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Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance

Cosmétiques — Méthodes d'essai de protection solaire — Mode opératoire d'immersion dans l'eau pour la détermination de la résistance à l'eau

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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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.

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Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance

1 Scope

This document specifies a procedure of water immersion for the in vivo determination of the water resistance of sunscreen products.

This document is applicable to products intended to be placed in contact with human skin including any component able to absorb, reflect or scatter UV rays and which, in addition, are designed to be less readily removed from the skin by water and/or during water immersion. It is intended to be read in conjunction with ISO 24444.

2 Normative references

The following documents are 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 24444:2019, *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

Note 1 to entry: For the purposes of this document, the simulated swim test device shall be in accordance with Annex A.

3.2
individual water resistance sun protection factor
individual water resistance SPF
SPF_{iwr}
SPF determined after the water immersion step on each subject

Note 1 to entry: SPF_{iwr} is calculated by a simple division of MED_{ipi} by MED_{iui}.

3.3
static sun protection factor
static SPF
SPF without water resistance challenge

Note 1 to entry: This is determined in accordance with ISO 24444.

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3.4
post-water immersion sun protection factor
post-water immersion SPF
arithmetic mean of all valid SPF_{iwr} (3.2) values for the study

Note 1 to entry: It is expressed to one decimal place by truncation.

3.5
water resistance sun protection factor
water resistance SPF
SPF_{wr}
arithmetic mean of all valid SPF_{iwr} (3.2) values

4 Principle

4.1 Main steps

All of the test steps set out in ISO 24444 apply. Clause 5 provides an additional step to be inserted in the test sequence described in ISO 24444:2019, 9.4. This water immersion step commences after the test products have been applied, following the dry-down period given in ISO 24444:2019, 9.4.10, and prior to the exposure to simulated sunlight given in ISO 24444:2019, 9.4.11 to 9.4.15. In all other respects, the principles and procedures of ISO 24444 apply. A tabulation of steps is set out in Table 1.

Table 1 — Main steps

Test requirements	ISO 24444	This document
Terms and definitions	applicable	applicable
General principle	applicable	applicable
Test subjects	applicable	not applicable
Apparatus and materials	applicable	not applicable
Reference sunscreens	applicable	applicable
Test conditions	applicable	applicable
Water immersion procedure	> > > > > > > > >	applicable
Reversion to ISO 24444		< < < < < < < < <
Procedure for UV exposure	applicable	not applicable
Subsequent procedure	applicable	not applicable

4.2 General principle

A controlled amount of sunscreen product(s) is applied to an area of each subject's skin, restricted to the back between the scapula line and the waist. The sunscreen test sample is challenged in situ when the test subject undertakes a period of water immersion in a simulated swim test device for a designated period of time. Following a further drying period, an area without any protection and the protected area are exposed to ultraviolet light using the same procedure as the static SPF test described in ISO 24444.

5 Test criteria

5.1 Selection of the test subjects

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

Since not all volunteers for static SPF testing are prepared to participate in water resistance testing, specific informed consent shall be obtained. The Declaration of Helsinki[3] is relevant to testing using

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