AS/NZS 2604:2012

Australian/New Zealand Standard™

Sunscreen products—Evaluation and classification

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The following are represented on Committee CS-042:

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Australasian Faculty of Occupational and Environmental Medicine
Australian Chamber of Commerce and Industry
Australian Food and Grocery Council
Australian Radiation Protection and Nuclear Safety Agency
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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 2604:1998.

The major changes in this edition are as follows:

(a) The raising of the sun protection factor (SPF) limit to 50+.

(b) A new method for measuring broad spectrum properties.

(c) Some modifications to the method of measurement of the SPF to bring this measurement into line with international practice.

(d) Changes to the classification of sunscreens to take account of the new limits to SPF and the new requirements for satisfying the claim of broad spectrum.

In the 1998 edition the maximum SPF that could be claimed on the label was 30+. This brought the Standard in line with changes to the SPF limit that had already occurred in Europe and Asia, and which had been anticipated to occur in the USA.

Since the second edition of this Standard 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 is now available. This is the basis for the new method defined in this Standard.

In previous editions of this Standard, 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. That is, the sunscreen should absorb UV radiation as uniformly as possible across the entire UV spectrum.

This Standard specifies methods for determination of the SPF and broad spectrum 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)

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 16–24 hours later. However, in the broad spectrum methods used in earlier editions of this Standard, 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.

Statements expressed in mandatory terms in notes to tables are deemed to be requirements of this Standard.

The terms ‘normative’ and ‘informative’ have been used in this Standard 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.

CONTENTS

Page

FOREWORD

Consumers need to understand that ultraviolet (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.

Terms not permitted by this Standard (see Clause 7.1)

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 Standard 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 hours 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 sun protection factor (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 Standard.

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 erythema) treated with a sunscreen product compared to that required on untreated skin. Test procedures referenced by this Standard 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 minutes exposure to sunlight. If it takes approximately 10 minutes 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 minutes.

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.

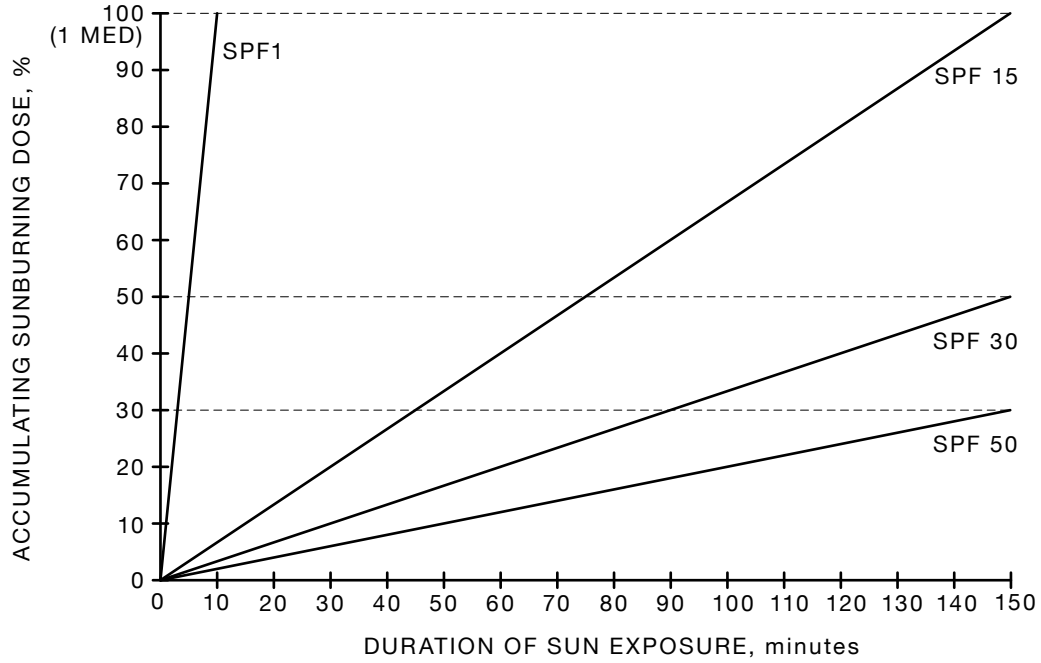
The following can be seen from Figure 1:

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

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

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

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



NOTES:

1 This diagram is based on a skin that will receive a perceptible sunburning dose (Minimum Erythemal Dose, or MED) in 10 minutes.

2 AT 10 MINUTES:

SPF 1 (no protection)	100% MED
SPF 15	6.7% MED
SPF 30	3.3% MED
SPF 50	2% MED

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 minutes 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 minutes or 300 minutes 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 minutes.

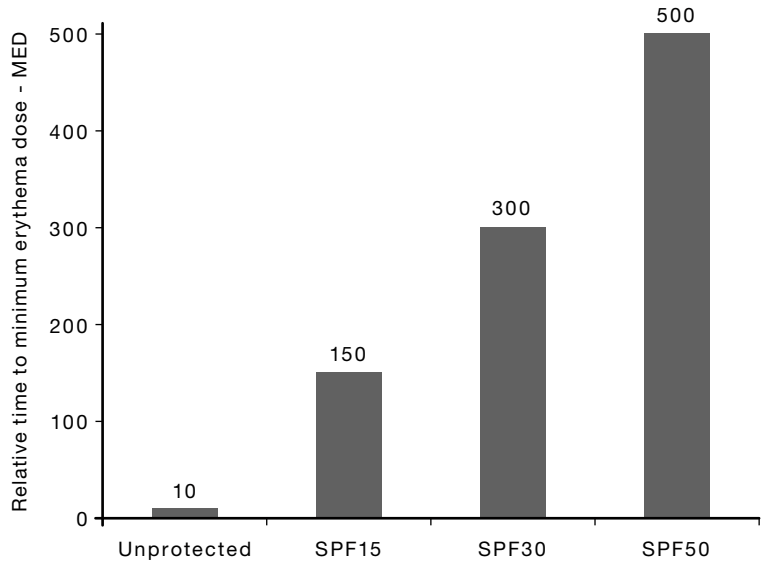


FIGURE 2 IDEALIZED COMPARISON OF PROTECTION PROVIDED BY SUNSCREENS OF INCREASING SPF

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 must be sensibly related to the processes operating when sunscreen products are used to prevent sunburn. They should 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.

Such calculations can never be exactly applied in use, and can only serve as a useful guide, especially as the skin's sunburn response is a delayed one. In practice the amount of sunscreen and the way it is applied will vary considerably, and this can markedly affect the duration of protection received.

In many cases, people do not apply the quantity of sunscreen necessary to achieve the dosage used in the measurement of SPF (2 mg/cm^2). 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 Standard will be reviewed as new information becomes available.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard
Sunscreen products—Evaluation and classification

1 SCOPE

This Standard 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 Standard also specifies appropriate detailed labelling requirements to be applied in conjunction with relevant legislation.

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

As this Standard 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 24444 is required for the determination of the sun protection factor (SPF). Reference to ISO 24443 is required for the determination of broad spectrum performance.

NOTE: A sample questionnaire for test subjects is given in Appendix E.

2 OBJECTIVE

This Standard is intended 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.

It is not the intention of this Standard to inhibit innovation, however the Committee recognizes 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 Standard should be justified to the relevant regulatory authority.

3 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS	
2610	Spa pools
2610.2	Part 2: Private spas
ISO	
24443	Determination of sunscreen UVA photoprotection *in vitro*
24444	Cosmetics—Sun protection test methods—*In vivo* determination of the sun protection factor (SPF)

4 DEFINITIONS

For the purposes of this Standard, the definitions below apply.

4.1 Broad spectrum product

A sunscreen product which has been shown, using the *in vitro* test method described in Appendix C of this Standard, to provide protection against the sun's terrestrial UVA and UVB rays.

AS/NZS 2604:2012 Sunscreen products - Evaluation and classification