

Cosmetics - Sun protection test methods - Percentage of water resistance (ISO 18861:2020)

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EUROPEAN STANDARD

EN ISO 18861

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Cosmetics - Sun protection test methods - Percentage of water resistance (ISO 18861:2020)

Cosmétiques - Méthodes d'essai de protection solaire -
Pourcentage de résistance à l'eau (ISO 18861:2020)

Kosmetische Mittel - Untersuchungsverfahren für
Sonnenschutzmittel - Prozentualer Anteil der
Wasserbeständigkeit (ISO 18861:2020)

This European Standard was approved by CEN on 5 December 2021.

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COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of ISO 18861:2020 has been prepared by Technical Committee ISO/TC 217 "Cosmetics" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 18861:2021 by Technical Committee CEN/TC 392 "Cosmetics" the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2022, and conflicting national standards shall be withdrawn at the latest by June 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

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Endorsement notice

The text of ISO 18861:2020 has been approved by CEN as EN ISO 18861:2021 without any modification.

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Test method	2
4.1 Outline of the method.....	2
4.2 Test subject selection.....	2
4.3 Test area.....	2
4.4 Product application.....	2
4.5 Water immersion procedure.....	2
4.6 Reference water resistant sun product.....	3
4.7 Determination of the minimum erythral dose (MED).....	3
4.8 Number of test subjects.....	3
4.9 Test chronology.....	3
5 Calculations and data handling	3
5.1 General.....	3
5.2 SPF before immersion.....	3
5.3 SPF after immersion.....	4
5.4 Individual percentage of water resistance.....	4
5.5 Mean percentage of water resistance.....	4
5.6 Calculation of lower confidence limit on the mean percentage of water resistance.....	4
5.7 Acceptance criteria for reference product P2.....	5
6 Test report	5
Annex A (normative) Simulated swim test device design	6
Annex B (normative) Test procedure and chronology	7
Annex C (normative) Standard reference sunscreen	10
Bibliography	11

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).

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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*.

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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