SLOVENSKI STANDARD
SIST EN ISO 24442:2022

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Nadomešča:
SIST EN ISO 24442:2012

Kozmetika - Metode za preskušanje zaščite pred soncem - Določevanje zaščitnega faktorja UVA in vivo (ISO 24442:2022)

Cosmetics - Sun protection test methods - In vivo determination of sunscreen UVA protection (ISO 24442:2022)

Kosmetik - Prüfverfahren für Sonnenschutzmittel - In-vivo-Bestimmung des UVA-Sonnenschutzes (ISO 24442:2022)

Cosmétiques - Méthodes d'essai de protection solaire - Détermination in vivo de la protection UVA d'un produit de protection solaire (ISO 24442:2022)

Ta slovenski standard je istoveten z: **EN ISO 24442:2022**

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71.100.70	Kozmetika. Toaletni pripomočki	Cosmetics. Toiletries

SIST EN ISO 24442:2022 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 24442

June 2022

ICS 71.100.70

Supersedes EN ISO 24442:2011

English Version

Cosmetics - Sun protection test methods - In vivo determination of sunscreen UVA protection (ISO 24442:2022)

Cosmétiques - Méthodes d'essai de protection solaire - Détermination in vivo de la protection UVA d'un produit de protection solaire (ISO 24442:2022)

Kosmetik - Prüfverfahren für Sonnenschutzmittel - In-vivo-Bestimmung des UVA-Sonnenschutzes (ISO 24442:2022)

This European Standard was approved by CEN on 3 June 2022.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 24442:2022) 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of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by December 2022.

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 24442:2011.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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Endorsement notice

The text of ISO 24442:2022 has been approved by CEN as EN ISO 24442:2022 without any modification.

INTERNATIONAL STANDARD

ISO 24442

Second edition
2022-06

Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection

Cosmétiques — Méthodes d'essai de protection solaire — Détermination in vivo de la protection UVA d'un produit de protection solaire

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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,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 392, *Cosmetics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 24442:2011), which has been technically revised.

The main changes are as follows:

— this document has been aligned with the revised ISO 24444.

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

This document specifies the procedure to determine the Ultraviolet A Protection Factor (UVAPF) of a sunscreen product using the persistent pigment darkening method according to the principles recommended by the Japan Cosmetic Industry Association (JCIA) in 1995[1]. The outcome of this test method can be used to determine the UVA classification of topical sunscreen products according to local regulatory requirements.

Topical sunscreen products are primarily rated and labelled according to their ability to protect against sunburn, using a test method to determine the in vivo sun protection factor (see ISO 24444). This rating evaluates filtration of sunburn generating radiation across the electromagnetic UV spectrum (290 nm to 400 nm). However, knowledge of the sun protection factor (SPF) rating does not provide explicit information on the magnitude of the protection provided specifically in the UVA range of the spectrum (320 nm to 400 nm), as it is possible to have high SPF products with very modest UVA protection [for example SPF 50 with a UVA protection factor (UVAPF) of only 3 to 4]. There is demand among medical professionals, as well as knowledgeable consumers, to have fuller information on the UVA protection provided by their sunscreen product, in addition to the SPF, in order to make a more informed choice of product, providing a more balanced and broader-spectrum protection. Moreover, there is also a demand to prevent UVA-induced darkening of the skin from a cultural point of view even without sunburn. Thus, persistent pigment darkening (PPD) was selected as an endpoint relevant to UVA. Although PPD reflects merely photo-polymerization of melanin monomers[2], it is evaluated as a representative of the biological reactions. The UVAPF value of a product provides information on the magnitude of the protection provided explicitly in the UVA portion of the spectrum, independent of the SPF values[3][4][5].

The test method outlined in this document is derived primarily from the UVAPF test methods as developed by the JCIA. Modifications have been made to attempt to be in line with updated International Standards for determination of sun protection factor without changing the integrity of the fundamental underlying principles of the test method.

Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection

1 Scope

This document specifies a method for the in vivo determination of UVA protection factor (UVAPF) 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 UVA radiation induced by solar ultraviolet rays.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 24444, *Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)*

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 https://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.

3.2
erythema
reddening of the skin caused by UV radiation

3.3
persistent pigment darkening
PPD
skin darkening that persists more than 2 h after the end of UVA exposure

3.4
sunscreen products
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* (3.2) and other ultraviolet induced damage

3.5
minimal persistent pigment darkening dose
MPPDD
lowest UVA dose that produces the first perceptible unambiguous persistent pigment darkening response with over more than 50 % of UV exposure subsite, observed between 2 h and 24 h after the end of the UVA exposure

3.5.1
$MPPDD_u$
MPPDD on unprotected skin

3.5.1.1
$MPPDD_{iu}$
MPPDD of an individual subject on unprotected skin

3.5.2
$MPPDD_p$
MPPDD on product protected skin

3.5.2.1
$MPPDD_{ip}$
MPPDD of an individual subject on protected skin

3.6
UVA protection factor
UVAPF
ratio of the minimal PPD dose on product protected skin ($MPPDD_p$) to the minimal PPD dose on unprotected skin ($MPPDD_u$) of the same subject:

$$UVAPF = \frac{MPPDD_p}{MPPDD_u}$$

Note 1 to entry: UVAPF is expressed to one decimal place by truncation.

3.6.1
individual UVA protection factor
$UVAPF_i$
ratio of the individual minimal PPD dose on product protected skin ($MPPDD_{ip}$) to the individual minimal PPD dose on unprotected skin ($MPPDD_{iu}$) of the same subject:

$$UVAPF_i = \frac{MPPDD_{ip}}{MPPDD_{iu}}$$

Note 1 to entry: $UVAPF_i$ is expressed to one decimal place by truncation.

3.6.2
product UVAPF
arithmetic mean of all valid individual $UVAPF_i$ values obtained from all subjects in the test

3.7
test area
area for testing on the back between the scapula line and the waist

Note 1 to entry: Skeletal protrusions and extreme areas of curvature should be avoided.

3.8
test site
area of the skin where a product is applied, or the site used for the determination of the unprotected MPPDD

3.9
exposure sub-sites
areas of skin that are exposed to UV-irradiation within a *test site* (3.8)

3.10
individual typology angle
ITA°
value characterizing the skin colour of the subject as measured by a skin contact reflectance spectrophotometer or skin colorimeter

Note 1 to entry: Refer to Annex E for the detailed requirements of the equipment/measurement.

4 General principle

The UVAPF test method is analogous to the test method used to determine the SPF of a sunscreen product. However, it utilizes only the UVA portion of the xenon arc lamp solar simulator of defined and known output to determine the protection provided by sunscreen products on human skin in the UVA portion of the spectrum.

The UVAPF test method uses PPD responses of the skin as the end point for evaluating transmitted UVA radiation.

The test shall be restricted to the area of the back of selected human subjects.

A section of each subject's skin is exposed to UVA radiation without any protection while another (different) section is exposed after application of the sunscreen product under test. One further section is exposed after application of an UVAPF reference sunscreen formulation, which is used for validation of the procedure.

To determine the UVAPF, incremental series of PPD responses are induced on a number of small sub-sites on the skin. These responses are visually assessed for presence of PPD 2 h to 24 h after UVA radiation, by the judgment of a trained and competent evaluator.

The $MPPDD_{iu}$ and the $MPPDD_{ip}$ shall be determined on the same subject on the same day. An $UVAPF_i$ for each subject tested is calculated as the ratio of $MPPDD_{ip}$ divided by $MPPDD_{iu}$, as in the formula given in 3.6.

The UVAPF is the arithmetic mean of all valid $UVAPF_i$ results from each subject in the test expressed to one decimal place.

5 Test subjects

5.1 Selection of the test subjects

5.1.1 General

There are strict requirements governing the inclusion and non-inclusion of test subjects which should be adhered to. The criteria shall be set out in Annex A.