Cosmetics - Sun protection test methods - In vivo determination of the sun protection factor (SPF) (ISO 24444:2019)

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 24444:2020 sisaldab Euroopa standardi EN ISO 24444:2020 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 24444:2020 consists of the English text of the European standard EN ISO 24444:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 15.01.2020.	Date of Availability of the European standard is 15.01.2020.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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English Version

Cosmetics - Sun protection test methods - In vivo determination of the sun protection factor (SPF) (ISO 24444:2019)

Cosmétiques - Méthodes d'essai de protection solaire - Détermination in vivo du facteur de protection solaire (FPS) (ISO 24444:2019)

Kosmetik - Untersuchungsverfahren für Sonnenschutzmittel - In-vivo-Bestimmung des Sonnenschutzfaktors (SSF) (ISO 24444:2019)

This European Standard was approved by CEN on 9 December 2019.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 24444:2020) has been prepared by Technical Committee ISO/TC 217 "Cosmetics" in collaboration with Technical Committee CEN/TC 392 “Cosmetics” the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2020, and conflicting national standards shall be withdrawn at the latest by July 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 24444:2010.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 24444:2019 has been approved by CEN as EN ISO 24444:2020 without any modification.

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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).

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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.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 erythemal response of the skin to ultraviolet (UV) radiation. The SPF is a ratio calculated from the energies required to induce a minimum erythemal 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.

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

1 Scope

This document specifies a method for the in vivo determination of the sun protection factor (SPF) of sunscreen products. It is applicable to products that contain any component able to absorb, reflect or scatter ultraviolet (UV) rays and which are intended to be placed in contact with human skin.

This document provides a basis for the evaluation of sunscreen products for the protection of human skin against erythema induced by solar ultraviolet rays.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
ultraviolet radiation
UVR
electromagnetic radiation in the range of 290 nm to 400 nm

3.1.1
ultraviolet B
UVB
electromagnetic radiation in the range of 290 nm to 320 nm

3.1.2
ultraviolet A
UVA
electromagnetic radiation in the range of 320 nm to 400 nm

Note 1 to entry: UVA II = 320 nm to 340 nm; UVA I = 340 nm to 400 nm.

3.1.3
erythemal effective irradiance
E_{er}
radiometric quantity derived by multiplying the spectral irradiance $E(\lambda)$ of the solar simulator with the erythema action spectrum[4] $s_{er}(\lambda)$ at each wavelength λ and integrating over wavelength range of 290 nm to 400 nm

$$E_{er} = \int_{290}^{400} E(\lambda) s_{er}(\lambda) d\lambda \text{ unit: W/m}^2 \text{ (eff.)}$$