Commentary article

SUN PROTECTION CHALLENGES

ULI OSTERWALDER

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Keywords:

- Sun Protection
- Ideal Sunscreen
- Safety
- Environment
- Compliance

TOPICS OF THE DISCUSSION

Here some of the questions that had been asked to the panel:

- Does the public understand the claims on sunscreen products? Is the SPF (sun protection factor) the only (or most important) performance parameter for a sunscreen product?
- Are sunscreen filters absorbed by the skin? Does this pose a health risk?
- Do sunscreen filters pose a hazard to the environment?
- Is there an ideal sunscreen product? or What is an ideal sunscreen product? Does it make sense to protect from Blue Light, Visible Light or Infrared Light? Does topical sun protection impair the vitamin D production in the skin?
- Compliance with sunscreen measures: The importance of the sensory properties of sun protection products. What fears does the public have in connection with sun protection products?

1) SUN PROTECTION FACTOR - SPF TESTING

The SPF testing procedure is globally standardized as ISO 24444:2019 and the comparable procedure described in the US-FDA monograph. The complexity of SPF testing and some intrinsic differences originating from human subjects, human sunscreen application and human readout, causes the method to bear a considerable random variability, in particular, between different laboratories performing these tests. Although ***in vitro*** SPF methods have been around for over 30 years, up to now, no ***in vitro*** method was accurate enough to be considered a replacement. In the last two decades other alternative methods such as ***in silico*** calculation and non-invasive ***in vivo*** testing by diffuse reflectance spectroscopy (aka HDRS) have also emerged and could be promising alternatives. An alternative SPF test method should agree with the current SPF ***in vivo*** procedures in terms of accuracy, defined as trueness and precision (repeatability and reproducibility), is easy to adapt by laboratories and cost-effective to perform. A multi-stakeholder initiative is forming an "ALT-SPF Consortium" (www.alt-spf.com) with the objective to evaluate and characterize alternative SPF against ISO 24444:2019 for a potential later replacement in claim substantiation. The considerable variability of the ***in vivo*** methods as well as the desire to understand the agreement and precision behavior of the alternative methods demand sophisticated statistical tools to analyze and, in particular, to characterize them for a general public use. Their aim is to deliver key features to rate agreement and to measure reproducibility, degree of systematic errors with different types of sunscreens, such as emulsion, one-phase and high-solid content products.

2) SAFETY

The biggest potential safety issue is the percutaneous absorption of UV filters. Although the systemic availability of some UV filters has been known for some time, attention to this issue only became more widespread

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Experts were invited to discuss trends and relevant aspects of Sun Care. Some topics of the panel discussion are highlighted and commented by Uli Osterwalder, Sun Protection Facilitator GmbH.

with a study conducted by the FDA and published in early 2019. Now the question arises: What does systemic availability mean? Opinions range from "continuing to use sunscreen" to "banning it completely", at least the UV filters that can be found in the body. Given that the purpose of applying sunscreens is to prevent damage, the latter is not justified as long as there is no evidence that these UV filters are harmful. Nevertheless, further studies are necessary and are required by the FDA. In the meantime, the available data on UV filters can be used to estimate their percutaneous absorption. The safety aspect is not only a question of chemical properties (hazardousness), but also of exposure, as Paracelsus "The dose makes the poison" stated 500 years ago. Both together, hazard x exposure, result in the risk management approach. It is therefore not a solution to call UV filters only because of their hazard potential. There is a way to keep exposure low by selecting UV filters. For UV filters to have a very low percutaneous absorption, two parameters are crucial: molecular weight and polarity, expressed as the oil/water partition coefficient. UV filters with inherently very low or no percutaneous absorption are particulate UV filters, both inorganic and organic. However, such an assessment is only an indication and does not replace a detailed risk assessment as defined, for example, in European legislation.

3) ENVIRONMENT

The ecological fate of sunscreens has become an important issue in recent years, triggered by the disappearance of parts of the world's coral reefs. Although global warming caused by climate change is the main cause of the destruction of coral reefs, sunscreens and especially some UV filters are in the spotlight. Climate change and the associated increase in water temperature has been linked to the massive coral bleaching observed worldwide. It is important to investigate the effects of UV filters. The situation is analogous to human safety, there should be a risk assessment approach.
A good example is the current labelling of inorganic zinc compounds as ecotoxic to the aquatic environment during transport. Zinc is an essential element needed for the optimal growth and development of all living organisms. Transport labelling is based on the inherent hazard profile for bulk materials and is mainly determined by the release and toxicity of Zn^{2+}. The observed toxicity is determined by concentration and exposure time. While it is true that some studies have shown that high Zn^{2+} concentrations and long exposure times can kill coral algae, most of these studies were performed in an isolated test system at unrealistically high concentrations that are not relevant to environmental field concentrations and conditions. In other words, the test conditions are far from being close to real life situations, so it is necessary to consider risk and exposure scenarios for the impact assessments.
Fortunately, in the much wider field of organic UV filters, major suppliers are now increasingly offering ecotoxicological profiles of sunscreen formulations to assess environmental effects. BASF has developed a special tool: the EcoSun Pass. UV filters of a given formulation are transparently assessed against 8 toxicological endpoints, which means that possible improvements in formulations with or without BASF ingredients are possible. DSM has also developed an eco-profiling tool and integrated it directly into its Sunscreen Optimizer. This allows sunscreen formulations to be optimized from both ecological and economic aspects.

4) IDEAL SUNSCREEN

Photoprotection in some form is almost as old as civilization, but in the early 20th century, lifestyle, media advertising and social trends promoted tanning as a sign of health and wealth. Early sunscreens met this demand by providing protective agents that allowed tanning without sunburn - a misguided concept that is still present today, as both biological reactions indicate a failure of sun protection.
Many cultures prevent sunburn, photo-aging and ultimately skin cancer by avoiding the sun and wearing protective clothing. Both reduce terrestrial solar radiation evenly without promoting UVB or UVA. In 1991, Brian Diffey proposed the principle of uniform protection in which a sunscreen product attenuates radiation evenly across the UV spectrum. The uniform reduction of UVB and UVA radiation, also known as "spectral homeostasis", attenuates the amount of the natural spectrum of sunlight without altering its quality, similar to the protection provided by neutral density filters such as densely woven textiles or interior shading. In sunscreens, such spectral homeostasis protection has only become possible in the last two decades with the new UVA and broadband UV filters. At the same time, uniform protection helps to produce more vitamin D than UVB-biased protection. Prior to the 2006 EU recommendation on UVA protection, such UVB-based sunscreens had blocked up to three times

Panel Discussion on SUN CARE

more vitamin D synthesis than sunscreens with uniform protection. What is the next step, should blue light, visible light or infrared radiation (IRA) also be covered? So far there is only a case for blue light, as an extension of the UV range up to about 500 nm, especially for darker skin types that are more susceptible to unwanted pigmentation and melasma, while IRA could actually be beneficial rather than harmful, just think of the benefits of photobiomodulation therapy. Here we are again; we need a risk management approach to figure out what needs to be done. It goes without saying that an "ideal sunscreen" must also be efficient and safe, and provide a pleasant experience when applied.

5) COMPLIANCE

The incidence rate of skin cancer is still increasing worldwide and there is a clear link with excessive UV exposure. We all know this, but why is there not good sunscreen compliance? Sun protection is much more complex than, for example, oral hygiene, where compliance is very good worldwide. UV intensity varies according to location, season and the course of the day, and it also changes according to weather conditions and the angle at which the sun hits the skin. Field studies with UV dosimeters have shown that the dose we receive, even on a full outdoor holiday in Tenerife with a high UV index, is about 4 minimum erythema doses (MED) for a person of skin phototype 2. This is enough for a severe case of sunburn to occur unprotected. However, one can easily protect oneself from it by using an SPF-15 formula which only gives a suberythemic dose without noticeable redness. An SPF 50 formula would reduce the erythemal irradiation package obtained to less than 10% for each day of exposure. Unfortunately, as many studies on the degree of application show, only 20% of the recommended amount of sunscreen is used, resulting in about one fifth of the nominal protection. Personal behaviour also has a cultural background, as one study shows, for example in France, which had the highest number of non-users, there is a desire to be tanned and a belief that sunscreen products counteract tanning. On the other side of the scale, in Korea, where the beauty trend of staying pale triggered a very high compliance rate of 88%. Respondents also stated that sunscreen products have some unpleasant properties, such as stickiness and greasiness when applied. In addition to education, there is therefore a need to develop formulations that are pleasant to use, with a dry feel and non-greasy properties. The appropriate technologies are available, e.g. sensory modifiers for dry handle, in-silico formulations-design with oil load management, pigmented UV filters and siliconized UV filters, e.g. polysilicone-15.

Panelists

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ON THE PATH TOWARDS THE IDEAL SUNSCREEN PRODUCT

An ideal sunscreen product should deliver protection across the entire UVA and UVB spectrum, additional protection against visible blue light, and be a light and pleasant formulation. With our broad range of filters and formulation ingredients at BASF, we are helping sunscreen formulators to meet these market demands. At the same time, we are addressing another important aspect of an ideal sunscreen product: environmental compatibility. Consumers increasingly demand for more sustainable products. With regards to suncare, the public discussion is focused on adverse effects on corals and marine life, endocrine disruption, and bioaccumulation.

To assess the environmental impact of the UV filters used in sunscreen formulations, BASF has developed a special tool: the EcoSun Pass. Its methodology supports the transparent and holistic assessment of UV filters based on internationally recognized criteria. These include acute and chronic aquatic toxicity, i.e. the intrinsic capability of a substance to cause damage to aquatic organisms after short-term or long-term exposure; toxicity to terrestrial organisms as well as to sediment-dwelling organisms; bioaccumulation, endocrine suspicion, and biodegradation. Each substance is assigned a specific environmental ranking.

All eco-ranked substances in a given formulation are then rated on an open-ended scale. We created an algorithm to calculate the effect of a sunscreen formulation on the environment that takes the eight parameters into account for each UV filter. The EcoSun Pass value for any given formulation is normalized for its sun protection factor to prevent sunscreens being rated as poor because of their high efficacy and filter concentration. The higher the EcoSun Pass value for a formulation, the more environmentally friendly it is.

The innovative tool enables us to advise formulators on which UV filter combinations are best suited for their application as soon as they are in the development phase. As well as considering environmental factors for individual UV filters, it provides a comprehensive environmental evaluation of the entire filter system within a sunscreen product. This enables our customers to evaluate their sunscreens based on all the relevant environmental aspects and allows for the eco-friendliest consumer product to be brought onto the market.

Our environmental impact assessment system works entirely independently of our product portfolio. UV filters from various producers of a given formulation are assessed transparently which means that potential improvements in formulations may or may not involve BASF ingredients. One approach to formulating sunscreens with improved environmental compatibility is to select the most efficient UV filters with better environmental profiles, and use the lowest possible concentrations. This also makes formulations as light as possible without compromising performance. The question of what an ideal sunscreen product looks like cannot be answered without addressing the topic of nanoparticles. It is a rather widespread fear that they cause undesired effects by penetrating the skin. However, percutaneous absorption depends on several properties, including chemical structure, molecular weight, solubility and polarity, as well as melting point. As far as organic and inorganic nano filters in our portfolio are concerned, they are both very unlikely to penetrate the skin. With particle sizes starting between 20 and 500 nanometers, they are vastly bigger than other common UV filters which are not classified as nano because they are soluble in oil or water. Nano particles are actually quite large in comparison to other cosmetic ingredients. For particulate UV filters such as MBBT, TBPT, ZnO and TiO_2, we can prove that efficacy increases with decreasing particle size. At the same time, smaller particles have a reduced white painting effect which means that they allow us to formulate more effective, lighter, and more transparent sunscreens.

Furthermore, nanoparticles have a very beneficial effect in three respects: besides absorbing UV light they reflect and scatter light due to their particulate nature. The structure of organic particles allows for the highest absorption which makes them more efficient than inorganic particles. Nano-sized filters are highly efficient and do not need to be dissolved in water or oil. This makes them an ideal ingredient of effective sunscreen products.

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DOES THE PUBLIC UNDERSTAND THE CLAIMS ON SUNSCREEN PRODUCTS? A DERMATOLOGIST PERSPECTIVE

Sun exposure has been always associated in the last decades with wellness, relax and vacations especially in the western world. As a consequence, the increase in chronic photodamage and skin cancers has been recorded after the '80s leading health authorities and dermatologists to promote educational campaigns and programs to inform the public on the possible dangers and risk of an uncontrolled/unprotected exposure to UV rays. Indeed, photoprotection is an important strategy to reduce skin cancer and prevent photoaging. Looking back over the past few decades, the work by health care providers, government agencies, and nonprofit organizations has raised public awareness on the harms associated with excessive UV exposure. Scientific Societies, as well, generated and widespread guidelines and information for doctors and the general public on the best practical behavior and conduct to prevent damages. There is still, however, much work to be done. In general, the public understands that healthy photoprotective behaviors involve sun avoidance, seeking shade, protective clothing and using sunscreens, but a large segment of the population still does not translate this insight into actual behavior modifications. Regarding sunscreens, labelling and SPF factors are still one of the major concerns. The patients ask very often dermatologists which SPF factor is needed to protect themselves; the information they have is contrasting since some of them think that a SPF 10 could be enough for a summer sunny day (single application in the morning!....otherwise they are concerned about not tanning!) while others buy on the internet a SPF 100+ stick (illegal claim in EU) and apply it repeatedly. Anyway, most of the patients apply the sunscreen at least two times a day (that isn't the ideal every 2 or 3 hours) nevertheless they have the consciousness that the product should be applied frequently during the day to keep optimal protection. Another important issue on labelling is that there is no indication on the amount to be applied. It is known that SPF calculation is based on the application of 2mg/cm2 of skin surface; several studies show that the average customers use a much lower amount thus reducing the potential protection and life of the product on the skin. Other questions could rise on the interpretation of UVA protection factor which is almost unknown to the patients: indeed the awareness of the differences between UVA and UVB rays and their different effects on skin damage is very low among the public and all the numbers displayed on labels and claims can generate further disorientation. Therefore it is important to stress these concepts in order to educate patients and make them more compliant with sunscreen use and promoting the understanding of possible risk after inappropriate application.

ENZO BERARDESCA
Professor, University of Miami

DOES IT MAKE SENSE TO PROVIDE PROTECTION FROM BLUE LIGHT, VISIBLE LIGHT OR IN-FRARED LIGHT?

Every day, the human skin is exposed to the damaging emissions radiating from the solar spectrum. These emissions can be divided into different types of radiation (1). Ultraviolet light makes up roughly 7% of the solar spectrum, and although not all of it reaches the earth there are compounds that work on the molecular level, such as sunscreens, available to protect the skin from damage. On the other hand, infrared emissions account for approximately 54% and visible light for the remaining 39% of the solar spectrum making it seem necessary for the creation of similar compounds that would block or reduce the damaging effects on the skin as well.

One of the main characteristics of cutaneous aging, that has been recently studied, is the involvement of heat, promoted in part by UV rays, but strongly attributed to the radiation present in the infrared (IR) spectrum (2). Heat is a form of energy that can be transmitted in different ways, either by direct contact, by conduction of electric currents or even by IR radiation. Despite these different forms of heat generation, the final outcome (thermal energy) is the same, manifesting as an increase in skin temperature.

Some studies have shown that skin temperature, as measured intra-dermally, increases from normal 37.2°C to 40-43°C after just 15-20 minutes of direct sun exposure during extreme summer periods (3). This means that even while using traditional photoprotection, (UVA / UVB sunscreen), the skin is still subject to damage from the intense heat caused by IR radiation – whose rays are not filtered or blocked by the sunscreens used in current formulations.

Radiant heat, such as that generated in heating plates, ovens, and similar devices, can also create skin changes similar to those found in aging photo-exposed skin. Over time, elastic fiber hyperplasia in combination with collagen degeneration (3, 4) has been observed.

In fact, heat is the primary stimulus for increased signs of metalloproteinases (MMPs) and reactive oxygen species (ROS), as well as the production of inflammatory mediators in the skin. Those mediators include pro-inflammatory cytokines, angiogenic factors and transcription factors as NF-kb, serine proteases and other signaling pathways, culminating in the degradation of the extracellular matrix and in the other signs of photoaging2-4.

In addition to IR radiation, recent studies have highlighted the biological consequences of being exposed to visible light. Considering the amount of the solar energy reaching the Earth's surface in the visible and infrared range,

an individual is exposed to significant daily amounts of infrared and visible light (VL). Visible light can significantly induce the production of reactive oxygen species, which promote the release of pro-inflammatory cytokines and expression of MMPs (5).
Since the skin is exposed to visible light during long periods throughout the day, the cumulative effects of visible light and the heat generated by exposure to IR can result in skin damage and premature tissue aging.

Many studies have reported the role, and therapeutic potential, of different classes of proteins which provide resistance to cellular stress. These are known as serine protease inhibitors, whose main role is to protect dermal collagen in the presence of heat and acute or chronic inflammatory processes (6). Serine protease inhibitors are known as serpins.
In the skin, both dermis and epidermis cells create serpins, which provide resistance to damage caused by stressors such as UV radiation, air pollution and heat (8). The main serpins described on the skin are colligin and headpin, which play similar roles in protection from collagen in the presence of endogenous stress (eg inflammation), or exogenous stress (eg heat or UV radiation).
Colligin is a collagen-binding glycoprotein, being phosphorylated in vivo and induced in the presence of heat6. It stimulates collagen production and protects procollagen and collagens I and IV from the action of degradation enzymes before or after the formation of the triple helix (6). Headpin plays a very similar role to colligin, but is more involved in protecting against damage from inflammation established in the tissue after exposure to UV and IR radiation, even controlling skin temperature (7).
Phytosterols from Physalis angulata possess immunomodulatory activity and have been described as acting not just as an anti-inflammatory, but also as a stimulant of headpin and colligin to protect against infrared and visible light damage. Physavie, developed by Chemyunion, has placed technology, innovation and green awareness on the same axis in an effort to shine a light on this essential daily skin care need.

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HOW TECHNOLOGY CAN SUPPORT THE INDIVIDUAL AND ENSURE COMPLIANCE IN SUN CARE

There have been incredible advances in sun care in the last 30 years, not least in the improvement of the sensory elements of sunscreen. High factor sunscreens, available since the advent of SPF in the 1980s, were a tough sell. Often these thick, opaque, heavy to apply creams created a physical barrier from the sun's harmful rays. However, people were put off by the sensation and appearance of these products.

Over the years we have seen great innovation and improvements. Manufacturers created chassis that were less opaque on the skin and deemed more acceptable for use by the consumer. The importance of SPF was still not widely understood, however, and popular brands of sunscreen often contained extremely low factors that we now understand to offer insufficient protection.

There was also confusion about how to apply sunscreen correctly to avoid sun damage. Sunlight was considered beneficial in many respects, and bronzed skin remained the hallmark of health and youth. If you did not burn, the popular belief was that no damage would be done. As a result, sunscreen was often applied too little, too late.

Although we now have a better understanding about the importance of sun care, the consumer remains confused about how to use sunscreen correctly to ensure they are fully protected. The British Association of Dermatologists reports that most people use less than half of the amount of sunscreen required to provide appropriate protection.

Like any skincare regime, to get the most out of your sun care it is vital to understand your own unique requirements. You need to know where you fall on the Fitzpatrick scale (a system devised to classify your skin type based on the amount of pigment your skin has, and its reaction to sun exposure) and what condition your skin is in.

Your surrounding environment is another factor to consider. For example, if you are in the city and likely to experience higher levels of pollution, your skin will have different needs than if you live on the coast, where abrasive wind is more likely to aggravate your skin.

We must also consider the changeable nature of skin. If you are doing something active, you are likely to perspire and need to reapply your product more regularly. Hormonal changes, such as those often experienced by women throughout pregnancy, can also impact the skin's sensitivity to sunlight.

Clearly, we must take a personalised approach to our sun care. But how can we expect people to fully understand and monitor all these changeable factors? Diagnostics and education are key to help the consumer better understand their own unique needs, but it is through technology that we will equip them to meet their sun care requirements and ensure compliance of product use.

Technology allows us to pull together the scientific data now available and present it to the customer in an easy to understand way. For example, apps can tell us the UV index in any location in real time. This, and additional information fed into an app, could be used to inform the consumer on what formulation they require at that time.

A consultation by a trained advisor can help consumers understand where they are on the Fitzpatrick scale, optical diagnostic tools can also be used to build confidence in the consumer on the accuracy of this measurement and is the first step in understanding what your individual skin really needs.

Although in sun care we see most focus on prevention, we should also consider what can be done to help repair already damaged skin. Older people, and those who have spent time in hotter climes, often have skin damage as a result of prolonged sun exposure. There are actives (natural ingredients scientifically proven to change skin at a cellular level) now available to help repair some of this damage, but they must be used consistently over time to see results.

Optical diagnostics can offer us the ability to measure gradual incremental improvement in pigmentation and therefore provide a guide to skin repair that has occurred to date which will encourage continued use, even though the results are not yet truly visible – much like the way one pound weight loss per week may not be noticeable, but when viewed on the measuring scales is likely to encourage someone to continue a new health regime until they achieve their target weight.

Technology also enables sun care brands to better connect with the consumer to advise, educate and inspire. Tutorial videos can offer information on how much product you need to use, and apps can remind you when you should apply it. These immediate reminders can be immeasurably helpful - life is busy and we don't always have time to think about the specific volume we should use of a product or exactly how long it had been since we last applied sunscreen. Technology can unburden the consumer by automatically flagging to them when exactly action is required.

The gamification of this process also inspires the consumer to compete with themselves to do better, much like a personal fitness tracker encourages us to take more steps. Have you met your sunscreen target for today? No – better top up then!

We have the data available to us to ensure we never again burn in the sun – the consumer only needs to comply. Technology can empower us to understand fully our unique sun care needs, in real time, minimising our risk of sun damage by getting the best result from the right formulation for the individual.

WILMA MCDANIEL
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FUN IN THE SUN? PROTECTING YOUR SKIN FROM THE SUN'S POWERFUL RAYS SAFELY

While outdoor activities provide benefits to consumers' physical and mental well-being, more time outdoors means more exposure to the sun's intense rays.

Although consumers are increasingly aware of the damage and the health risks that the sun can cause to unprotected skin, only 50% of Americans protect their skin from the sun when outdoors, according to the American Academy of Dermatology.

As scientific advancements in sun care technologies continue to expand and sun protection becomes easier and part of a daily routine, multifunctional benefits, including transparency, durability, spreadability and overall feel within sun care products and daily wear cosmetics are crucial.

One key factor causing challenges for recommended skin protection routines is conflicting information around UV filters and potential ocean pollution. More and more eco-conscious consumers are seeking solutions that are safe for people and the planet, without sacrificing performance.

SUNSETTING BARE MINIMUM SUN CARE

At minimum, most consumers want SPF 30 or higher, as well as a broad spectrum of capabilities with up to 80 minutes of water or sweat resistance. These attributes ensure protection against UV rays to reduce the risk of skin cancer and sunburn while providing long-lasting protection through swimming, sweating or traveling through humid climates. These standards form the foundation of a successful sun care product, but consumers increasingly desire sun protection and daily wear cosmetics that go beyond this to fight prematurely ageing skin, fine lines, wrinkles and age spots.

Growing interest from consumers and the overall industry in multi-functional products is driving demand for ingredients that serve multiple functions in their formulations. Dow's scientific background and broad portfolio has led to innovations that allow a combination of high skin protection and additional claims against the damage of UV rays like wash-off resistance, improved spreadability, longer wear and a sensory profile that pleases, without causing irritation or whitening effects.

COMBATTING MID-ACTIVITY MELT

Highly active consumers seek products that will stand up to sweat as they run, hike, bike, swim, climb and otherwise engage in fast-paced, outdoor activities. For these consumers, sun protection must be a simple "set it and forget it" activity, with formulas that boast high water and sebum repellency, high rub-off resistance and high film flexibility and integrity. Dow's first waterborne silicone film-former, Acrylates/Polytrimethylsiloxymethacrylate Copolymer and Laureth-1 Phosphate forms a lightweight film on the skin, improving sun care products' long wear and preventing mid-activity meltdown.
Similarly, Dow's hybrid film former Acrylates Copolymer (and) Acrylates Polytrimethylsiloxymethacrylate Copolymer combines aspects of acrylic and silicone acrylate chemistries to exhibit high water repellency, high sebum repellency and high film flexibility, leading the way in next-generation sun care for the active consumer.

SAFELY PROTECTED UNDER THE SUN

As consumers become more knowledgeable about sun care products, they're calling for increased transparency from suppliers, particularly regarding conflicting information about potential ocean and coral reef damage caused by sun care products. The resulting confusion can negatively impact skin protection routines.

In response to the desire for product safety and transparency, Dow has developed a brand-new bio-based and readily biodegradable SPF Booster that enables greater SPF efficiency in sun care and daily skin care. Derived from Forest Stewardship Council (FSC)-certified wood pulp, it works with both organic and inorganic UV filters and delivers a myriad of benefits by reducing dependence on UV actives, enabling aesthetically pleasing formulations with non-whitening effects and minimizing the irritation that actives can cause, all while supporting market demand for naturally sourced formulations that are safe for the environment. This innovative SPF booster demonstrates in vitro and in vivo SPF boosting performance.

SHINING LIGHT ON NEW SOLUTIONS

The ideal sun protection product addresses the concerns of all consumers, from the daily commuter to the outdoor adventurer, functioning as more than just sun protection, but as a cornerstone of an effective skincare routine and on-the-go lifestyle. As today's consumers demand multifunctional efficiency and protection, new innovation is crucial and suppliers must work to deliver solutions to meet a range of needs, all while ensuring safety of people and the planet.

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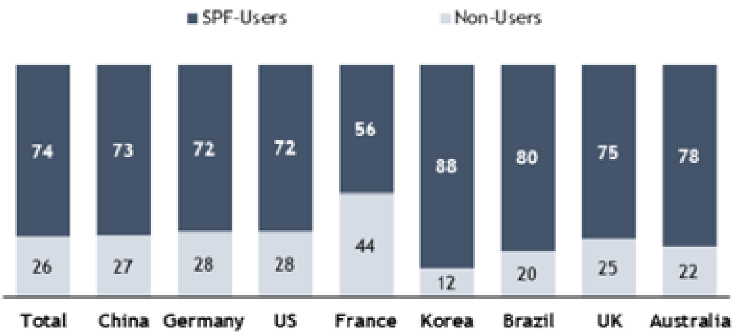
Dow Home and Personal Care

CONSUMER COMPLIANCE AND THE IDEAL SUNSCREEN

Skin cancer incidence rates around the globe are still growing and there are few indications on the horizon that this trend is going to diminish. Although there is a clear link here with UV exposure, it is less clear how overexposure to UV happens. Here is a brief estimate of our daily UV burden in summer, keeping in mind that UV intensity varies throughout the day, and also it changes due to weather conditions and the angle at which the sun hits the skin. Field studies with UV dosimeters on beach goers, skiers(1) and outdoor workers (2, 3) have shown that the dosage we receive, even on a full outdoor holiday in Tenerife with a high UV index, amounts to about 10 SED which corresponds to about 4 MED for a skin type 2 person. This is enough for a serious case of sunburn to occur if unprotected. However, one can easily protect against this by using an SPF 15 formula, resulting in only a suberythemal dosage with no perceivable redness. An SPF 50 formula would cut the erythemal radiation package received to less than 10 % for each day exposed. However, this would only be true if sunscreen is used at all, and at the same dosage as tested, i.e. 2 mg/cm2. Unfortunately, as many use level studies show, this is not generally the case. Often, only 20 % of that amount is used (4). In addition to the question of not using enough sun protection, we wanted to better understand how consumers view sunscreens and how they use them, so in 2017, we carried out an international survey involving 5600 Caucasian respondents in eight countries. On a global average, about one quarter of participants reported never using sunscreens at all, and of those who did, more than 50 % said they only apply them on specific occasions. Moreover, many beach goers said that they do not cover their whole body and leave areas such as the torso out completely. All these factors lead to significant UV exposure and certainly offer a partial explanation as to why skin cancer rates are still rising.



Usage by country (past 12 months, 2017), Basis: All respondents, Question: SPF stands for Sun Protection Factor and is typically displayed in sun products. Question: "Off the top of your head, did you happen to use products containing SPF protection in the past 12 months?"

Our study also looked at the reasons for this behavior. Partly, it is due to beliefs, e.g. in France, which had the highest amount of non-users there is a desire to be tanned and a belief that sunscreens counteract tanning, which they do, particularly if compared to a sunburn-related, inflammation enhanced tanning. From this perspective, it seems "logical" therefore not to use sunscreens. A completely different picture could be found in Korea. Here, the beauty trend of staying pale triggered a very high compliance rate at 88%. Responders also indicated that sunscreens have some unpleasant features, such as stickiness and greasiness during application. This subconsciously fosters some not very logical avoidance rationalization e.g. "my skin doesn't need protection", or "it wasn't sunny this year". Benefits of sun-bathing are also used sometimes to rationalize exposure, e.g. "I need to make Vitamin D" or simply, "the sun feels good on my skin". Non-users are less likely to believe the link between sun exposure and skin cancer and that sunscreens can break it, which is why they choose not to use sunscreen at all.

All these points would seem to be interconnected and suggest that even more concerted efforts and more differentiated approaches to sun protection are needed if we are to have an impact on the skin cancer incidence rate. First and foremost, we need to create pleasant-to-use formulas with a dry touch and non-greasy features, both to attract consumers and to move their unconsciously saved experiences away from avoidance rationalization. The technologies exist, e.g. dry touch sensory modifiers, in silico formulation design with oil load management(5), pigmentary UV filters, and siliconized UV-filters, e.g. Polysilicone-15.

The good old Sun has its positives and negatives. Sunscreens, their packaging, their stories, including their eco-impact, and their sensory features need to connect more effectively with consumers, in particular those large groups of permanent and temporary non-users. Communication can be helped by speaking more about managing, being actively in control of sun exposure and intensity received, rather than talking about "sun protection" which implies that "the Sun is bad" and to be feared. Wording such as this is likely to contradict the positive feelings many people have towards the Sun and could lead to lower consumer engagement and deliberate, post-rationalized denial of the risks. We also need to connect products more specifically and more personally to dedicated consumer groups, such as beach goers, "men" (where sunscreen avoidance is higher than among women), mountaineers, outdoor workers (where sunscreens are often forgotten), instead of broad "one fits all" campaigns. We definitely think it is worth the effort for all of us, because we all benefit from it.

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IS THE SPF (SUN PROTECTION FACTOR) THE ONLY (OR MOST IMPORTANT) PERFORMANCE PARAMETER FOR A SUNSCREEN PRODUCT?

Throughout the years, consumers have had a constantly evolving relationship with the sun. In the 1960s & 70s there was a rise in tanning. However, by the 1980s & 90s the threat of the Sun's UV radiation was taken more seriously & advances in sunscreen technologies lead to an increase in sun protection products. With over 3 million global incidences of skin cancer, 86% of which are attributed to the sun & where 50% may be avoided with the use of a good quality sunscreen, protection from the sun remains the main priority of sunscreen products. However, increasing consumer demands, environmental concerns & regulations have led to a rapid development in sunscreen formulations.

SUN PROTECTION FACTOR

In the early years of sunscreens, attention was focused on protection against the UVB rays from the sun which are responsible for immediate & obvious skin damage, such as sunburn. Sun Protection Factor (SPF) was developed as the measure of protection a sunscreen can provide against mainly UVB rays. It is determined according to how long it takes for skin treated with sunscreen to burn compared to untreated skin. However, it does not represent protection against UVA radiation.

BROAD-SPECTRUM PROTECTION

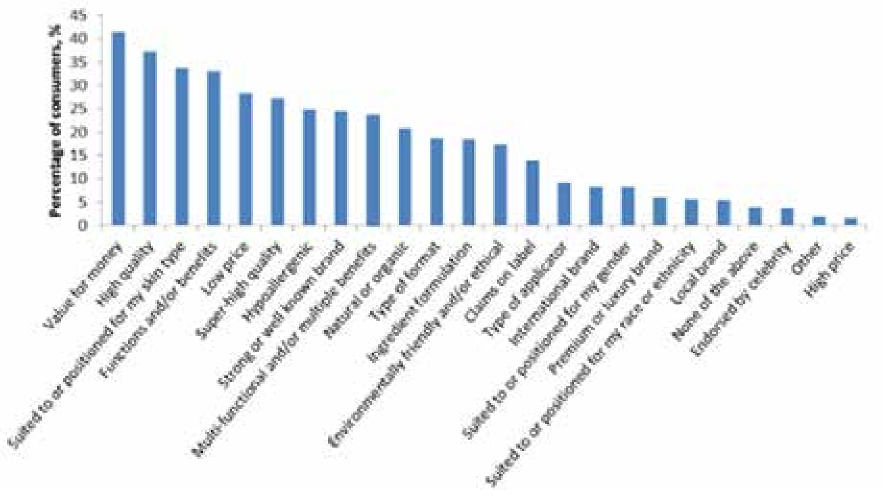
With research revealing that both UVA & UVB radiation can cause biological damage, later sunscreen development was focused on formulations offering balanced UVA & UVB protection. With the release of 2006/647/EC, European developers were especially focused on broad spectrum sunscreens from 2006 to 2013. The possible threat from infrared & high-visibility blue light was also suggested, leading to further research into formulations that could offer even wider protection.

YEAR-ROUND PROTECTION

Consumers are becoming more aware of the year-round effects of UV radiation on the skin's health & appearance. This has led to consumers increasingly using sun care products before exposure to the sun; with the global sunscreen market expected to reach $11.71 billion by the end of 2025. However, consumers have also begun seeking out sunscreen ingredients in other personal care products & demanding their sun protection products offer more than just UV protection. This has resulted in the increased development of multifunctional ingredients. Ingredients are now expected to fulfil a variety of roles within a formulation (UV protection, light & pollutant protection, anti-ageing etc) & formulations need to offer a multitude of benefits to fit current active lifestyles (long-lasting, water-resistant, fast-acting).

CONSCIOUS CONSUMERISM

The rise of conscious consumerism, driven by the growing buyer power of Millennials & Gen Z, has resulted in consumers becoming increasingly knowledgeable & mindful of the ingredients that are present in the products they buy. The increasing popularity of clean beauty means that consumers are focusing on natural ingredients that are produced with consideration to both human health & the environment. The possible detrimental effect UV filters can have on marine life has been coming under increased scrutiny, driving research into ways sunscreen products can minimise their environmental impact. There is a growing demand by consumers for safety, transparency & sustainability when they are purchasing a product. They are also not satisfied with the ingredients simply being derived from nature, but for them to have been ethically & sustainably sourced.
Consumer concerns of sustainability & ethics are not limited to the ingredients in their sunscreen products but extend to the manufacturers & brands. Conscious consumerism means that the sustainability & corporate social responsibility of the brand & its whole supply chain is taken into consideration before purchasing a product. This often includes the packaging, with many consumers demanding recyclable, reusable or biodegradable packaging for any products they purchase. The rise in the Vegan & Vegetarian lifestyles has also resulted in an increase in



Reasons for purchasing sunscreen or dedicated sun protection products (Euromonitor Beauty Survey)

Consumer Preferences

- Higher Sun Protection
- Beyond Sun Protection
- Water Resistance
- Improved Sensorial Feeling
- Mildness
- Convenience
- Added Benefits

demand for vegan & vegetarian beauty products, including sunscreen products.

SELFIE GENERATION

The proclivity of consumers to document their lives online in video & picture form has caused further complications when formulating sunscreen products. Consumers are demanding that their products not only offer superior protection from UV radiation & other pollutants but to also be cosmetically & sensorially appealing. Sunscreen products need to spread easily, have a light feel, pleasant smell & avoid the white cast & glare when photographing.

CONCLUSION

While there are varying preferences across the world that determine sunscreen product purchasing, there are some common themes & SPF is no longer alone as the most important parameter . Accordingly, there are many added value benefits that the consumers consider before making a purchase decision alongside SPF. The increasing demands of consumers to be provided with innovative & novel ingredients containing multifunctional formulations that offer long-lasting, broad-spectrum protection that are aesthetically pleasing & environmentally safe will always offer important performance parameters when developing sunscreen products.

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A BALANCED VIEW ON THE ENVIRONMENTAL EFFECTS OF UV FILTERS: A CASE STUDY ON ZINC OXIDE

It is estimated that more than 30% of the world's coral reefs have disappeared in recent years and roughly 90% of the remaining reefs are currently in jeopardy of survival. This fragile ecosystem is not only a source of natural beauty, but supports roughly 25% of all marine life—it's rapid depletion is of great concern.
Global warming brought about by climate change is one of the major contributing factors to the destruction of coral reef destruction. Climate change and the related increase in water temperature has been linked to the massive coral bleaching that has been observed across the world. Separately, and importantly, we also understand that the impact of certain UV filters used in sunscreens can also contribute to reef damage.

Consumers are continually hearing conflicting reports about the safety of both mineral-based and synthetic chemical-based UV filters, which leads to confusion in the marketplace. As bans on some synthetic chemical filters are being put in place, the general public is left questioning the impact of everyday sunscreens. At the same time, consumers need to protect themselves from harmful UV radiation that leads to sunburns and skin cancer. The confusion is certainly understandable from an industry perspective.
For consumers to feel empowered in their purchasing behavior, a true balanced view of the environmental effects of sunscreen needs to be presented. The key to achieving this balanced view is to move from a hazard profile to a risk and exposure scenario to look at the actual impact different products have on the environment. As zinc oxide has been considered to be one of the more reef-safe UV filters, we dive into its assessment here.
Zinc is an essential element which is needed for the optimal growth and development of all living organisms. Due to its general natural availability and unique characteristics, zinc is an essential component of many metabolic processes that sustain life for all organisms. Nevertheless, Zn and zinc compounds are labeled as ecotoxic for the aquatic environment for transportation(1).

This labeling is based on the intrinsic hazard profile for bulk materials and is mainly driven by the release and toxicity of Zn^{2+}. The observed toxicity is determined by concentration and exposure time. It is true that some studies have shown that high Zn^{2+} concentrations and long exposure times can kill coral algae, but most of these studies have been done in an isolated test system at unrealistic high concentrations that are not relevant to the field concentrations and conditions in the environment. In other words, test conditions are nowhere close to actual real-life situations, hence the need to look at risk and exposure scenarios for the impact assessments.
In addition, not being considered in most environmental toxicity studies is the concept of rapid degradability of ZnO. Rapid degradability can be considered as an equivalent concept to biodegradability for inorganic compounds. Studies have demonstrated that dissolved Zn^{2+} ions are rapidly complexed by ligands in soil and surface waters, rendering them bio-unavailable, further reducing the assumed toxicity.

Determination of reliable concentrations of ZnO in surface waters as a result of its use as a UV filter is key in a risk and exposure assessment. This is not an easy task due to low concentrations in the environment. A comprehensive evaluation was recently performed by EverCare on measured and estimated concentrations of Zn in both fresh and marine waters, including those of touristic shore areas. This has demonstrated that the observed ZnO

levels remain well below the PNEC value of zinc oxide and as such has no observed adverse or toxic effect (2,3). Consequently, due to the use of ZnO as UV filter in sunscreens, Zn^{2+} concentrations do not reach levels that provide toxicity or do harm to corals.
As consumers are being overwhelmed with conflicting news headlines about which UV filters are reef-safe, a true risk and exposure scenario needs to be presented for a full assessment.
As can be seen with ZnO, while there are concerns associated with Zn concentrations from an intrinsic evaluation of ZnO, an accurate assessment of ZnO in coastal waters provides a different conclusion. Therefore, consumers should feel confident in their choice of ZnO as one of the safer UV filter choices for the environment.

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IS THERE AN IDEAL SUNSCREEN PRODUCT?

An ideal sunscreen product can be difficult to obtain. Consumers want an effective sunscreen that provides water/sweat resistance; however, they also prefer an aesthetically pleasing sensory experience, without whitening or a greasy or sticky skin feel.
Hydrolyzed Jojoba Esters are a COSMOS approved ingredient used by formulators to create the ideal sunscreen. Known for its substantivity and ability to keep small molecules (e.g. sunscreen actives, humectants, etc.) at the skin surface for longer, it can be used at low loading levels to improve water resistance, all while providing a consumer perceptible soft and smooth skin feel. Additionally, it is a multifunctional ingredient with clinically proven benefits to skin hydration, barrier function, enlarged pore reduction, and redness reduction, making it particularly ideal for daily-use moisturizers that include sunscreen actives.
The ideal sunscreen should not only provide SPF protection, but also deliver additional skin benefits, providing consumers with one product that meets all their needs.
Ethyl Macadamiate is another ingredient often used as a natural silicone alternative that has been used to build the ideal sunscreen. Ethyl Macadamiate provides SPF boosting of mineral sunscreen actives with a silky, smooth silicone-like after feel. This allows for lower usage levels of titanium dioxide and zinc oxide, and therefore leads to less of a whitening effect on the skin. The reduction of the whitening effect caused by mineral sunscreen actives is especially important when building the ideal sunscreen for the environmentally conscious consumer. Mineral sunscreens are more appealing to these consumers since evidence suggests that organic sunscreen actives damage coral reefs.
Ethyl Macadamiate is useful to the formulator at the bench as it assists with titanium dioxide particle dispersion and organic sunscreen solubilization, making the incorporation of sunscreen actives easier. Ethyl Macadamiate also helps pigment dispersion and stabilization, which is applicable to color cosmetic products that make SPF claims. Additionally, Ethyl Macadamiate also increases skin hydration and skin radiance, and was preferred by more than 80% of female consumers in a mineral sunscreen for silky, less greasy skin, and the lightest product on the skin (as compared to caprylic/capric triglyceride oil), making it a useful ingredient within the ideal sunscreen.

IS THE SPF (SUN PROTECTION FACTOR) THE ONLY (OR MOST IMPORTANT) PERFORMANCE PARAMETER FOR A SUNSCREEN PRODUCT?

SPF is a very important indicator for sunscreen performance; however, it is not the only factor as proper application, reapplication behavior, and water resistance properties of the sunscreen play a significant role in the effectiveness of a product. Without compliance and proper use, SPF is irrelevant.
Proper use of sunscreens requires better consumer education on exactly how a sunscreen should be used and how often it should be reapplied. The FDA monograph requires that sunscreens be applied 2mg/cm^2 during SPF testing; however, most consumers don't apply nearly enough to their skin during actual use. Additionally, it is recommended that sunscreens are applied 30 minutes prior to sun exposure and every two hours during exposure. This is another recommendation that consumers tend to ignore. More effort needs to be taken by the industry, dermatologists, etc., to better inform the consumer of how to use sunscreens and the consequences of improper use.
Compliance by the consumer of proper sunscreen use will require formulation of products that consumers really want to use. The more positive experience a consumer has, the more likely they are to continue to use a product. Additionally, sunscreen formulas should be built to be multifunctional, so consumers have more than one reason to use them. Two natural ingredients that can be used to achieve this goal are Hydrolyzed Jojoba Esters and Ethyl Macadamiate.
COSMOS approved Hydrolyzed Jojoba Esters not only provides water resistance to sunscreens, but also provides skin hydration, barrier function improvements, redness reduction, and an improved consumer experience to the end user. Its substantivity allows Hydrolyzed Jojoba Esters to trap small molecules like sunscreen actives and humectants at the skin's surface for longer periods of time, while also providing a cushiony, soft skin feel.
Ethyl Macadamiate not only helps the formulator by boosting SPF, increasing titanium dioxide dispersion, and improving solubilization of organic sunscreen actives, but also improves skin hydration, skin radiance, and consumer perception of skin feel after use. Additionally, Ethyl Macadamiate can be used as a replacement for volatile silicones by mimicking their skin feel properties, resulting in a silky, smooth, non-greasy after feel, further promoting the continued and frequent application of the sunscreen.

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A NEW STANDARD FOR SUNSCREEN PERFORMANCE TESTING WILL MAKE SPF NUMBERS MORE MEANINGFUL FOR CONSUMERS

HOW IS SPF CONSIDERED BY DIFFERENT STAKEHOLDERS?

SPF (sun protection factor), as defined by the US Food and Drug Administration, is a measure of how much solar energy (UV radiation) is required to produce sunburn on protected skin (i.e., in the presence of sunscreen) relative to the amount of solar energy required to produce sunburn on unprotected skin. SPF indicates a sunscreen's ability to protect against the assault of erythema-causing UVB rays.

UVA Protection Grade (PFA or PA) or UVA Protection Factor (UVA-PF) is defined similarly as a measurement of skin pigmentation change (darkening).

HOW ARE SPF/UVA-PF NUMBERS INTERPRETED BY CONSUMERS?

Unfortunately, these standard definitions for SPF and UVA-PF/PA do not enable consumers to make meaningful decisions about their sunscreen purchases. For most consumers, SPF and PFA value are no more than numbers on a label that indicate a sunscreen product's relative quality. But these numbers do not clearly convey accurate performance information. Skin damage from UV rays is not perceivable by human eyes until the harm is already done. Without actionable indicators on quality or application guidance, consumers often rely on a confusing mix of advertising and popular opinion to help them make purchase choices.

HOW ARE SPF/UVA-PF NUMBERS USED BY THE BRAND OWNERS AND WHY ARE THEY HINDERING DEVELOPMENT?

In most countries, commercially launching a sunscreen product requires a manufacturer to produce ***in vivo*** SPF test results and related PFA numbers for display on labels. ***In vivo*** tests are not reproducible and repeated tests are often needed to arrive at the desired results. This is both expensive and time-consuming.

During an ***in vivo*** test, skin color changes are visually assessed after a set amount of simulated sunlight irradiation is induced on an area of skin to which a specified dosage of sunscreen has been applied by hand. The same amount of irradiation is then induced on skin to which no sunscreen has been applied. Despite the fixed sunscreen dosage as defined by weight per skin area, consistent coverage in terms of uniform sunscreen film thickness cannot be achieved with common finger rubbing practice. This inevitable randomness coupled with variations in both irradiation conditions and operators' color assessment makes ***in vivo*** test results nothing more than directional averages. The same formulation can often yield very different SPF numbers when tested in different ***in vivo*** labs, or even in the same lab. Lack of reliable performance testing protocols significantly hinder the development of highly efficacious sunscreen products and prevent brands from clearly differentiating themselves and using performance as a competitive advantage.

HOW ARE SPF/UVA-PF USED BY SUNSCREEN FORMULATORS/INGREDIENT PROVIDERS?

Common ***in vitro*** tests often yield highly random results and require significant training on finger-rubbing skills. They are therefore not practical for the purpose of directing product development. Lacking clear and precise quantitative testing protocol for product performance significantly hinders a formulator from creating and designing better sunscreens for both sun protection and skin feel. An ingredient provider cannot precisely develop better-performing sunscreen ingredients if there is not a quantitative methodology for performance testing with a clearly-defined standard deviation level.

HALLSTAR SOLUTIONS

Hallstar has developed and patented a sunscreen performance testing platform based on an exact and consistent deposit of sunscreen films of known micron-meter thickness. The absorbance and the associated SPF and PFA values of the post-irradiated film can be accurately measured using a UV-Vis spectrophotometer equipped with an integrated detector. Essentially, the strength of absorbance (i.e., the ability to absorb UV rays) of any sunscreen film can be repeatably, reproducibly and scientifically measured. Sunscreen formulation performance comparison and ingredient performance evaluation can be carried out using established process standard deviation. By employing this new testing platform, formulators and ingredient developers can be confident in their research and development direction while saving significant time and cost.

To further the quantification of sunscreen performance directly on human skin, Hallstar developed a smart camera device that connects to mobile phones and accurately captures UV absorbance of sunscreen film on skin in real time. An accompanying mobile app correlates the visibly captured UV absorbance data with the percentage of UV absorbance at that film thickness as established by our sunscreen performance testing platform. In this way, a real-time quantitative display of sunscreen's protection power on individual user's skin can be achieved.

Hallstar sunscreen technology is based on our patented photostabilization design principle. Using Hallstar photostabilizers (e.g., INCI: Ethylhexyl Methoxycrylene, INCI: Acrylates Copolymer, INCI: Butyloctyl Salicylate) enables efficient, elegant and safe sun care through photostabilizing organic and inorganic UV filters, making them more efficient and avoiding ROS generation. These photostabilizers also protect light-sensitive skin care actives such as retinoids and resveratrol. In addition, Hallstar's newest disruptive chemistry (INCI: Bis(Cyano Butylacetate) Anthracenediylidene), which we call an ANTEoxidant, takes anti-photoaging to a new level with its mechanism for photostabilizing common endogenous skin chromophores, enabling comprehensive skin-aging solutions beyond conventional sunscreens.

The full collection of Hallstar Sun Care Solutions offers the cosmetic industry unique ingredients, scientific testing, and innovative visualization of sunscreen performance to enable and convey sunscreen performance directly to consumers. We hope this will result in better protection of consumer skin and enable a freer lifestyle that embraces the sun.

EILEEN ZHANG
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VALIDATED *IN-VITRO* SPF METHOD

In the past years, sun protection has been deeply improved in terms of balance (UVB, UVA, Blue Light, Infrared, etc.), claims (Sun Protection Factor – SPF, UVA Protection Factor – UVAPF, Critical Wavelength – CW, Water Resistance – WR, etc.), formulation, understanding sunlight and testing methods, regulations, awareness from consumers, etc.

There are different methods available for the sunscreen testing procedure. These methods are relatively complex and require significant experience, processes and equipment. Fortunately, standards are available in order to harmonize these methods worldwide, mainly, according to ISO (International Organization for Standardization).

Nowadays, from the ISO projects, several methods are already available or under development (other methods may be added in the future for standardization process such as the Blue Light assessment, Photostability, In-Vitro Water Resistance, etc.), such as:

- In-Vivo SPF according to ISO 24444 (published)
- In-Vivo UVAPF according to ISO 24442 (published)
- In-Vitro UVAPF - CW according to ISO 24443 (published)
- In-Vivo WR procedure according to ISO 16217 (publication in 2020)
- In-Vivo WR percentage calculation according to ISO 18861 (publication in 2020)
- In-Vitro SPF according to ISO 23675 (under development)
- In-Vivo/In-Vitro Hybrid Diffuse Reflectance Spectroscopy SPF – UVAPF according to ISO 23698 (under development)

Among all these methods, the In-Vitro SPF is strongly required by the industry and governmental organizations delivering results equivalent to the ISO 24444 method. As evidence, the degree of protection should be measured using standardized, reproducible testing methods and take photo-degradation into account as recommended by the European Commission (1).

Let's study the alternative In-Vitro sunscreen test method under the project ISO 23675.

IN-VITRO SPF METHOD PRINCIPLE

The In-Vitro SPF method in progress at the ISO level (projects ISO 23675) includes new requirements and appliances to ensure the reliability of the results for the In Vitro determination of UVA protection. The method is validated by Cosmetics Europe (CE) in a recent publication (2) and incorporates many of the recommendations issued by the ISO 24443. Given below are the different simplified steps(3-4):

1. As for the ISO 24443, topographic parameters of the substrate shall be controlled and respected as a control chart for both molded and sandblasted PMMA plates. Both substrates are used with different quantity of products (1.3 mg/cm² for molded HD6 and 1.2 mg/cm² for sandblasted SB6).
2. The temperature of the interface substrate/sample shall be controlled during the whole process.
3. As the method consists of assessing the residual transmission of a product spread in a thin layer on substrates, to ensure reproducibility, it has been demonstrated that automated spreading is the only way by using a robotic arm with specific characteristics such as the HD-SPREADMASTER.
4. After the drying step and prior to any UV irradiation, the acquisition of the initial UV absorbance spectrum, the characteristics and the performance of the spectrophotometers and their regular checking with specific calibration are necessary.
5. After a mathematical adjustment of the initial UV absorbance spectrum using correction factors, a single UV exposure dose D (MED/h) is applied with a solar spectrum similar to the In Vivo SPF ISO 24444. It will be mandatory to control the emission of the source in order to calculate and justify the dose.
6. Finally, a second In-Vitro absorbance measurement of the sunscreen product after UV exposure is required in order to calculate the final In-Vitro SPF after mathematical adjustment.

ACCEPTANCE OF THE ALTERNATIVE SPF METHOD

Even if it was never raised so far for other sun protection testing methods, one of the problems created for the In-Vitro SPF method validation was that no acceptance criteria existed among the ISO TC217 (Technical Committee for Cosmetics) WG7 (Working Group for Sun Protection Test Methods) consensus.

To respond to this issue, after a huge work from different parties (ISO TC217 WG7 Ad Hoc group, CE, statisticians, experts, etc.), an international consensus was proposed and accepted years ago by checking:

- The ascertain minimal method bias (matrix effect, overall bias, etc.).
- At least 95% of the paired SPF values for 24 products, derived from the 3 in-vivo test institutes (at least 5 test subjects per laboratory) and the 3 in-vitro testing labs (both in a blinded fashion), fit within the upper and lower limits of a funnel across the full range of labeled SPF categories (SPF 6, 10, 15, 20, 25, 30, 50 and 50+).

During this time, even if other proposals were proposed regarding validation criteria and even if some of them may be interesting, nowadays no new consensus from the different experts in the sun protection testing fields changed at the international level. In other terms, the minimum criteria proposed and accepted by the ISO/TC217/WG7 years ago remain valid and already include a balance between the statistical requirements, the cost efficiency and the realistic feasibility.

CONCLUSION

Today, all barriers are solved for the alternative In-Vitro SPF method according to the ISO 23675 projects, including:

- The technical limits (the method is reproducible and correlated to the In-Vivo SPF values),
- The fulfillment of the ISO acceptance criteria (as explained in a publication about the CE method (2)),
- The established international majority consensus.

To summarize, this most advanced In-Vitro SPF method is based on the UV transmittance measurement process using a multi-substrates approach (molded and sandblasted PMMA plates) with correction factors, a robotic spreading and a UV exposure step.

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DO I REALLY NEED TO LOOK LIKE A GHOST THIS SUMMER?

Zinc oxide as a UV filter is currently gaining attention in the sunscreen market. A focus on reef-friendly ingredients and the revised proposal for the US FDA sunscreen ingredients monograph have found ZnO to emerge as one of the safest options. Many formulators are perceiving this pull from the market and are shifting to develop more ZnO based sunscreens. However, there is still some bias that mineral sunscreens lack sensorial benefits having a heavy texture and whitening effect. Fortunately, with the right choice of ZnO and dispersing agent, today's ZnO based sunscreens deliver efficacy with a high level of transparency and consumer desired textures.

REGULATORY ASPECTS ARE SHIFTING CONSUMER AWARENESS

Beginning this year, the Pacific island state of Palau was the first nation to enact a ban of some synthetic chemical UV filters that have been found to contribute to bleaching of coral reefs. Other regions such as Hawaii and Key West in the US have enacted similar bans to start in 2021 and more are expected to follow. Increased media coverage and social media influencers have made the public aware that ZnO is a prominent UV filter suitable for use in reef safe sunscreens, resulting in a shift in the consumer market.

Moreover, the alternative solutions in terms of UV filters are under scrutiny after the FDA published a study showing that most of the synthetic chemical UV filters used in sunscreens were found in the bloodstream of the end users. The recent proposal by the FDA for the sunscreen monograph has listed ZnO and TiO2 as the only GRASE ingredients and approved as Category I filters. The recent classification of TiO2, a category 2 carcinogen (inhalation) in Europe, further reduced the panel of UV filters and increased the attraction of ZnO in sunscreen formulations even more.

EFFICACY WITH UNCOMPROMISED AESTHETICS

A first important factor will be the choice of ZnO. EverCare offers three grades of ZnO with tailored performance and transparency. The balanced UV/Vis curves of EverCare's zinc oxides allows it to be used as a single UV filter while reaching the needed UVA factors thresholds.

BENEFITS OF USING ZINC OXIDE WITH POLYHYDROXYSTEARIC ACID IN SUNSCREEN EMULSIONS

Innospec supplies two grades of polyhydroxystearic acid (PHSA) which are highly effective dispersants and stabilizers for ultrafine grades of mineral UV filters such as zinc oxide and titanium dioxide in the oil phase of sunscreen emulsions. These PHSA grades are extremely useful for sunscreen emulsion formulations for providing long term formulation stability, preventing the emulsifier from acting as a dispersing aid - further enhancing emulsion stability, and inhibiting the emulsifier from carrying ZnO into the aqueous phase of the emulsion.

The effective dispersing and stabilizing properties of the PHSA grades can also markedly increase the UV absorption of sunscreens containing mineral UV filters while also increasing the optical transparency of the sunscreens to reduce the whitening effect that is often observed in formulations with these UV filters without dispersant.

The improvement in UV absorption from using the PHSA grades thus enables cost savings to be made due to lower loading of ZnO being required to give a particular SPF. Another important benefit of the PHSA grades is that they markedly reduce the viscosities of the pigment dispersions at dose rates of only a few percent or less allowing higher concentrations of ZnO to be used when required for high SPF formulations. This viscosity reducing property of the PHSA grades in the presence of mineral UV filters gives improved emulsion textures for formulations, making them very pleasant to use.

INGREDIENT OF CHOICE

The choice of grade of PHSA will depend upon a formulator's desired end properties for their particular composition and the other ingredients of choice in the composition. EverCare have successfully formulated several elegant, stable and highly effective 'reef-safe' example sunscreen compositions with their zinc oxide grades using a PHSA dispersant supplied by Innospec.

These example formulations demonstrate that Innospec's PSHA grade and EverCare's zinc oxide grades can be used together to create environmentally friendly, high performing sunscreen compositions which are pleasant to use and give a good appearance on the skin.

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DOES IT MAKE SENSE TO PROTECT FROM BLUE LIGHT, VISIBLE LIGHT OR INFRARED LIGHT?

THE IMPACT OF SOLAR IRRADIATION BEYOND THE UV RANGE ON SKIN

Sunlight reaching the Earth is composed of UVB (290-320 nm), UVA (320-400 nm), Blue Light, also known as High Energy Visible (HEV, 400-450 nm), other Visible (VIS, 450-700 nm), IR-A (700-1400 nm) and IR-B (1400-3000 nm). Scientific knowledge of the effects produced on skin by solar irradiation beyond the UV is rapidly progressing.
According to the Grotthus-Draper law, the light must be absorbed by skin in order to trigger biological responses in cells. When absorbed, the energy of photon is transferred to the chromophore; the radiation penetration depth is affected by position and absorption spectrum of the chromophore. The second process to occur is scattering; it is dependent on the wavelength of photon, which also impacts the depth of penetration into the skin. Skin contains endogenous chromophores, e.g. urocanic acid, amino acids, porphyrin, melanin, hemoglobin, bilirubin, carotenoids, riboflavin, water. Some chromophores absorb only in UV or in IR range, and others absorb throughout the UV-VIS (1).
Arguably, the broad span from 290 to 1400 nm is the most biologically relevant.
Zastrow ***et al***. determined that excessive free radical's formation occurs in the epidermis and dermis at all UV, VIS and near-IR wavelengths; and the approximately 50% of free radicals were generated in the VIS and IR spectral regions. In addition, the free-radical action spectrum was established for 290-700 nm range (2). According to Oplander ***et al.*** the interaction of HEV with porphyrin-containing enzymes and flavoproteins generated Reactive Oxygen Species (ROS) contributing to skin photoaging (3). HEV induced a long-lasting hyperpigmentation that was more pronounced versus UVB-induced (4). Dr. Murad summarized that the excessive HEV exposure accelerates the oxidation process, which elicits inflammation and damages the skin barrier, making it more prone to signs of aging, increased uneven skin tone, dullness, pigmentation, fine lines and wrinkles. According to Cho ***et al.*** exposure to VIS and IR-A from natural sunlight upregulated matrix metalloproteinases MMP-1 and MMP-9 expression in skin, and decreased Type I procollagen synthesis (5).

NOVEL INGREDIENTS

Recent studies conducted by Kobo Products showed that coated TiO_2 of about 35 nm (primary particle size) can block HEV very effectively. Transparent red iron oxide used at a very low level was shown to neutralize the whitening/bluing, enabling a higher TiO_2 use level without imparting the aesthetics of the final formulation.
As a result, 40% or more of HEV attenuation can be achieved by easy-to-use dispersion TPN45TELR (6).
Two grades of microne range TiO_2: TiO_2-IR-300 and A1K-TiO_2 are capable to effectively attenuate IR, and provide thermoprotection to the skin ***in vivo*** (7).
EMD found that coated TiO_2 (Eusolex TC and Eusolex T-AVO) attenuate HEV.
In addition, skin color correcting fillers, e.g. RonaFlair Balance Blue can provide HEV light mitigation (8).

OUTDOOR EVALUATIONS

Global Solar Power Meter (bandwidth 400-1100 nm) and Solameter 9.4 (bandwidth 422-499 nm), both from Solar Light Company, Inc. are being utilized to quantitatively estimate sunscreens protection potential against VIS + IR-A and HEV portions of natural sun light - in the outdoor settings. These parameters are tested by applying sunscreen in reproducible manner to suitable substrate (Vitro Skin N-19 from IMS, Inc.) and measuring its ability to attenuate irradiation in the respective wavelength ranges. Attenuation is calculated as a percentage of irradiance blocked by the test article assuming that irradiance data recorded for the blank substrate is 100 percent.

PATH FORWARD

In addition to established effects of UV radiation, HEV, VIS, and IR-A parts of the solar spectrum are increasingly recognized as contributors to skin photodamage from sun exposure.

The development of multifunctional sunscreen formulations capable of providing measurable protection beyond UV is a challenging technical task and an opportunity for further work. This task requires the development and utilization of novel ingredients and relevant testing methodologies (9). It was established that certain mineral sunscreen actives used alone or in conjunction with organic actives, particulate materials, e.g. silica, hydrated silica, talc, and iron oxides can contribute to sunscreen's attenuation in HEV, VIS and IR region.

According to Diffey, in the quest for new developments, it is vital not to compromise integrity by sacrificing the scientific rigor of assessing the real need for protection against every potential hazard. Retaining the confidence of consumers in the authenticity of products is paramount (10).

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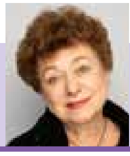

CURRENT CHALLENGES FOR SUNSCREENS

The main concerns of consumers are the effectiveness of sunscreens, their sensory characteristics, affordable costs, safe for use and environmentally friendly. If all these variables are not taken into account in the development of a sunscreen product, the result may be in detriment of its correct use. An inadequate sensorial or high cost can lead to inappropriate frequency of use during the exposure period, the reduction of the product dose to levels lower than recommended, and/or the chance for our product not to be of the consumers preference. The consumer will hence choose the product they consider as appropriate for all the mentioned characteristics (sensory, safety, cost, environment).

Many inquiries today are related to the safety of the sunscreen product and the information gathered through social networks mentions, for example, the recent observations by the United States FDA regarding the absorption of organic filters through the skin and its consequences on health. In February 2019, the U.S. Food and Drug Administration issued a proposed rule to update the sunscreen monograph in the United States. The key point is to re-evaluate the safety of the sunscreen active ingredients. From this rule, physical filters: Titanium Dioxide and Zinc Oxide, are the only filters considered as GRASE (Generally recognized as Safe and Effective); on the other side, two organic filters are discarded as they are not-GRASE; while for the rest of the 12 listed organic filters they must be all further evaluated for their absorption and potential toxicity. However, the FDA authorities have confirmed their recommendation for not stopping using these filters.

Another point under discussion is the approval of laws in some coastal places with coral reefs around the globe, to ban the sale of sunscreen products with some of these organic filters.

The European Commission recently published and confirmed its decision to classify titanium dioxide as a Category 2 carcinogen by inhalation. There are many doubts and there is a lot of confusing data or misinformation for the consumer, reason why we believe that, as sunscreens manufacturers, we need to be thoroughly trained and inform ourselves to educate and educate the consumer in choosing the best product and its correct use.

Same concept applies for doubts concerning production of vitamin D by our skin. There is some consensus that using sunscreen for daily and recreational photoprotection does not compromise skin synthesis of vitamin D, even when applied in optimal conditions. But consumer doubt persists whether to protect himself from the sun or not in order to get enough Vitamin D.

Skin damage caused by the incidence of infrared rays and the highest energy visible light, or blue light, has been investigated in recent years. This leads to ask ourselves if regular exposure to these types of radiation specifically contributes to the damage of our skin. Or perhaps, in order to optimize protection efficiency, it is worth adding agents that protect us from these wavelengths.

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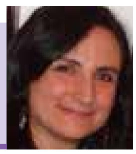

NATURAL SUNSCREENS: IS THIS THE FUTURE OF SUN PROTECTION?

Sales of natural and organic cosmetic & personal-care products have been steadily growing for the last 15 years with a worldwide turnover amounting to approximately 8.4 billion USD in 2010 (1) and forecast to reach 16 billion USD at a CAGR of 10% by 2020 (2).
This reflects a general Consumer's need for greener products, not only within the beauty industry but in all paths of life, e.g. electric cars, sustainable houses, reduction of single-use plastic, etc.
Growing awareness of the impact of our daily activities on the environment has been driving Consumers to opt for products they perceive as being safer and more benign to Nature.
Consequently, there has been an increased demand for "natural" cosmetic & personal-care products, including sunscreens.
With ongoing and growing debate regarding some organic UV filters being harmful to the aquatic environment (e.g. coral bleaching) and potential endocrine disruptors, many Brands are turning to formulating more natural sunscreens.
But what does exactly "natural sunscreen" mean?
Please note, hereinafter, the word "natural" is used in its broadest sense, i.e. to define ingredients that are "***derived (somehow) from nature***" including by mean of chemical transformation.
This may or may not meet some of the definitions adopted by natural & organic Standards used by certification bodies commonly found in the cosmetic industry.
As for all-things-natural, the main issue is that there is not any globally harmonised and legally recognised Regulatory framework that the industry can refer to when developing natural products.
This leads to confusion for the formulator as to which guideline to follow, especially when having to design products supposed to be then distributed in different geographical areas, with, sometimes, completely different understanding and acceptance of natural products.
If we simplistically break a sunscreen down into two main "formulation blocks", i.e. the UV filters and the base (a bit like in pharmaceutical preparations with the drugs and the excipients), then one could come up with at least three scenarios to describe a natural product with sun protection properties:

1. UV filters and base are natural.
2. Natural UV filters are used in a non-natural base.
3. Non-natural UV filters are used in a natural base.

However, it could seem reasonable that only scenarios (1) and (2) are suitable to describe natural sunscreens, i.e. products containing natural UV filters.

Needless saying real life is much more complicated as different ingredients can bear different degrees of "naturalness" with some complex molecules displaying both "natural" and "non-natural" moieties.
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.
These Standards state, more or less unambiguously, that only non-nano Titanium Dioxide and Zinc Oxide are considered natural UV filters.
To understand how tricky it can be to formulate natural sunscreens, one should consider the amount of powder, i.e. Titanoum Dioxide and Zinc Oxide, needed to hit the desired target in terms of both UVB and UVA protection.
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 relevant amount of solids into a complex system that, ultimately, must be pleasant to apply onto the skin and efficacious possibly without leaving any sort of white mark on the skin!
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 Perlagonic-Acid-based esters by ROELMI HPC, sustainably obtained from non-edible fractions of plants, can help create a better dispersion of UV filters, thus resulting in possible reductions 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, thus resulting in a lower actual protection than what declared on label.
Titanium Dioxide and Zinc Oxide have traditionally been thought to generate heavy and unpleasant sensorial profiles, but this has changed significantly in recent years with Manufacturers of raw materials committed to providing better dispersions with particle size distributions designed to optimise protection properties and minimise the so-called "whitening" effect.
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 toxicological profile on the skin which makes them more suitable for certain types of skin (e.g. children, atopic skin, etc.).
To conclude, however, it is worth mentioning that in recent years inorganic UV filters have been the subject of safety and regulatory scrutiny: with potential issues related to aquatic toxicity and carcinogenicity, one would wonder what formulators will be left with to design effective sunscreens.
Fortunately, academic research has been looking at what the future of natural sun protection may look like, and this goes well beyond the use of inorganic oxides.
UV protection properties of substances found in Nature are being investigated by several research groups, for example by Prof. Steven Bailey (3) (University of South Alabama, USA) with the topical use of naturally occurring folates and by Prof. Antony Young (4) (Kings College, UK) with the use of marine mycosporine as potential biocompatible sunscreens.

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ARE SUNSCREEN FILTERS ABSORBED BY THE SKIN? DOES THIS POSE A HEALTH RISK?

Sunscreen is used to protect against the sun's potentially dangerous ultraviolet rays.

Types of sunscreen.

a. Mineral Sunscreen –contain inorganic ingredients.
b. Chemical Sunscreen – these comprise of organic UVA & UV B absorbers.

The chemical sunscreens are the ones that have now been confirmed to enter the blood stream, but it is still unknown if this is cause for concern. Research reported in JAMA (1). The study conducted in a clinical pharmacology unit and examining among healthy participants, all 6 of the tested active organic ingredients administered in 4 different sunscreen formulations were systemically absorbed and had plasma concentrations that surpassed the FDA threshold. These findings do not indicate that individuals should refrain from the use of sunscreen.

Woodcock, director - FDA's Center for Drug Evaluation and Research says, "This finding calls for further industry testing to determine the safety and effect of systemic exposure of sunscreen ingredients" (2).

This is not evidence that sunscreens are harmful. It's entirely possible that the amounts absorbed are completely safe. Because of the lack of any data showing increases in problems related to them, it probably is safe. Sunscreens are a key component of preventing skin damage that can lead to skin cancer.

The F.D.A.'s guidance says that any active ingredient that achieves systemic absorption greater than 0.5 nanograms per milliliter of blood should undergo a toxicology assessment. The clinical trials show that most of the sunscreens used showed the absorption of sunscreens more than 0.5 nanogram per milliliter. Hence FDA has recommended the toxicological assessment to see if it causes "cancer, birth defects or other adverse effects" (3).

Dr. Green from NYC, says no. "Until we know further, it is important to continue to use sunscreen since it is a good way to protect skin from the sun's UV rays and a lot of these agreements have been around for a very long time" (4).

DOES TOPICAL SUN PROTECTION IMPAIR THE VITAMIN D PRODUCTION IN THE SKIN?

We all need vitamin D. It spurs bone growth, and without it we'd be at high risk of conditions such as osteoporosis. It also gives an important boost to the immune system.

Many people think that using sunscreen leads to vitamin D deficiency. The best way to obtain enough of the vitamin is through unprotected sun exposure which can lead to other serious problems.

"Studies have never found that everyday sunscreen use leads to vitamin D insufficiency. In fact, people who use sunscreen daily can maintain their vitamin D levels (5)."

Studies have shown that use of an SPF 15 or higher broad-spectrum sunscreen reduces your chances of developing carcinoma by about 40 percent, melanoma by 50 percent and premature aging by 24 percent (5). Sunscreens filters out most of the sun's UVB radiation which is the major cause of sunburn causing skin cancer. UVB wavelengths (280–320 nm) happen to be the wavelengths that trigger vitamin D production.

Clinical studies have never found that everyday sunscreen use leads to vitamin D insufficiency. In fact, the studies shows that people who use sunscreen daily can maintain their vitamin D levels.

One of the explanations for this may be that no matter how much sunscreen you use, some of the sun's UV rays reach your skin. SPF 15 sunscreen filters out 93 percent of UVB rays, SPF 30 keeps out 97 percent, and SPF 50 filters out 98 percent. This leaves anywhere from 2 to 7 percent of solar UVB reaching your skin, that's if you use them perfectly.

International Units (IU) vitamin D recommended by the Institute of Medicine and The Skin Cancer Foundation for the average person between the ages of 1 and 70. (400 IU for infants and 800 IU is recommended for adult) (5) . Production of vitamin D varies on time and seasons. In the summer at noon, a fair complexion skin would need 6 minutes of sun exposure to achieve 1,000 IU of vitamin D in Miami; in Boston, the same person would need 1 hour.

The percentage of UV light penetration in skin even after the application of the sunscreen is enough to produce the required vitamin D.

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ARE NANOPARTICLES ABSORBED BY THE SKIN?

The skin is the body's largest organ, its role is to protect the body against diseases caused by organisms and mechanical damage, act as a barrier to potentially dangerous chemicals and to reduce water loss from the body.

Nanoparticles, which are tiny particles that are less than one hundredth of the thickness of a human hair, are used in sunscreens and some cosmetic and pharmaceutical creams (1).

The dermal application of drugs is promising due to the ease of application. In this context nano-scale carrier systems were already evaluated in several studies with respect to the skin interaction and the impact on drug penetration.

The interaction of nanoparticles with skin and especially skin models is an intriguing field. However, the data obtained do not show a clear image on the effect of nano-carriers. Especially the penetration of such particles is an open and controversially discussed topic (2).

Nanoparticles (size 1–100 nm) behave on skin in a different way if compared to the homologous bulk material. Nanoparticles (NPs) skin absorption is a wide issue, which needs to be better understood (3).

The role of NPs intrinsic characteristics (size, shape, charge, surface properties), the penetration of NPs through the intact or impaired skin barrier, the penetration pathways which should be considered and the role of NPs interaction in physiological media.

Studies discovered that even the tiniest of nanoparticles did not penetrate the skin's surface. The use of TiO2 and ZnO NPs inside skincare products is extremely common, Most of sunscreens containing TiO2 and ZnO were formulated with NPs. Sunscreen use is highly recommended in order to prevent sunburn, skin cancer, photo aging and skin wrinkles. Sunscreens containing NPs may be more transparent resulting aesthetically more acceptable for the consumers. Titanium dioxide skin penetration and its effects have been extensively studied, due to the wide use in sunscreens (4).

One main difference should be made between metal and non-metal NPs. Both kinds have a secondary NPs size which is given after interaction in physiological media, and allows a size-dependent skin penetration: NPs 4 nm can penetrate and permeate intact skin, NPs size between 4 and 20 nm can potentially permeate intact and damaged skin, NPs size between 21 and 45 nm can penetrate and permeate only damaged skin, NPs size > 45 nm cannot penetrate nor permeate the skin.

These findings have implications for pharmaceutical researchers and cosmetic companies that design skin creams with nanoparticles that are supposed to transport ingredients to the deeper layers of the skin.

The results of the work, published in the ***Journal of Controlled Release***, suggest that it might be possible to design a new type of nanoparticle-based drug formulation that can be applied to the skin and give controlled release of a drug over a long period of time.

This would enable sustained delivery of the active drug, potentially reducing the frequency with which the patient would have to apply the formulation to the skin.

The scientists used a technique called laser scanning confocal microscopy to examine whether fluorescently-tagged polystyrene beads, ranging in size from 20 to 200 nanometers, were absorbed into the skin.

They found that even when the skin sample had been partially compromised by stripping the outer layers with adhesive tape, the nanoparticles did not penetrate the skin's outer layer.

CONCLUSION

- NPs are localized only in the outer layer of the stratum corneum also when damaged or irradiated skin protocol was used.
- Consumer may draw the conclusion that nanoparticles in their skin creams, are 'carrying' an active ingredient deep into the skin, this is patently not the case.
- NP's used in sunscreens to protect the skin from harmful UV rays, they have not been found able to penetrate the skin barrier in healthy animals, which also is the case with other very small particles
- The growing number of nanoparticle occurrence in manufacturing and application need a better understanding of the relevant mechanisms of nanoparticulate penetration into skin, not least for an adequate risk assessment.

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PERCUTANEOUS ABSORPTION OF SUNSCREEN FILTERS

Although skin is a vital barrier to the outside world, it is permeable to certain substances, such as used in topical pharmacotherapy. It is therefore not surprising that certain xenobiotics intentionally applied to skin (drugs) (1) or accidentally reach the skin (pesticides) (2,3) cross the skin barrier. Even before the turn of the millennium, it became clear that sunscreen filters from sunscreen products and cosmetics can be systemically absorbed and detected in urine (e.g., para-amino-benzoic acid (4)). Numerous investigations in subsequent years have confirmed and extended these observations (5,6). Concerns have become omnipresent that topical application of some of these substances to large body areas and frequent reapplication increase the systemic burden. In 2008 this has been impressively documented by Calafat and coworkers who detected benzophenone-3 in 96.8% of the urine samples from a representative sample of the U.S. general population > or = 6 years of age (7). In two very recent investigations in humans, Matta and coworkers determined in the first study whether the sunscreen filters (avobenzone, oxybenzone, octocrylene, and ecamsule) of 4 commercially available sunscreen products under maximal use conditions (i.e., application at least every 2hrs) were absorbed into systemic circulation (8). In the second study the systemic absorption and pharmacokinetics of sunscreen filters (in addition to the above: homosalate, octisalate, and octinoxate) after single application and maximal use conditions of 4 commercially available sunscreen products was assessed (9). Systemic absorption of all sunscreen filters - determined in plasma - was considerable and surpassed the FDA threshold for potentially waiving some additional safety studies for sunscreens. Although the results are not surprising from a physicochemical point of view (see Table 1), the data has triggered a broad and ongoing public discussion on the safety of sunscreen products. The media has embedded the findings into prominent headlines such as "Sunscreen chemicals soak into bloodstream after single day of use" (The Times) or "Chemicals in sunscreen are absorbed into your blood at concentrations up to 419 TIMES above `what is safe to avoid cancer" (Mail Online) (10). Against this background, Matta's statement in both papers "these results should not indicate that individuals should refrain from sunscreen use" becomes incomprehensible for many and further unsettle consumers.

FACTORS INFLUENCING ABSORPTION

A prerequisite for absorption through skin is linked to specific features of a) the ***filter substance***, b) the ***vehicle***, c) the ***skin condition*** and in the end d) the ***exposure*** (11,12). Of particular significance for percutaneous absorption are the ***physicochemical properties*** of the ***filter substances***. The following properties may be indicative of very low or no percutaneous absorption. Molecular weight: >500Da; degree of ionization: high; polarity: log $P_{o/w}$ -1 or 4; melting point: >200°C and topological polar surface area: >120Å^2 (13). Some approved filters show these properties (see Table 1). ***Vehicle*** ingredients may also affect skin filter permeability by interacting with stratum corneum. Both, volatile and non-volatile vehicle ingredients have the potential to temporarily decrease Stratum corneum

SCCS No.	INCI	Acronym/Notice	Molar Mass (g/mol)	Partition Coefficient log $P_{o/w}$
1	4-Aminobenzoic acid (PABA) and its esters	moved to Annex II		
2	Camphor benzalkonium methosulfate	is not freely available		
3	Homomenthyl salicylate	HMS	262	> 6 (1)
4	Benzophenone-3	B3	228	3.45 (1)
5	Urocanic acid and its ethyl ester	moved to Annex II		
6	Phenylbenzimidazole sulfonic acid	PBSA	274	- 1.42 (1)
7	Terephthalylidene dicamphor sulfonic acid	TDSA	563	3.83 (2)
8	Butyl methoxydibenzoylmethane	BMDBM	310	6.1 (1)
9	Benzylidene camphor sulfonic acid	is not freely available		
10	Octocrylene	OCR	361	6.1 (1)
11	Polyacrylamidomethyl benzylidene camphor	is not freely available		
12	Ethylhexyl methoxycinnamate	EHMC	290	> 6 (1)
13	PEG-25 PABA	-	357	1.35 (2)
14	Isoamyl p-methoxycinnamate	IMC	248	4.78 (1)
15	Ethylhexyl triazone	EHT	823	7 (1)
16	Drometrizole trisiloxane	DTS	502	10.81 (2)
17	Diethylhexyl butamido triazone	DBT	766	4.12 (1)
18	4-Methylbenzylidene camphor	MBC	254	5.1 (1)
19	3-Benzylidene Camphor	moved to Annex II		
20	Ethylhexyl salicylate	EHS	250	6.36 (1)
21	Ethylhexyl dimethyl PABA	n.d.	277	5.76 (2)
22	Benzophenone-4 / Benzopheone-5	B4 / B5	308	0.313 (1)
23a	Methylene bis-benzotriazolyl tetramethylbutylphenol	MBBT	659 (4)	12.7 (3)
24	Disodium phenyl dibenzimidazole tetrasulfonate	DPDT	677	2.4 (1)
25	Bis-ethylhexyloxyphenol methoxyphenyl triazine	BEMT	628	> 5.6 (1)
26	Polysilicone-15	BMP	> 6000	n.d.
27a	Titanium dioxide	TiO_2	80 (4)	n.a.
28	Diethylamino hydroxybenzoyl hexyl benzoate	DHHB	398	6.2 (1)
29	Tris biphenyl triazine	TBPT	538 (4)	10.4 (1)
30a	Zinc oxide	ZnO	81 (4)	n.a.
31	Phenylene bis-diphenyltriazine	PBDT	541 (4)	6.41 (2)

Table 1: EU-approved sunscreen filters, their acronyms, molar mass and partition coefficients.

Twelve filters (SCCS No. 3,6,7,8,10,12,14,18,20,21,24,28) have one and four filters (SCCS No. 15,16,17,25) have two physicochemical parameters indicating low or no percutaneous absorption. The particulate filters (SCCS No. 23a,27a,29,30a,31) and polysilicone-15 (SCCS No. 26) have molar masses that virtually exclude percutaneous absorption.

LILA backed compounds are particulate. GREEN backed physicochemical parameters are indicative of very low or no percutaneous absorption (molar mass: >500Da; polarity: log Po/w -1 or 4 (13))
Current Annex II at https://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20II_v2.pdf
(1) measured, (2) calculated using the QSAR (quantitative structure activity relationship) model, (3) calculated using the fragment method, (4) the molar mass of the particles is greater than 1'000'000Da, n.a. not applicable, n.d. no data/information

integrity. Typical examples are alcohol, water, propylene glycol or ingredients with emulsifying properties (14). Due to evaporation of vehicle ingredients a supersaturated solution state can lead to increased percutaneous absorption (15). Percutaneous absorption is often - but erroneously - associated with the galenic form (e.g., spray, lotion, cream). Only the sum of the ingredients that make up the galenic form is responsible. This includes both the ingredients that evaporate after application and those that remain on the skin afterwards (16). In general, one expects ***diseased and damaged skin*** to be much more permeable to externally applied substances. This has been confirmed in studies for a few substances, e.g., water, 5-FU or triamcinolone acetonide. However, in a majority of investigated substances in various skin conditions absorption through clinically diseased skin was enhanced only to a modest degree compared with intact skin (17). Reliable data on percutaneous absorption of sunscreen filters in damaged or diseased skin is not publicly available. ***Exposure*** is also of significant concern (13). It includes method of application, concentration of filter in the marketed product, quantity of product used at each application, frequency of use, total area of skin contact, duration of exposure, target consumer groups, location of use (indoors/outdoors) and ventilation.

ABSORPTION OF SUNSCREEN FILTERS AND REGULATION

Jurisdiction in relation to sun protection products is globally very diverse and complex. Depending on country or region, products can be found in the regulatory category medicinal products (drugs), medical devices and cosmetics. Although safety requirements for sunscreen products and filters are very similar for both medicinal products and cosmetics, the small differences have led to very different situations globally. The FDA may waive some safety studies when systemic absorption does not surpass a certain threshold (18,19) whereas the EU is focused on the Margin of Safety (MoS) – the ratio of No Observed Adverse Effect Level (NOAEL) and Systemic Exposure Dose (SED). For substances with health thresholds (i.e, not genotoxic and not carcinogenic), a MoS >100 is generally considered safe (13). All sunscreen filters approved in Europe meet this criterion.

OUTLOOK

As can be deduced from Table 1, percutaneous absorption cannot be excluded with some filters. In Europe, sunscreen filters are approved by the European Commission and listed in ANNEX VI in the REGULATION (EC) No 1223/2009 on cosmetic products (20,21). Efforts are underway to reduce percutaneous absorption through galenical measures (22). The molar mass of particulate filters prevents percutaneous absorption. They are therefore a viable alternative to non-particulate filters.

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NEW DEMANDS ON PHOTOPROTECTORS

Sun protection is being one of the most innovative areas within the cosmetic sector in recent decades.

From the beginning, sun protection products were designed to protect against immediate visible signs of solar exposure, such as solar burns, which are primarily caused by UVB solar radiation. To avoid these burns, solar protectors with limited sensory properties were used, which left whitish residue on the skin, were difficult to spread, and usually causing itching in the eyes.

Currently, consumers are overinformed and aware of the use of photoprotectors to avoid, moreover, medium or long-term effects such as photoaging, wrinkles or spots caused mainly by UV-A radiation, or the risk of skin cancer.

Moreover, to these concerns, recently added, protection from light from screens and devices, causing the so-called "digital photoaging", the risk of vitamin D deficiency, hormonal effects, or environmental risk, among others.

One of the challenges facing the industry is to facilitate the adherence to product applications for consumers. If the usage for this type of product was limited to seasonality, we now find differences in frequency coming to its use all year long. The consumer is more aware of routinely applying sunscreen to protect against accidentally accumulated exposures to the sun during day-to-day activities such as moving to work, doing outdoor sports, shopping, etc.

Improvement in the sensory properties of these products is a very important factor in their effectiveness because laboratory conditions rarely reflect the amount of actual application, and this, therefore, implies that the amount of protection that the product declares is likely to be lower under real conditions. It is therefore important that, in addition to conducting studies of solar protection factor assessment, we should pay attention to sensory testing, where different consumer profiles reflect their views on aspects such as ease of absorption, texture, and ease of application, among others.

Moreover, among the most recent fears of consumers, there is the risk of vitamin D deficiency, due to the dissemination of information in the media under laboratory conditions in which a decrease in vitamin D synthesis has been observed.

Following the recommendations of many specialists and since studies on reducing vitamin D production have constraints, it is important from industry to emphasize that many publications are often showing that the use of sunscreen on a daily basis is an effective method in preventing skin cancer. However, this subparagraph is concerned by the industry.

Finally, we are beginning to understand and redefine clinically-based mechanisms and implications that other sun spectrum radiations may have in the skin, such as visible light and more specifically blue light.

The primary source of visible light is the sun, plus electronic devices such as computers, mobile phones or television sets, among others, are artificial sources of this type of radiation. The visible light (400-700 nm), consists of blue light, which corresponds to the shortest wavelength, 450-495 nm, closer to UV radiation.

The first tests of efficacy against blue light allow us to identify cosmetic products capable of reducing blue light-induced oxidation and protecting skin cells. They usually take keratinocytes, fibroblasts, and reconstructed tissues and allow us to select the best formulations and/or ingredients to protect our skin.

Recently, clinical manifestations induced by visible light include the ability to cause pigmentation changes in individuals with dark skin. This new research poses major challenges in innovation for the industry, which will seek to assess the effectiveness of new solar protectors against pigmentation disorders, for example, by following MASI pigmentation scales, quantitative measures for melanin, etc.

Frequent exposure to these devices is of interest in this light source with effects on the skin yet to be known and gives way to a wide range of research.

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