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What's New in the Estimation of SPF and UVA-PF?

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ABSTRACT

Up to very recently the assessment of SPF was performed "in vivo" by ISO 24444 standard, while for UVA-PF ISO 24443 "in vitro" standard was used, which still needed and empirical coefficient derived from the SPF "in vivo" to normalize the results.

Since some years ago, ethical critics have been made to the fact that human beings were submitted to UVA radiation to evaluate the SPF. The European Community recommended replacing those standards with new ones that allow all determinations to be made in vitro. But, as simple it may seem the purpose, it could not be achieved because there was no good correlation between the results obtained by spectrophotometry and those obtained from human panels.

Since December 2024, after an extended circular test performed in Europe monitored by the ISO/TC 217, Cosmetics Committee validated the new standards ISO 23675 (In vitro determination of Sun Protection Factor (SPF)) and ISO 23698 (Measurement of sunscreen efficacy by diffuse reflectance spectroscopy).

With horizon 2025, these new ISO standards will replace the actual ones into the European Community and later, most probably, within Mercosur and America in general.

Due to their complexity, to be implemented they need expensive equipment and thorough training of technical personnel. Prudence would indicate preparing in time for the changes. If not, our enterprises (specially the smaller and those who are not internationalized and producing sun care cosmetics) will be handicapped.

In this paper we try to present the new techniques, emphasizing the equipment needed. We do also an explicit critic on the fact that they are based on an irradiation source (Xenon arc) designed only for the 40o latitude of the northern hemisphere, compatible with the mediterranean summer sun in Europe, but not representative at other latitudes.

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Introduction

Currently, the standards still in force for evaluating the protection provided against solar radiation in Mercosur and the European Community are ISO 24444-2019 (Determination of the sun protection factor "in vivo"), ISO 24442-2022 (Determination of UVA protection "in vivo"), and ISO-24443-2021 (Determination of UVA protection "in vitro") [1]. In the United States of America, the FDA uses a different standard, which fundamentally differs in the estimation of UVA protection, as it uses the concept of "critical wavelength" [2].

ISO 24444 has received numerous criticisms , mainly based on the ethical issue of using human volunteers to verify the degree of injury (erythema) that the skin suffers when exposed to solar radiation [2]. But also referring to the difference between real solar radiation and the one used in ISO 24444, as it lacks wavelengths above 400nm, and emits more in the UVB and less UVA than necessary [3]. Additionally, it has little to do with the radiation received in the Southern Hemisphere at our latitudes [4-6]. Lastly, and not least, the poor reproducibility that the method has shown in inter-laboratory tests, particularly for high protection factors [3-7].

Regarding ISO 24442 ("in vivo") and 24443 ("in vitro") used for UVA, which have good correlation with each other, the second is the most used. In it, the sample is spread in a thin film on a standardized PMMA plate, which supposedly reproduces the skin surface. The homogeneity and reproducibility of the film are fundamental for a good measurement. The "in vitro" transmittance is measured, and then the sample is subjected to a standardized dose of UVA radiation. The irradiation step is necessary because the filters currently used to obtain a broad protection spectrum are not completely photo-stable [8-10]. Finally, the transmittance of the irradiated sample is measured again. However, the protection (SPF) obtained in this way does not correlate well with that obtained by the "in vivo" method. For this reason, the standard provides for the use of an adjustment parameter, which is precisely based on the SPF obtained for the same sample with ISO 24444. In other words, it falls back on the same objections mentioned earlier. For this reason, the European Community recommended finding alternative analytical methods for evaluating the solar protection

of cosmetic products that were more accurate and reproducible than those currently used [11].

Although the directive was clear, there are multiple reasons why this has not been possible until now. We can mention long testing times, high development costs, the high variability of "in vivo" and "in vitro" methods obtained by different operators and laboratories, and finally, the low correlation between the results obtained in both cases [12].

All these inconveniences seem to have been overcome by a joint task force, coordinated by the ISO/TC 217 Cosmetics Technical Committee, in which the main producers of sunscreens and various academic institutions participated. The conclusions and main characteristics of the methodologies are presented in this work.

ISO 23675: 2024– FPS 'in vitro' (Double Plate Method) [13] Differences with ISO 24444

- Human experimentation is not required. It uses "in vitro" spectrophotometry.
- Two different UV-transparent PMMA substrates are used, one sandblasted and the other molded. At least three sandblasted and three molded plates must be used. They must be thermostated for 12 hours at 27°C before use.
- The use of an automatic robot to spread the sunscreen on the transparent substrate is mandatory to ensure the homogeneity and reproducibility of the obtained film (a fundamental step).
- The same irradiation source as in ISO 24444 is used.
- The spectrophotometer used for transmittance measurement must allow the plates with the sunscreen spread to be placed horizontally to limit product migration.
- The spectrophotometer must allow up to nine measurements on each plate (16 cm²) in less than two minutes.
- The solar simulator (Xenon arc with appropriate filters) must maintain the temperature at (27±2)°C and not generate air currents over the plates to avoid breaking the formed film.
- As in the 2021 version of ISO 24443, three different reference sunscreens are needed: P2 (SPF 2-24); P6 (SPF 25-49); and P8 (SPF greater than 50).
- As in ISO 24443, transmittance is measured first on the non-irradiated sample and then on the irradiated sample.
- The required characteristics of the spectrophotometer are identical to those of ISO 24443.

Figure 1 Summarizes the Distinct Stages of Execution:

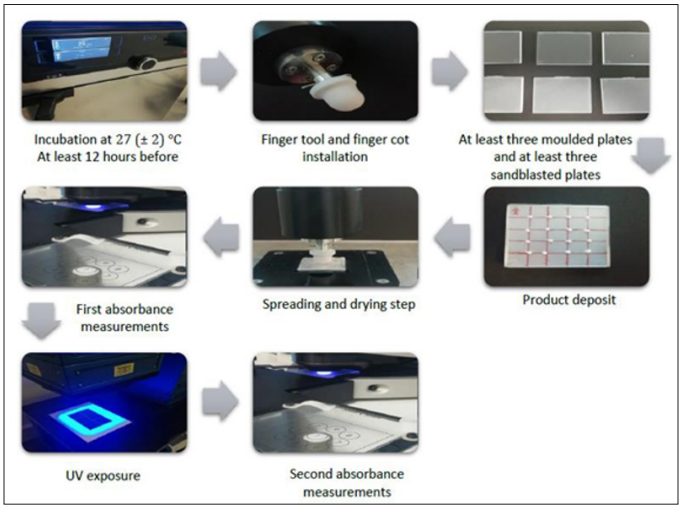

Figure 1: Sequence of Operations to Execute ISO 23675. adapted from Cosmetics Europe Annex I Protocol in vitro SPF Double Plate method [14].

Figure 2 Shows the Sequence of Movements that the Robot Must be Able to Perform to Spread the Sample Homogeneously on the PMMA Plate

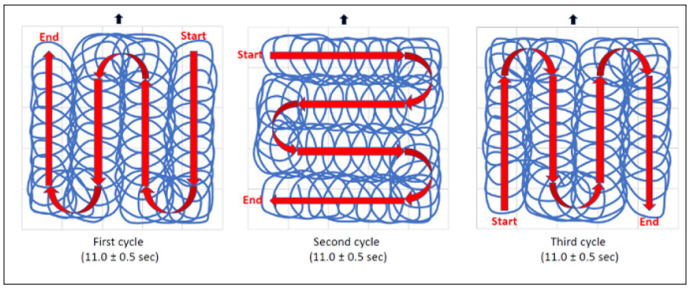

Figure 2: Sequence of Movements of the Robot Arm. adapted from Cosmetics Europe Annex B Automatic Spreading Robot Specifications.

Calculations are performed by averaging the absorbance measurements of the three sandblasted and three molded plates taken in pairs, affected by an empirical coefficient that depends on the cosmetic form of the tested product.

The exposure time of the plates to the irradiation source is calculated similarly to that used in ISO 24443.

Finally, the final values of "in vitro" SPF and "in vitro" UVA-PF are calculated by integrating the individual absorbance values obtained for each wavelength with and without irradiation and averaged by the erythema action spectrum (in the first case) and the PPD action spectrum (in the second). The values of the latter are detailed in the standard in 1nm steps, which is why the spectrophotometer used must discern the wavelengths with the same precision.

The procedure and, above all, the calculation is very complex and cumbersome. It is hardly manageable manually, requiring calculation programs that collect the data and perform the computation automatically.

In summary, it is necessary to have an irradiation source with incorporated PMMA plate cooling and the possibility of exposing them placed horizontally (such as, for example, the Suntest CPS+ from ATLAS), a robot to spread the samples that meets the standard requirements, and a spectrophotometer that also allows scanning and measuring the samples quickly with an integrated calculation program (the most used is the UV-2000S Transmittance Analyzer from Labsphere).

A total estimated investment of no less than USD 200,000. And a recommendation from Cosmetics Europe (since both this method and the alternative by diffuse reflectance, which we will present next, require training and experience) to familiarize with them and the calculations as soon as possible. before they replaced completely ISO 24444 and ISO 24443.

ISO 23698:2024 – Measurement of Sunscreens Efficacy by Diffuse Reflectance Spectroscopy (DRS)

The previous double plate method is a refinement of earlier methods, aiming to eliminate all sources of variability they presented (such as variations in skin type in panels for "in vivo"

determination, differences in the application of the protective film both on human skin and on PMMA plates, runoff and/or destruction of the film by heating, etc.). It also addresses human factors in operators from different laboratories due to their training and other causes attributable to chance.

In contrast, the application of diffuse reflectance to evaluate the protective capacity of a cosmetic against solar radiation employs a completely new technique and concept, managing to eliminate the ethical objections previously cited, mainly regarding ISO 24444 [15-19].

Preliminary Considerations

- No artificial device can completely reproduce human skin.
- Diffuse reflectance provides a unique approach to measure "in vivo" absorbance with very low UV radiation doses that do not cause cellular damage.
- By combining the UVA absorbance characteristics of the protector, measured by DRS, with the complete absorbance curve measured "in vitro" and using a "hybridization" process of both measurements, an SPF can be estimated that has shown good correlation with the measurements performed "in vivo" by ISO 24444.
- The technique is called "Hybrid Diffuse Reflectance Spectroscopy" (HDRS).
- By exposing the sample to "in vitro" radiation, the UVA-PF can be predicted.
- There are devices to perform DRS both monochromatically and polychromatically. The analytical technique used differs according to the available equipment.

Figure 3 Graphically Shows what is Understood by Diffuse Reflectance.

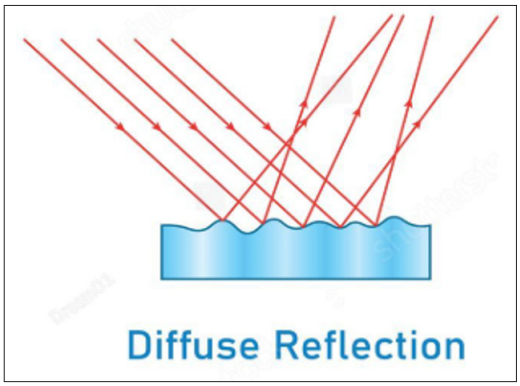

Figure 3: Graphical Scheme of How Radiation Diffuses when it hits an Irregular Surface like the Skin.

Figure 4 Shows a Complete Scheme of how a Measurement is Performed on a Person's Back by Diffuse Reflection. Given that the Applied Radiation is Extremely Small (the Intensity of the DRS Instrument is About 0.3 mW/cm², 200 Times Lower than that Used for ISO 24444), Erythema is Avoided.

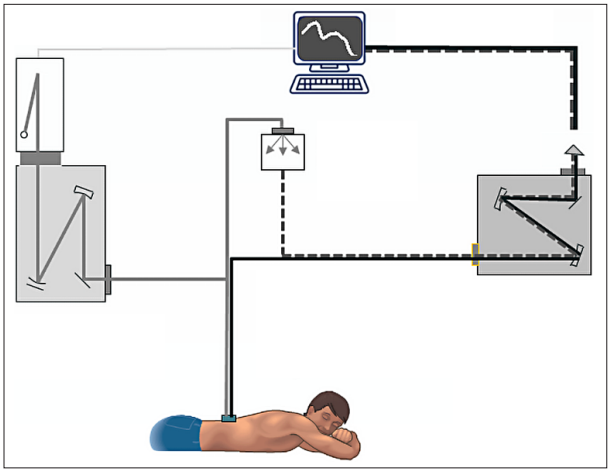

Figure 4: The spectrophotometer must have two fiber optic beams. One conducts UV radiation to the area with sunscreen, and the other collects the diffuse reflectance once it has passed twice through the filtering film. Adapted from Rohr M, Ernst N, Schrader A. Hybrid diffuse reflectance spectroscopy: Non-erythemal in vivo testing of sun protection factor. Skin Pharmacol Physiol. 2018, 31, 220-228.

The limitation of the method is that the skin reflects very little radiation at wavelengths below 320 nm, as melanin, DNA, and proteins absorb in the UVB. Therefore, the "in vivo" measurement can only be performed between 320 and 400 nm. The solution found was to "attach" to the "in vivo" obtained curve the missing part of the spectrum from an "in vitro" measurement. The "in vitro" measurement between 290 and 320 nm is performed following the ISO 24443 technique.

The spectrum is "normalized" to the same scale with a proportionality factor at 345 nm, as schematized in Figure 5.

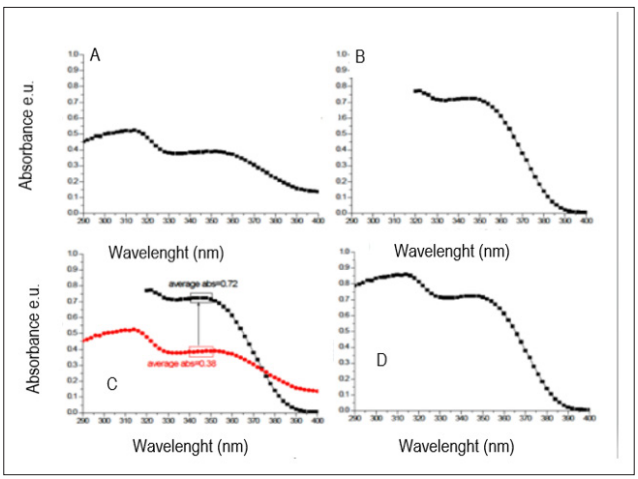

Figure 5: A is The Complete Spectrum Determined "in vitro" with ISO 24443 (290-400 nm), B is the Spectrum Detected by Diffuse Reflectance (320-400 nm), C shows the Splice of Both Spectra by Scale Normalization at 345 nm, and D is the Complete Diffuse Reflectance Curve Obtained. Adapted from Ruvolo E, Chu, M, Grossman F, Cole C, Kollias N. Diffuse Reflectance Spectroscopy for Ultraviolet A Protection Factor Measurement: Correlation Studies Between in vitro and in vivo Measurements. Photodermatol. Photoimmunol. Photomed. 2009, 25, 298-304.

The calculations are cumbersome because they must be performed in 1 nm intervals, both for the erythema action spectrum (in the UVB), the PPD spectrum (in the UVA), and the spectral irradiance by diffuse reflectance (UV-SSR). It is practically impossible to perform these calculations manually, which is why the few available equipment on the market suitable for using this technique have integrated, in addition to the double fiber optic, the possibility of programming the calculations to be performed automatically. For this reason, they are very expensive.

For informational purposes only, and not exclusively, we mention some of the equipment and manufacturers cited in the literature: Bentham double beam monochromator System (Bentham Instruments Ltd. UK), HORIBA Aqualog (Horiba Scientific Ltd. Japan), Poly602R and Mono602R (SOLARR Light Company LLC, USA).

Conclusion

After several decades in which the methods for determining SPF and UVA-PF to qualify the protection provided by sunscreens against UV radiation remained unchanged conceptually, except for refinements in the techniques used to reduce inter-laboratory discrepancies and between results obtained "in vivo" and "in vitro," an international consensus has been reached to adopt two new methods. These methods aim to overcome the ethical and implementation criticisms that ISO 24444 and ISO 24443 had.

These methods will likely also be implemented in Mercosur in Within short to medium term.

Both ISO 23675 (determination of SPF and UVA-PF "in vitro") and ISO 23698 (determination of SPF and UVA-PF by diffuse reflectance) require a significant initial investment in modern equipment and extensive training for the personnel who will operate it.

It seems advisable to prepare immediately to face the changes. Not doing so would mean widening the technological gap with developed countries and loss of competitiveness for the cosmetic industry.

As a suggestion, given the high investment required, which may be impossible for small and medium enterprises, it would be worth considering developing regional or country shared reference centers that could offer the service to the local markets.

Conflicts of Interest

The author has no conflicts of interest to declare.

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