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Kozmetika - Preskusne metode za zaščito pred soncem - Vodoodpornost - Odstotek vodoodpornosti

Cosmetics - Sun protection test methods - Water resistance - Percentage of water resistance

Cosmétiques - Méthodes d'essai de protection solaire - Résistance à l'eau - Pourcentage de résistance à l'eau

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Cosmetics — Sun protection test methods — Water resistance — Percentage of water resistance

Cosmétiques — Méthodes d'essai de protection solaire — Détermination du pourcentage de résistance à l'eau

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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.

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 documents 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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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*.

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

The protection which cosmetic products containing organic or inorganic sunscreens provide against sunburn is neither absolute nor permanent.

One of the many factors that can have an effect on the level of protection given by these products is water contact. UV absorbers in the formulation can leach out or be physically removed by the washing action in the sea or swimming pool.

In order to make the sun products more effective; manufacturers have developed formulations which are more substantive to the skin during water immersion. These products have been variously labelled as water resistant, very water resistant.

In order to substantiate these product efficacy claims, a number of methods has been developed and published: including a method promulgated in the United States of America FDA monograph on OTC sunscreen drug products (Federal Register/ Vol. 58, No 90). Standard methods have also been published in Australia/New Zealand (AS/NZS 2640) and in the Republic of South Africa (SABS1557).

The method for conditions required for water resistance SPF test exists as an international standard, ISO 16217 and requires a sun protection factor to be measured following a defined water immersion procedure. With the use of a spa-pool, a Jacuzzi® or a bathtub, each of which may vary in design but must comply with the norm.

This norm describes the procedure for water resistant percentage calculation, based on water immersion procedure described in ISO 16217, which is the ratio between before and after bath SPF.

The SPF measurement procedure is that described by ISO.

All references to the Sun Protection Factor (SPF) Test Method herein, relate to that document or to later versions as may be published from time to time.

The reader should ensure that the current version of the ISO 24444 standard Sun Protection Factor (SPF) test method is followed.

Cosmetics — Sun protection test methods — Water resistance — Percentage of water resistance

1 Scope

This document intends to evaluate the Water Resistance Retention percentage, by comparing the Sun Protection Factor (SPF) before water immersion (hereafter referred to as the "static" SPF) and after a fixed period of water immersion (hereafter referred to as the "wet" SPF).

2 Normative references

The following document is 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 24444:2010, *Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)*

ISO 16217, *Cosmetics - Sun protection test methods - Water resistance - Water immersion procedure*

3 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 http://www.electropedia.org/

3.1
Simulated swim test device
spa, whirlpool or similar device which is designed for water immersion and which fits the requirements of ISO 16217 in Annex A

3.2
standardised water
Water for use in the Simulated Swim Test Device shall comply with the requirements of ISO 16217 in Annex B

3.3
SPF_{is}
static SPF, determined without water immersion step on each subject as described in ISO 24444

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

3.4
SPF before water immersion
arithmetic mean of all valid SPF_{is} values for the study, expressed to one decimal by truncation

3.5
SPF_{iwr}
SPF determined after water immersion step on each subject as described in ISO 24444

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

3.6
SPF post water immersion
arithmetic mean of all valid SPF_{iwr} values for the study, expressed to one decimal by truncation

4 Test method

4.1 Outline of the method

The principle is to compare the Sun Protection Factor for a sunscreen product after a period of immersion in water with the static SPF without immersion in water.

4.2 Test subject selection

Participants are enrolled for the study according to the criteria described in ISO 24444. At least 10 subjects shall be selected.

All testing shall be done in accordance with the Declaration of Helsinki[1] and national regulations, if any, regarding human studies. Informed, written (signature) consent shall be obtained from all test subjects. The consent should include specific consent to participate in water resistance testing including length of time – temperature of the water – likelyhood of becoming chilled during testing.

4.3 Test area

As per the requirements of ISO 24444, the individual product test sites and the unprotected test site shall be delineated within the region between the scapula line and the waist. Additionally, the test sites shall be configured such that they will be fully immersed when the test subject is located comfortably in the simulated swim test device. Test product application to test sites should be randomized on each individual subject and over the whole test panel, as described in ISO 24444 standard.

4.4 Product application

The product shall be applied according to the procedure set out in ISO 24444.

4.5 Water immersion procedure

The static SPF (SPF_{is}) is determined according to the current published ISO 24444 standard.

To determine the SPF after water immersion (SPF_{iwr}), ISO 24444 standard is followed to the point where the product under test has been applied to the subject's skin.

Product treated skin is then immersed in water according to the process described in ISO 16217 standard.

The following sequence of immersion and rest period shall be followed:

— 20 min of immersion of the test subjects with water circulated for the full period;

— 5 min to 20 min drying time with no toweling permitted between immersion periods.

For 40 min water resistance, repeat this sequence two times.

For 80 min water resistance, repeat this sequence four times.

