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Cosmetics — Sun protection test methods — Percentage of water resistance

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

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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 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).

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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*.

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 or 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 (SABS 1557).

The method for conditions required for water resistance SPF test exists as an International Standard, i.e. ISO 16217, and requires a sun protection factor to be measured following a defined water immersion procedure.

This document 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 24444.

All references to the sun protection factor (SPF) test method herein, relate to ISO 24444.

The reader should ensure that the latest version of ISO 24444 sun protection factor (SPF) test method is followed.

Cosmetics — Sun protection test methods — Percentage of water resistance

1 Scope

This document specifies a procedure for evaluating 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 16217:2020, *Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance*

ISO 24444:2019, *Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)*

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 designed for water immersion

[SOURCE: ISO 16217:2020, 3.1]

3.2
standardized water
water for use in the *simulated swim test device* (3.1)

3.3
static sun protection factor
static SPF
SPF_{is}
SPF without water resistance challenge

3.4
SPF before water immersion
arithmetic mean of all valid SPF_{is} (3.3) values for the study, expressed to one decimal by truncation

3.5
individual water resistance sun protection factor
individual water resistance SPF
SPF_{iwr}
SPF determined after the water immersion step on each subject

3.6
SPF post water immersion
arithmetic mean of all valid SPF_{iwr} (3.5) 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 (SPF) 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 in accordance with the criteria described in ISO 24444. At least 10 subjects shall be selected.

The Declaration of Helsinki[1] is relevant to testing using human subjects. 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 — likelihood 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.

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 in accordance with the ISO 24444.

To determine the SPF post water immersion (SPF_{iwr}), ISO 24444 shall be 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.

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 towelling permitted between immersion periods.

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

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

For extended water resistance times, repeat this process as appropriate.

At the conclusion of the final immersion period, allow the test subjects to dry (no towelling- off of test sites) in the air for at least 15 min.

No water droplets shall be visible and additional drying time may be required (at most 60 min) prior to initiating any exposure as described in ISO 24444.

This SPF post water immersion (SPF_{iwr}), shall then be compared with the static SPF (SPF_{is}), and the percentage of water resistance shall be calculated.

4.6 Reference water resistant sun product

The reference sunscreen shall be the product described as P2 High SPF Reference Standard in ISO 24444:2019, Annex C. This reference sunscreen has been shown to be water resistant.

Inclusion of the reference sunscreen in respect of water resistance performance is not required for each test subject and may be validated separately at least every 8 weeks (or 10 tests when more than 10 tests are conducted within 8 weeks).

The static SPF with no immersion shall be validated as described in ISO 24444.

The mean SPF of P2 after water exposure shall fall between the values specified in Annex C.

The formula, manufacturing instructions, stability and physiochemical specifications for the reference product are given in ISO 24444.

4.7 Determination of the minimum erythemal dose (MED)

Minimum erythemal doses (MEDs) are determined according to the appropriate clause of the ISO 24444. The dose increment used to determine the unprotected and protected MEDs for the SPF after immersion shall be the same as used to determine the MEDs for the SPF before immersion.

SPF measurements before and after water immersion shall be determined in the same laboratory on the same panel of subjects as part of the same test sequence.

4.8 Number of test subjects

According to ISO 24444, up to 25 subjects should be selected for the study. A minimum of 10 subjects and up to 20 valid subjects should complete the test, with the exact number being defined by the need to satisfy the prescribed statistical acceptance criteria.

For details of statistical definitions, procedure and calculations refer to Clause 5 and to ISO 24444.

4.9 Test chronology

The sequence in which the static and wet SPFs are determined may be critical and so it is strongly recommended that they are determined in the sequence described in the test procedure chronology (see Annex B).

5 Calculations and data handling

5.1 General

The following calculations shall be performed.

5.2 SPF before immersion

The SPF before immersion is calculated as the mean of the total individual static SPF values (SPF_{is}), determined on all subjects completing the procedure. A corresponding 95 % bilateral confidence