

Cosmetics - Sun protection test methods - Water immersion procedure for determining water resistance (ISO 16217:2020)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 16217:2021 sisaldab Euroopa standardi EN ISO 16217:2021 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 16217:2021 consists of the English text of the European standard EN ISO 16217:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 15.12.2021.	Date of Availability of the European standard is 15.12.2021.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 71.100.70

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autoriõiguse kaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about standards copyright protection, please contact the Estonian Centre for Standardisation and Accreditation: Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

**Cosmetics - Sun protection test methods - Water
immersion procedure for determining water resistance
(ISO 16217:2020)**

Cosmétiques - Méthodes d'essai de protection solaire -
Mode opératoire d'immersion dans l'eau pour la
détermination de la résistance à l'eau (ISO
16217:2020)

Kosmetische Mittel - Untersuchungsverfahren für
Sonnenschutzmittel - Wasserimmersionsverfahren zur
Bestimmung der Wasserbeständigkeit (ISO
16217:2020)

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of ISO 16217:2020 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 16217:2021 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.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 16217:2020 has been approved by CEN as EN ISO 16217:2021 without any modification.

Contents

Page

Foreword	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Principle	2
4.1 Main steps	2
4.2 General principle	2
5 Test criteria	2
5.1 Selection of the test subjects	2
5.2 Test area	3
5.3 Product application	3
6 Water immersion procedure	3
6.1 Room conditions	3
6.2 Water quality	3
6.3 Immersion sequencing cycle	3
6.4 Positioning of test subjects	3
6.5 Drying after immersion	4
6.6 Reversion to ISO 24444 procedure	4
7 Water quality and condition	4
8 Procedural validation	4
8.1 General	4
8.2 Calculation of the individual water resistance SPF (SPF_{iwr})	4
8.3 Calculation of the water resistance SPF (SPF_{wr})	5
8.4 Statistical criterion	5
9 Test report — post-water immersion SPF	5
Annex A (normative) Simulated swim test device design	6
Annex B (normative) Standardized water requirements	7
Annex C (normative) Standard reference sunscreen	8
Annex D (normative) Product positioning on test subjects	9
Bibliography	10

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.

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.