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**Kozmetika - Preskusne metode za zaščito pred soncem - Vodoodpornost -  
Postopek s potopitvijo v vodo**

Cosmetics - Sun protection test methods - Water resistance - Water immersion  
procedure

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Cosmétiques - Méthodes d'essai de protection solaire - Résistance à l'eau - Mode  
opératoire d'immersion dans l'eau

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## Cosmetics — Sun protection test methods — Water resistance — Water immersion procedure

*Cosmétiques — Méthodes d'essai de protection solaire — Résistance à l'eau*

ICS: 71.100.70

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## 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](http://www.iso.org/directives)).

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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](http://www.iso.org/members.html).

# Cosmetics — Sun protection test methods — Water resistance — Water immersion procedure

## 1 Scope

This International Standard describes a procedure of water immersion for the in vivo determination of water resistance of sunscreen products using a water immersion procedure.

This standard 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 shall be read in conjunction with ISO 24444, Cosmetics — Sun protection test methods — in vivo determination of Sun Protection Factor (SPF).

## 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 17025:2017, *General requirements for the competence of testing and calibration laboratories*

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

ISO 18883, *Cosmetics — Sun protection test methods — Determination of percentage of water resistance*

## 3 Terms and Definitions

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

### 3.1

#### **simulated swim test device**

A spa, whirlpool or similar device which is designed for water immersion and which fits the requirements of this standard as defined in [Annex A](#).

### 3.2

#### **standardised water**

Water for use in the Simulated Swim Test Device shall comply with the requirements of [Annex B](#) of this Standard.

### 3.3

#### **MED<sub>iui</sub>**

MED<sub>iui</sub> is the individual MED value for the unprotected site.

### 3.4

#### **MED<sub>ipi</sub>**

MED<sub>ipi</sub> is the individual MED value for the sunscreen protected site after immersion.

### 3.5

#### **individual SPF<sub>iwr</sub>**

SPF determined after water immersion step on each subject.  $SPF_{iwr} = MED_{ipi} \text{ protected skin} / MED_{iui} \text{ unprotected skin}$  determined after water immersion.

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### 3.6

#### static SPF

The SPF determined according to ISO 24444 that is without water resistance challenge.

### 3.7

#### SPF post water immersion

Arithmetic mean of all valid SPFiwr values for the study, expressed to one decimal place by truncation.

### 3.8

#### SPFw

SPFw is the SPF determined after immersion, SPF static without immersion.

### 3.9

#### SPFwr

SPFwr (SPF – water resistant) = average of all qualifying SPFiwr values

## 4 Principle

### 4.1 Main steps

All of the test steps set out in ISO 24444 apply, with the addition as described in Section 5 being inserted between Section 6.4 and 6.5 of the test sequence described in ISO 24444. This water immersion Step is completed after the test products have been applied, following the dry down period of ISO 24444, (Section 6.4.5) and prior to the exposure to simulated sunlight (Section 6.5). In all other respects, the principles and procedures of ISO 24444 apply. A tabulation of steps is set out below.

**Table 1 — Main steps**

Test Requirements	Ex ISO 24444	Ex This Standard
Definitions	applies	applies
General Principle	applies	applies
Test Subjects	applies	X
Apparatus and Materials	applies	X
Reference Sunscreens	applies	applies
Test Conditions	applies	
Water Immersion Procedure	>>>>>>>>	applies
Reversion to ISO 24444		<<<<<<<<<<<<
Procedure for UV exposure	applies	X
Subsequent Procedure	applies	X

### 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 utilizing 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 according to the criteria described in ISO 24444. At least 10 subjects shall be selected.

As not all volunteers for static SPF testing are prepared to participate in Water Resistance testing, specific Informed consent shall be obtained. All testing shall be done in accordance with the Declaration of Helsinki [1] and national regulations, if any, regarding human studies. 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.

### 5.2 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.

### 5.3 Product Application

The product shall be applied according to the procedure set out in ISO 24444.

## 6 Water Immersion Procedure

### 6.1 Room conditions

The temperature of the swim immersion room shall be maintained in the range of 20 °C to 26 °C.

### 6.2 Water Quality

The Simulated Swim Test Device shall be filled with Standardized Water as described in [Annex B](#).

The temperature of the water shall be maintained at  $(30 \pm 2)$  °C for the duration of the test period.

### 6.3 Immersion Sequencing Cycle

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 – 20 min drying time with no toweling permitted between immersion periods.

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

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

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 prior to initiate any exposure as described in Section 8.4.10 of ISO 24444.

### 6.4 Positioning of Test Subjects

The position of subjects needs to take into account various shapes of spa baths.

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The positioning of the subject in the water immersion device shall be such that it minimizes the possibility of the subject touching the test areas on the back with the spa sides or another test subject, and is comfortable for the subject.

The test subjects shall sit in a position such that water jets cannot impinge directly on the test sites.

### 6.5 Drying after Immersion

After the completion of the final immersion session, the test areas shall be allowed to dry until no water droplets are visible and for at least 15 minutes prior to initiating any UV exposures.

### 6.6 Reversion to ISO 24444 procedure

On completion of the water immersion procedure, complete the solar simulator exposure steps of the ISO 24444 Test Method, resuming at Section 6.4.5

## 7 Water Quality and Condition

The Simulated Swim Test Device shall be filled with Standardised Water as described in [Annex B](#).

The temperature of the water shall be maintained at  $(30 \pm 2) ^\circ\text{C}$  for the duration of the test period.

The temperature of the swim immersion room shall be maintained in the range of  $20 ^\circ\text{C}$  to  $26 ^\circ\text{C}$ .

## 8 Procedural Validation.

The reference sunscreen shall be the product described as P2 High SPF Reference Formula in ISO 24444, (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. In this case, at a compliant mean based on at least 10 results shall be established and a moving average maintained, based on additional data accumulating from revalidation on an on-going basis.

The SPF with no immersion (static) shall be validated as described in 24444 Section 7.

The mean SPF of P2 after water exposure shall fall between the values specified in [Annex C](#).

## 9 Calculation of the Water Resistance Sun Protection factor and statistics

### 9.1 Calculation of the individual Water Resistance SPF (SPFiwr)

Individual water resistance retention shall be calculated for each individual subject where concurrent static SPF data also exist. The procedure for calculation of Individual water resistance retention is set out in ISO 18883:— "Cosmetics - Sun protection test methods - Determination of percentage of water resistance"

The SPFiwr of the reference sunscreen and the product under test for each subject is calculated as below:

$$SPFiwr = \frac{MED(protectedskin)}{MED(unprotectedskin)} = \frac{MEDpwr}{MEDuwr}$$

### 9.2 Calculation of the Mean Water Resistance SPF (SPFwr)

The SPF result for the test product and for the reference sunscreen formulation is calculated as the arithmetic mean of all valid individual SPFiwr values as defined in section 3.