



SLOVENSKI STANDARD
kSIST-TP FprCEN ISO/TR 26369:2009
01-junij-2009

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Cosmetics - Sun protection test methods - Review and evaluation of methods to assess the photoprotection of sun protection products (ISO/TR 26369:2009)

Kosmetik - Untersuchungsverfahren für Sonnenschutzmittel - Überprüfung und Bewertung von Verfahren zum Feststellen des Lichtschutzes von Sonnenschutzmitteln

Cosmétiques - Méthodes d'essai de protection solaire - Revuesystématique et évaluation des méthodes usuelles de mesure de la protectionsolaire fournie par les produits de protectionsolaire

Ta slovenski standard je istoveten z: FprCEN ISO/TR 26369

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TECHNICAL REPORT
RAPPORT TECHNIQUE
TECHNISCHER BERICHT

FINAL DRAFT
FprCEN ISO/TR 26369

April 2009

ICS 71.100.70

English Version

**Cosmetics - Sun protection test methods - Review and
evaluation of methods to assess the photoprotection of sun
protection products (ISO/TR 26369:2009)**

Cosmétiques - Méthodes d'essai de protection solaire -
Revue systématique et évaluation des méthodes usuelles
de mesure de la protection solaire fournie par les produits
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Kosmetik - Untersuchungsverfahren für Sonnenschutzmittel
- Überprüfung und Bewertung von Verfahren zum
Feststellen des Lichtschutzes von Sonnenschutzmitteln

This draft Technical Report is submitted to CEN members for Technical Committee Approval. It has been drawn up by the Technical Committee CEN/SS H99.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (FprCEN ISO/TR 26369:2009) has been prepared by Technical Committee ISO/TC 217 "Cosmetics" in collaboration with Technical Committee CEN/SS H99 "Products for household and leisure use - Undetermined" the secretariat of which is held by CMC.

This document is currently submitted to the parallel TC Approval.

Endorsement notice

The text of ISO/TR 26369:2009 has been approved by CEN as a FprCEN ISO/TR 26369:2009 without any modification.

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TECHNICAL
REPORT

ISO/TR
26369

First edition
2009-##-##

**Cosmetics — Sun protection test
methods — Review and evaluation of
methods to assess the photoprotection of
sun protection products**

*Cosmétiques — Méthodes d'essai de protection solaire — Revue
systématique et évaluation des méthodes usuelles de mesure de la
protection solaire fournie par les produits de protection solaire*

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Fax + 41 22 749 09 47
E-mail copyright@iso.org
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ISO/CEN PARALLEL PROCESSING

This draft Technical Report has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft Technical Report is hereby submitted to a parallel three-month P-member vote in the ISO/TC concerned and technical committee approval vote in CEN.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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.

ISO/TR 26369 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

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Cosmetics — Sun protection test methods — Review and evaluation of methods to assess the photoprotection of sun protection products

1 Scope

This Technical Report reviews and evaluates the methods which are currently used to assess, for regulatory or self-regulatory purposes, the photoprotection of sun protection products applied on the human body.

It is applicable to SPF and UVA protection, and both *in vivo* and *in vitro* methods.

This Technical Report does not include the aspects of labelling in a wide sense.

2 Terms and definitions

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

2.1

ultraviolet

UV

electromagnetic radiation with a wavelength shorter than that of visible light, but longer than soft X-rays and so named because the spectrum consists of electromagnetic waves with frequencies higher than those that humans identify as the color violet (purple)

NOTE In this Technical Report the following wavelengths are considered: UVA: 320 nm to 400 nm; UVB: 290 nm to 320 nm.

2.2

sun protection factor

SPF

(of a sunscreen) laboratory measurement to assess the effectiveness of sunscreens against UV erythema

NOTE 1 The higher the SPF, the more protection a sunscreen offers.

NOTE 2 The SPF is a ratio between the ultraviolet dose required to produce minimal erythema reaction (redness) in protected skin (skin with sunscreen) compared to unprotected skin (skin without any sunscreen).

3 Principle

This systematic review and evaluation of the methods are conducted for development of those ISO Standards which assess the photoprotection provided by sun protection products applied on the human body. It will serve as a technical/scientific framework to identify the most suitable methods for standardization.

The key parameters and elements are listed in Tables 1 to 6 in order to enable an easy comparison of the methods.

ISO/TR 26369:2009(E)**4 Sun protection test methods****4.1 SPF *in vivo***

The SPF *in vivo* methods currently used are given in Table 1.

4.2 SPF *in vitro*

The SPF *in vitro* methods based on transmittance evolved from the Diffey proposal and new methods based on measurement of free radicals or use of skin biopsies are given in Tables 2 and 3. The relevant parameters of methods based on transmittance are given in Table 4.

4.3 UVA *in vivo*

The methods reviewed by ISO/TC 217 are given in Tables 5 and 6.

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Table 1 — SPF *in vivo* methods currently used

Parameters	International 2006 [1] ^a	FDA 1999 [2]	Australia 1998 [3]
UV definition (UVB, UVA)	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	UVB: 290 nm to 320 nm UVA: 320 nm to 400 nm	Solar UVR: 290 nm to 400 nm UVB: 290 nm to 320 nm UVA: 320 nm to 400 nm
Volunteers selection			
Ethical considerations	Helsinki, national regulations, medical status	Not defined	Medical questionnaire
Age limitation	Yes, excluded below age of consent	Not defined	Not defined
Informed consent	Yes, with signatures	Yes	Yes
Exclusion criteria	Pregnant, lactating women Photosensitizing medication Dermatological problems, history of abnormal response to sun Tanning beds No sun damage, marks, blemishes or nevi	Skin disease, abnormal responses to UV, phototoxic or photo-allergic response, medication (topical or systemic) known to produce abnormal sunlight responses Sunburn, scars, active dermal lesions and uneven skin tones on the areas to be tested	Abnormal response to medication, UV radiation, allergies to topically applied cosmetics Phototoxic or photosensitizing medication
Test subjects			
Skin phototype and skin colour	Fitzpatrick skin type (s) I, II, III or skin colour (ITA° value > 28° very fair, fair-skin and intermediate skin colour) and untanned on the test area	Phototypes I, II, III Fair skin colour	Phototypes I, II, III Fair skin colour
Test area	Back, between scapula line and waist Skeletal protrusions and extreme areas of curvature should be avoided	The back between the belline and the shoulder blade (scapulae) and lateral to the midline	Back, clean dry skin, without any suntan or sunburn, active dermal lesions, excessive hair, uneven skin tones
Time, interval between two tests	No less than 2 months, sufficient interval for reversal of skin tanning until the site is clear	Not defined	Not defined
^a The numbers in brackets refer to the Bibliographic references.			