

SLOVENSKI STANDARD oSIST prEN ISO 18861:2021

01-september-2021

Kozmetika - Metode za preskušanje zaščite pred soncem - Odstotek vodoodpornosti (ISO 18861:2020)

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

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

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

<u>oSIST prEN ISO 18861:2021</u>

https://standards.iteh.ai/catalog/standards/sist/55484be0-8640-4e73-be9e-

Ta slovenski standard je istoveten 2:7/osist prEN ISO 18861

ICS:

71.100.70 Kozmetika. Toaletni pripomočki

Cosmetics. Toiletries

oSIST prEN ISO 18861:2021

en,fr,de

oSIST prEN ISO 18861:2021

iTeh STANDARD PREVIEW (standards.iteh.ai)

oSIST prEN ISO 18861:2021 https://standards.iteh.ai/catalog/standards/sist/55484be0-8640-4e73-be9e-89d9307ff5c7/osist-pren-iso-18861-2021

INTERNATIONAL STANDARD

ISO 18861

First edition 2020-09

Cosmetics — Sun protection test methods — Percentage of water resistance

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

iTeh STANDARD PREVIEW (standards.iteh.ai)

oSIST prEN ISO 18861:2021 https://standards.iteh.ai/catalog/standards/sist/55484be0-8640-4e73-be9e-89d9307ff5c7/osist-pren-iso-18861-2021



Reference number ISO 18861:2020(E)

iTeh STANDARD PREVIEW (standards.iteh.ai)

oSIST prEN ISO 18861:2021 https://standards.iteh.ai/catalog/standards/sist/55484be0-8640-4e73-be9e-89d9307ff5c7/osist-pren-iso-18861-2021



COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

ISO 18861:2020(E)

Contents			Page
Fore	word		iv
Intro	oductio	n	v
1	Scon	e	1
- 2	Norr	nativo roforoncos	1
2			I
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	
	4.7	Determination of the minimum erythemal dose (MED)	
	4.8	Number of test subjects	
	4.9	Test chronology	
5	Calculations and data handling		
	5.1	General	
	5.2	SPF before immersion	
	5.3	SPF after immersion	4
	5.4	Individual percentage of water resistance	4
	5.5	Mean percentage of water resistance it changes	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 https://standards:iteh:ai/catalog/standards/sist/55484bc0-8640-4c73-bc9c-	5
Anne	ex A (no	ormative) Simulated swim test device design 1-2021	6
Anne	ex B (no	ormative) Test procedure and chronology	7
Anne	ex C (no	ormative) Standard reference sunscreen	
Bibli	ograpl	IY	

ISO 18861:2020(E)

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 <u>www.iso.org/</u> iso/foreword.html. (standards.iteh.ai)

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.isoorg/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. IEW

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. https://standards.iteh.ai/catalog/standards/sist/55484be0-8640-4e73-be9e-

89d9307ff5c7/osist-pren-iso-18861-2021

oSIST prEN ISO 18861:2021

iTeh STANDARD PREVIEW (standards.iteh.ai)

oSIST prEN ISO 18861:2021 https://standards.iteh.ai/catalog/standards/sist/55484be0-8640-4e73-be9e-89d9307ff5c7/osist-pren-iso-18861-2021

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) **Teh STANDARD PREVIEW**

3 Terms and definitions (standards.iteh.ai)

For the purposes of this document, the following terms and definitions apply.

https://standards.iteh.ai/catalog/standards/sist/55484be0-8640-4e73-be9e-ISO and IEC maintain terminological/databases for use imstandardization at the following addresses:

— ISO Online browsing platform: available at <u>https://www.iso.org/obp</u>

— IEC Electropedia: available at <u>http://www.electropedia.org/</u>

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

ISO 18861:2020(E)

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. **(standards.iteh.ai)**

4.3 Test area

oSIST prEN ISO 18861:2021

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.