AS/NZS 2604:2021

Australian/New Zealand Standard™

Sunscreen products — Evaluation and classification

AS/NZS 2604:2021

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Australian Radiation Protection and Nuclear Safety Agency
Australian Society of Cosmetic Chemists
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Australian/New Zealand Standard™

Sunscreen products — Evaluation and classification

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Preface

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee CS-042, Sunscreen Agents, to supersede AS/NZS 2604:2012.

The objective of this document is to produce a means of testing and labelling sunscreens that will assist consumers to select a product which best suits their need for skin protection from the adverse effects of UV radiation.

This document is not intended to inhibit innovation, however it is recognized that there will often be a delay between the emergence of a new, valid claim, and the development of an agreed test method. Therefore, any claim of sunscreen efficacy not covered by the provisions of this document needs to be referred to the relevant regulatory authority.

The major changes in this edition are as follows:

(a) This revision completes the transition of methods for determining broad spectrum, sun protection factor (SPF) and water resistance from local Australian and New Zealand test methods to globally written, agreed and published ISO standards for all participating members to adopt.

(b) ISO 24444:2010, *Cosmetics — Sun protection test methods — in vivo determination of the sun protection factor (SPF)*, has been superseded by ISO 24444:2019. The key change is to improve the reproducibility and reliability of this test method. Specific changes include —

  (i) replacement of the Fitzpatrick Skin Type for volunteer selection by a colorimetric instrument measurement;

  (ii) the addition of three new standard sunscreens P5, P6 and P8 for use with sunscreen tests for SPF 25 and above; and

  (iii) photographic examples of erythema responses for grading of results. A sample questionnaire for test subjects is included, removing the need for Appendix E of AS/NZS 2604:2012.

(c) The water immersion procedure for the determination of water resistance now follows ISO 16217:2020, *Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance*. Australia and New Zealand still retain the 4 h water resistance test period and claim, and continue to determine SPF after immersion as the SPF value to use for labelling SPFs.

(d) The new and revised ISO standards include normative requirements for standardized formats for test and results reporting.

(e) Clarification of the definition of the difference between Primary and Secondary Sunscreens. This document now advises taking into account the overall presentation and purpose of a sunscreen when assigning a sunscreen as a primary or secondary sunscreen.

(f) Introduction of instructions for the recommended method of application of sunscreen aerosols and sunscreen spray pump packs to ensure even and generous dosing applied from the correct distance and under optimum conditions while avoiding inhalation.

This document was first issued in 1983 as AS 2604:1983 with a maximum SPF of 15+. It was requested by the then Commonwealth Department of Health. The second edition was issued in 1986 as AS 2604:1986 where the definitions of secondary sunscreens, broad spectrum and water resistance were added. The third edition was issued in 1993 as AS/NZS 2604:1993 and was a joint Australian and New Zealand Standard with tighter limits on water resistance. The fourth and fifth editions were issued in 1997 as AS/NZS 2604:1997, with maximum SPF of 30+, and in 1998 as AS/NZS 2604:1998, with revised categories in line with SPF 30+. The sixth edition was issued in 2012 as AS/NZS 2604:2012 and raised the SPF maximum to SPF 50+ and introduced test method references to ISO 24443 for *in*

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vitro broad spectrum measurement and ISO 24444 for *in vivo* SPF, aligning these methods with international practice.

This document specifies methods for determination of the broad spectrum, SPF, and water resistance by reference to the following:

ISO 24443, *Determination of sunscreen UVA photoprotection in vitro*

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

ISO 16217, *Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance*

When the SPF of a sunscreen is measured, the sunscreen is spread onto the skin of human volunteers and then irradiated with a dose of simulated sunlight sufficient to evoke a minimal redness in the skin when viewed 16 h to 24 h later. However, in the broad spectrum methods used in earlier editions of this document, the sunscreen was irradiated only briefly, and so the sunscreen was not subjected to prolonged exposure to simulated sunlight. In order to make the measurement of broad spectrum properties more realistic the sunscreen sample is now subjected to a dose of simulated sunlight before measurement of broad spectrum properties. This UV exposure will ensure that the sunscreen still meets the requirements for classification of broad spectrum after exposure to sunlight.

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The terms “normative” and “informative” are used in Standards to define the application of the appendix to which they apply. A “normative” appendix is an integral part of a Standard, whereas an “informative” appendix is only for information and guidance.

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Contents

Preface ii

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 1

4 Classification of sunscreen products 3
- 4.1 Types 3
- 4.2 Labelled SPF 4
- 4.3 Category description 4

5 Performance requirements 4
- 5.1 General 4
- 5.2 SPF determination 4
  - 5.2.1 Without claim of water resistance 4
  - 5.2.2 Where water resistance is to be claimed 4
- 5.3 Broad spectrum performance 5

6 Labelling 5
- 6.1 General 5
- 6.2 Primary sunscreen products 5
  - 6.2.1 Mandatory labelling 5
  - 6.2.2 Optional labelling 6
- 6.3 Secondary sunscreen products 6
  - 6.3.1 Mandatory labelling 6
  - 6.3.2 Optional labelling 7

Appendix A (normative) **Method for the determination of the SPF** 8

Appendix B (normative) **Determination of water resistance** 9

Appendix C (normative) **Determination of broad spectrum performance** 10

Introduction

Consumers need to understand that UV radiation comes from both direct sunlight and indirect sources. Substantial amounts of the sun's UV radiation are scattered from the open sky and reflected from the environment (e.g. snow, sand, water, clouds and the sky itself). This means that you can be sunburned in shade and that the risk of sunburn is greatly increased near sources of reflected radiation, such as snow and water.

UV radiation from the sun reaching the skin is a continuous process with the skin accumulating damage as long as it is exposed to the sun. This may lead eventually to premature ageing of the skin, skin cancer and other adverse effects.

The best way to protect against the serious long-term ill effects of the sun is to reduce the total duration of exposure, particularly in the middle of the day, and to complement this by using a combination of shade, a sun-hat, adequate clothing, sunglasses and a sunscreen product. According to present knowledge, sunscreen products should not be regarded as the sole means of protecting the body.

In the 1998 edition, the maximum sun protection factor (SPF) that could be claimed on the label was 30+. The addition of higher SPF categories has brought the document in line with changes to the SPF limit that have occurred in Europe, Asia and the USA.

Since the second edition of this document in 1986, broad spectrum properties of sunscreens have been measured *in vitro* by a number of different techniques. However, none of these techniques had been adequately validated and the different methods led to different outcomes. With improvements in technology, and following collaborative work between laboratories in many countries globally, a validated method for measuring broad spectrum properties became available in the 2012 edition. In previous editions of this document, percent transmission of UV radiation through a preparation of the sunscreen was used to evaluate broad spectrum properties. Regardless of the SPF of the product, the requirement for achieving broad spectrum status was the same; e.g. a SPF 30 and a SPF 4 sunscreen were both required to transmit less than 10 % UV up to 360 nm. However, there is now global consensus that protection in the UVA should increase concomitantly with SPF. Also, the sunscreen should absorb UV radiation across the entire UV spectrum from wavelengths 290 nm to 400nm.

The test for water resistance included in previous editions is now replaced with a harmonized test as described in ISO 16217.

Terms not permitted by this document (see Clause 6.1)

The term "waterproof" is misleading and is not permitted. It may be interpreted to mean that the sunscreen will not wash off, and therefore reapplication after water immersion is not necessary. This document acknowledges that sunscreens will wash off when immersed in water, and it is for this reason that a time limit is applied to water resistance claims, e.g. SPF 30, 4 h water resistance.

The term "sunblock" is misleading and is not permitted because it may be interpreted to mean that 100 % of the sunburning radiation is blocked by the sunscreen. Sunscreen actives are filters that prevent varying amounts of sunburning radiation from reaching the skin; however, some of the sunburning radiation does get through, no matter how high the SPF. If the skin is exposed to the sun for too long the skin will become sunburnt. The sunburn we see and feel signifies that a threshold of tolerance (where the cumulative UV dose has damaged the skin and provoked repair and recovery processes) has been passed. It is this accumulation of sunburning dose over time, with and without the protection of a sunscreen, which is the basis for the SPF test method given in this document.

The term "sweat proof" is misleading and is not permitted. "Sweat resistance" is not a substitute for "water resistance" as described within this document.

Explanation of SPF determination

The SPF informs consumers of the efficacy of the sunscreen against sunburn and helps them select a product appropriate to their skin sensitivity and exposure to the sun. The SPF is the ratio of the UV radiation dose that is required to produce a recognizable constant response on skin (minimum

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erythema) treated with a sunscreen product compared to that required on untreated skin. Test procedures referenced by this document employ minimum erythema as the constant skin response and "solar simulator" lamps as the UV source.

One of the reasons that the upper limit of SPF was previously restricted to 30+ was a concern that there were errors in SPF measurements, due to differences between the quality of sunlight and that of the simulated sunlight (solar simulator emission) that is used in the laboratory to measure SPF. These errors arise because the spectrum of UV light emitted by the solar simulator is deficient at the very short UVB and long UVA wavelengths. However, it is now understood that, provided the sunscreen absorbs UV radiation adequately across the entire UV range, these differences are less significant.

The length of exposure to sunlight that will result in a threshold sunburn (the minimum erythemal dose) will vary from person to person. However, the meaning of the SPF number, which provides information to the consumer about different sunscreens, can be most simply explained by using the example of unprotected skin which shows a minimum sunburn after 10 min exposure to sunlight. If it takes approximately 10 min for that unprotected skin to receive a minimum sunburning dose, then the same skin with an SPF 15 sunscreen, liberally and evenly applied, would theoretically take approximately 15 times as long to receive the same sunburning dose, i.e. 150 min.

The idealized diagram in Figure 1 compares how skin receives a sunburning dose of sunlight without the protection of a sunscreen, and with the protection of SPF 15, SPF 30 and SPF 50 sunscreens.

The following can be seen from Figure 1:

(a) Unprotected skin (SPF 1) receives 100 % of a sunburning dose after 10 min of exposure.

(b) If protected by an SPF 15 sunscreen, it will receive 6.7 % of the sunburning dose in 10 min, 20 % in 30 min, and 100 % in 150 min.

(c) If the same skin is protected by SPF 30 sunscreen, it will receive 3.3 % of a sunburning dose in 10 min, 10 % in 30 min, and 50 % in 150 min.

(d) Skin protected by a SPF 50 sunscreen will receive 2 % of a sunburning dose in 10 min, 6 % in 30 min, and 30 % in 150 min.

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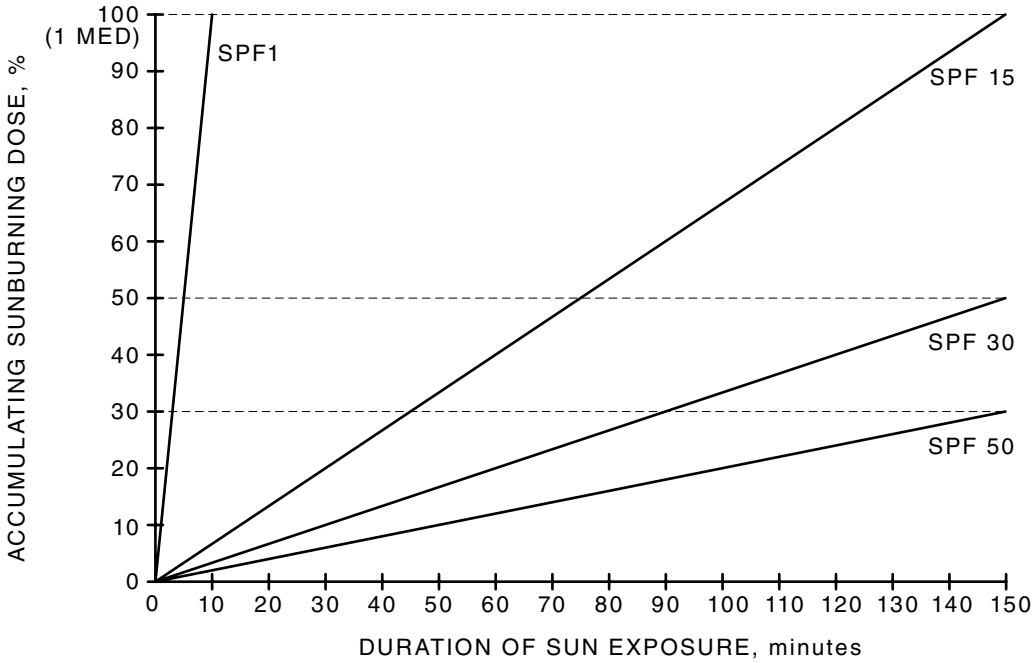

Key

At 10 min:

SPF 1 (no protection) = 100 % MED

SPF 15 = 6.7 % MED

SPF 30 = 3.3 % MED

SPF 50 = 2 % MED

NOTE: This diagram is based on a skin that will receive a perceptible sunburning dose (minimum erythemal dose, or MED) in 10 min

Figure 1 — Idealized comparison of protection provided by sunscreens of increasing SPF

It can be seen from the diagram in Figure 2 that, if unprotected skin receives 100 % of a sunburning dose after 10 min of exposure, it will be designated SPF 1. If skin is protected with a SPF 15 sunscreen or a SPF 30 sunscreen it will take 150 min or 300 min respectively to receive a 100 % sunburning dose (a minimal erythemal dose). Skin protected by a SPF 50 sunscreen will receive a 100 % sunburning dose in 500 min.

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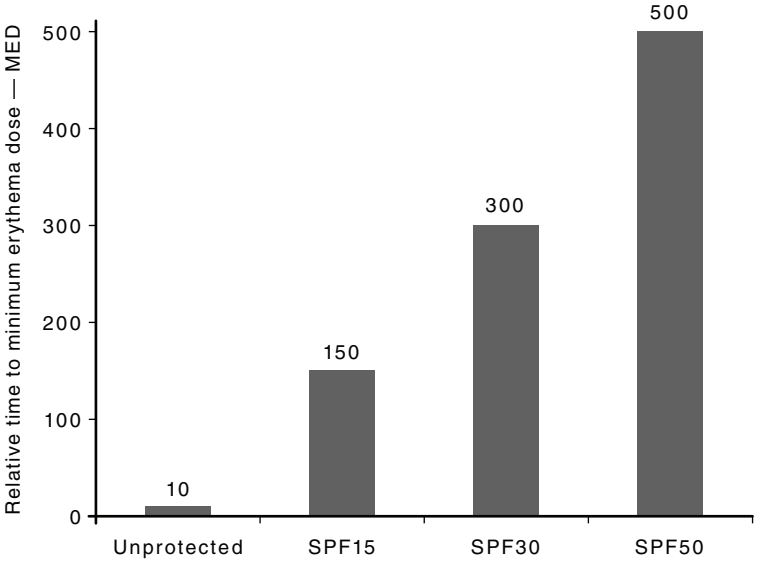

Figure 2 — Idealized comparison of protection provided by sunscreens of increasing SPF

The amount of protection against sunburn offered by different sunscreens can be compared by simply looking at the ratio of their SPF numbers. Therefore, for any exposure duration, an SPF 50 sunscreen has double the protection of an SPF 25 sunscreen.

Theory versus practice

Performing evaluations by exposing ordinary skin to natural sunlight is impractical. There are so many variable factors which contribute significantly to the result that a single random determination is unlikely to coincide with the most probable result obtained from a large number of determinations on different persons. Consequently, it is necessary, in a system intended to give a useful comparison of the potential protective efficiency of a wide range of sunscreen products, to specify certain constraints in the method. Such constraints can be sensibly related to the processes operating when sunscreen products are used to prevent sunburn. They may also be widely acceptable and readily realized in practice so that comparative evaluations can be made and, preferably, accepted in different locations, both nationally and internationally.

Theoretical calculations do not apply exactly in practice, and can only serve as a useful guide, especially as the skin's sunburn response is a delayed one. Also, the amount of sunscreen and the way it is applied will vary considerably, and this can markedly affect the duration of protection received.

Significantly, the quantity of sunscreen necessary to achieve the dosage used in the measurement of SPF (2 mg/cm^2), in many instances, is not applied. In these circumstances the expected sun protection will not be achieved.

Sunscreens require reapplication to maintain their optimum level of protection. Reapplying the sunscreen does not remove the portion of the sunburning dose already received, though it may decrease the severity of burning from any further sun exposure. Therefore, sun protection factors are properly regarded as a relative ranking of their protection, rather than as an absolute statement of the factor by which the duration of natural sunburn is increased.

Since the purpose of sunscreens is to reduce and prevent skin damage caused by sunlight exposure, the meaning of SPF numbers should not be misconstrued as a justification to prolong or extend sun exposure.

As the role of solar radiation in the production of skin damage generally remains the subject of continuing research, this document will be reviewed as new information becomes available.

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Australian/New Zealand Standard

Sunscreen products — Evaluation and classification

1 Scope

This document sets out procedures for determining the performance of sunscreen products in terms of their mean protection factors. It includes test methods for both broad spectrum and water resistant sunscreen products. This document also specifies appropriate detailed labelling requirements to be applied in conjunction with relevant legislation.

This document applies to sunscreen products represented as being suitable for topical use to protect human skin from the adverse effects of solar UV rays. It applies to both primary and secondary sunscreen products as defined.

As this document addresses protection against solar radiation incident upon the surface of the Earth, protection against UVC does not fall within its scope, as it is filtered out by the Earth's atmosphere.

Reference to ISO 24443 is required for the determination of broad spectrum performance.

Reference to ISO 24444 is required for the determination of the sun protection factor (SPF).

Reference to ISO 16217 is required for the determination of water resistance.

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.

ISO 24443, *Determination of sunscreen UVA photoprotection in vitro*

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

ISO 16217, *Cosmetics — Sun protection test methods — Water immersion procedure for determining water resistance*

3 Terms and definitions

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

3.1
broad spectrum product
sunscreen product which has been shown, using the *in vitro* test method, to provide protection against the sun's terrestrial UVA and UVB rays

Note 1 to entry: The *in vitro* test method is specified in Appendix C.

3.2
category description
designation of the level of protection given by a grouping of label sun protection factors

3.3
critical wavelength
wavelength at which 90 % of the cumulative area under the total absorbance curve from 290 nm to 400 nm occurs

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