SLOVENSKI STANDARD
SIST EN ISO 24444:2011

01-april-2011

Kozmetika - Preskusne metode za zaščito pred soncem - Določevanje faktorja zaščite pred soncem (SPF) in vivo (ISO 24444:2010)

Cosmetics - Sun protection test methods - In vivo determination of the sun protection factor (SPF) (ISO 24444:2010)

Kosmetik - Untersuchungsverfahren für Sonnenschutzmittel - In-vivo-Bestimmung des Sonnenschutzfaktors (SSF) (ISO 24444:2010)

Cosmétiques - Méthodes d'essai de protection solaire - Détermination in vivo du facteur de protection solaire (FPS) (ISO 24444:2010)

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71.100.70	Kozmetika. Toaletni pripomočki	Cosmetics. Toiletries

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EUROPEAN STANDARD

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EN ISO 24444

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English Version

Cosmetics - Sun protection test methods - In vivo determination of the sun protection factor (SPF) (ISO 24444:2010)

Cosmétiques - Méthodes d'essai de protection solaire - Détermination in vivo du facteur de protection solaire (FPS) (ISO 24444:2010)

Kosmetik - Untersuchungsverfahren für Sonnenschutzmittel - In-vivo- Bestimmung des LSF (Lichtschutzfaktors) (ISO 24444:2010)

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Contents

Page

Foreword

This document (EN ISO 24444:2010) 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 NEN.

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The text of ISO 24444:2010 has been approved by CEN as a EN ISO 24444:2010 without any modification.

INTERNATIONAL STANDARD

ISO 24444

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

Cosmétiques — Méthodes d'essai de protection solaire — Détermination in vivo du facteur de protection solaire (FPS)

Reference number
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Contents

Page

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.

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ISO 24444 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

Introduction

The level of sun protection provided by sunscreen products has traditionally been estimated using the sun protection factor or SPF test, which uses the erythemal response of the skin to ultraviolet (UV) radiation. The SPF is a ratio calculated from the energies required to induce a minimum erythemal response with and without sunscreen product applied to the skin of human volunteers. It uses ultraviolet radiation usually from an artificial source.

Different standard methods are available and described in the technical report ISO/TR 26369[4].

These standards are similar by some parameters but different by others. Differences can lead to discrepancy of results. Harmonization is therefore necessary to get the same SPF value for a single product whatever the country in which it is tested.

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

1 Scope

This International Standard specifies a method for the *in vivo* determination of the sun protection factor (SPF) of sunscreen products. This International standard 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.

It provides a basis for the evaluation of sunscreen products for the protection of human skin against erythema induced by solar ultraviolet rays.

2 Terms and definitions

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

2.1
ultraviolet radiation
UVR
electromagnetic radiation in the range of 290 nm to 400 nm

2.1.1
ultraviolet B
UVB
electromagnetic radiation in the range of 290 nm to 320 nm

2.1.2
ultraviolet A
UVA
electromagnetic radiation in the range of 320 nm to 400 nm

NOTE 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
sunscreen products
products containing any component able to absorb, reflect or scatter UV rays, which are intended to be placed in contact with human skin

2.4
minimal erythemal dose
MED
lowest dose of ultraviolet radiation (UVR) that produces the first perceptible unambiguous erythema with defined borders appearing over most of the field of UV exposure, 16 h to 24 h after UV exposure

2.4.1
MEDu
MED on unprotected skin

2.4.2
MEDp
MED on product protected skin

2.5
individual sun protection factor
SPFi
ratio of the minimal erythemal dose on product protected skin (MEDp) to the minimal erythemal dose on unprotected skin (MEDu) of the same subject:

$$SPFi = \frac{MED(\text{protected skin})}{MED(\text{unprotected skin})} = \frac{MEDp}{MEDu}$$

NOTE SPFi is expressed to one decimal place (see 7.1).

2.6
sun protection factor of a product
SPF
arithmetic mean of all valid individual SPFi values obtained from all subjects in the test

NOTE SPF is expressed to one decimal place (see 7.2).

2.7
test area
back between the scapula line and the waist

2.8
test site
site where a product is applied or the site used for the determination of the unprotected MED

2.9
exposure sub-sites
skin exposed spots

2.10
individual typology angle
ITA°
value characterizing the skin colour of the subject

3 General principle

The SPF test method is a laboratory method that utilizes a xenon arc lamp solar simulator (or equivalent) of defined and known output to determine the protection provided by sunscreen products on human skin against erythema induced by solar ultraviolet rays.

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

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

To determine the sun protection factor, incremental series of delayed erythemal responses are induced on a number of small sub-sites on the skin. These responses are visually assessed for presence of redness 16 h to 24 h after UV radiation, by the judgment of a competent evaluator.

The minimal erythemal dose (MED) for unprotected skin (MEDu) and the MED obtained after application of a sunscreen product (i.e. the MED for product protected skin, MEDp) shall be determined on the same subject on the same day. An individual sun protection factor (SPFi) for each subject tested is calculated as the ratio of individual MED on product protected skin divided by the individual MED on unprotected skin i.e. MEDp/MEDu.

The sun protection factor for the product (SPF) is the arithmetic mean of all valid SPFi results from each subject in the test.

4 Test subjects

4.1 Selection of the test subjects

4.1.1 General

For subject inclusion and non inclusion criteria, refer to Annex A.

4.1.2 Skin phototype of the test subjects

Test subjects included in the SPF test shall be only phototypes I, II or III according to Fitzpatrick[7] or shall have an ITA° value > 28° by colorimetric methods (see Annexes A and E) and be untanned on the test area. An SPF test should not contain subjects who are all of the same phototype.

A competent scientist or technician should examine each subject to ensure that there is no condition which might put the subject at risk and that the outcome of the test cannot be compromised by adverse skin conditions such as sun damage, pigmentation marks and previous history of abnormal response to the sun (see Annex A).

4.1.3 Age restriction

Test subjects below the age of consent or older than 70 y shall not be included in the SPF test panel.

4.1.4 Frequency of participation in tests

Since a sufficient interval after a previous test is needed in order to allow for reversal of skin tanning resulting from that previous test, a test site that has been exposed to UV should not be used in a subsequent test before two months have elapsed and the site is clear.

4.1.5 Ethics and consent

All testing shall be done in accordance with the Declaration of Helsinki[8] and National Regulations regarding human studies, if any.

Informed, written (signature) consent shall be obtained from all test subjects.

4.2 Number of test subjects

The minimum number of valid SPFi results shall be 10 and the maximum number of valid SPFi results shall be 20. In order to achieve between 10 and 20 valid results, a maximum of five individual invalid results may be excluded from the calculation of the mean SPF. Consequently the actual number of test subjects used will fall between a minimum of 10 and a maximum of 25 subjects (i.e. a maximum of 20 valid results plus 5 rejected invalid results).

Results may only be declared invalid and excluded from the calculation of the mean SPF according to 6.7.4 or because of non-compliance with the related protocol.