Panel Discussion on Sun Protection

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The 15th Sun Protection Conference SUN19 in London (June 4-5, 2019) is a good reason to look at the current status of the most important questions on Sun Care in respect of trends, regulatory news and testing methods. Besides its brands and testing methods the area of Sun Care is quite unique in respect of regulations which are more complex than for other categories of Personal Care products, as the products are fairly near to pharmaceutical products. The typical consumer of sun screens is usually alerted by the danger of prolonged exposure to sunlight and, when trying to shop a fitting product for the next holidays at the seaside, will ask: is the product ok from performance point of view, is the feeling pleasant on the skin and is the fragrance nice? Does the Sun Care treatment survive a swim or two in the sea? And how much does it cost? And the stickers "natural product" and "not animal tested" on the bottle are preferred by most consumers as well. For the cosmetic manufacturer, there is a need to fulfil all these demands. In the following Panel Discussion we will collect some up to date answers from leading experts in the field of sun care.

The current trend for natural and sustainable products in Personal Care is not easy to cope within the Sun Care field as the oxide filters which are considered acceptable have still their issues and need a lot of formulation art and as well boosting additives which increase their performance. There is as well a limit for the Sun Protection Factor (SPF) as a number of higher than 50 or 60 is not meaningful anymore in real use. An SPF of 100 cannot be the target, again it is the formulation which must be so pleasant for the user that the Sun Care product is used in the required order and quantity to be sufficient for the claim. And as well the other megatrend of personalization of Personal Care products ends again in the question of setting up compositions which allow a defined tanning for individual consumers. The classic sun screen formulator skills to achieve a good dispersion and a sufficient rheological profile are still required for the next generations of Sun Care products.

From regulatory point of view Europe is now one of the more constant regions with the long established positive list of UV filters which leave formulators a lot of room as it contains a long list of actives. Environmental considerations have not been in focus of the EU-Cosmetics Regulation but with the REACH system a standard has been established which manages as well the Sun Care ingredients. In the US, the monograph of the FDA has a much smaller list of UV actives and further issues arose as actives are considered to cause harm to coral reefs which can have an impact on legislation in the future.
This is as well a major topic and area of continuing research in Australia. In Australia the situation is complicated by the fact that Sun Care products are either cosmetics or are regulated as therapeutic goods when the SPF is above 15.

Finally, the SPF testing needs discussion as well. The *in-vivo* testing of the SPF is now for a decade regulated according to ISO 24444. Still the demand for tests which are not causing sunburns to test persons is obvious. The *in-vitro* testing was long considered not reliable and the results could differ from test institute to test institute. This may change as a new method, Hybrid Diffuse Reflectance Spectroscopy (HDRS) is now emerging as a potential replacement for *in-vivo* testing. HDRS has been accepted by the ISO for consideration as an *in-vitro* test, still it is a hybrid method as it has an *in-vivo* part which is non-invasive and therefore ethically acceptable.

With climate change and growing exposure to sun light the need for safe and high performing Sun Care products is a challenge for the formulator as he has to consider as well all the other demands from the consumers and has to keep as well an eye on the environmental impact. Here new formulations, with boosting concepts based on ingredients which are as natural and sustainable as possible are required, and a regulatory and testing framework which is supporting this task. We are happy that with the 11 statements from globally well-known experts in this virtual panel discussion we can deliver a timely overview for you.

PANELISTS

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ALL COSMETICS ARE EQUAL, BUT SOME ARE MORE EQUAL – THE EU REGULATORY APPROACH ON SUNSCREENS

Gerald Renner
Director Technical Regulatory Affairs - Cosmetics Europe

In 1976 the EU decided to include sunscreens in the scope of its cosmetics legislation, going against the international trend of treating such products – due to their recognised public health benefit – as drugs / quasi-drugs or some kind of 'special' cosmetics. The EU rationale was the wish to give easy public access to sun protection and to stimulate future innovation, both of which are limited under drug-type legislation. The decision was facilitated by the fact that the EU legislation provided a detailed safety / regulatory framework, thus ensuring a high level of consumer protection.

It is, however, fair to say that sunscreens take a somewhat special place in the cosmetics legislation. Records show that the original draft definition of a 'cosmetic' had to be tweaked to accommodate sunscreens, by adding 'protecting' and 'keeping in good condition' as acceptable cosmetic functions. Also, already in 1976 it was clear that UV filters would be regulated through a positive list, although it was only formally introduced in 1983.

With regard product efficacy, the EU cosmetics legislation provides general rules to ensure that claims are fair and not misleading the consumer. But whilst these rules apply equally to all cosmetics, sunscreens are again more equal. Over the past 20 years industry developed a series of recommendations on UV-protection measurement (SPF, UVA, water resistance) and labelling (SPF, protection classes, UVA logo, use instructions).

ISO has taken an important role in validating measurement methods and providing a basis for their international regulatory acceptance. Indeed, since 2008 the EU Commission formally recommends the use of ISO methods (preferably *in-vitro*) for the substantiation of UV protection claims. The EU Commission also took over most of industry's recommendations regarding labelling of sun products.

Whilst the human safety and efficacy of EU sunscreens are taken as a given, concerns have been raised that the EU Cosmetics Regulation does not cover environmental aspects and cosmetics might therefore "escape" environmental legislation. Environmental assessments are indeed excluded from the cosmetics legislation, but only because a meaningful environmental management of chemicals has to be based on the overall environmental exposure. Consequently, all environmental aspects of cosmetics are covered under the EU Chemical Legislation (REACH). In this context, some UV filters have been flagged for potential environmental persistence, largely because they are designed to be stable and withstand harsh exposure to UV light. More detailed environmental assessments are ongoing and, if necessary, environmental risks can and will be managed under REACH.

For over 40 years the EU approach on sunscreens has been successful and, even with the advent of innovative ingredients and products (e.g. nanotechnology filters, secondary sun protection products), has not required fundamental changes. The EU positive list includes more than 30 safe and effective UV filters, protection claims are based on standardised and objective methodologies, and harmonised labelling allows easy comparison between products. EU sunscreens continue to be recognised and appreciated internationally for their proven safety and efficacy.

REGULATION OF SUNSCREENS IN AUSTRALIA

Belinda Carli
Director - Institute of Personal Care Science

Australia has the highest rates of skin cancer in the world, so it's no wonder our Regulators take sunscreens seriously. In Australia, sunscreens can be regulated as:

Cosmetics:

- moisturisers with SPF ≤15 where the SPF is a secondary claim;
- when they are balms or coloured cosmetics (any SPF rating)
- can contain any sunscreen active within limits of Regulation 9.1 of the Australian Regulatory Guidelines for Sunscreens (ARGS) and may contain any excipient ingredients suitable for use in cosmetic products in Australia.

OR

Therapeutic goods:

- Moisturisers with SPF > 15 and/or claims are predominantly about the sun protection activity of the product rather than its moisturising or other action and/or representations are made about protection from skin cancer or other physiological damage induced by the sun.
- when considered a Therapeutic good, the product must be listed with the TGA and has additional regulatory requirements.
- must only contain sunscreen actives within limits of Regulation 9.1 (ARGS) and only excipients in Regulation 9.2.

Whether cosmetic or therapeutic, any product making a claim about sun protection must be tested in accordance with ISO 24443 (UVA In Vitro) and ISO 24444 (In Vivo SPF). The UVAPF must be at least 1/3 the SPF rating on the product. Current SPF ratings are limited to SPF50+ on products; and additional safety is required for any sprayable products. Water resistance claims may be made according to the following time limits, when tested according to the standard AS/NZS 2604:2012 (Figure 1).

Maximum water resistance time claim	Must achieve at least SPF rating
Not permitted	< 8
40 minutes	8 < 15
2 hours	15 < 30
4 hours	≥ 30

Figure 1.

The term 'sunblock' is perceived to be total protection against the sun and is not permitted, while the terms 'sweat proof' and 'waterproof' imply that the product will still provide its stated SPF rating when skin has been wetted by sweat and water, which is not possible, as some of the product will be removed and they are therefore also not permitted. Sweat resistant and water resistant are permitted as long as testing has been conducted to support these statements and maximum times are listed as per water resistance tests.

ARE SUNSCREENS DAMAGING OUR REEF SYSTEM?

There is a lot of conflicting information and various studies supporting both a yes and no answer, as well as a 'depends' on concentration, depth of water and population of tourism. An excellent report compiled by Dr Elizabeth Wood (1) summarises most of the studies to date while identifying knowledge gaps, the shortcomings of ex-situ studies, and further research required. The latest study by Fel et. al (2), suggests normal levels of 5 UV filters tested do not negatively impact the photosynthetic abilities of coral (benzophenone-3 was not included in this study). There is also the question of the impact of heat stress from increased water temperatures. At this stage, we should be continuing investigations, reading research critically and considering how it may apply in-situ in line with consumer use rates, marine exposures in high-tourism areas and the ongoing global warming of our oceans. In addition, before a product claims 'reef safe' it should be subjected to ISO regulated Ecotoxicity Tests in the Marine Environment and OECD Biodegradability tests rather than just avoiding the use of certain UV filters. We should also be considering what other contaminants may be impacting our marine environments as sunscreens aren't the only chemicals to reach our waters.

REFERENCES

1. Wood E (2018) Impact of sunscreens on coral reefs. International Coral Reef Initiative (ICRI) Plan of Action 2016-2018, https://www.icriforum.org/sites/default/files/ICRI_Sunscreen.pdf
2. Fel et. al., Photochemical response of the scleractinian coral Stylophora pistillata to some sunscreen ingredients. Coral Reefs. 2019; 38 (1): 109-122. Accessible here: https://link.springer.com/article/10.1007/s00338-018-01759-4.

REGULATION OF SUNSCREENS IN EUROPE

Giulio Pirotta
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Sunscreens are always big topic for the cosmetic industry. Developing a new formula is many times a big challenge and it is not unusual that 2-3 years of development are needed in order to achieve a good result.
Sunscreens in Europe are regulated as cosmetics, this means flexibility for formulators and new formulations and new molecules available to consumer each year. Quite nice situation compared to other geographic areas such as USA, Australia or Canada.
UV filters are allowed by the European Commission after a scrutiny process from SCCS, but actually no new significative dossier is under scrutiny. The actual situation is quite stable and also no specific move is looking at the environment, that we should remember is under the umbrella of REACH and so ECHA.
This doesn't mean that no new ingredients have been made available the last years; a great number of SPF boosters, actually regarded as "normal" ingredients have been marketed.
These ingredients are really helpful to boost the SPF protection in the new formulas allowing to manage lower quantities of UV filters in order to have the same or higher degree of SPF value.
This development gained momentum under the pressure of the public opinion, really concerned for the environmental impact of sunscreens. Various studies demonstrated the high concentration of sunscreens in the coastal systems and highlighted some real or potential damages for the marine system.
Either organic and physical filters have their negative impact. Starting from these concerns some states (Hawaii, Key west, Florida) in US forbid the use of some specific UV filters involved in the bleaching process of corals. Hawaii claims to be the first state to ban certain sunscreens as a measure to protect the state's essential coral reefs.
Basically, a limited ban of sale of sunscreens containing two chemicals, oxybenzone and octinoxate, has been signed. This legislation, due to the OTC status of suncreens in USA, is not applied to medically prescribed sunscreens or makeup. However, the ban drew opposition from many when it was proposed, largely from sunscreen manufacturers and medical groups.
Discussion in Europe is starting, but not yet raised to the need of a regulatory act, this may be also because the cosmetic industry is developing some strategies to be more sustainable and minimize the environmental impact of the product. New rules may be implemented in the context of a tighter environmental approach or the update of the cosmetic regulation, but not in the immediate future.
Also, Brexit and its consequences will affect these products not in the near future.
Among the approaches applied we have: the use of minimum amount of UV filters in formula with enhanced performances, higher water resistance, SPF boosters, research of new vegetable derivatives in order to help the protection, high biodegradability of the ingredients.
The European approach to cosmetics and, in this case sunscreens, gives the opportunity to develop quite interesting products with the support of high-quality research.

SUN PROTECTION: WHAT IS THE ADDED VALUE OF YOUR INGREDIENT?

Perfect Sun Protection by Photostabilization

The sun care industry is facing rapid rising global demand and is challenged by constant changing regulatory environment. In the meantime, consumers are becoming more educated and are demanding highly effective products with perceivable benefits, achieved by ingredients that are benign to the environment.

Hallstar's photoprotection platform, including cutting-edge photostabilizers, scientific testing service and comprehensive formulation solution, coupled with elegant emulsifying and emollient technology in our Functional Naturals and Aesthetic Naturals platforms, enable the cosmetic industry and consumers access to robust, pleasant, perceivable and personalized sun care products.

A key contribution of **Hallstar** photostabilizers is that they enable high performing and broad-spectrum sun protection with low usage level of key UV filters, avoiding complications associated with employing complex UV filter combinations. These photostabilizers help both organic and inorganic UV filters to achieve their maximum efficacy within a formula. As a result, formulators are less dependent on excessive filter dosage or UV filter combinations.

To better equip sun care producers and consumers with tools to determine the efficacy of their products, **Hallstar** offers highly reproducible SPF/PFA test services, including real-time visual tools for consumers, enabling the development of personalized products.

Hallstar believes by working collaboratively with our clients, we will deliver safe, robust, pleasant and customized sun care solutions that truly allow consumers to enjoy the sun.

*Key photoprotection products from **Hallstar**: SolaStay® S1, AvoBrite®, Polycrylene®, HallBrite® BHB, HallBrite®* EZ-FLO TDX/PLUS, *HallBrite®* EZ-FLO ZDX/PLUS, *Micah®*

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REGULATION OF SUNSCREENS IN USA

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The job of a cosmetic chemist is challenging for a number of reasons including pressures from marketing, the lack of new technologies, and cost restrictions. While we strive to create the most effective formulas possible, forces outside of R&D put roadblocks that hamper innovation.

Perhaps the most significant aspect hindering development is having to navigate uncertain regulations that restrict formulations. This isn't as much of a problem with products that qualify as cosmetics like shampoos, moisturizers, or nail polish. For these, formulators can create most any product they want as long as it can be proven safe and doesn't make any drug claims.

But for products that actually have an impact on the body's metabolism or treat a disease, things are much more restrictive. These products are classified as over the counter drugs and are covered by the FDA monograph system.

A monograph is essentially a recipe book that tells formulators exactly which active ingredients, doses, and formulation types can be used for creating an over-the-counter drug. This document also gives the exact claims that can be made about the product while describing other labeling requirements. Things subject to monograph restrictions in the US include things like anti-acne products, anti-dandruff products, skin bleaching and sunscreens.

Creation of the sunscreen monograph was first initiated in the late 1970's, but it wasn't until 1993 that the FDA published the first tentative final monograph (1).
This document listed around 20 approved sunscreen active ingredients that were proven safe and effective. While the monograph isn't finalized, the FDA expects industry to follow these guidelines. It's uncertain when the final monograph will be approved, but the FDA has issued a few new rules related to sunscreen labeling and product forms.

Unfortunately, the process of finalizing the monograph was so slow that newly discovered, effective sunscreen molecules were not included, so US formulators can't use them. Currently, the FDA's has a list of 16 approved sunscreens but only half of these are commonly used due to lack of availability, aesthetic reasons, skin irritation, and bad reputations (2). Of these, only two offer good UVA protection. When compared to the EU which has 27 approved sunscreens, formulating sunscreens in the US is much more limited.

And it's going to get even more limited. Recently, governments in Hawaii and Key West, Florida have banned two sunscreen actives due to a concern of the impact on coral reefs. While the legality of the local government's action is uncertain, formulators must take it into consideration when creating products that may be used in these markets.

All this means is that until the FDA changes the system by which UV blockers get approved, sunscreens in the US will not likely change much from the products we have now. There won't be improvements in UVA blocking ability, there won't be new product forms, and the primary innovation will be found in novel marketing stories.
The reality is since the current products are mostly effective it's unlikely the FDA will address the issue of limited formulation options any time soon. For formulators and consumers alike this is understandably discouraging.

REFERENCES

1. https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm072134.htm#Original
2. https://cen.acs.org/articles/93/i20/Decade-FDA-Still-Wont-Allow.html

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FORMULATION OF NATURAL SUNSCREENS: A FORMULATOR'S PERSPECTIVE

Andrea Mitarotonda
Consultant in Cosmetic Formulation Chemistry

It is everyday experience that exposure to the sun can have many beneficial effects, going well beyond the mere beautifying properties of a good tan.

The mood-enhancing properties of a nice sunny day needn't proving and neither do the metabolic pathways through which the human body can produce Vitamin D from sun rays.

Fortunately enough, science has also demonstrated the dark side of sun exposure as well as that it is still possible to enjoy it by adequately protecting the skin with suitably designed sunscreens.
Put this together with the steadily growing trend of "natural cosmetics" and you have the perfect recipe for the increased Consumer's desire to use natural sun protection.

But what does exactly "natural sun protection" mean?
As for all-things-natural, there is no Regulatory framework defining their features and this leads to confusion for both Consumers and Formulators.

If we think of a sunscreen as being formed by two main formulation blocks, i.e. the UV filters and the base, then one could think of at least three scenarios to define a natural sun-care product: (1) both blocks are "natural", (2) only the UV filters are "natural" and (3) "non-natural" UV filters are used within a "natural" base.

In order to define the degree of naturalness of the product in question, one could refer to the very many Natural and Organic Standards present in the market, e.g. COSMOS, NaTrue, NSF ANSI 305, etc.

One point is (more or less) in common between all of them, i.e. the only UV filters "allowed" by the various Standards are Titanium Dioxide and Zinc Oxide, normally in their non-nano form.

Some of these Standards have come up with their own definition of nano, making things more or less complicated and probably overlooking the real degree of complexity hidden behind such a matter as the definition & measurement of the particle size of these materials, e.g. use of number VS weight distributions, use of primary VS secondary particle size, etc.
To understand how complex it can be to formulate a natural sunscreen, one should think of the amount of powder needed to hit the desired target, i.e. a certain SPF, say 30, with adequate UVA protection (as per the Regulatory guidelines of each market) and possibly water resistance.

Of course both Titanium Dioxide and Zinc Oxide can do the job, either alone or sometimes combined (especially when targeting high & very high SPF), but still, it is a lot of (white) powder that one has to incorporate in a product.

And white powders tend to leave white marks on the skin, as much as white paint on a wall!
The Formulator's skills are still very much relevant as this is a case of dispersing a significant amount of solids into a complex system that, ultimately, must be pleasant to apply and efficacious.
Dispersing agents and good rheology modification are of paramount importance.
Also, a well designed and balanced oil phase is critical to achieve good results: for example, the use of CELUS B esters, sustainably obtained from non-edible fractions of plants, can help create a better dispersion of UV filters, thus resulting in possible reduction of the total concentration of powders as well as a silky and soft sensorial profile.
In fact, aesthetic properties of sunscreens have been frequently overlooked: as demonstrated by various Authors, for example M. Pissavini, a high SPF cream with unpleasant sensorial profile will not be applied as much and as frequently as it should be and therefore it will result in a lower actual protection than what declared on label.
Inorganic UV filters, normally used to formulate natural sun protection products have traditionally been thought to cause heavy and unpleasant sensorial profiles, but this has changed significantly in recent years with Manufacturers of raw materials committed to providing better dispersions and particle size distributions designed to optimise the protection properties and minimise the so called "whitening" effect on the skin.

Moreover, Formulators of natural sunscreens can avail of new studies demonstrating additional benefits of inorganic oxides, for example anti-oxidation properties, protection against IR radiation, free-radical scavenging properties and a more favourable toxicologic profile on the skin which makes them more suitable for certain types of skin (e.g. children, atopic skin, etc.).
To conclude, we must mention that the new frontiers of natural sun protection go well beyond the use of traditional oxides.

Studies performed at academic level are showing the UV protection properties of natural substances as demonstrated for example by Prof. Steven Bailey (University of South Alabama, USA) with the topical use of 5-MTHF and by Prof. Antony Young (Kings College, UK) with the investigations on the use of marine mycosporine as potential biocompatible sunscreens.

SUN PROTECTION: WHAT IS THE ADDED VALUE OF YOUR INGREDIENT?

Which benefit would you sacrifice in skin and sun care applications, affordability or performance?
Hopefully you wouldn't have to give up either, but historically, formulators have had to pick between the two based on their ability to formulate with either organic or silicone acrylate film formers. With a new, innovative "hybrid" solution from **Dow**, they no longer must choose between these benefits and are able to offer more high-quality, high-performance solutions for today's mass consumer market.
Launched at in-cosmetics Global 2019, EPITEX™ 99 Polymer leverages **Dow**'s expertise in silicone and acrylic technologies to lead the way for next-generation skin and sun care products. The new water-based film former solution combines sought-after qualities such as the long-lasting wear performance of traditional silicone acrylate technology and the affordability of acrylic making it suitable for mass market cosmetics.
The new ingredient offers a number of both formulator and consumer advantages, creating products that not only protect but please. In addition to affordability, the polymer enables excellent sebum resistance, long wear with rub-off resistance, superior wash-off resistance and wear comfort. Due to its proven compatibility with common cosmetic ingredients, EPITEX™ 99 Polymer can be easily incorporated into a variety of popular consumer products, such as sunscreen, BB creams, water-based eyeliner and more.
This new hybrid paves the way for more inclusive beauty by improving the availability of quality care for as many consumers as possible, while continuing to meet the beauty standards set by today's consumers.

consumer.dow.com/beauty consumer.dow.com/contactus

EFFECTIVE SUN PROTECTION: DO WE NEED AN SPF 100 OR JUST AN SPF 30 WITH EXCELLENT SENSORIAL PROPERTIES?

Marc Pissavini
R&D Director Basic Research - COTY

When the SPF number was first introduced in the 70's, protection levels were typically of the order of SPF4 to a maximum of 15. Improvements in formulation skills and technologies, together with the availability of improved sun filter ingredients, have resulted in a steady increase in the SPF number that can realistically be delivered by a sunscreen product. Today, some products claim a SPF around 100 or more. Is there any rational behind this or not? In another words "what is the highest SPF that might be needed in a normal use?"

In 2002, Cosmetics Europe (formally Colipa) proposed an SPF cap at 50+ (SPF equal to 60 or more) (1).

The justification given by the Cosmetics Europe experts is simple. The maximal accumulated exposure to ultraviolet rays (latitude 30°) at sea level amounts to about 25 MED per day.
So, a product with an SPF 26 should be sufficient. But in practice, there are a number of factors which impact on the actual SPF experienced by a sunscreen user, most of them behavioural! The SPF25 calculated above should be adjusted to SPF 50+ in order to take into account the more sensitive skin types, the application rate applied by users, the typical exposure time, the incident angle of the sun and a safety margin.

But it has also been shown (2) that two products containing the same mixture and concentration of active UV filters but with differences in their galenic properties, will result in different SPFs. Clearly, the galenic, or cosmetic, properties of sunscreens are important in determining the protection experienced by consumers during normal usage. It is the cosmetic attributes of a product that drive the quantity applied, which in turn is directly linked to the homogeneity of spreading and consequently to the in-use SPF (3-4). Therefore, the overall effectiveness of a sunscreen product depends not only on its active UV filter(s) (5-9), but equally importantly on its application thickness and how pleasurable the product is to use. Those products that spread easily are associated with a subjective assessment of a 'pleasurable product', which results in a higher application thicknesses and hence greater delivered photoprotection, which translates into a beneficial health consequence of sunscreen users.

In fact, the SPF claim on the packaging is only partially informative, "it is a relative ranking scale of effectiveness against erythema, which serves as a benchmark for consumer choice".

So, the proposed SPF50+ product is sufficient even if skin type I individuals were to apply too little product and then expose themselves to a day of maximal intensity sunlight. Consequently, an SPF 100 seems too high, a SPF 30 too low and a SPF50+ should be the highest SPF that might be needed in a normal practice (1, 10). But equally important is to choose a sunscreen with good galenic properties, which will allow the product to be spread as homogeneously as possible.

REFERENCES

1. M Brown, A. Chardon "Justification for an SPF Cap" Nov 2002, Colipa
2. M. Pissavini, B. Diffey, S. Marguerie, T. Carayol and O. Doucet « Predicting the efficacy of sunscreens in vivo veritas" " Int. Journal of Cosm. Sci., 2012, 34, 44–48
3. M. Pissavini, B. Diffey, "The likelihood of sunburn in sunscreen users is disproportionate to the SPF " Photodermatol Photoimmunol Photomed 2013; 29: 111–115
4. Diffey, B.L. and Grice, J. "The influence of sunscreen type on photoprotection." Br. J. Dermatol. 137, 103–105 (1997).
5. M. Pissavini, O. Doucet and B. Diffey, "A novel proposal for labelling sunscreens based on compliance and performance" Int. Journal of Cosm. Sci., 2013, 35, 510–514
6. Fageon, L., Moyal, D., Coutet, J. and Candau, D. "Importance of sunscreen products spreading protocol and substrate roughness for in vitro sun protection factor assessment." Int. J. Cosmet. Sci. 31, 405–418 (2009).
7. Lademann, J., Schanzer, S., Richter, H. et al. „Sunscreen application at the beach." J. Cosmet. Dermatol. 3, 62–68 (2004).
8. Lademann, J., Rudolph, A., Jacobi, U., Weigmann, H.-J., Schaefer, H. and Sterry, W. "Influence of nonhomogeneous distribution of topically applied UV filters on sun protection factors." J. Biomed. Opt. 9, 1358 (2004).
9. Bimczok R, Gers-Barlag H, Mundt C et al. "Influence of applied quantity of sunscreen products on the sun protection factor – a multicenter study organized by the DGK Task Force Sun Protection." Skin Pharmacol Physiol 2007; 20: 57–64.
10. https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-03019.pdf?utm_campaign=pi%20subscription%20mailing%20list&utm_source=federalregister.gov&utm_medium=email.

HOW TO DEVELOP PERSONALIZED SUN AND SUNLESS TANNING PRODUCTS

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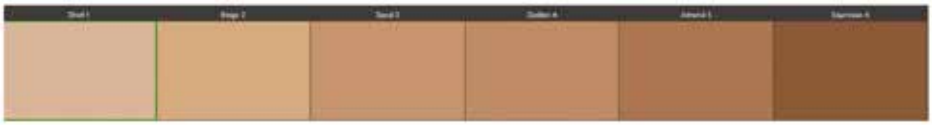
Personalized sunscreen and sunless tanning (self-tan) products could give the users an appealing option for customized experiences. Such products could target consumer's individual needs while providing specialized protection and tailored performance. Consumers are keen to embrace their uniqueness, and many are interested in tailored products because it is especially for them; helping them feel like more than just a demographic (1).

The development of personalized sunscreen and sunless tanning products requires different considerations and formulation strategies.

Personalized Sun Protective Products
A family of broad-spectrum SPF 30 skin perfecting liquids was recently introduced to the market by Rodan & Fields, LLC. The products were developed to provide multiple short- and

long-term skin benefits for all ethnicities and offer the ability to unlock personalized options. These lightweight, non-comedogenic, tinted products contain ZnO 3.74%; TiO2 3.2%; Octinoxate 3.49% - in conjunction with amino acid technology and anti-oxidation/pollution ingredients.
Their colors were measured by X-Rite VS450 spectrophotometer (D65/10°; CIEL*a*b color space), as follows:



Their ITA° values were calculated according to (2): ITA°=arctg ((L*-50)/b*) x (180/π). Results are presented below:

Product	L*	a*	b*	ITA°	ITA° Ranges for Skin Color Types
Shell 1	74.78	11.05	20.42	51	41° < ITA° < 55 Light
Beige 2	70.96	13.12	25.86	39	28° < ITA° < 41° Intermediate
Sand 3	63.51	16.29	26.1	27	10° < ITA° < 28° Tanned
Golden 4	60.26	16.1	25.21	22	10° < ITA° < 28° Tanned
Almond 5	52.5	17	26.65	5	-30° < ITA° < 10° Brown
Espresso 6	39.79	16.59	25.53	-22	-30° < ITA° < 10° Brown

Users could select the shade of Radiant Defense SPF 30 matching their individual skin color types or combine two shades to achieve the right tone. These multifunctional products will provide natural-looking coverage, help to visibly improve skin tone and texture, repair skin's moisture barrier and defend against environmental aggressors.

In addition, sunscreen brands could achieve personalization via specialized innovations, with recent product launches providing protection beyond UV (e.g. Blue light, IR, pollution); and care for micro-pigmented skin, tattoos, hands, scalp, and hair (1).
We found that mineral sunscreen actives used in conjunction with certain organic sunscreen actives, particulate materials, e.g. silica, hydrated silica, talc, and iron oxides contribute to sunscreen's improved absorbance in Blue Light region (3).

Personalization of Sunless Tanning Products
Sunless tan is generated by the Maillard reaction of DHA and/or erythrulose with the amino acid groups in peptides and proteins that are present the skin stratum corneum. DHA is considered a safe skin coloring agent. Sunless tanners contain DHA in concentrations ranging from about 1.25% to 15%. The percentages correspond with the product coloration levels from light to dark. The sunless tan usually takes 2- 4 hours to begin appearing on the skin surface and will continue to darken for 24-72 hours, depending on formulation type. Different skin types react differently with DHA due to the individual amino acid content, moisture level, initial skin tone, pH and thickness. The result could be an uneven tan, one that is too dark or too light, or an orange color. According to Mintel sunless tanning segment needs to re-focus on convenience of the application, shade quality and long-lasting effects; and more can be done to boost consumer interest and usage (1). Various ingredients can modify, enhance and personalize the shade quality obtained with DHA on skin, and provide the long-lasting effects. Examples of such ingredients include amino acids (4), amino-substituted silicone compounds (5), polyacrylamide (6), amphoacetate derivatives (7), thickeners, humectants, sunscreen actives, vitamins, emollients, antioxidants (8), and polymers (9).

In 2018 the sunscreen and sunless tanners' market in the US was $1.4 billion - with 74% of adults using these products. Mintel predicts that interest in products with added protection benefits and natural offerings will result in 12% growth through 2023 (1), and personalization of these products could contribute to this growth trend.

REFERENCES

1. Mintel.com
2. Chardon, A., et al., *Int. J. Cosm. Scien*., 1991. 13, 191-208.
3. Dueva-Koganov, O.V., Skin Protection: Evolving knowledge, formulation and evaluation trends, Podium Presentation at 6th Annual Conference Future of Dermatologicals and Cosmeceuticals, 2018. Iselin, NJ.
4. Robinson, L., et al., US 5,603,923; 1997. Artificial tanning compositions having improved color development.
5. Lentini, P., et al., US 5,503,824; 1996. Skin tanning compositions.
6. Ziegler, P.D., et al., US 5,232,688; 1993. Self-tanner cosmetic compositions.
7. Dueva-Koganov, O.V., et al., US 7,378,084; 2008. Sunless tanning composition and method of sunless tanning.
8. Jermann, R., et al., *Int. J. Cosm. Scien*., 2002. 24, 1-8.
9. Dueva-Koganov, O.V., et. al. The Impact of Polymers in Sunless Tanning Delivery Systems. Podium Presentation at SCC Annual Scientific Seminar, 2007. New York, NY.

THE FUTURE OF SPF TESTING: *IN-VITRO* OR *IN-VIVO*?

Sébastien Miksa
General Manager - HelioScreen

In the global context, we can state that the ISO methods are the most used worldwide and should be preferred when they are authorized by national regulations. Regarding the Sun Protection Factor (SPF) assessment representing mainly the UVB protection, only the *in vivo* method (biological process based on erythema apparition on human skins) is harmonized according to the ISO 24444 project since its publication in 2010.

As an evidence, the development of an *in vitro* method (analytical process based on transmittance assessment on substrates) should be preferred for ethical reasons (non-human UV exposure compared to *in vivo* method) and due to potential advantages, such as speed, cost and continuous improvement of repeatability and reproducibility. In this way, recently, Cosmetics Europe proposed the validation of a new *in vitro* SPF method giving reproducible and equivalent results to *in vivo* method and taking into account photo-degradation. This alternative method based on multi-substrates approach fulfilled acceptance criteria proposed by both Cosmetics Europe and ISO TC217/WG7 and is currently in progress under project ISO/AWI 23675.

Moreover, another method is under development (project ISO/AWI 23698) to potentially replace the *in vivo* SPF assessment method with the Hybrid Diffuse Reflectance Spectroscopy (HDRS) approach which combines advantages and deficits of both *in vivo* (for UVB part) and *in vitro* (for UVA part) methods. Nevertheless, in the same time, recent publications could suggest that this HDRS method could be improved by using a UV-LED based system offering an *in vivo* non-invasive way to determine simultaneously UVB and UVA parts.
Finally, until improvements and method developments are published, as the sun protection assessment of sunscreen products directly impacts human health, we should consider both *in vivo* and *in vitro* sun protection assessment methods in combination to offer good and reliable UV protection to consumers.

Why results are so different between testing houses?
During the last decade, consumer cultural evolution, the understanding and the awareness relating to UV exposure changed. This fact leads to propose new UV filters, new textures, new labeling and new UV protection assessment methods. Moreover, standardized methods have been developed at an international level for a global harmonization and include the respect of several rules such as the support of the test (human skin or PMMA plates), application including quantity and spreading, the UV irradiation with specific solar simulators and performance measurement (biological endpoint or transmittance). In fact, during this methods development, the different reasons which can lead to variability have been considered through the (i) technology variability, (ii) intrinsic product variability and (iii) intrinsic method variability.

Nevertheless, besides all these great innovations, in the same time, no more strict control of how the sunscreen tests are performed has been proposed. Indeed, different points cannot be considered during method development such as human error, equipment default, failure to respect the protocol, none quality system, lack of expertise/knowledge, misunderstanding of method/process/parameters, etc.

Therefore, in complement to the control of the key parameters during sun protection assessment methods, the control of the different sunscreen testing institutes by means of a third-party audit or recognition should be requested by the different stakeholders to positively influence the objective of a good UV protection and to improve reliability and relevance of sun protection assessment. Finally, to provide worldwide consistency of results regarding the sun protection performance, the competency of the laboratory shall be checked using unknown products too.

THE FUTURE OF SPF TESTING: *IN VITRO* OR *IN VIVO*?

Stephan Bielfeldt
Vice President and Director Science and Innovation - proDERM

Currently the *in vivo* SPF-method is a candidate for being replaced. From the ethical point of view, a non-invasive method if suitable would be highly appreciated to replace a method that causes sunburn.

However, no satisfying *in-vitro* method is available. For decades *in-vitro* methods for SPF testing have been explored, but the outcome is still poor. The reason being, that there is no *in-vitro* substrate available that sufficiently represents human skin. Whoever wants to establish an *in-vitro* method has to face the fact that the disadvantage of such a method would be low precision.

Promising results from an *in vivo/in vitro* hybrid method were recently published (1, 2). The Hybrid Diffuse Reflectance Spectroscopy method (HDRS) combines a non-invasive *in vivo* measurement on human skin with a spectroscopic *in vitro* assessment on plastic plates. During the *in vivo* assessment, the unique conditions of human skin are taken into account, where as the long-term irradiation with UV-light, to test for photo stability, is performed *in vitro*. It is my personal opinion, that such a non-invasive hybrid method will be the future for SPF testing.

References

1. Rohr, M., Ernst, N., & Schrader, A. (2018). Hybrid Diffuse Reflectance Spectroscopy: Non-Erythemal *in vivo* Testing of Sun Protection Factor. *Skin pharmacology and physiology*, *31*(4), 220-228.
2. Ruvolo Junior, E., Kollias, N., & Cole, C. (2014). New noninvasive approach assessing *in vivo* sun protection factor (SPF) using diffuse reflectance spectroscopy (DRS) and *in vitro* transmission. *Photodermatology, photoimmunology & photomedicine*, *30*(4), 202-211.

Why results are so different between testing houses?
In the recent years great efforts were undertaken to reduce the variability among testing houses and a considerable progress should not be neglected. However, there are a lot of difficult procedures involved with in vivo SPF test methods, so that the remaining variation can be well explained:

- The correct minimal erythema dose has to be detected for each volunteer, individually.
- Application and spreading of tests product is skilled work for a technician and it needs a lot of training to do it correctly.
- The volunteers' body movements during irradiation can lead to blurred erythema spots, which can lead to misinterpreting results.
- Subjective visual evaluation of erythema spots is necessary to assess the individual SPF of the product and simultaneously an untreated area has to be evaluated. The slightest difference in interpretation of erythema spots during this process can clearly lead to different SPF results.

While the training procedures for technicians are usually comparable within a test center, the training in another testing house might be slightly different. As explained above, the *in vivo* SPF test method is very sensitive to even slight variations in product application, irradiation and evaluation. As a consequence, distinctly different results may occur between testing houses.

SUN PROTECTION: WHAT IS THE ADDED VALUE OF YOUR INGREDIENT?

To protect their skin against the damaging effects of UV light, consumers are looking for effective sunscreens that are easy to apply and feel light on the skin. For manufacturers, that's particularly challenging when also striving for a high sun protection factor (SPF).

Most UV filters are oils or oil-soluble. A higher SPF usually requires a larger oil phase, which affects sensory properties. Few UV filters are available for the water phase – one of them is Tinosorb® A2B (INCI: Tris-Biphenyl Triazine (nano)).

Microparticles scatter UV light
Tinosorb A2B is a highly efficient, photostable UV filter, with particle sizes smaller than 100 nanometers. Its superior absorption spectrum and scattering effect of micronized particles provides increased SPF performance with a lower UV filter concentration when compared to other ingredients. By complementing conventional oil-soluble filters with its high efficacy against UVB radiation (wavelength between 290 and 320 nanometers) and UVA2 (320 to 340 nanometers), it closes the current gap in the UVA2 spectrum. Furthermore, Tinosorb A2B also has a boosting effect in the UVA1 spectrum.

Feels light on everyone's skin
Tinosorb A2B provides high SPF performance at a low concentration rate, allowing manufacturers to easily formulate aqua light sunscreens and daily face care formulations that are also suitable for children and people with sensitive skin. It can be processed cold and does not contain preservatives.

Tinosorb A2B is the first nano form UV filter to be included in the positive list (Annex VI) of the EU Cosmetics Regulation in 2014. Since then, two more **BASF** nano filters have followed: Z-Cote® (INCI: Zinc Oxide (nano)) in 2016 and Tinosorb® M (INCI: Methylene Bis-Benzotriazolyl Tetramethylbutylphenol (nano)) in 2018. With their inclusion into Annex VI, the safety of the UV filters in nano form has been specifically assessed and they are officially approved for the use in European cosmetic products.

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THE FUTURE OF SPF TESTING: *IN-VITRO* AND *IN-VIVO*? WHY RESULTS ARE SO DIFFERENT BETWEEN TESTING HOUSES? *IN VIVO* SUN PROTECTION EVALUATION: A COMPLEX AND SENSITIVE ISSUE

Anne Charpentier
CEO - Skinobs

The sun protection objectivation subject represents a complex issue between *in silico*, *in vitro*, *in vivo* and hybrid methods at least as important as the challenge of the formulation itself. First, it is interesting to consider **what criteria mainly influence** the performance of UV protection products: composition, repartition, photostability, absorbance and distribution of the inorganic and organic filters, galenic (spray, compact powder, oil, cream…), properties to form a stable, homogeneous and resistant film, pleasant to apply. In real use conditions, this performance is impacted by other criteria such as individual wrinkles, skin locations, sweat, hair, application procedures and quantity.

The sunscreen products on the market have to claim the UVB and UVA protection based on several methods. For this purpose, the ISO norms are highly recommended:

- **The *in vivo* testing**: with the 2 international norms, ISO 24444 for SPF (Sun Protection Factor) UVB index and ISO 24442 (2011) for UVAPF (UVA Protection Factor).
- **The *in vitro* value,** ISO 24443 (2012) for UVA PF and the Critical Wavelength. For the UVB testing on emulsion architecture, a new method, developed by Cosmetics Europe, has been accepted by the ISO (Nov.2018) and could be potentially a new international method within 2-3 years.
- **The *vitro/vivo* hybrid** method by **HDRS (Hybrid Diffuse Reflectance Spectroscopy),** (*In Vivo*-UVA/*In Vitro*-UVB) has been also accepted by the ISO (Nov.2018) and could be potentially a new international method within 3 years.

What are the key points of the SPF determination relevance?
Beyond the product galenic influence, the criteria which will influence dramatically the inter and intra Lab centres **repeatability and reproducibility** are:

- The support of the tests: the subject inclusion for *in vivo* (Phototype, skin state…) and the substrate material for *in vitro*,
- The application (homogeneity, quantity, spreading) and the formulation type,
- The irradiation source (UV spectrum),
- The measurement of the biological endpoint for the *in vivo* tests (erythema or pigmentation) and UV analyser for the *in vitro* methods.

These elements are crucial and demonstrate the great importance of **the human behaviours and the device reliability** in the respect of the good practices. Variability of the results of the *in vivo* testing is well known and can lead to different results depending of the testing centers.

The claiming of the *in vitro* SPF test enables generally **the correlation** with *in vivo* values. HelioScreen's scientific director, Sébastien Miksa, confirms that the multi-substrates of the *in vitro* approach based on correction factors allows to obtain a high correlation coefficient with *in vivo* SPF values.

What are the next challenges to optimize these objectivations?
Technically, it seems important to **increase the reproducibility and the accuracy** of the *in vitro* and *in vivo* testing by implementing systematic control testing such as BIPEA inter laboratory comparison tests and audit of the global process such as SUNCERT diagnostics. The gap between standardised application versus **real-life conditions of use** may also be deeply studied including anti-salt, anti-sweat or anti-sand claim substantiation.

On the **ethical point of view,** the application of erythema on the subjects which causes skin damages doesn't seem to be a long-term solution for SPF assessment. Fortunately, the HDRS method or *in vitro* method should propose a **new perspective** within the next years.

Could we open the field of the claim substantiation with the objectivation of all the **various damages that UVB, UVA, Blue Light, Infrared** may cause? Beyond anti-sun spectrum objectivation, and index determination, can we evaluate complementary photo ageing performances such as antioxidants, anti-free radicals, anti-ageing, anti-dark spots…?

Finally, we can expect that both worldwide **industries and regulatory authorities** harmonise the reference methods all over the world and continue with the labelling rules. It will guarantee the appropriate respect of the **human health** (nano, endocrine disruptor…) and **the sustainability for the nature** (ecotoxicity testing, coral protection) while keeping the evolution of the high performance of the sun protection products with all the complementary functionalities the consumers can expect.

THE FUTURE OF SPF TESTING: *IN VITRO* OR *IN VIVO*? WHY RESULTS ARE SO DIFFERENT BETWEEN TESTING HOUSES?

Ana García Blanco
in vivo Tolerance Test Manager - Zurko Research

Over the years, the development of standards for leading studies to regulate the sun protection of cosmetics has focused mainly on the *in vivo* field but for the last years with more advances and technologies, the *in vitro* testing has been gaining more prominence"
Throughout the European Commission recommendation regarding solar products in 2006, it is clear that the studies that must be carried out are those that were standardized in those years, and both, to evaluate the protection against UVB and UVA, were *in vivo*. These methods consist of irradiating the skin and causing lesions in the skin (erythema and pigmentation) on volunteers, generating an ethical problem.

However, the recommendation also emphasizes that preference to *in vitro* testing as well as, advising companies to develop and fine-tune methods that allow *in vivo* studies to be left behind should be given Nowadays, an *in vitro* alternative to the determination of UVA protection is available, and a standardized procedure for UVB protection *in vitro* through ISO is beginning to be developed.

In vivo method, in accordance with ISO 24444: 2010, is now under review by the working groups associated with that entity. The data that has been collected over the years by the several companies that are dedicated to the sun products testing of sites under this standard, show a very wide variability. These differences may be due to the fact that certain parameters are either not delimited correctly or certain controls are missing in order to standardize various factors that were previously not taken into account.

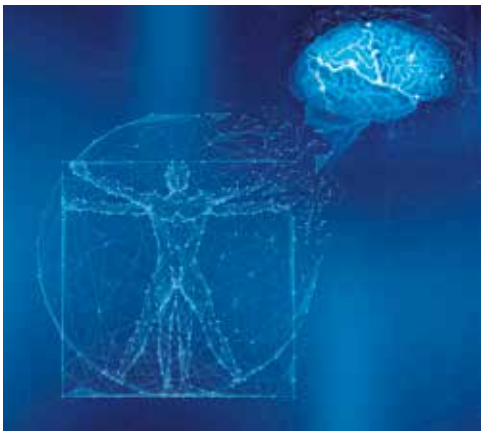
Regarding the experimental zone in the realization of these studies, the people skin is one of the main problems. It is well known that not all the skin of the same person reacts in the same way to sun exposure, with more sensitive and others more resistant areas. In the current procedure is established a range of pigmentation of the skin so that the volunteer can participate in the studies, and in addition, the pigmentation of the experimental zones of each subject cannot differ much to minimize the possible differences that the mentioned pigmentation can generate in the response to solar irradiation. However, the most important factor is usually in the results reading, since it is done by experienced technicians, but nowhere it is established what their training should be or if there are patterns / guides to follow to establish the results.

The cosmetics industry, each time more global, demands new studies every day in the sunscreen field, which are able to encounter the demand for safer products, able to protect the skin against the different radiation that affects us day after day. These studies must be accepted by everyone and for that they must be reproducible and ethically sustainable, which leads us to conclude that the future must be and will be *in vitro* testing.

who is who in... **THE FUTURE OF COSMETICS: WELL-BEING AND NEUROCOSMETICS**

Every now and again many studies are published which demonstrate the connection between the skin and the nervous system. It refers to emotional cosmetics, the use of cosmetics to achieve well-being.

We know the impact that feelings have in our skin (stress, sadness, fatigue, lack of sleep ...). Therefore, lately there is a trend for neurocosmetics, which in addition to improving the appearance of the skin, increases our well-being sensation, connecting skin and brain nuclei.



For this reason nowadays there are cosmetics with psychoactive ingredients that act by inhibiting, or increasing the release of skin neurotransmitters. These have the ability, topically, to regulate the release of the inflammatory substance through the stimulation of endorphins. It helps the improvement of cutaneous cellular functioning, leading to a softer, relaxed and protected skin.

It is also important to understand that the skin as a peripheral system receptor of stress is an external organ exposed to environmental factors, where both the cosmetics that we use, the food we eat, the physical activity we perform, social relationships, to the appropriate rest, are a whole cluster of factors that are reflected in our skin.

The current trend of anti-aging products seems to be directed each time to a more personalized cosmetic, focusing not only in treating the skin but also acting on the neurotransmitters that correlate with the skin. This refers to increasingly specialized products with the approach on caring for our microbiome and exposome, while generating at the same time stimuli to our nervous system.

At **Zurko** Research we keep up-to-date of the latest trends in the cosmetic industry, in order to offer personalized studies for innovative products, helping to validate their efficacy and safety, with the latest technology in the field of *in vivo* testing. Evaluating wrinkles with the newest equipment.

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