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Foreword

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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).

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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

Exposure to solar ultraviolet radiation (UVR) is the main environmental source of acute and chronic damage to human skin. Skin cancer is the most prevalent form of cancer of the body and is primarily driven by exposure to sunlight. Protection against exposure to solar UVB and UVA radiation is, therefore, an important public health issue. The use of topically applied sunscreens is a critical part of holistic programs of consumer UVR protection, including the use of appropriate clothing, hats and minimizing exposure to the sun.

The sun protection factor (SPF) has historically been measured by an *in vivo* method (see ISO 24444) to communicate the magnitude of the protection provided by sunscreens from sunburning UVR. Other test methods have been developed and provided to assess the breadth and magnitude of the protection in the UVA portion of the sun's spectrum (see ISO 24442 and ISO 24443).

This test method given in this document is an alternative to ISO 24443 and ISO 24444 methods.

Invasive methods based on tests conducted on human beings are ethically problematic, time-consuming and very costly. Therefore, it has long been desired to develop alternative methods to assess both the magnitude and breadth of protection afforded by sunscreens that do not require invasive procedures and that reliably provide equivalent testing sensitivity and accuracy as the existing invasive *in vivo* testing methods.

The hybrid diffuse reflectance spectroscopy method described herein, provides a non-invasive optical assessment of the protection provided by topically applied sunscreen products as measured *in situ* on human skin as used by consumers, without requiring physiological responses and causing no physical harm to the test subject. By combining full spectrum *in vitro* spectroscopic measurements of the sunscreen, with optical measurements of the sunscreen transmission in the UVA on human skin, a hybrid spectrum is derived that provides full assessment of both magnitude and breadth of sunscreen protection in both the UVB and UVA regions of the sun's spectrum, correlating closely with *in vivo* SPF, *in vitro* UVA-PF and critical wavelength test results demonstrating equivalence of this test method against ISO 24444 and ISO 24443 methods.

Cosmetics — Measurement of the sunscreen efficacy by diffuse reflectance spectroscopy

1 Scope

This document provides a procedure to characterize the sun protection factor (SPF), UVA protection factor (UVA-PF) and critical wavelength (CW) protection of sunscreen products without requiring biological responses. The test method is applicable for emulsions and single-phase products. The method has not been evaluated for use with powder forms sunscreen products.

This document gives specifications to enable determination of the absolute spectral absorbance characteristics of a sunscreen product on skin to estimate sunburn and UVA protection. It 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.

2 Normative references

There are no normative references in this document.

3 Terms, definitions and symbols

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

absorbance

A

measure of the energy blocked, either by optical absorption or by physical scattering/reflection

3.1.2

absorbance spectrum

$A(\lambda)$

sunscreen optical absorbance at wavelength λ

Note 1 to entry: Logarithm to the base 10 of the reciprocal of the spectral transmittance $\tau(\lambda)$. $A(\lambda) = -[\log_{10} \tau(\lambda)]$.

3.1.3

absorbance by diffuse reflectance spectroscopy

absorbance by DRS

$A_{\text{DRS}}(\lambda)$

absorbance spectrum calculated from DRS as a function of wavelength λ

Note 1 to entry: The absorbance spectrum relevant to this document is 320 nm to 400 nm.