

**Cosmetics - Sun protection test methods - In vivo
determination of sunscreen UVA protection (ISO
24442:2011)**

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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|---|--|
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ICS 71.100.70

English Version

**Cosmetics - Sun protection test methods - In vivo determination
of sunscreen UVA protection (ISO 24442:2011)**

Cosmétique - Méthodes d'évaluation de la protection
solaire - Détermination in vivo de la protection UVA (ISO
24442:2011)

Kosmetik - Prüfverfahren für Sonnenschutzmittel - In-vivo-
Bestimmung des UVA-Sonnenschutzes (ISO 24442:2011)

This European Standard was approved by CEN on 14 December 2011.

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Foreword

This document (EN ISO 24442:2011) 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of an identical text or by endorsement, at the latest by June 2012, and conflicting national standards shall be withdrawn at the latest by June 2012.

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Endorsement notice

The text of ISO 24442:2011 has been approved by CEN as a EN ISO 24442:2011 without any modification.

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Introduction

This International Standard 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/FDIS 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 (e.g. SPF 50 with a 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. 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.

The test method outlined in this International Standard is derived primarily from the UVAPF test methods as developed by the JCIA. Modifications have been made to attempt to harmonize with other methodologies 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 International Standard specifies an *in vivo* method for assessment of the UVA protection factor (UVAPF) of topical sunscreen products. This International Standard is applicable to cosmetics, drugs and other products intended to be topically applied to human skin, including any component able to absorb, reflect or scatter UV rays.

It provides a basis for the evaluation of sunscreen products for the protection of human skin against UVA radiation from solar or other light sources.

2 Terms and definitions

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

2.1

ultraviolet radiation

electromagnetic radiation in the range of 290 nm to 400 nm

NOTE UVB = 290 nm to 320 nm; UVA = 320 nm to 400 nm (UVA II = 320 nm to 340 nm; UVA I = 340 nm to 400 nm).

2.2

erythema

reddening of the skin caused by UV radiation

2.3

persistent pigment darkening

PPD

skin darkening that persists more than 2 h after the end of UVA exposure

2.4

minimal persistent pigment darkening dose

MPPDD

lowest Ultraviolet A (UVA) dose that produces the first perceptible unambiguous persistent pigment darkening response with defined borders appearing over most of the field of UVA exposure, observed between 2 h and 24 h after the end of the UVA exposure

NOTE The MPPDD on unprotected skin is referenced as “MPPDDu”, and the MPPDD on sunscreen-protected skin is referenced as “MPPDDp”.

2.5

individual Ultraviolet A protection factor

UVAPFi

ratio of the minimal persistent pigment darkening dose on product-protected skin (MPPDDp) to the minimal persistent pigment darkening dose on unprotected skin (MPPDDu) of the same subject:

$$\text{UVAPFi} = \frac{\text{MPPDDp}}{\text{MPPDDu}}$$

2.6

UVA protection factor of a product

UVAPF

arithmetic mean of all valid individual UVAPFi values obtained from all subjects in the test