KEY POINTS

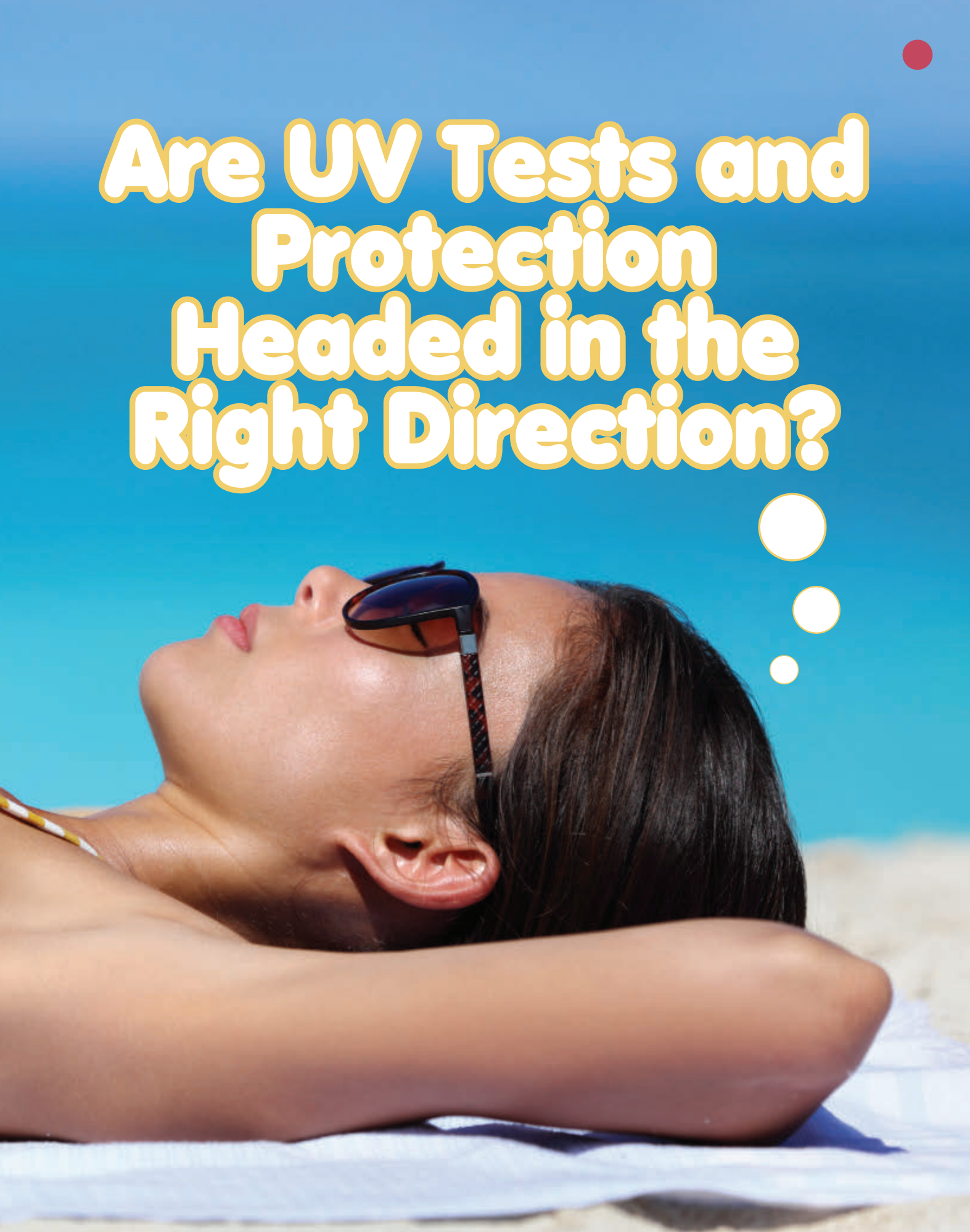
- Knowledge in sun protection has become more comprehensive, making sunscreen testing and development more challenging.
- This article explores what we know and what is needed in terms of sunscreen testing, regulation and consumer communication.

Anna Ludwikowska, Ph.D.
Eurofins Cosmetics & Personal Care, Gdańsk, Poland

Work on the first sunscreen products began in the 1930s. Initially, such products were often unappealing in consistency and offered very low protection. It was not until the 1980s that the first products protecting against UVA and UVB radiation appeared on the market. Today, consumers can choose from a wide range of sunscreen products with broad spectrums of protection, not only against UV radiation, but also blue/visible light (VIS) and near-infrared A (IRA). The knowledge in this field is becoming more and more comprehensive, which sometimes means existing theories require revisiting and revising.[1-6]

With advances in the development of sunscreen products, it has become necessary to develop methods to accurately determine their effectiveness. Nowadays, two in vivo methods,

Are UV Tests and Protection Headed in the Right Direction?



Scientific evidence shows sunscreens are an effective way to reduce skin cancer risk but at the same time, the SPF world is facing the question: Are sunscreens safe?

ISO 24444: 2019 and FDA 2011, with complex protocols are available and widely used. While these methods should be used as references, in theory, preference should be given to in vitro test methods without volunteers since under the given circumstances, the methods are required to provide equivalent and reproducible results. Also, as in vivo methods may raise ethical concerns, increasing efforts to find sufficient replacements are justified. Currently, two alternative ISO methods are under validation and expected to be published in 2025.[1-9]

It would seem that the situation in SPF testing is promising, and that stable and safe sunscreens are being produced. But is this really so? Scientific evidence shows sunscreens are an effective way to reduce skin cancer risk but at the same time, the SPF world is facing the question: are sunscreens safe? In fact, nowadays, U.S. and European regulators are questioning the human health and environmental safety of 12 sunscreens filters.[8-10]

How does this affect both consumers and producers? An initial thought is: should the industry be concerned about presumptions that never gain the support of credible research? To answer these questions, it is first worth stepping back to review the roles and goals of sunscreens.

Sunscreen Product Success

By definition, per ISO 24444: 2019, sunscreen products are, "products containing any component able to absorb, reflect or scatter UV rays, which are intended to be placed on the surface of human skin with the purpose of protecting against erythema and other ultraviolet-induced damage."[8] As it is well-known, sunscreen products play an important role in protecting skin against the negative consequences of excessive exposure to UV radiation. In relation, the essential components of sunscreen products are UV filters. Such substances must fulfill certain requirements, such as efficacy at low concentrations and stability.

Penetration into the living layers of the epidermis is also undesirable, especially if products are designed for children or individuals with compromised skin. In most cases, physical (mineral) and chemical UV filters are combined in order to obtain broad-spectrum protection. Natural substances that can absorb UV radiation are also being introduced more frequently into formulations. Antioxidants, by neutralizing free radicals generated by UV, play an important role, additionally lowering the risk of skin damage.[2-3, 9, 11-13]

After decades devoted to creating new formulas and improving existing ones, the industry has achieved several milestones in terms of sunscreen success, including:

• Broad spectrum and high SPF sunscreens.

In 2019, the U.S. Food and Drug Administration (FDA) proposed all sunscreens with SPF values of 15 and above should satisfy broad-spectrum requirements. This includes a proposed new requirement that broad-spectrum products meet a UVA I/UV ratio of 0.7 or higher, and that the maximum labeled SPF value be raised to SPF 60+ based on evidence showing additional meaningful clinical benefits associated with broad-spectrum sunscreen products with an SPF of 60 (for more on the FDA proposal, see Page 6207[12]).[10-12]

• Updated methods for testing sunscreens and some new additions.

For water-resistance testing, ISO 16217 (WR), available since May 2020, and ISO 18861 (WR%), available since September 2020 and two alternative SPF methods: ISO 23675 Cosmetics—Sun Protection Test Methods—In vitro Determination of Sun Protection Factor; and ISO 23698 Cosmet-

The global sunscreen market is expected to expand at a CAGR of 5.6% from 2021 to 2031, with SPF 50+ leading the segment.

Source: Transparency Market Research

ics Sun Protection Test Methods—Measurement of Sunscreen Efficacy by Diffuse Reflectance Spectroscopy. The last two methods are in a validation phase.[14-17]

• **A wide range of products** with more user-friendly applications, colors and scents, and with proven water resistance, sweat resistance, sand resistance and a few other claims.

• **Knowledge** as to why the use of sunscreen products is so important.

It would seem that with such achievements and unquestionable evidence, sunscreens would be a very important part of a complete sun protection strategy. Furthermore, that the use of sunscreen products would become routine, at least for people staying in the sun for longer periods—especially during peak hours and peak seasons for both UVA and UVB radiation. But is this really so?

Are we sure we have adequate knowledge of this topic and that we interpret the existing knowledge correctly? And are we sure that the knowledge available online and even in scientific publications is free from errors?

Sunscreen Product Struggles

On the other hand, sunscreen development has struggled in terms of:

• **Grading systems** and the classification of sunscreen products.

Table 1. Worldwide Implementation of FDA Final Monograph 2011 and ISO Standards for Sunscreen Evaluation[18]

REGION	SPF in vivo	UVA PF in vivo	UVA PF in vitro	Water Resistance
Europe	ISO 24444: 2019	ISO 24442: 2011	ISO 24443: 2021	ISO 16217
				ISO 18861
United States	FDA 2011	Not required	FDA 2011	FDA 2011
Canada	ISO 24444: 2019	ISO 24442: 2011	FDA 2011	FDA 2011
	FDA 2011		ISO 24443: 2021	
Mexico	ISO 24444: 2019	ISO 24442: 2011	FDA 2011	FDA 2011
	FDA 2011		ISO 24443: 2021	ISO 16217
				ISO 18861
MERCOSUR[1]	ISO 24444: 2019	ISO 24442: 2011	ISO 24443: 2021	FDA 2011
	FDA 2011			ISO 16217
				ISO 18861
South Africa	ISO 24444: 2019	ISO 24442: 2011	ISO 24443: 2021	SANS 1557:2014
India	ISO 24444: 2019	ISO 24442: 2011	FDA 2011	
	FDA 2011		ISO 24443: 2021	
Japan	ISO 24444: 2019	ISO 24442: 2011	Not required	ISO 16217
				ISO 18861
Korea	ISO 24444: 2019	ISO 24442: 2011	Not required	ISO 16217
				ISO 18861
ASEAN[2]	ISO 24444: 2019	ISO 24442: 2011	ISO 24443: 2021	ISO 16217
				ISO 18861
Australia	ISO 24444: 2019	Not required	ISO 24443: 2021	ISO 16217

ASEAN = Association of Southeast Asian Nations; FDA = U.S. Food and Drug Administration; ISO = International Standards Organization; MERCOSUR = Mercado Común del Sur

[1] Argentina, Brazil, Paraguay, Uruguay and Venezuela

[2] Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Philippines, Singapore, Thailand and Vietnam

In Europe, the UK, Southeast Asia, Africa and Japan, sunscreens are cosmetics. In the U.S., they are drugs and in Australia, they are both cosmetics when SPF is a secondary function or therapeutics when SPF is a primary function. The truth is that products such as tinted bases, foundations and lip preparations with sunscreens added, as well as any skin care product containing SPF, are considered differently depending on the region of the world.

• **Different requirements regarding applicable testing methods** (see **Table 1**).

• **Different labeling of sunscreen products.**

The labeling of sunscreens is especially inconsistent in the field of UVA protection. Each country has its own way of testing and labeling products. Non-uniform labeling leads to consumer confusion and, consequently, a greater chance of manufacturers misleading consumers with incorrect indications on their sunscreens (see **Table 2**).[9, 19-21]

The EU has made it mandatory for products to obtain a minimum level of UVA protection in which the ratio of the protection factor measured as PPD must be at least 1/3 of the labeled SPF; this means UVA protection must be increased with increasing SPF protection.[19-20]

From time to time, there are voices stating this ratio is too ambitious, in particular for products with a high SPF. However, there is scientific proof that certain biological damage in the skin can be prevented and/or reduced if the ratio of the protection factor is at least 1/3 of the factor measured under the SPF testing method.

In Europe, SPF must be numerically stated on the packaging, while a statement of protection against UVA is not obligatory.[8, 19-20] Sunscreens on the European market can include a UVA mark in a circle on their labels if the sunscreen meets two conditions:[19-20] the UVA-PF reaches at least 1/3 of the SPF and the critical wavelength is equal or greater than 370 nm.

In the U.S., the evaluation of UVA protection is carried out according to FDA 2011. This method introduced the criterion of critical wavelength, which allows sunscreens with very low UVA protection to be placed on the market.[9]

As mentioned, in 2019, due to more and more scientific evidence linking UVA exposure to skin cancer and other health risks, the FDA proposed adding, to the current broad-spectrum test, a requirement that broad-spectrum products meet a UVA I (340–400 nm)/UV ratio of 0.7 or higher.[10, 12]

• **Beliefs and claims that may discourage the use of sunscreen products.**

For example:

- o There is a need to wear sunscreen indoors, every day, no matter the location, time of day or time of year;
- o Sunscreen chemicals can be absorbed into our blood;

Table 2. Summary of UVA Standards and Associated UVA Protection Claims[9, 19-21]

Region	Europe Australia MERCOSUR*	UK	JAPAN	USA
Method	ISO 24443	Boots star rating	ISO 24442	FDA
UVA factor in vitro in vivo	UVA-PF and CW UVA-PF (PPD)	UVA: UVB ratio -	- UVA-PF (PPD)	CW -
UVA claim and conditions	UVA UVA-PF/ SPF ≥ 1/3 and CW ≥ 370 nm	 from three tofive stars	PA+(UVA-PF 2-4) PA++(UVA-PF 4-8) PA+++(UVA-PF 8-16) PA++++(UVA-PF ≥ 16)	Broad spectrum when CW ≥ 370 nm

* *Argentina, Brazil, Paraguay, Uruguay and Venezuela*

Standardized test methods on corals should be implemented to avoid misleading results. UV filter pollution is only one of many factors that can lead to coral bleaching and death.

- o Sunscreen reduces vitamin D production;
- o Sunscreen can cause cell damage and cancer;
- o Sunscreen may contain endocrine disruptors;
- o Sunscreen products destroy coral reefs; and
- o Many others.

By looking deeper into the scientific literature, we should be closer to the truth but we find claims of the harmfulness of UV filters and their potential threat to human health and the environment, as well as claims ensuring we have nothing to fear and the potential UV threat is only marginal. Who is right and how can the truth be balanced? What does the average user, who has nothing to do with the cosmetic, chemical or pharmaceutical industries, think about it?

Even with professional education, in a sea of contradictory statements, one can feel completely lost. For example, some information indicates there is no evidence that sunscreens have major adverse effects on vitamin D synthesis but there are also opposing opinions.[22-24]

The first papers suggesting UV filters may disrupt endocrine pathways raised direct concern for European environmental scientists in 2001. Since then, much research has been carried out, both in vivo (in humans, rodents, fish and worms) and in vitro, the results of which suggest that many of the commonly used organic UV filters have endocrine-disrupting properties; but the studies vary widely in terms of dosing and exposure to specific UV filters.[25-26]

There is also no evidence of the presence of TiO_2 or ZnO in human blood or urine from the forms of these ingredients that are used sunscreens, only for other forms of them.[28-29]

Furthermore, it is not proven that UV filters in sunscreens are directly responsible for the damage of coral reefs and marine life. Regardless, in 2018 and 2019, the state of Hawaii and Florida's Key West banned the sale of sunscreen products containing oxybenzone and octinoxate; Thailand did in some of its parks in 2021.[26, 27]

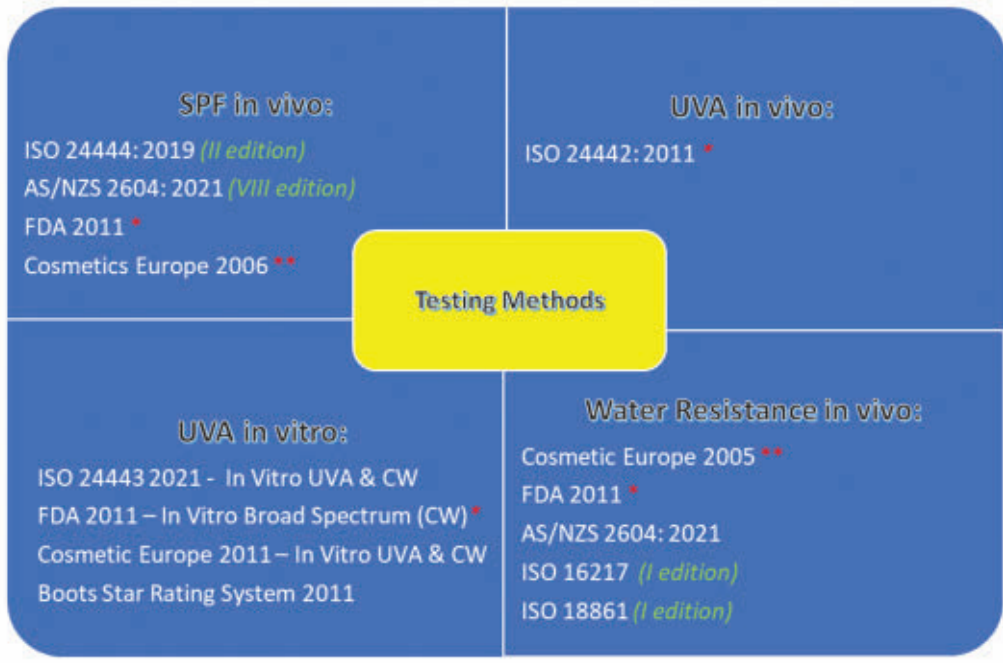
Do global warming, ocean acidification and rapidly increasing pollution have no impact on coral reef damage or marine life? Would anyone like to spend the summer holidays in Hawaii or Thailand without sunscreen? It is worth noting, here, that the Hawaiian ban has been challenged by the American Academy of Dermatology (AAD) and the Hawaiian Dermatological Society due to the fact that a decrease in the availability of broad-spectrum sunscreen ingredients may pose a risk to public health.[25, 26]

On this subject, what we know for sure is that the impact of UV filters on coral health requires clarification and that standardized testing methods on corals should be implemented to avoid misleading results. UV filter pollution is only one of many factors that can lead to coral bleaching and premature death.[25, 26]

• Questions over the safety of more than 12 sunscreen filters in terms of human health and the environment.

According to FDA, since the beginning of 2019, only two active ingredients—i.e., zinc oxide and titanium dioxide—from the list of 16 currently marketed are generally recognized as safe and effective (GRASE) for use in sunscreens. Two other ingredients, PABA and trolamine salicylate, are not GRASE for use in sunscreens due to safety concerns.

Moreover, there are 12 ingredients (cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone and avobenzone) for which there is insufficient safety data to make a positive GRASE deter-



** Methods for which new editions are under preparation*
*** Products tested under older methods generally do not need to be retested, as they remain valid, but there is trend to move toward ISO methods.*

Figure 1. Summary of test methods for sunscreen products

mination at this time. To address these 12 ingredients, the FDA has asked industry and other stakeholders for additional data. Several guidances have been published to help companies understand what data the agency believes is required.[10, 12] The question now is: what is left for sunscreen manufacturers and users in an era of skin cancer scourge if the safety of almost all existing sunscreens (except ZnO and TiO_2) is questioned?

Current Sunscreen Test Methods

All sunscreen test methods should provide the most equivalent and accurate results possible, demonstrate improved precision, and be easy to use by laboratories as well as cost effective to perform. The following methods are valid worldwide (see **Figure 1**). Note that since the ISO 24444, ISO 24442 and ISO 24443 methods are well-known and repeatedly described, only the changes introduced to these methods in their new editions will be mentioned.

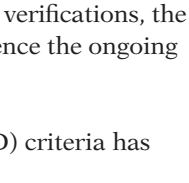
New edition of ISO 24444: 2019: The new edition of ISO 24444 was released at the end of 2019. The purpose of the changes in the new edition was to improve the reproducibility and repeatability of the test method. Even in the best-trained laboratory with constant competency verifications, the obtained results may be influenced by human factors; hence the ongoing efforts to improve and standardize skills.

These modifications include the following:[8]

- The definition of the minimal erythema dose (MED) criteria has been revised.
- The choice of eligible test subjects is now based solely on individual typology angle (ITA°), with a requirement for the average ITA° of the test panel to be within a range of 41° to 55°, and a minimum of three subjects to be within two of the three ITA° ranges.
- The ITA° is used to define the range of unprotected MED doses for the provisional or test day unprotected MED determination (if no provisional MEDu determination is made).
- Three new reference sunscreen products have been approved and added: P5, P6 and P8. Patterns are selected based on the expected SPF:
  - o ***P5:*** 23.7–37.4 (average: 30.6) for products with the expected SPF ≥ 25 but less than 50;
  - o ***P6:*** 31.0–54.9 (average: 43.0) for products with the expected SPF ≥ 25 but less than 50; and
  - o ***P8:*** 43.9–82.3 (average: 63.1) for products with an expected SPF ≥ 50.
- New test methods have been provided to determine the uniformity of the beam of both large and small beam-size solar simulators. A requirement for uniformity equal to or greater than 90% has been added.
- Sunscreen application procedures have been described in greater detail.
- An informative Annex has been added with photographic examples of erythema responses and guidelines for grading.
- Reporting tables and requirements for their presentation have been modified to provide more complete information on test results.

Standardizing Safety

*Check out **ISO Validation and Sun Protection Tests** in our **April 2020 edition.***



- And, the bibliography has been updated.

In this edition, even more emphasis was placed on controlling the equipment (solar simulators) and maintaining the highest quality of its operation. This concerns the obligation to check the beam's uniformity every six months for multiports, every month for monoports, and that the lightbulb has been written as an optical part of the simulator, which results in the need to recalibrate the simulator after the bulb's replacement.[8] This requirement for uniformity greater than or equal to 90% in the real world turned out to be very difficult to meet, and for most older types of simulators, was impossible to achieve.

In terms of the requirement of ITA°, in the updated version it is written, "When possible, there should be subjects with ITA°s in each of the following three ITA° bands: 28° to 40°; 41° to 55°; and > 56°. Where this is not possible, there shall be at least three individuals in each of two of the three ITA° bands described in the previous sentence."[8]

As a consequence, studies often are extended in time to meet this requirement. Despite obtaining the required number of validated results meeting the statistical criteria, laboratories are forced to plan additional volunteers. How does this relate to the ethical concerns of in vivo research? It could be said that these additional subjects are unnecessarily exposed and generate additional costs.

All these changes, made for a good cause, put an additional financial burden on companies testing sun protection products and lead, perhaps unintentionally, to irradiating even more people than necessary.

New ISO methods for water-resistance test: Until recently, the water resistance of sunscreen products was mainly determined by two methods: FDA 2011 and COLIPA 2005 (see **Table 1**). Both methods have similar test conditions but differ significantly in terms of claiming the product's water resistance. In the case of COLIPA 2005, the product after the bath must achieve at least 50% of the SPF value obtained before the bath. Also, the labeled SPF is the one obtained during the static part of the test, with additional information about water resistance. In the case of FDA 2011, the labeled SPF is that which is obtained after immersion (wet).[10, 12]

In May 2020, the continuation of ISO 24444: 2019 was issued; note those standards should be read together: ISO 16217:2020, Cosmetics—Sun Protection Test Methods—Water Immersion Procedure for Determining Water Resistance; and in September 2020, ISO 18861—Cosmetics—Sun Protection Test Methods—Percentage of Water Resistance.[8, 14-15]

ISO innovation in comparison with the previously applicable methods of water-resistance testing introduces the control of the water's parameters to ensure better adhesion of the tested product to the skin.[14, 15] The controlled parameters include:[14, 15]

- Water flow rate between 0.02 m/s and 0.05 m/s;
- Conductivity ≥ 500 mS;
- pH between 6.5 and 7.5; and
- Temperature between 28°C and 32°C; this parameter was already required by the FDA and COLIPA methods.

As a result, laboratories testing SPF products have invested in flow meters, conductometers and pH meters. Consequently, technicians require more time for preparation, since all measurements must be conducted immediately before the volunteer enters the water, and the cost of the study is higher.

New edition of AS/NZS 2604: 2021: This standard specifies methods for determination of broad-spectrum, SPF and water-resistance by referencing the following ISO standards:[30]

- ***ISO 24443:*** determination of sunscreen UVA photoprotection in vitro;
- ***ISO 24444–Cosmetics–Sun Protection Test Methods:*** in vivo determination of the sun protection factor (SPF); and
- ***ISO 16217–Cosmetics–Sun Protection Test Methods:*** water immersion procedure for determining water-resistance.

With regard to broad-spectrum, SPF and water-resistance, the Australian method does not differ from ISO standards in terms of methodology but only in terms of defining sunscreen products and labeling; in Australia, for primary and secondary sunscreen products, the labeled SPF cannot be lower than 4 (see **Table 3**). In Europe, there is no such division and the lowest labeled SPF is 6 (see **Table 4**). In Australia, a product that claims water resistance should have a labeled SPF, determined after immersion, of not less than 8 (see **Table 5**).[30-33]

New edition of ISO 24443: 2021: This in vitro method is well-known and has been used since 2012 for the determination of the UVA sun protection factor in many countries—except

China, Korea and Japan, where is not accepted at all; and in the USA, where the FDA 2011 is compulsory.[26] A new edition of this method has been available since December 2021.[20]

The main changes to the previous version are as follows:[20]

- The temperature range has been narrowed to 27–32°C, maintained throughout the process;
- A second type of plates has been added, sandblasted PMMA plates, with the required application rate of 1.2 mg/cm^2. The amount of application for molded PMMA plates remains the same, i.e., 1.3 mg/cm^2;
- A positive-displacement automatic pipette has been added for droplet deposition;
- The sample application has been described in a very detailed way, unlike the previous version, with the possibility of using a robot (mechanical fingertip) for the application;
- Calculation of coefficient *C* has been accepted from the in vivo SPF screening,

Table 5. Labeling in Australia—Water Resistance[30-32]

Tested SPF after immersion	Maximum water resistance claimable
At least 4 but less than 8	No claim
At least 8 but less than 15	40 min
At least 15 but less than 30	2 hr
At least 30 or above	4 hr

Table 3. Labeling in Australia—Static SPF[30-32]

SPF	Labeled SPF	Category description	Broad spectrum		
				Secondary	
			Primary	Skin care	Color/Lip
1 to 3	Not allowed	Not allowed	Not allowed	Not allowed	Not allowed
4 to 14	4, 6, 8, 10	Low	Compulsory	Compulsory	Optional
15 to 29	15, 20, 25	Medium or moderate	Compulsory	Compulsory	Optional
30 to 59	30, 40, 50	High	Compulsory	Compulsory	Compulsory
60 or higher	50+	Very high	Compulsory	Compulsory	Compulsory

Table 4. Labeling in Europe[33]

Labeled category	Labeled SPF	Measured SPF	Minimum UVA-PF	Minimum CW	Minimum Water Resistance*
Low protection	6	6 – 9.9	1/3 of labelled SPF	370 nm	Mean %WWR – d
	10	10 – 14.9			≥ 50%
Medium protection	15	15 – 19.9			
	20	20 – 24.9			
	25	25 – 29.9			
High protection	30	30 – 49.9			
	50	50 – 59.9			
Very high protection	50 +	≥ 60			

**Only if product makes this claim*

Natural substances that can absorb UV radiation are also being introduced more frequently into formulations.

with specific conditions based on SEM and percentage of variability; and a new range has been proposed from 0.6 to 1.6;
- A new high-UVA PF standard of P8 has been added. Moreover, the frequency of testing should be once per month for both standards;
- A critical wavelength calculation has been introduced; and
- The UVA irradiation dose has been limited to 36 J/cm^2.

Additionally, the SPF world is waiting for new editions of:
- ISO 24442:2011—Cosmetics—Sun Protection Test Method—In vivo Determination of Sunscreen UVA Protection, which is supposed to be published in May 2022;
- FDA 2011 Monograph, status unknown;
- ISO 23675—Cosmetics—Sun Protection Test Methods—In vitro Determination of Sun Protection Factor,[16] which is supposed to be published in 2025; and
- ISO 23698—Cosmetics Sun Protection Test Methods—Measurement of Sunscreen Efficacy by Diffuse Reflectance Spectroscopy[17], which also is supposed to be published in 2025.

The in vitro SPF protection test method ISO 23675 is at an advanced stage of preparation. This method is based on the spectroscopic measurement of UV radiation transmission on a suitable substrate (PMMA and sandblasted plates) and the use of obtained results in a statistical model. In this way, it is possible to predict the SPF value. The reports so far indicate a promising correlation between the results obtained with the in vitro SPF method and the values of SPF in vivo; in this method, a special robot is used to apply products to standardize the application and decrease human error.

Finally, the ISO 23698 method, based on measuring the effectiveness of sun protection by diffuse reflection spectroscopy, is also under advanced development. Hybrid diffuse reflectance spectroscopy (HDRS) is based on non-invasive diffuse reflection spectroscopy (DRS) involving humans, but UV exposure is negligible. UVA protection is assessed directly by the in vivo reflectance spectrum. Since the return signal is not sufficient in the UVB range, the SPF is calculated by extrapolating the UVA curve using an in vitro measurement, making it a hybrid method.[16-17, 34-36]

Conclusions

Taken together, here is what we know:
- Sunscreens are definitely essential for protection against UV radiation but they only protect us effectively if properly applied—emphasis should be placed on

educating the public on this issue.

- Standardizing the labeling of sunscreen products is a necessary and crucial element of building consumer awareness, which will support the selection of the appropriate product.
- There are concerns about the safety of some ingredients used in sunscreen products that require further investigation but this should not result in the demonization of nearly all existing sunscreen products.
- There are many available sunscreen products on the market but taking into account increasing incidences of melanoma mortality for men, there is a need for sunscreen claims more attractive to them.
- Many new requirements appear in the revised methods that can be costly and time-consuming; there is some doubt as to whether they are justified and necessary. The effects of these changes on repeatability and reproducibility should be reviewed.
- Lastly, the in vitro methods for SPF testing under development require reliable validation and comparison with the results of the existing methods. The obtained results should be presented in a credible manner, leaving no doubts as to their truthfulness.

Overall, the knowledge is quite large, the tools in terms of both sunscreen products and their testing methods are quite impressive. What is needed is some improvement and verification and, most importantly, a clear, consistent message.

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