sup>st</sup> **cosmetic** protecting from UV - 1946

## HELIOSCREEN HISTORY

- New reproducible Helioplate **SB6** (sandblasted)
- **HelioScreen Asia Co., Ltd.** creation (joint venture with Thai Chemico Ltd Cie)
- Appliance **HD-SPREADMASTER** (robotic spreading)
- Member of the **ISO expert group** for sun protection evaluation method
- **HD6 substrates** in all current worldwide standards and methods
- Reference plate **HDO** & S2 standard
- Certification Bureau Veritas Certification **ISO 9001**
- Partnership with **Labsphere Inc.**
- Patent Helioplate **HD2 & HD6** (molded)
- Member **AFNOR** ISO sun group
- Helioscience becomes **HelioScreen**
- Starting of HelioScreen's **globalization** (Agents worldwide)
- **ANSM** Expert for the sun protection
- Partnership with **DERMSCAN** for In Vivo / In Vitro tests
- **D. Lutz** founded the Helioscience Cosmétique laboratory

AFNOR: French Agency for Standardization

ANSM (ex-AFSSAPS) : The French National Agency for Medicines and Health Products Safety

Cosmetics Europe (ex-COLIPA): The Personal Care Association in Europe

FDA: Food Drug Administration in USA


ISO: International Organization for Standardization

## Sun risk prevention


The summer is here! Sea, sun and beach seem so good and you are so excited! But a lot of false friends are also ready such as Mr SunBurn, Mr SkinCancer and Mr SkinAgeing!

The major cause for see these false friends is too much exposure to ultraviolet (UV) radiation from the sun. Indeed, skin can burn in as little as 15 minutes in the summer sun so it is important to protect your skin from UV radiation.

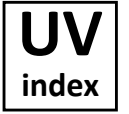
Damages due to these false friends are largely preventable. Thus, protect yourself against them by using a combination of these five steps:




Apply sunscreen generously to clean, dry skin 20 minutes before you go into the sun. Reapply sunscreen every two hours, or more frequently if washed, rubbed, or sweated off.




Wear sun protection clothing and sunglasses to protection skin from sun exposure.



Prevent overexposure to the sun's rays by means of the UV Index which predicts exposure levels.



Avoid sun exposure between 10 am-4 pm.



Seek shade when UV rays are the most intense.

## In Vitro E-SPF determination for lens

Several studies highlighted the danger of Ultraviolet (UV) irradiation for human's body parts and different sun protection assessment brought by sunscreens, fabrics and lens have been developed.

First warning information about UV impact on eyes have been introduced in 80's and many papers have been published after this.[1-5]. Furthermore, health concern about also importance of eyes protection has allowed the publication of standard. [6]. Nevertheless, even if the commonly used "100% UVA UVB" mention exists, it doesn't provide complete information on the overall UV protection of a lens. Indeed, total UV radiation is based in physical effects of lens, UV transmission attenuation with reflected/scattered depending on frame characteristics (frame coverage, distance from the forehead, antireflective coatings, etc.) and back-reflection of UV due to concave face of the lens and antireflective coatings (Figure 1).

Recent proposal announces the introduction of the Eye-Sun Protection Factor (E-SPF) from Essilor company as a new international index providing UV protection level [7-8] and could be the best way for total UV assessment. In fact, transmission ( $\tau_{UV}^{0^\circ}$ , UVR reaching the eye at an angle of  $0^\circ$ ) and back-reflection of beams included in a solid cone centred on an angle of  $145^\circ$  ( $R_{UV}^{145^\circ}$ ) are the relevant denominators for the E-SPF (see Equation 1-3). Where  $E_s(\lambda)$  is the spectral distribution of solar radiation and  $S(\lambda)$  is the relative spectral function efficiency.

According to the results, a table for labelling (see Table 1) has been developed in order to defined reductions in transmission such as definition used for SPF. Clearly, the higher UV reduction, the higher E-SPF and a logo has been created (Figure 2) for helping consumers.

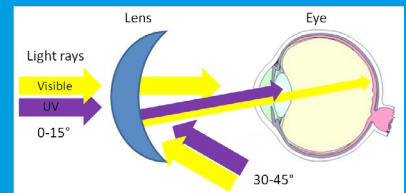


Figure 1

$$In\ vitro\ E-SPF = \frac{1}{\tau_{UV}^{0^\circ} + R_{UV}^{145^\circ}}$$

Equation 1

$$\tau_{UV} = \frac{\int_{\lambda=380\text{ nm}}^{\lambda=280\text{ nm}} \tau(\lambda) \cdot E_s(\lambda) \cdot S(\lambda) \cdot d\lambda}{\int_{\lambda=380\text{ nm}}^{\lambda=280\text{ nm}} E_s(\lambda) \cdot S(\lambda) \cdot d\lambda}$$

Equation 2

$$R_{UV} = \frac{\int_{\lambda=380\text{ nm}}^{\lambda=280\text{ nm}} R(\lambda) \cdot E_s(\lambda) \cdot S(\lambda) \cdot d\lambda}{\int_{\lambda=380\text{ nm}}^{\lambda=280\text{ nm}} E_s(\lambda) \cdot S(\lambda) \cdot d\lambda}$$

Equation 3

$\tau_{UV}^{0^\circ}$	$R_{UV}^{145^\circ}$	E-SPF <sup>TM</sup>
5%	10%	7
5%	5%	10
1.5%	5%	15
0%	4%	25
0%	2%	50

Table 1



Figure 2

[1] Rosenthal FS, Bakalian AE, Taylor HR. The effect of prescription eyewear on ocular exposure to ultraviolet radiation. Am J Public Health 1986; 76: 1216-1220.

[2] van Norren D, Gorgels TG. The action spectrum of photochemical damage to the retina: a review of monochromatic threshold data. Photochem Photobiol 2011; 87: 747-753.

[3] Hoover HL. Solar ultraviolet irradiation of human cornea, lens, and retina: equations of ocular irradiation. Appl Opt 1986;25: 359-368.

[4] Andley UP, Malone JP, Townsend RR. Inhibition of lens photodamage by UV-absorbing contact lenses. Invest Ophthalmol Vis Sci 2011; 52: 8330-8341.

[5] J Krutmann, F Béhar-Cohen, G Ballet, T Ayguavives, P Ortega Garcia, P Peña-García, C Remé & J Wolffsohn. Towards standardization of UV eye protection: what can be learned from photodermatology? Photodermatol Photoimmunol Photomed 2014; 30: 128-136

[6] ISO 8980-3:2013 Ophthalmic optics – Uncut finished spectacle lenses – Part 3: Transmittance specifications and test methods. www.iso.org/iso/catalogue\_detail?csnumber=51052 (Accessed Apr 20, 2014)

[7] Citek K, Johnson E, Keita G. Eye-Sun Protection Factor (E-SPF<sup>TM</sup>): a new index that considers spectacle lens coating, curvature, configuration, and coverage. Association for Research in Vision and Ophthalmology Annual Meeting, Fort Lauderdale, FL, USA, 2012.

[8] Behar-Cohen F, Ballet G, Ortega Garcia P et al. Ultraviolet damage to the eye revisited: Eye-Sun Protection Factor (E-SPF<sup>TM</sup>), a new UV-protection label for eyewear. Clin Ophthalmol 2013 (accepted for publication).

## Worldwide regulation for sun protection

Since first sunscreen efficiency evaluation, regulations continuously change. In order to have products safe on the market, it is very important to follow up-dated standards and methods. But, although a global harmonization is in course, each country has its own particularity. We are pleased to summarize all current standards and methods according to market zone for helping you.

	Broad spectrum In Vitro	UVA-PF & CW In Vitro	SPF In Vivo	SPF In Vivo	UVA-PF In Vivo
	FDA MONOGRAPH 2011	ISO 24443 2012	ISO 24444 2010	FDA MONOGRAPH 2011	ISO 24442 2011
<b>AFRICA</b>	NO	<b>YES</b> *according to SANS 1557:2013	<b>YES</b> *according to SANS 1557:2013	NO	<b>YES</b> *according to SANS 1557:2013
<b>ASEAN</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>
<b>ASIA</b>	NO *accepted by China & Taiwan	<b>YES</b> *excepted China, Korea Japan	<b>YES</b> *excepted China	NO *accepted by China, Korea & Taiwan	<b>YES</b> *excepted China & Korea (JCIA PPD method)
<b>EUROPEAN UNION</b>	NO *rarely	<b>YES</b>	<b>YES</b>	NO	<b>YES</b>
<b>MERCOSUR</b>	NO	<b>YES</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>
<b>NORTH AMERICA</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>	<b>YES</b>
<b>OCEANIA</b>	NO	<b>YES</b> *according to AS/NZS 2604	<b>YES</b> *according to AS/NZS 2604	<b>YES</b> *excepted Australia	<b>YES</b> *excepted Australia
<b>USA</b>	<b>YES</b>	NO	NO	<b>YES</b>	NO

SPF: Sun Protection Factor  
CW: Critical Wavelength  
UVA-PF: UVA Protection Factor

**AFRICA:** South Africa.  
**ASEAN:** Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam.  
**ASIA:** China, India, Japan, Korea, Russia and Taiwan.  
**EUROPEAN UNION:** Austria, Belgium, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Czech Republic, Romania, United Kingdom, Slovakia, Slovenia, Spain and Sweden.  
**MERCOSUR:** Argentina, Brazil, Chile, Paraguay, Uruguay and Venezuela.  
**NORTH AMERICA:** Canada and Mexico.  
**OCEANIA:** Australia and New Zealand.  
**USA:** Alaska and United States.

Furthermore, improvement of sun protection for consumer leads to propose recommendations of several types: labelling, conditions of use, measurement methodologies of protection values, specific tests of security and stability. Thus, the table here below presents an overview about the sun protection claiming which is often complicated such as each country has one more time its own particularity.

	SPF protection category				UVA protection category			
	Low	Medium	High	Very High	UVA Protection (Logo)	PA Protection (PA+, PA++, PA+++, PA++++)	Boots Star Rating System (***, ***, ****)	Broad spectrum
<b>AFRICA</b>	6, 10	15, 20, 25	30, 40, 50	50+	UVA-PF ≥ 1/3 SPF & CW ≥ 370 nm	-	-	-
<b>ASEAN</b>	6-10	15-25	30-50	≥ 50	UVA labeling not specified but all accepted			
<b>ASIA</b>	No protection category required. Chinese: SPF 2 min - SPF 30+ max India: SPF 50 max Japan: SPF 2 min - SPF 50+ max Korea: SPF 50 max Russia: Tends to align with EU Taiwan: SPF 50+				Russia: Tends to align with EU	India Japan Korea	-	-
<b>EUROPEAN UNION</b>	6, 10	15, 20, 25	30-50	50+	UVA-PF ≥ 1/3 SPF & CW ≥ 370 nm	-	Also recom- manded for UK	-
<b>MERCOSUR</b>	6-14.9	16-29.9	30-50	>50 to <100	UVA-PF ≥ 1/3 SPF & CW ≥ 370 nm	-	-	-
<b>NORTH AMERICA</b> <small>Mexique Canada</small>	6, 10	15, 20, 25	30-50	50+	UVA-PF ≥ 1/3 SPF & CW ≥ 370 nm	-	-	-
	-	15-29.9	30-50	50+	UVA labelling optional - no guidance but all potentially accepted			
<b>OCEANIA</b>	4, 6, 8, 10	15, 20, 25	30, 40, 50	50+	UVA-PF ≥ 1/3 SPF & CW ≥ 370 nm	-	-	-
<b>USA</b>	No protection category required. Proposal for SPF 50+ limit in future				-	-	-	Broad spectrum ≥ 370 nm

## II. In Vitro comparison method: producing, ageing, formulation

### II.a. Introduction

Beyond the determination of the sun protection by means of In Vivo and/or In Vitro methods for claiming, we must not forget that sunscreen is designed to protect the consumer. It is therefore necessary not only ensuring a «level» and «quality» of protection, but it must also ensure its stability and conformity: batch to batch when it is industrially manufactured; or when it is subjected to small minor changes that do not require a complete review of all tests; or when the product ages.

As there are several endpoints - SPF (Sun Protection Factor), UVA-PF (UVA Protection Factor), CW (Critical Wavelength)... - a single checking is not possible to ensure the equivalence between the products but a global comparison is required. The In Vitro comparison method based on a statistical interpretation has been already published<sup>[1]</sup> and also described in a previous HelioNews (HN5). For reminder, two rules must be followed:

- Compare at the same time and same conditions
- 3 checking based on curves, variability and averages.

The aim of this paper is to present results about one application of In Vitro comparison method extracted from a publication<sup>[2]</sup>: the ageing control of a sunscreen.

### II.b. Results

A study has been performed based on sun protection assessment of three types of product (SPF15, SPF30 and SPF50) during one year (t0, t1, t2, t6 and t12 months) and compared to the references products (t0). From the results presented in Figures, different conclusions can be made about the stability of sunscreens according to comparison method.

First, according to the type of product, it seems that the sun protection performance observed by means of the comparison method could decrease in time (out of Dispensation limit) according to product due to ageing without any significant modification detection by UV filters dosage.

Second, the comparison values based on total UV absorbance spectrum demonstrate that the comparison method is perfectly dedicated for the ageing test as it is simpler and stronger. Furthermore, this method well predicts the trend of stability of the product with minor variation highlighted but not rejected (Acceptation area, Threshold area and Dispensation Limit evolution).

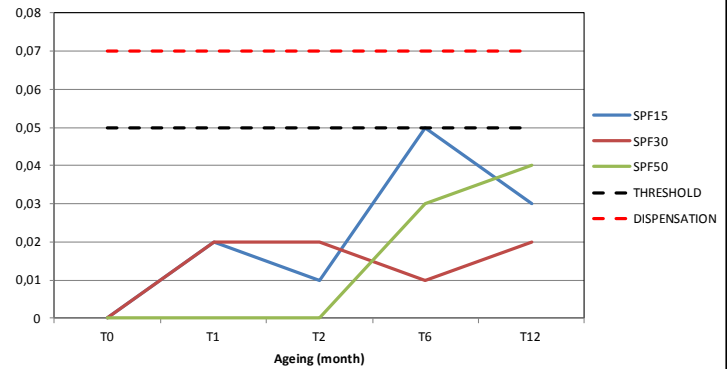
### II.c. Conclusion

In conclusion of this part, this method can be used to compare products supposed to be similar during ageing. It appears that the comparison method is a powerful tool for sunscreen development and quality control which by principle checks conformity of the tested product compared to a standard. Indeed, it has been demonstrated that without any strict control of the product based on UV measurement, if the sun protection effectiveness decreases during ageing, it could be no detected and the consumer could have a health risk during UV exposure.

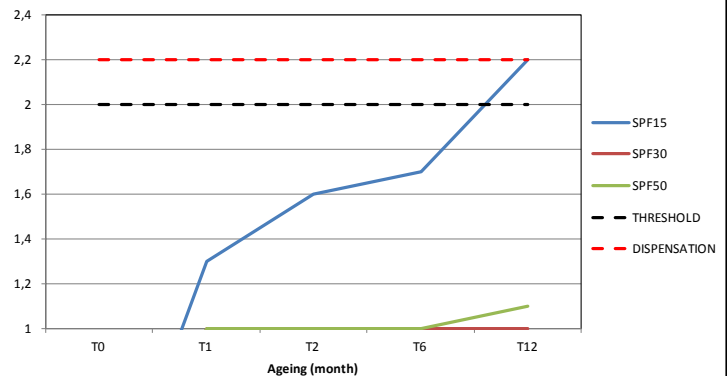
According to other applications and conclusions very close, the health authorities worldwide should always check the quality control of sunscreen protection efficiency according to different batches, ageing or formula clearly not based on theory but on a practical test by means of an adapted comparison method.

[1] Dominique Lutz and Sébastien Miksa. In vitro comparison - A new accessible and reliable statistical method to compare the global UV protection properties of cosmetics. H&PCToday and Monographic supplement SUN CARE - Vol 8(4) July/August 2013  
[2] D. Lutz, S. Miksa and C. Guy. Sunscreen products: Some practical applications for a new comparison test method to help Development and ensure Quality controls. H&PCToday July/August 2014

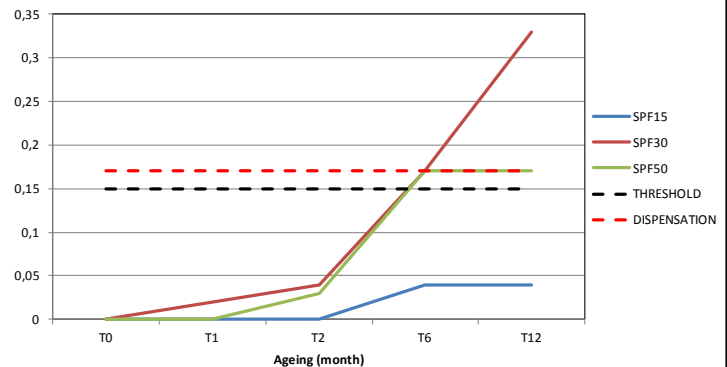
Curve comparison according to product ageing



Standard Deviation comparison according to product ageing



Average comparison according to product ageing



### Scientifics articles

[Photodermatol, Photoimmunol, Photomed • June 2013:](#)  
- M. Pissavini, B. Diffey. *The likelihood of sunburn in sunscreen users is disproportionate to the SPF.*

[IFSCC Magazine • 4/2013:](#)  
- S. Pyle, D. Lynn, D. Ross. *In vitro Study into the SPF and UVA-PF Using Different Applicators*

[PERSONNAL CARE Magazine • June 2014:](#)  
- S. Miksa, D. Lutz et C. Guy. *Overview of sun protection factor assessment methods.*

[H&PC Today • April 2014:](#)  
- G. R. CASALE, A. M. SIANI, A. COLOSIMO. *A UV Index sundial on compact disk.*

[H&PC Today • August 2014:](#)  
- D. Lutz, S. Miksa et C. Guy. *Sunscreen products: Some practical applications for a new comparison test method to help Development and ensure Quality controls.*

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[Industries Cosmétiques N°2 – Supplément Contrôles Essais Mesures N°47 • JUIN 2014](#)

- D. Lutz. *AVIS D'EXPERTS | Contrôle de la production. Produits revendiquant une protection solaire : Enfin un outil adapté permettant le contrôle lors de la mise sur le marché.*