

HelioNews

CELEBRATING
ORIGINAL
SPECIAL REPUBLICATION
15 years 1999-2014



HelioScreen

News about In Vitro Sun Protection Testing

editorial

Contents

- Editorial
- ISO 24443 standard / New rules for In Vitro testing.
- New services and product from HelioScreen Labs
- A New logo for HelioScreen labs

Highlight of the month :

ISO 24443: The rules that will change requirements for In Vitro Testing.

- HDX plates a new proposal for thermo stability control .

In the next issues..

In Vivo/ In Vitro test Do we have really to choose ?

HelioScreen Labs

44, rue Léon Blum

60100 Creil

Phone: +33 3 44 24 33 29

administra-

tion@helioscreen.fr

Updated version

Few modifications have been performed (highlighted with *) in order to avoid misleading in comparison with original version in French.

That is completed! The first international method using *In Vitro* testing, is now ready to be published ! Indeed the COLIPA UVA method already allowed to switch from *In Vivo* methods towards *In Vitro* ones as recommended by EU in 2006, but in fact, most of the laboratories have been still using *In Vivo* ppd UVA method because products are also marketed in no EU countries.

Now we can expect most of the legislations and local regulations will be in line with ISO standard conditions and *In Vitro* testing will be more and more trusted.

HelioScreen Labs has developed a very complete offer for *In Vitro* testing from substrate, to a complete offer of tests.

In Vitro testing is more complicated than it looks like and there is still a lot a work to do to reach a world while consensus for every kind of testing.

But all the same, this association of *In Vivo* and *In Vitro* testing methods allows now a complete analysis of the properties of any product. New standard UVA 24443 is an illustration of this association.

Again HelioScreen has been a fore runner with its partner DermScan on this concept with the first *In Vivo/ In vitro* Eu and US pack and now new original propositions for testing to be presented very soon!

Indeed *In Vitro* methods are not just for claiming, or to reduce the cost for compulsory tests but this is to allow a comprehensive development for the Sun protective formulas.

You can take now for sure we (HelioScreen Labs) will be still a main actor in the future.

DL

ISO 24443 UVA: The rules that will change requirements for In Vitro Testing.

This article will be developed By D Lutz 17 April 2012, 14:00 – 18:00, Plano Salas Hall Europa 1.1at In Cosmetic 20142 Barcelona in the scientific seminar: "Spotlight on Sun Protection "

As the new UVA international standard ISO 24443 is **the first world-wide *In Vitro* accepted method**, we can expect the conditions described within for realization will be more or less the base for a consensus for further methods based on the assessment of UV transmittance through a thin film spread on a roughened substrate.

The fact is *In vitro* methods are not yet widely accepted or at the least if quite used for screening not at all with the same rules and methodology. This can lead to results sometimes very dispersed between testers.

Clearly every one refers to the description more or less suggested first by B Sayre and then by B Diffey in 1989 in the whole principle but it is far from being sufficient.

In EU where Critical Wavelength is compulsory, you can take for sure its determination is in most cases not realized in the conditions described by COLIPA in its last revision (2011). included in the institutes

Till now, except the COLIPA method for UVA determination, (3) there was no description of the rules we have to keep with to ensure the reliability of the method.. But there are plenty of labs or institutes who perform *In Vitro* screening but not yet Colipa method.

As an example in EU where CW is compulsory, You can take for sure its determination is in most cases not at all realized in the conditions described by COLIPA in its last revision (2011). This is not only the case for industries but also for most of institutes.

That mean this test is not conducted as it is defined from the rules! Do you think it would be acceptable for the *In Vivo* evaluation ? (see p2)

New services and products proposed by HelioScreen labs

As the specialist of in vitro testing, HelioScreen Labs now proposes new services and products to fulfil requirements on new norm and allow to get reliable results for your testing:

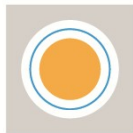
New! • **Reference sunscreen S2** (annexe E for ISO 24443 UVA and annexe C for ISO 24442 UVA).

• **Standard reference plates** for linearity assessment (Annex A Calibration of UV spectrophotometer). (See p 4).

New! • Service of **spectroradiometric irradiance measurement of UV exposure source** (only in EU) (Annex B ISO24443)
• **HD6 PMMA plates with certificate of compliance** (annex D ISO 24443)



S2 standard



HelioScreen

A New logo for HelioScreen Labs. *

HelioScreen labs has been created now more than 10 years ago and can be considered as a fore runner for In Vitro Tests.

Created 12 years ago under the Trade name of Helioscience, it changed the name in HelioScreen Labs five years ago as the same time it developed an international network of distributors both for tests and its well known patented substrate Heliplate HD6.

HelioScreen Labs moved recently in the north of Paris in a larger building, with available about five hundred square meter, a very modern and adapted laboratory and we are now in best condition to offer now full services in the best conditions.

Proposing now a wide offer of tests, services, specific substrate, calibrations, training, standard,



all services and products which are needed for In Vitro evaluation of sunscreen protection, Helioscreen has also developed a large network of collaborations and representations all over the world. HelioScreen now have to be identified within a new opportune offer of services for this kind of testing by companies which sometimes try to create the confusion.



HelioScreen has now also changed its logo Protect its particular identity and allow a clear identification and no confused one is the goal of this new graphic chart.
New trade name, new building and now a new logo but clearly an old and long expertise in the field of sun protection.

.. That happened under the sun ...

A new column for debate in Cosmetic & Toiletries.

A new column of Cosmetic & toiletries is proposed as a complement of indication about formulas and innovation. Following editor's information, this is intended to provoke constructive debate within the industry to lead toward an eventual resolution.

A good initiative in our opinion and the first debate is proposed by B Diffey with an article "What should the minimum Recommended SPF Be to avoid sunburn?

The question had already be on debate and especially from Health authorities. Recently The national institute for Health and clinical excellence in UK issued public guidance on skin cancer protection and recommended than sun screen had at least a protection of 15.

This is also as precised by B Diffey in his article (CT Feb 2012) more or less what have been mentioned by FDA in its last revision of the monograph in addition with broadspectrum requirement.

Nanotechnology in cosmetic and Sunscreen. A review proposed by Xia WU.

We know nanoparticles are found to improve the stability and efficiency of cosmetics. They are widely used in sunscreen especially with formulas containing metal oxides (TiO₂ and ZnO).

The author proposes a review or their use and properties in a very interesting paper in the April issue of CT.

Consumers are aware of nanotechnology regulations !

A coalition of 6 consumers safety and environmental groups has intending an legal action against FDA for having not mention any rule in its last monograph concerning sun protection with the use of nanotechnology.

There was a previous petition in 2006 and FDA is mentioned having accepted the use of nanotechnology without any rule about safety.

FDA had already answered mentioning it is a so complex debate, it has been impossible to fix specific rules and will need further information based on research to conclude;

ISO 24443 UVA: The rules

As a matter of fact, people are not all the time aware of these rules and just trust the tester (Institutes/ Universities etc...).

This time will be shortly over!

New International 24443 standard defines very precisely compulsory conditions and equipment for such an application.

Appliances

Most of laboratories have appliances proposed on the market which comply with the rules. The minimum required dynamic range is fixed at a minimum level of 2.2 absorbance units.

But also it is precised than "maximum measured absorbance should be within the dynamic range of the device..." That means clearly 2.2 may be too low for certain products

And as a matter of fact it is added: "In the case the yield measurement exceed the determinate upper limit of spectrophotometer, it is advised to retest on another ad hoc appliance!! "

So on a practical point of view this limit can be really too low to satisfy all measurements.

There is now a requirement for two calibrations and they must be documented.

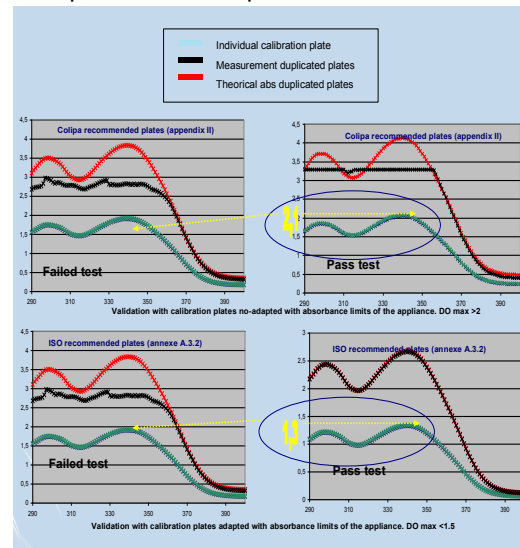
1/ Calibration system for accuracy

Dynamic range must be check with an Holmium Oxide filter.

2/ Calibration system for linearity

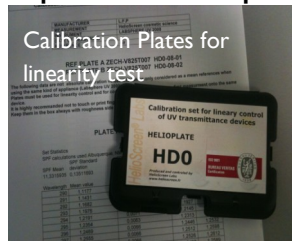
Linearity test must be performed with 2 transparent UV stabilized PMMA reference plates.

For this calibration, it is advised to be in line with the limits of its proper appliance. Also on this there is a little difference between Colipa and ISO recommendation, I would say some improvement due to the knowledge came from application of Colipa method. and those described by ISO standard there is a little difference: The difference is just on the maximum absorption value of the plate of reference.



that will change requirements for In Vitro Testing.... (continuation p 1)

As a matter of fact, when considering this test with plates described by COLIPA and those described by ISO standard there is a little difference: **The difference is just on the maximum absorption value of the plate of reference**



We can see on the previous graph the use of two kind of plates for calibration ("Colipa conditions" (Schoenberg plates) up and "ISO conditions" (Helioplates HD0) down). Also two different appliances (right and left) . First passes and the second fails.

Only the choice of the reference plates within the range of ISO will allow linearity testing interpretation between these two appliances.

If the appliance doesn't allow measurements over a value of 2.8/3 (which is already higher than the required limits), the test is impossible with the plates recommended by COLIPA on the upper part) . There is no difference between the two measurements as there is some saturation.

Within the ISO specifications for the standard plates, the difference is readable. We can state the right appliance pass unless the left fail!

Clearly this couldn't have been the case for a spectrophotometer which allow measurement of high value of absorption, but it is not required and also not representative of most of the spectrophotometer on the market for this purpose !

So the conclusion is you have to choose correctly the plates for control unless you will be unable to control correctly the linearity.

UV exposure appliance.

The UV exposure is a very important step in the method and must be conduct in ad hoc conditions.

Still these days, most of the irradiation step are conducted with appliances (such as sun test) without the knowledge of the emission in UV and especially in UVA range..



Specifications of UV emission is defined and

set point total irradiance	UV 280 – 400 nm	UV-A 320 – 400 nm
	W/m ²	W/m ²
500 W/m ²	76,2	71,3

Example of UVA calibration from HelioScreen labs

obtained with most of the appliances "normally used" in the labs nowadays but there are now new very important requirements:

Calibration system for initial monitoring and Calibration system for control before testing.

The standard make compulsory to check the

UV emission at least every 18 months with a spectroradiometric inspection (to do it by one self if equipped or to ask some expert to do this).

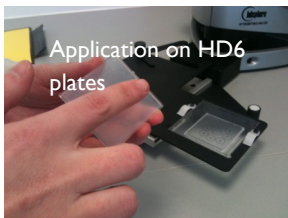
This allow at the very least to be able to calculate the relation between the delivery dose and the time required for exposure.

But it is also now compulsory to check appliance before each application with a radiometer.

So the requirement is to have the calibration of the UV exposure (certificate or home measure if equipped) and additionally to have a least a radiometer with sensibility in UVA range calibrated for the same spectrophotometer.

So the time when it was possible to use the UV Visible exposure source already existing for ageing or stability testing is over. This appliance must be now dedicated and controlled.

Substrate



Every one agrees substrate is indeed an important parameter to ensure reliability and this is one of the element most studied by ISO committee which realized several international ring tests when establishing the rules on the base of COLIPA method.

ISO requires plates defined as follow:

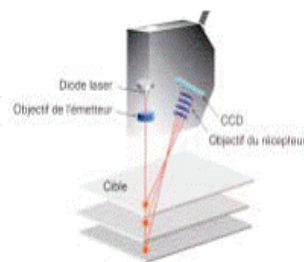
"A Polymethacrylate (PMMA) plate with a molded surface that has the following surface parameters (Fig 1) within the upper and lower limit values was qualified for use for this In Vitro UVA test method via ring testing »

Why being so specific?

Indeed the method is based on transmission and measurement of a thin layer of product spread on a substrate and it is understandable this is an important not to say essential parameter to ensure the reliability of the method.

First, it has been demonstrated, or must exactly confirmed the roughness is important and high roughness (5/6 microns) allow better correlation than 2 microns. This has been also demonstrated by COLIPA in the mean time.

But it is not sufficient and it has been also demonstrated the quality and remained topographic properties of the plates is an essential parameter to ensure reproducibility.



Altisurf. From Altimetreor substrate quality certification (Use by HelioScreen Labs)

A surface profile has been described It was in fact a control card which had been defined, based on the statistical results of a great number of batches ,for the Helioplates HD 6 plates published by Pissavini and al.

It has been now proposed, as a normative rule and it has also be as so for the last revision of the Colipa method (2011).

Measurement of this parameters must be docu-

Plate roughness parameters Fig 1						
PMMA plates should have surface topography characteristics that meet the following measurement targets and ranges, measured using instrumentation of the type referenced above:						
Target Roughness with Upper and Lower Limits						
Parameter	Ra	Rv	Rdq	A1	SSc	Vvv
Target value	4.853	13.042	11.122	239.750	0.033	1.044E-6
Upper Limit	5.170	13.669	12.411	284.256	0.046	1.663E-06
Lower Limit	4.535	12.414	9.833	195.244	0.020	4.248E-07

mented or performed with a specific non contact surface topographic analysis consisting in an optical sensor based on the white light monochromatic aberration principle which allow a high resolution.

Product of reference S2

Also as for COLIPA method a reference sun-screen has been chosen as the product for in vivo testing calibration with a normal correction with the C factor on the base of a value of 16 for the SPF and excepted UVA pf in this bracket.

This is not in our opinion the best choice as long S2 is poorly stable and difficult to be spread either In Vivo or In Vitro. There is a great correction with a low C coefficient but on the other way it allow the validation on difficult conditions.

CONCLUSIONS

The 24443 standard has define very specific, calibration and checking, most of the time as normative rules which are summarized in the chart 1.

This is what you have to fulfill with if you are performing the tests in your laboratories or what you have to check and require if you test through any institute.

We can state now this new ISO 24444 standard for UVA determination is really a reliable method which allow correlation with In Vivo ppd methods.

Clearly, there are still difficulties for products out of the range of the correction admitted calculation but it is really an artifact on the transmission measurement, not a failure of this method.

This is the first In Vitro worldwide method and for this reason **it is important to consider conditions , normative rules and obligations as there insure the reliability of the results.** The same tests have been realized for year without any rules or consensus.

For these reasons we can also consider the publication of this method will also change all the context around in vitro testing as it has been the case for in vivo testing years ago.

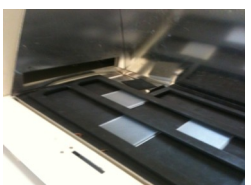
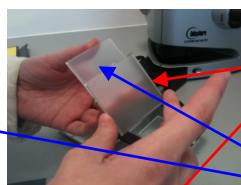
HD"X": Proposal for thermo stability evaluation during photostability test.

When performing a test of photo stability, we are never sure the possible degradation is only due to photo exposure.

Unless the control of the temperature in the sun test, some product may be quite sensible to the elevation of temperature.

It is advisable to check by controlling the effect of temperature and it is possible by exposing separately the product in an oven or covering the product while irradiating.

Considering the geometry of Helioplates HD which have been conceived to avoid any contact of the roughened surface when we apply the product, HelioScreen has developed a specific HELIO-PLATE HD X including some UV filter.



HDx plates containing UV absorbers

HD6 plates with spread product for testing

Plates HDX are disposed over HD6 plates to avoid UV transmission unless other HD6 plates are not covered

During the photo stability test, it is advisable to put on product in the same condition but covered with this plate which block the UV. Degradation can be then estimated either for thermo and photo degradation on a very easy way.

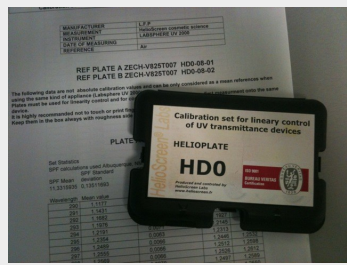
The HDX plates allow to compare the behaviour for UV+ heat exposure with only heat exposure.

Some times what we thought being a photo degradation is a thermo degradation. In these examples it is shown products with quite the same residual efficacy after irradiation but with two

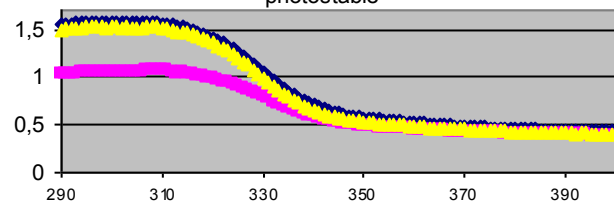
different behavior.

In first one, it is essentially due to photo stability, in second partly due to photo instability and partly to thermo stability.

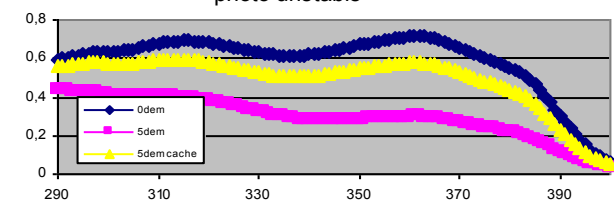
HD"0": A proposal for linearity control of the appliances



Example of a product thermo stable but not photostable



Example of a product thermo AND photo unstable



Strange allusion

B Diffey, the very well famous sun protection expert critiques the current SPF method and asks all the actors to think about a new way to express the sun protection. At the very least, he proposes a debate on what could be essential in addition with a minimal required protection around 15.

Just to remind B Diffey is most of the time the one who allows the determination of the in vitro SPF, proposing either a transmission method and a substrate 30 years ago.

Reglementation

Unless the two first ISO standard 24444 and 24442 respectively for In Vivo SPF and UVA pf determination has been already published, the UVA in vitro standard 24443, unless accepted and in FDIS stage has not been published yet. However it has been the base for the revision of New Zealand and Australia AS/NZS 2604 standard either for SPF and UVA protection determination. Australia would have liked to propose a combined standard for SPF and Water resistance, but it has been finally agreed to proceed separately with the new draft standard ISO/WD 16217.

Scientific articles

"A new method to reproduce In Vitro Cosmetic Product photo stability finding" By M Pissavin and al (C&T March 2012)

The author proposes a new way to determine the photo stability of a sunscreen. Unless the process of photo degradation is still conducted as with the Colipa method for UVA (exposure of a product spread on roughness PMMA moulded plate), the authors pointed out the lack of reproducibility inter laboratories when re-measuring the plates proposes to estimate the residual filters by using a re-dissolution and measuring residual absorbance in solution.

Nanotechnology in cosmetics: A Review By Xiao Wu, (C&T March 2012)

A review of application and consequences of the nano technology including in sun protective products.

Companies information

International Beauty Office now offers to the French and EU companies a new branch to hand over any legal question for cosmetics and perfumery product in EU market. **Laboratory BIO-EC** specialist in preparation of human skin models now proposes new services in cosmetogenomic. **Intercheck** specialising in analysis and inspection has announced a new service based on consumer panel for used tests.