

COSMETICS EUROPE RECOMMENDATION N° 26

ON THE USE OF ALTERNATIVE METHODS TO

ISO24444:2019

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Cosmetics Europe Recommendation On the Use of Alternative Methods to ISO24444:2019

For decades, the Sun Protection Factor (SPF) has been measured on the skin of human volunteers *in vivo*. The current *in vivo* SPF test method used in Europe (ISO24444:2019) has been developed by a large number of global experts in the International Standards process and is used widely for substantiation of labelled protection claims or in-market control.

Supported by the European Commission (who explicitly encouraged the development of alternatives in its Recommendation 2006/647/EC), the sun protection industry has continued to innovate around developing new SPF test methods for many years.

It is essential, however, that any alternative method demonstrates a sufficiently high statistical correlation with the current gold-standard *in vivo* SPF test method (ISO24444:2019). Predicting *in vivo* SPF test results using alternative methods has, however, proved an extremely hard scientific challenge.

Several alternative methods are in various stages of development, and five methods are currently undergoing statistical characterisation vs the gold standard ISO24444:2019 method in a multi-stakeholder technical consortium (ALT-SPF¹). Two of those methods have ring-study data evaluating their correlation with ISO24444:2019. Results of these methods have been published in peer-reviewed journals for a high number of sun protection products and both are formal work items in the final stages of standardisation in the ISO/TC217/WG7 'Sun Protection Test Methods' Working group²:

- 1) The *In Vitro* 'Double Plate' Method (ISO Committee Draft 23675)^{3,4}
- 2) Hybrid Diffuse Reflectance Spectroscopy or HDRS (ISO Committee Draft 23698)⁵

¹ <https://www.alt-spf.com/>

² <https://www.iso.org/fr/committee/54974/x/catalogue/p/0/u/1/w/0/d/0>

³ M. Pissavini, C. Tricaud, G. Wiener, A. Lauer, M. Contier, L. Kolbe, C. Trullás Cabanas, F. Boyer, V. Nollent, E. Meredith, E. Dietrich, P.J. Matts, "Validation of an *In Vitro* Sun Protection Factor (SPF) method in blinded ring-testing." *Int. Journal of Cosm. Sci.*, Vol 40, Issue 3, 2018.

⁴ M. Pissavini, C. Tricaud, G. Wiener, A. Lauer, M. Contier, L. Kolbe, C. Trullás Cabanas, F. Boyer, E. Meredith, J. de Lapuente, E. Dietrich, P.J. Matts, "Validation of a new *in vitro* Sun Protection Factor method to include a wide range of sunscreen product emulsion types" *Int. Journal of Cosm. Sci.*, Vol 42, Issue 5, 2020.

⁵ Eduardo Ruvalo, Mathias Rohr, Sergio Oliveira, Luciano Nogueira, José Carvalho, Curtis Cole "Multi-laboratory study of hybrid diffuse reflectance spectroscopy to assess sunscreen SPF and UVA-PFs" *Photoderm Photoimmun Photomed*, June 2021.

These two methods are expected to be the first alternative SPF methods to be published as full ISO standards, as early as 2025 (whereupon they will be preferred reference alternative methods, as stated in the European Commission Recommendation of 2006⁶).

Considering that correct use of these two methods requires adequate training and experience, we strongly recommend that CE members (and the test laboratories with whom they work) familiarise themselves with them as soon as possible so that, prior to the publication of the final ISO standards, they may be considered as alternative SPF tests to ISO24444:2019.

However, until such time that these two methods are published as final ISO standards, in the event of discrepancies in results with ISO24444:2019, the latter should continue to be considered as the gold standard.

[Annex I: Double Plate Method Protocol](#)

[Annex H of Annex I](#)

[Annex II: HDRS Method Protocol](#)

⁶ COMMISSION RECOMMENDATION of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto (notified under document number C(2006) 4089) (Text with EEA relevance) (2006/647/EC)