Irish Standard
I.S. EN ISO 24443:2021&LC:2022

Cosmetics - Determination of sunscreen UVA photoprotection in vitro (ISO 24443:2021, Corrected version 2022-02)

I.S. EN ISO 24443:2021&LC:2022

Incorporating amendments/corrigenda/National Annexes issued since publication:

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This document is based on: *Published:*

This document was published under the authority of the NSAI and comes into effect on:

2022-04-26

ICS number:

71.100.70

NOTE: If blank see CEN/CENELEC cover page

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National Foreword

I.S. EN ISO 24443:2021&LC:2022 is the adopted Irish version of the European Document EN ISO 24443:2021, Cosmetics - Determination of sunscreen UVA photoprotection in vitro (ISO 24443:2021, Corrected version 2022-02)

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In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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Corrected Version

Reference: EN ISO 24443:2021

Title: Cosmetics - Determination of sunscreen UVA photoprotection in vitro (ISO 24443:2021, Corrected version 2022-02)

Work Item: 00392037

Brussels, 2022-03-16

Please include the following minor editorial correction(s) in the document related to:

the following language version(s) :
- ☒ English
- ☒ French
- ☐ German

for the following procedure :
- ☐ PQ/UQ
- ☐ Enquiry
- ☐ 2nd Enquiry
- ☐ Parallel Enquiry
- ☐ 2nd Parallel Enquiry
- ☐ Formal Vote
- ☐ 2nd Formal Vote
- ☐ Parallel Formal Vote
- ☐ 2nd Parallel Formal Vote
- ☐ UAP
- ☐ TC Approval
- ☐ 2nd TC Approval
- ☐ Publication
- ☒ Parallel Publication

It has been brought to our attention that this document, issued on 2021-12-15, requires modification.

ISO has published (Corrected version 2022-02) of ISO 24443:2021 in English and French versions.

Titles and European forewords have been updated accordingly.

Please find enclosed the updated English and French versions.

We apologise for any inconvenience this may cause.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 24443

December 2021

ICS 71.100.70

Supersedes EN ISO 24443:2012

English Version

Cosmetics - Determination of sunscreen UVA photoprotection in vitro (ISO 24443:2021, Corrected version 2022-02)

Cosmétiques - Détermination in vitro de la photoprotection UVA (ISO 24443:2021, Version corrigée 2022-02)

Kosmetische Mittel - In-vitro-Bestimmung des UVA Schutzes von Sonnenschutzmitteln (ISO 24443:2021, korrigierte Fassung 2022-02)

This European Standard was approved by CEN on 17 October 2021.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 16 March 2022.

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 24443:2021) 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 2022, and conflicting national standards shall be withdrawn at the latest by June 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 24443:2012.

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

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.

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 24443:2021, Corrected version 2022-02 has been approved by CEN as EN ISO 24443:2021 without any modification.

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I.S. EN ISO 24443:2021&LC:2022

INTERNATIONAL STANDARD

ISO 24443

Second edition
2021-12

Corrected version
2022-02

Cosmetics — Determination of sunscreen UVA photoprotection in vitro

Cosmétiques — Détermination in vitro de la photoprotection UVA

Reference number
ISO 24443:2021(E)

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Published in Switzerland

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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,* 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 24443:2012), which has been technically revised.

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

— acceptance of moulded and sandblasted PMMA plates, according to specifications described in Annex D;

— product application fitted to 1,2mg/cm^2 for sandblasted plates;

— description of application gesture according to tested products;

— introduction of a new high UVA PF standard P8;

— introduction of critical wavelength calculation;

— calculation of coefficient "*C*" accepted from in vivo screening SPF, with specific conditions based on SEM and percentage of variability, and new range proposed from 0,6 to 1,6;

— limitation of UVA irradiation dose to 36 J/cm^2.

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.

This corrected version of ISO 24443:2021 incorporates the following corrections:

— Formulae (2) and (4) have been corrected;

— in 6.7.2, the significance of SEM has been explained;

— in A.5.1, the transmission values for sandblasted PMMA plates have been corrected;

— Bibliographic references have been corrected.

Introduction

This document specifies the procedure to determine the ultraviolet protection factor (UVA-PF) of a sunscreen product using the in vitro UVA-PF according to the principles recommended by the European Cosmetic and Perfumery Association (COLIPA) in 2011. 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 (e.g. SPF 50 with a UVA-PF of only 3 to 4). There is a 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. The UVA-PF 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 document is derived primarily from the in vitro UVA-PF test method as developed by COLIPA.

Cosmetics — Determination of sunscreen UVA photoprotection in vitro

1 Scope

This document specifies an in vitro procedure to characterize the UVA protection of sunscreen products. Specifications are given to enable determination of the spectral absorbance characteristics of UVA protection in a reproducible manner.

In order to determine relevant UVA protection parameters, the method has been created to provide an UV spectral absorbance curve from which a number of calculations and evaluations can be undertaken. These include calculation of the Ultraviolet-A protection factor (UVA-PF) [correlating with in vivo UVA-PF from the persistent pigment darkening (PPD) testing procedure], critical wavelength and UVA absorbance proportionality. These computations are optional and relate to local sunscreen product labelling requirements. This method relies on the use of static in vivo SPF results for scaling the UV absorbance curve.

This document is not applicable to powder products such as pressed powder and loose powder products.

2 Normative references

There are no normative references in this document.

3 Terms, definitions, symbols and abbreviated terms

3.1 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/

3.1.1
UV
ultraviolet radiation
electromagnetic radiation in the range of 290 nm to 400 nm

3.1.2
UVB
ultraviolet B
electromagnetic radiation in the range of 290 nm to 320 nm

3.1.3
UVA
ultraviolet A
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.