

SLOVENSKI STANDARD SIST EN ISO 23675:2025

01-marec-2025

Kozmetika - Preskusne metode za zaščito pred soncem - Določanje faktorja zaščite pred soncem (SPF) in vitro (ISO 23675:2024)

Cosmetics - Sun protection test methods - In vitro determination of sun protection factor (SPF) (ISO 23675:2024)

Kosmetische Mittel - Untersuchungsverfahren für Sonnenschutzmittel - In vitro Bestimmung des Sonnenschutzfaktors (SSF) (ISO 23675:2024)

Cosmétiques - Méthodes d'essai de protection solaire - Détermination in vitro du facteur de protection solaire (FPS) (ISO 23675:2024)

Ta slovenski standard je istoveten z: EN ISO 23675:2025

ICS:

71.100.70 Kozmetika. Toaletni

pripomočki

Cosmetics. Toiletries

SIST EN ISO 23675:2025

en,fr,de

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 23675:2025

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN ISO 23675

January 2025

ICS 71.100.70

English Version

Cosmetics - Sun protection test methods - In vitro determination of sun protection factor (SPF) (ISO 23675:2024)

Cosmétiques - Méthodes d'essai de protection solaire -Détermination in vitro du facteur de protection solaire (FPS) (ISO 23675:2024) Kosmetische Mittel - Untersuchungsverfahren für Sonnenschutzmittel - In vitro Bestimmung des Sonnenschutzfaktors (SSF) (ISO 23675:2024)

This European Standard was approved by CEN on 22 November 2024.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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, Türkiye and United Kingdom.

https://standards.iteh.ai/catalog/standards/sist/6ef516ed-2c61-47ad-9ee8-10b95847ac38/sist-en-iso-23675-2025



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

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

EN ISO 23675:2025 (E)

Contents	Page
European foreword	3

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 23675:2025

European foreword

This document (EN ISO 23675:2025) 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 2025, and conflicting national standards shall be withdrawn at the latest by July 2025.

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.

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, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 23675:2024 has been approved by CEN as EN ISO 23675:2025 without any modification.

SIST EN ISO 23675:2025

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 23675:2025



International Standard

ISO 23675

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

Cosmétiques — Méthodes d'essai de protection solaire — Méthodes d'essai de protection solaire (FPS)

Document Preview

First edition 2024-12

ent Freylew

SIST EN ISO 236/5:2

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 23675:2025

https://standards.iteh.ai/catalog/standards/sist/6ef516ed-2c61-47ad-9ee8-10b95847ac38/sist-en-iso-23675-2025



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: +41 22 749 01 11 Email: copyright@iso.org Website: www.iso.org

Published in Switzerland

Con	tent	5	Page
Forew	vord		v
Intro	ductio	n	vi
1	Scon	е	1
2	-	native references	
3		ns and definitions	
4	Princ	ciples	4
5	U	ents and/or materials	
	5.1	Sample substrate — Double plate	
	5.2 5.3	Reference sunscreen Finger-cot	
	5.3 5.4	Blank	
_			
6	Appa 6.1	Spectrophotometers	
	0.1	6.1.1 Specification	
		6.1.2 Monitoring	
	6.2	Automatic positive-displacement pipette	
	6.3	Analytical balance	
	6.4	Robot	
		6.4.1 Specifications	
	6.5	6.4.2 Monitoring Solar simulator	
	0.5	6.5.1 General	
		6.5.2 Quality of solar simulator radiation	
		6.5.3 Maintenance and monitoring the solar simulator	6
7	Proc	edure Document Preview	7
,	7.1	Outline of the test procedure	
	7.2	Preparation of reagents and materials	
		7.2.1 Plate preparation and handling 236/5:2025	8
		1s7.2.2 at/Finger cot ndards/sist/6ef516ed-2e61-47ad-9ee8-10b95847ac38/sist-en-iso-236	
	7.3	Product application on plates and robot automatic spreading	
		7.3.1 Weighing of product and application on plates	
	7.4	7.3.2 Automatic spreading Measurement of initial absorbance using two plate types (290 nm to 400 nm)	
	7.7	7.4.1 Blank measurement	
		7.4.2 Initial absorbance measurement	
		7.4.3 Calculation of pre-irradiation in vitro SPF _i	11
	7.5	Calculation of irradiation dose (based on pre-irradiation in vitro SPF_i)	12
	7.6	Irradiation with calculated dose	
	7.7	Measurement of post-irradiation absorbance using two plate types	12
	7.8 7.9	Calculation of post-irradiation in vitro SPF_i Calculation of final in vitro SPF_i of each pair of plates	12
	7.10	Calculation of final in vitro SPF of the product	13
		7.10.1 General	
		7.10.2 Validation of final in vitro SPF	13
8	Test	report	14
		ormative) UV exposure and erythemal action spectra and solar simulator UV	
		trum	16
Anne	x B (no	rmative) Specification sample plate	20
		rmative) SPF reference sunscreen products	
		ormative) White petroleum and glycerin	35

Annex E (normative)	Spectrophotometers specification and monitoring	37
Annex F (normative)	Robot specification.	4 1
Bibliography		43

iTeh Standards (https://standards.iteh.ai) Document Preview

SIST EN ISO 23675:2025

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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).

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

Chronic exposure to solar ultraviolet radiation (UVR) is the main environmental source of damage to human skin. Consumer protection against exposure to solar UVB and UVA radiation is, therefore, an important public health issue. The use of sunscreens is a critical part of holistic programs of consumer UVR protection, including the use of appropriate clothing, hats and minimising exposure to the sun around its zenith.

The in vivo sun protection factor (SPF) is historically measured by an in vivo method (see ISO 24444) to communicate the amplitude of protection offered by sunscreens from erythemally-effective solar UVR. [2] In recent years, additional test methods have been developed to measure the breadth of protection from solar UVR, namely the in vivo human persistent pigment darkening (PPD) test [3] (and associated UVA-PF) and an in vitro equivalent. [4][5][6][7]

Invasive methods based on tests conducted on human beings are ethically problematic, time-consuming and very costly. Therefore, it has for long been a desire to develop an in vitro SPF test method, [8][9][10][11][12][13] [14][15][16][17] recognising the potential advantages of such methodology, including:

- a) the use of a non-human model,
- b) the significant improvements in speed and cost,
- c) the improved repeatability and reproducibility,
- d) the elimination of technically-challenging procedures (e.g., MED determination) and
- e) the use of a method which is significantly more amenable to continuous improvement.

This in vitro SPF method is based on UVR transmittance spectroscopy, whereby spectrophotometric measurement of UVR transmission through appropriate UVR-transparent substrates, allows prediction of in vivo SPF values. [18][19][20][21][22] This in vitro SPF method revealed a strong reproducibility and correlation with in vivo SPF values. [23][24][25]

Document Preview

SIST EN ISO 23675:2025

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

1 Scope

This document specifies a method for the in vitro determination of sun protection factor (SPF). This method is applicable to sunscreen products in form of an emulsion or alcoholic one-phase formulation, excluding in form of a loose or compressed powder or stick. Specifications are given to enable determination of the spectral absorbance characteristics of SPF protection in a reproducible manner.

Use of this method is strictly for the determination of a static sun protection factor. It is not applicable for the determination of water-resistance properties of a sun protection product.

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 tps://standards.iteh.ai)

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

sunscreen product

product 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 and other ultraviolet induced damage

3.2

emulsion

fine dispersion of minute droplets of one liquid in other(s) in which it is not soluble or miscible

3.3

in vitro sun protection factor

SPF_{in vitro}

protection factor of a sun protection product against erythema-inducing radiation calculated with spectral modelling between 290 nm and 400 nm

3.4

reference solar spectrum

$I_{\alpha\alpha}(\lambda)$

spectral irradiance of mid-summer sunlight in the spectral range of 290 nm to 400 nm, at a latitude of 40 $^{\circ}$ N, a solar zenith angle of 20 $^{\circ}$ and an ozone layer thickness of 0,305 cm, as defined in Annex A

3.5

solar UVR simulator

solar ultraviolet radiation simulator

light source emitting a continuous spectrum $[S(\lambda)]$ with no gaps or extreme peaks of emission in the UV region

Note 1 to entry: The solar simulator has a spectral quality that complies with the required acceptance limits in $\frac{Annex\ A}{A}$.

3.6

erythemal action spectrum

$E(\lambda)$

relative effects of individual spectral bands of an exposure source for an erythema response

Note 1 to entry: The symbol for the erythemal action spectrum is defined as $s_{\rm er}(\lambda)$ in ISO/CIE 17166 and $E(\lambda)$ in the ISO 24443.

Note 2 to entry: This entry was numbered 17-401 in CIE S 017:2011.

[SOURCE: CIE-ILV 17-26-065]

3.7

spectrophotometer

instrument for measuring the ratio of 2 values of a radiometric quantity at the same wavelength

Note 1 to entry: This entry was numbered 17-1235 in CIE S 017:2011.

[SOURCE: CIE-ILV 17-25-008]

3.8

monochromatic absorbance

$A(\lambda)$

sunscreen absorbance at wavelength λ calculated as logarithm to base 10 of the reciprocal of the spectral internal transmittance, $T(\lambda)$

$$A(\lambda) = -\log 10 \ T(\lambda)$$

[SOURCE: CIE-ILV 17-24-090]

3.9

irradiance at a point of surface

$I(\lambda)$

quotient of the radiant flux $d\Phi e$ incident on an element of the surface containing the point, by the area dA of that element

Note 1 to entry: Expressed in W⋅m⁻².

Note 2 to entry: Note that the symbol for the irradiance is defined as E in CIE-ILV 017:2020 but because it could be confused with the symbol used in ISO 24443:2021 for the erythemal action spectrum, here we use $I(\lambda)$.

Note 3 to entry: This entry was numbered 17-608 in CIE S 017:2011.

[SOURCE: CIE-ILV 17-21-053]

3.10

spectroradiometer

instrument for measuring radiometric quantities in narrow wavelength intervals over a given spectral region

Note 1 to entry: This entry was numbered 17-1236 in CIE S 017:2011.

[SOURCE: CIE-ILV 17-25-007]