HelioNews 2011 N° 11

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HelioNews

The current events of the sun protection proposed

CELEBRATING 15 years 1999-2014 — SPECIAL REPUBLICATION

HelioScreen

Summary

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Updated version

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

Editorial …

We are not at the end of the long way which will carry out towards a method for the *In Vitro* SPF evaluation considered by every one as reliable. If it is obvious for me that the evaluation of the SPF by this method is already quite reliable in case…. we have a great experience, knowledge to make "adaptation" for certain products and so compensate some technical difficulties to get good spreading. But we cannot be satisfied with this established fact. The pressure of the timing in the international authorities who would like to standardize a method is strong because of the laid down rules. A group of international experts, to which I am belonging, has been constituted under proposal of ISO TC217 to try to propose new ways more effective than that which we use to follow ring test after ring test. Colipa also did an important and interesting work on the subject without succeeding in putting a final key at the proposal for a reliable method in all the cases.

Health authorities are impatient rightly while pointing out that all the same if all is not perfect, the existing method gives significant and reproducible results. As an expert of these tests for quite several years, we have our analysis of the possible reasons inducing these difficulties. The fact is there is no other way for us to circumvent every day. The time of this debate has come! We already proposed a new substrate to cure the problems of reproducibility as far as possible, it is now necessary to go further and our laboratory cannot remain without making proposal. To paraphrase JFK, we could state that *In Vitro* tests being the essence of our trade and made it possible for our laboratory to exist. We should not ask us what *In Vitro* tests did for us but what we can do for them! This is why it seems important for me to express my convictions on the subject and to hope to contribute positively to the long way towards THE universal method. DL

Is the improvement of interface properties Plate/ Product , a key for SPF evalua-

In Vivo towards *In Vitro* : A difficult evolution..

As in much of other fields of evaluation, the *In Vitro* methods for the control of the effectiveness of the solar products have to substitute the *In Vivo* ones for ethical and any other reasons. Additionally, They would be also sometimes, no other choice to go towards *In Vitro* evaluation due to the evolution of the products and/or new requirements for further controls which could be inaccessible by *In Vivo* methods (i.e photostability / Critical Wavelength..).

As in much of other fields, *In Vivo* methods have been used for evaluation for years. They have been relatively well accepted in the whole world and quite well understood by the consumers. The switch from *In Vivo* methods evaluation towards simulations based on physical analysis, mathematical calculations, seems always criticisable because one moves away from the real conditions of application, directly on the skin. Justified or not, a method based on voluntaries may have sometimes variability which one accepts easier than the unavoidable weakness of any test of modelling.

Then it is often complicated to forget the quite old reference frames (biological reaction of the subject.) to consider another approach - more analytical. For the validation of the methods of substitution, It is necessary imperatively to compare and trust the reference results of the *In Vivo* initial method.

In Vivo towards *In Vitro* : A possible confusion..

The principle of *In Vitro* test consists in measuring the capacity of a product "to block" or "to deviate" part of the UV energy by mean of the measurement of the residual spectrum of transmission of an UV irradiation which crosses it.

(continuation page2)

A new representation of HelioScreen in China

After the last representations in USA (2009) and Japan (2010) , Helioplates are now directly available in China and Taiwan since last month.

Customers from this part of the world can contact directly our representative

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Publisher : D Lutz dlutz@helioscreen.fr

finally rather easily these difficulties by developing "adaptations" according to the type of product .This is largely demonstrated when it is possible to confront the working methods of manipulators of various laboratories for example at the time of a ring test with testing within the same laboratory but with people from different companies.

Whereas it would seem obvious to be posed the relevance of multiple methodologies, as it is shown in a pragmatic way that only, a certain adaptation to the products (and according to products!) makes it possible to generally guarantee a relevant result, our objective is to seek THE universal method which will guarantee all the results.

Worse, to validate the method, when any new method is proposed, a ring test is organized….with several products, and thus one obtains a result which is an average which depends on the choice of the panel of products. In case it arises acceptable, it may appear ineffective further on for another panel of products..... **It appears for the same rather illusory reason to seek which is the good gesture, the good pressure, to adapt to a known result, since this adaptation will be valid only for the type of product considered or at least rather close. And yet it is obvious that it will be necessary to find a method and not methods....**

Possible reasons for variability and poor correlation

Once best acquired reproducibility, the correlation will have to be guaranteed! However it is shown that we can have a good reproducibility and not inevitably a good correlation. The reciprocal is of course, completely false. In order to find solutions, it will thus be advisable first of all to consider the reasons which explain why there is bad reproducibility and/or a bad correlation.

The reasons could be exogenous (1) or endogenous (2). In order not to mix all the problems, the principal reasons of the dispersion of the results and sometimes of their bad correlation with the In vivo results are recalled in the following table (see below).

Once more the good correlation is defined as the comparison of the average *In Vivo* and *In Vitro* results.

Various exogenous or endogenous problems are too often present in the process of ring tests to estimate validation of a method. Most of the time, they are even badly identified and likely not to allow a good estimation of the reliability of the method.

Our present purpose is however to only consider the endogenous problems involved in spreading out. Indeed those represent an imperative reason of variability even of bad correlation which are truly due to the principle even of in vitro method.

Spreading is an essential parameter for reliability of the test !

One should keep in mind the reliability of the measurement of transmission will directly depends on the properties of the film of product formed on the substrate. Regularity of this one will affect the homogeneity of the measurement.

The product will have itself to be applied under rigorous conditions but will have to also be in the physicochemical state most stable as possible. It is thus strongly indicated to pre condition the product at a constant temperature and relative humidity before the test. In the same way, the plates cannot be completely inert with their environment and according to the temperature and the ambient HR will be able to also take different energies of surface even different conformations. The same applies to the difference of the conditions of conditioning for either substrate and the products, right before the test. Tests carried out in our laboratory made it possible to define substantial difference on a cosmetic product running for the evaluation of the same product conditioned to a certain temperature on plates conditioned under different conditions.

The problem of the difficulty of spreading out is directly related to the variability of affinity between a material whose properties of surface are fixed and those of various products which have variable properties. The physical laws and thermo dynamic cannot be opposed to any approaches methodologies which would define adapted gesture (way of proceeding, pressure etc…) for the resolution of problem of interface of which will unrelentingly depend quality on film and thus on that of our measurement.

Product conditioned 24H at	Substrate conditioned 24H at	SPF Value Mini CI 95%	SPF Value Maxi CI 95%	UVA pf Value Mini CI 95%	UVA pf Value Maxi CI 95%
25°c	15°c	49,3	58	22,8	26
25°c	25°C	57,2	63,2	26	28,2
25°c	35°c	65,4	73,8	28,2	31,2

Indicative test of the influence of the conditioning conditions for substrate and product on the SPF and UVA pf values.

Surface properties are also an essential parameter for quality of spreading :

If the improvement of the recent new proposed HD6 substrate due to the fact the topography is perfectly controlled will improve the reproducibility, the question of the physical adequacy between substrate and product cannot be universally solved. The proposal of any another material (even with essential the pre required conditions), of any other roughness would not come either to better end due to the essential thermodynamic rules.

Whereas it is logical in other industries to pose the problem of interface as one wants to put in intimate contact two products with antagonistic properties, as in the industry of sticks, serigraphy or even in cosmetic as we can considers there are same problems applied to the liquids, it seems that in this case, one wants to be obstinate to seek the solution in the address of the manipulator, the complexity of the method of application or the intermediate product miracle.

	Concern	Description of the problem (no exhaustive ??..)	Influence on reproducibility	Influence on correlation
1	Product	1 Bad stability (or evolution while spreading) 2 Limit or bad of solubility for certain filters .(some times solved with slight heating such as while In Vivo testing or pre irradiation in vitro step) 3 Contains a product or combination which boosts the *In Vivo* SPF for biological reasons. 4 Photo instability 5 Bad pre conditioning of the product. 6 Evolution while spreading (great loose of solvent, precipitation etc..)	+++ ++ +++	+++ ++++ +++ + to ++ + +++
1	Referential	1 The *In vivo* value with which is compared the *In Vivo* one is badly estimated. (Most of the time it is a problem of comparability between two mean values than should be better compared between confidential intervals ranges). 2 Influence of appliances on results (i.e in a ring test with several appliances) (see next page).	 +	++
2	Substrate	1 Roughness badly appropriate (too much/ too low or not regular) 2 Quality of the surface (irregularity intra and/or inter plates). 3 The spreading has been done in bad conditions. lack of experience) 4 bad pre conditioning of the plate. 5 Bad affinity product/plates = INTERFACE properties	++ +++ ++++ + +++++	+ + ++++ + +++++

Patents ...

- **Patent** EP2275176 deposed 19/01/11 by JOHNSON & JOHNSON CONSUMER [US] concerning : Detecting topic antisun composition by fluorescence. :

A method of detecting the presence or amount of sunscreen on an explants of skin using a kit comprising a composition comprising one or more oil or water soluble ultraviolet sunscreen agents and a fluorescent chromophore, wherein the fluorescent chromophore is oil soluble and has a wavelength of excitation greater than about 400 nm; and a device for determining the presence of the composition on a surface, which device comprises a light emitter, a light detector, an electronic evaluation system to determine the level of fluorescence of the fluorescent

-Patent *7891361*

Publication date: Feb. 22, 2011

Assignee: PhotoMedex

According to this invention, skin disorders such as atopic dermatitis, dyshidrosis, eczema, lichen planus, psoriasis and vitiligo, are treated by applying high doses of UV light to afflicted regions of an individual's skin. The dosage exceeds 1 MED as determined for the particular patient and may range from about 1 MED to about 20 MED or higher. The UV light has a wavelength within the range of about 295 nm to 320 nm are delivered by a specialized handpiece.

-**Patent** *7888001*

Publication date: Feb. 15, 2011

Assignee: STC.UNM

This patent describes a system and methods of establishing a Melanocyte Protection Factor (MPF), which indicates the level of protection against DNA damage to a target cell, such as the level of protection a particular sunscreen offers against UVA rays when compared to the unprotected case, i.e., no sunscreen. The invention determines and records levels of stable melanin radicals (SMR) in a target cell. Light is applied to the target cell forming light-induced melanin radicals (LIR). The levels of SMR and intensity of LIR are measured to determine the amount of incident light reaching the target cell.

- **Patent** *US7897779 deposed 1/03/11 by DSM IP ASSETS BV [NL] and concerning :* ***Ionic UV-A sunscreens and compositions containing them :***

The present invention relates to novel 1,4-dihydropyridine derivatives, to novel cosmetic or dermatological sunscreen compositions containing these derivatives and the use of these derivatives for photoprotecting human skin and/or hair against UV radiation, in particular solar radiation.

- Patent WO2011003655 deposed 13/01/11 by HENKEL AG & CO KGAA [DE]; YUECEL SEVDA [DE]; WALDMANN-LAUE MARIANNE [DE]; DICKHOF SUSANNE [DE]; JANSEN FRANK [DE] concerning : **METHOD FOR PRODUCING STABLE EMULSIONS, IN PARTICULAR SUNSCREEN FORMULATIONS :**

The invention relates to a method for producing emulsions comprising complexing agents, wherein the steps: a) providing an oil phase; b) incorporating at least one complexing agent into the oil phase, wherein the complexing agent is present in solid form; c) mixing with a water phase; and d) emulsifying are performed in sequence, providing shelf-stable and color-stable emulsions.

.. It happened under the sun

TiO2 a carcinogen ???

"Personal Care Products Council (PCPC)" prevents industry that TiO2 would be likely to be classified soon like carcinogen and fast request an action to dispute this classification

Nano sized TiO2 challenged again...

The nano titanium dioxide can be the pulmonary cause of ignition According to a recent study, the nanoparticules of dioxide of titanium (TiO2), largely used in the sun lotions, cause an ignition of the lungs in the event of inhalation. (www.premiumbeautynews.com 25/01/2011)

In 2011, the industry of the beauty will be green

To produce and to market more ecological products will be the principal challenge of the industry of the cosmetics in 2011, according to Mintel Beauty Innovations. (www.premiumbeautynews.com January 7, 2011)

Sunscreen to prevent cancers

Australian researchers have conducted a randomized trial on more the 1,600 Queesland residents and found that participants in the control group developed twice more melanomas than those applying (...) (www.premiumbeautynews.com August2, 2010)

Interpretation of SPF In Vivo results: Analysis and Statistical publication:

By: Marc Pissavini and Olivier Doucet, Coty-Lancaster; and Olivier Brack, Statistique Industrielle KHI2 Consulting (KSIC)

Empirical Evaluation of a Simple Analytical Formula for the Ultraviolet Index - Manuel Antón, and co - Photochemistry and Photobiology, Volume 87, Issue 2, p 478–482, 03/04/2011

This paper focuses on the estimation of the UV Index (UVI) for all sky conditions using a simple analytical parameterization involving three independent variables: the solar zenith angle, the total ozone column and the clearness index.

Is the improvement of interface

This product is spread, beforehand on a substrate in a layer as thin as on the skin when the product is test by *In Vivo* process. It is thus advisable to define an "ad hoc" substrate. The *In Vivo* test consists in evaluating the shift of the time of appearance of a specific biological response of the skin when this one is subjected to a certain irradiation with or without application of protective product.

It is often assumed that it seems essential for *In Vitro* test to be close as well as possible to the *In Vivo* conditions and by consequences of the real application, to improve the relevance of the test of substitution. This can generate counterproductive results!

Let us take two examples:

Concerning the substrate, it may be pretended it is better to require a topography close to the skin (unless it is completely indefinable so much the subjects are different) than the search for the most regular possible topography. Indeed the substrate must be defined as so to ensure what is essential in the test: a capacity to allow the best homogeneity of the film with lower thickness as possible since the physical law which is used depends directly on its quality (uniformity, thickness…).

It is not possible to spread out the product on the substrate right by depositing it and just apply a slight spreading: Most of the time, the product should "be forced" to be spread out to break more or less bringing energy depending on the forces of contact. This is made possible thanks to the roughness which allows shearing and finally allow the "best" contact as possible between the product and the substrate. One could believe that this roughness has been introduced to simulate the surface of the skin!! Not at all, the skin has properties which avoid this kind of chemical incompatibility with properties based on hydrophobic/hydrophilic balance.

The roughness of the substrate will then be defined either by the specialist of transmission measurement, as the maximum roughness making it possible to overcome the repulsion with spreading out while preserving a "minimal" thickness of film compatible with the physical laws and the performance of our apparatuses, Or ,it will be defined by the practitioner of the *In Vivo* test as the roughness closer as possible to the one of the skin or at the very least which would allow, thickness of film identical to the quantity spread out during the *In Vivo* test (2 mg/cm ²).

The goal of this discussion is thus to only contribute, but with the glance of the analyst (who often seems to be lacking), to the sempiternel debate of obtaining the "ad hoc" conditions of a measurement giving access the same results as those obtained by the *In Vivo* tests. Because it is the objective …and not that to define the best method in the absolute… what would be impossible besides since our comparative reference frame is not other than the result *In Vivo*!

Why *In vitro* results may be so variable ??

The first goal of an evaluation is to obtain a good reproducibility of measurements. It must be guaranteed either intra laboratory, or inter laboratories. All the manipulators know pertinently that in the current state of the art, this reproducibility is very dependent on the product. Certain products can be tested by no initiated persons with completely acceptable results whereas other products tested by entrusted manipulators show results very dispersed not to say… random! As a matter of fact the "expert" laboratories are left

The solution if it exists will pass by the reduction of the forces of contact and the possibility of being able to play on those according to the products to test.

How can we act on interface properties substrate/ product ??

The first approach is that which would consist in proposing a range of different substrates with different surface properties. This possibility had been considered by our laboratory during the development of the Helioplates HD6 but the choice for testing laboratories would have been enough complicate for the user and undoubtedly difficult to impose. Another possibility is the modification of the properties of surface of the substrate right before its use. This can be carried out by a chemical way or a physical way.

The chemical way would consist in proceeding as for the mixture liquid / liquid than the cosmetic industry solve every day by introducing the "ad hoc" tenside to the interface. Then, it would be advisable to define a product having on the one hand a fixed affinity for the PMMA and on the other hand a variable affinity according to the product to be tested. The solution to spread on the plate out a specific product as a pre treatment, even with a character with high wettability or amphoteric properties could not be either a universal solution but would undoubtedly improve a great number of cases.

The physical way would consist in treating the surface of the plate by modifying the energy of surface by a treatment ionizing and by adapting it to the measured product.

The finality of both approaches would be thus in some extent being able to adapt the affinity of the surface of the plate to that of the product to be measured. The forces of repulsion would be thus overcome and one can imagine that the product would be spread out unconstrained excessive or gesture particular. It seems indeed essential that the test become less "product depending" and thus doesn't need to much adaptation of the method to ensure the film forming ! It is however completely clear that the objective is not to return either the contact produced/plate such as that of water on a blotter but one can hope that this approach which requires an important and rigorous work that is to say an effective solution with the problem of spreading out and thus as a consequence for the final correlation.

Conclusions and perspectives :

Although these solutions are currently studied by our laboratory, it is premature to give indications on the results. No conclusion on the pertinence of these assumptions can be given to date but it seems that the difficulties related to spreading out can find a solution by the modification of the interfacial properties between the product and the substrate. Our conviction is that a solution could be considered only if spreading out is improved not only by the definition of ad hoc conditions for spreading out but by the limitation of the physical and thermodynamic constraints related to diversity of the products. Even if the experiment of the user remains important, it does not have to remain dominating on the quality of the test.

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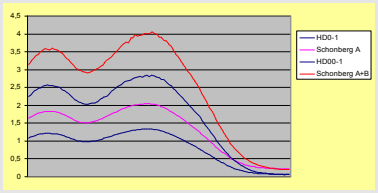
Influence on the SPF/ pf UVA values measured (without any influence of spreading) depending on the kind of appliance.



Four PMMA plates (2 molded and 2 sandblasted) including filters at different levels in order to simulate the absorption of a product with different level of protection have been measured in 6 different laboratories (using 1 or 2 appliances) in total 4 different kinds of appliances and 8 measurements including 4 measurements on the same kind of appliances (UV 2000 Labsphere) . The measurements have to be done without any influence of spreading as long it consisted in measuring directly the plates.

According to the spectrums (see above), SPF and UVApf expected ranges results was as follow:

	SPF	UVA pf
HD0-1	around 10	around 5,5
Schonberg A	around 28	around 8
HD00-1	around 60	around 10,5
Schonberg A+B	around 150	around 21

There is a little dispersion within the plates (better for molded than sand blasted) but results were very unexpected as long there were quite significant differences for SPF and pfUVA values depending on all appliances. These differences have been expressed either for pf UVA (with ppd curve) and SPF (with Albuquerque and SSR curves). Final results have been expressed as the mean and the maximum dispersion between appliances. Maximum difference refers to difference between higher and lower SPF values

As there are great differences between appliances (see 1st part of the table below), we also considered the results from the same kind of appliance in the down part of the table. Unless it is totally acceptable in these conditions, it is clear not all the labs have the same equipment and it would be considered when comparing results in the validation of any method.

	HDO	Schön A	HD00	Schô A+B
Dispersion of SPF between all the appliances (nbre 8)				
SPF mean dispersion inter appliances	5%	14%	9%	23%
SPF MAXIMUM dispersion inter appliances	13%	34%	18%	45%
SPF Albuquerque source. Minimal	9,4	23,1	52,3	112,0
SPF Albuquerque source Maximal	10,8	34,8	68,9	203,0
Dipersion of SPF between appliances for the same model (UV 2000) (nbre 4)				
SPF mean dispersion inter appliances	3%	6%	2%	4%
SPF MAXIMUM dispersion inter appliances	3%	8%	1%	5%
SPF Albuquerque source. Minimal	10,3	30,9	65,9	189,0
SPF Albuquerque source Maximal	10,8	34,8	68,9	203,0

Scientific articles

- Identifying melanogenesis inhibitors from *Cinnamomum subavenium* with *in vitro* and *in vivo* screening systems by targeting the human tyrosinase - Hui-Min Wang, Chung-Yi Chen, Zhi-Hong Wen - Experimental Dermatology
Volume 20, Issue 3, pages 242–248, March 2011

Comparison of the diagnostic accuracy of whole-body MRI and whole-body CT in stage III/IV malignant melanoma - Daniel Hausmann, Susanne Jochum, Jochen Utikal, Richard Christian Hoffmann, Christian Zechmann, Kurt Wolfgang Neff, Sergij Goerdt, Stefan Oswald Schoenberg, Dietmar Jörg Dinter - JDDG: Journal der Deutschen Dermatologischen Gesellschaft
Volume 9, Issue 3, pages 212–221, March 2011

Nanoparticles: small and mighty - Alison Wiesenthal MD, Lindsey Hunter BS, Shuguang Wang PhD, Jeffrey Wickliffe PhD, Michael Wilkerson MD - International Journal of Dermatology, Volume 50, Issue 3, pages 247–254, March 2011

Photodamaging effects of porphyrins and chitosan on primary human keratinocytes and carcinoma cell cultures - Mirela Susan MD, Ioana Baldea MD, Simona Senila MD, Victorina Macovei MD, Simina Dreve PhD, Rodica Mariana Ion PhD, Rodica Cosgarea MD, PhD - International Journal of Dermatology, Volume 50, Issue 3, pages 280–286, March 2011 -

Interest in cosmetic improvement as a marker for tanning behavior: a survey of 1602 respondents - Shelley Cathcart MD, Jamie DeCoster PhD, Marian Northington MD, Wendy Cantrell CRNP, Craig A Elmets MD, Boni E Elewski MD - Journal of Cosmetic Dermatology, Volume 10, Issue 1, pages 3–10, March 2011

Companies information

Shiseido : A new president still for a world while development.
Shiseido Has new president M. Hisayuki Suekawa, 51 , will held the Japenese company. He will replace M. Shinzo Maeda, 63, in April 2011. (www.premiumbeautynews.com)
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