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Cosmetics — Sun protection test methods — In vivo determination of sunscreen UVA protection

Cosmétique — Méthodes d'évaluation de la protection solaire — Détermination in vivo de la protection UVA

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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.

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 24442 was prepared by Technical Committee ISO/TC 217, *Cosmetics*.

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.

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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:

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

2.6
UVA protection factor of a product
UVAPF
arithmetic mean of all valid individual UVAPFi values obtained from all subjects in the test