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Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)

*Cosmétiques — Méthodes d'essai de protection solaire —
Détermination in vivo du facteur de protection solaire (FPS)*



Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

This second edition cancels and replaces the first edition (ISO 24444:2010), which has been technically revised.

The main changes compared to the previous edition are as follows.

- The definition of the minimal erythema response (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° for the test panel to be within the range 41° to 55°, with a minimum of three subjects within two of the three ITA° ranges.
- The ITA° is used to define the range of unprotected MED doses for the provisional or the test day unprotected MED determination (if no provisional MEDu determination is made).
- Three new reference standard sunscreens have been validated and added to the method to validate SPF test panels for products with SPF equal to 25 or higher (P5, P6 and P8).
- New test methods are provided to determine the uniformity of the beam of both large and small beam size solar simulators. A requirement for uniformity greater than or equal to 90 % has been added.
- Sunscreen application procedures have been described in greater detail.
- An informative [Annex F](#) has been added with photographic examples of erythema responses with guidelines for grading.
- The reporting tables in [Annex G](#) and the requirements in [Clause 11](#) have modified to provide more complete information on the results of the testing.
- The bibliography has been updated.

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Introduction

The level of sun protection provided by sunscreen products has traditionally been estimated using the sun protection factor or SPF test, which uses the erythematous response of the skin to ultraviolet (UV) radiation. The SPF is a ratio calculated from the energies required to induce a minimum erythematous response with and without sunscreen product applied to the skin of human test subjects. It uses ultraviolet radiation usually from an artificial source.

Different standard methods are available and described in ISO/TR 26369^{[1]-[3]}.

Since the publication of the first version of this document, harmonization has been achieved in many member countries. The objective of this updated version is to further improve reproducibility between test sites, so as to obtain the same SPF value.