AS/NZS 2604:1998

Australian/New Zealand Standard™

Sunscreen products—Evaluation and classification

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee CS/42, Sunscreen Agents. It was approved on behalf of the Council of Standards Australia on 31 July 1998 and on behalf of the Council of Standards New Zealand on 24 August 1998. It was published on 5 October 1998.

The following interests are represented on Committee CS/42:

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Australasian Faculty of Occupational Medicine
Australian Association of Certification Bodies
Australian Cancer Society
Australian Chamber of Commerce and Industry
Australian Pharmaceutical Manufacturers Association
Australian Radiation Laboratory
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee CS/42, Sunscreen Agents, to supersede AS/NZS 2604:1997.

The major changes in this edition are a revision of the category descriptions, and the inclusion in the Foreword of an explanation of the sun protection factor (SPF) rating system. The category descriptions were altered in both the 1993 edition and this edition. In the 1993 edition the term 'maximum' assigned to SPF 15 and 15+ was replaced by 'very high', as 'maximum' can imply 'will not burn' or 'absolute protection'. The whole Table assigning category descriptions to tested protection factors has now been revised to reflect current perceptions of the degree of sunscreen protection offered by those protection factors. Sunscreens with tested protection factors in the range 4 to 8 which were previously ascribed a 'moderate protection' description are now designated as 'low protection' sunscreens, and sunscreens with SPFs of 2 to 4 are 'very low protection'. The range 8 to 15 is now 'moderate' and 15 to 30 is 'high'. A new range 30 or more has been assigned 'very high'.

The major change in the previous edition was the lifting of the maximum SPF that may be claimed on the label of a product from 15+ to 30+. A limit of SPF 30+ was agreed to as a compromise between the consumer's right to know the SPF and the decreasing accuracy in measuring SPF in the higher SPF ranges. The change was made after careful consideration by the Committee of all of the issues involved. Although many people can avoid overexposure to the sun, there are individuals in the community who are concerned to minimize their exposure to ultraviolet radiation, as well as individuals who, for whatever reason, do not or are not able to practice sun avoidance and who may therefore require a very high level of protection. It also anticipated a move towards international harmonization, in recognition of a trend in other countries, including the USA, for a limit of 30+ to be recommended.

Other significant changes in the previous edition include a change in the times for which water resistance may be claimed (to more closely align the water resistance claims with the length of adequate protection likely to be provided by the sunscreen) plus a requirement that all claims of water resistance shall be qualified by a time for which the water resistance is claimed. Also, an alternative reference sunscreen with a higher SPF was included, reflecting the shift to higher SPF products.

Measurement limits for the solar simulator output were also introduced. The Committee acknowledges that further refinements to the simulator specification are needed, and has submitted a proposal to the International Commission on Illumination (CIE), for the development of a new, internationally acceptable specification.

The Committee recognized that many people do not apply sunscreens correctly, and that individual behaviour cannot be addressed within this Standard, and recommends that the correct use of sunscreens be addressed through public education.

In raising the SPF limit from 15+ to 30+, the Committee was concerned that the higher protection values might be obtained by greatly increasing the concentration of organic sunscreen active ingredients in some products, rather than by maintaining lower concentrations and using more skilful formulation techniques to achieve the higher protection values.

In Australia, sunscreens can only be supplied if they are listed on the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG), and compliance with this Standard is a condition of listing on the ARTG. Approval of particular sunscreen active ingredients and maximum permitted concentrations are the responsibility of the Therapeutic Goods Administration.

NOTE: The TGA can be contacted at PO Box 100, Woden A.C.T. 2606. The phone number for the TGA Information Line is 1800 020 653. Sunscreens are classified as non-prescription medicines for the purpose of enquiry.

In New Zealand, at the date this Standard was published, sunscreens were classified as cosmetics and did not require the consent or approval of the Ministry of Health before being marketed. However, it is expected that legislation to control sunscreens as Therapeutic Products will be enacted in New Zealand in the future. Until that time, the Ministry of Health recommends that companies marketing sunscreens in New Zealand comply with this Standard. Further information on requirements in New Zealand, including on the progress of the legislation, can be obtained from the Ministry of Health.

NOTE: The Ministry of Health can be contacted at PO Box 5013 Wellington New Zealand.

This Standard carries forward from AS/NZS 2604:1997 the method of evaluating the performance of sunscreen products based on the ability of sunscreens to limit solar erythema on human skin. The information obtained by testing is expressed in the form of a label protection factor. The Standard also describes the requirements for labelling sunscreen products so that the information obtained by testing will be useful to most consumers.

In regard to labelling, the 1993 edition of AS/NZS 2604 recognized the increase in the level of consumer understanding of the label protection factor (more commonly known as the sun protection factor, or SPF). It therefore required that the SPF replace the category description as the mandatory labelling on primary and secondary sunscreens. Also in that edition, the link between category description and skin type was removed. The advice was regarded as no longer being appropriate as it might imply that people with a darker skin type would not benefit from a higher SPF product.

When preparing the 1993 edition, the Committee became concerned that unlimited claims for water-resistant sunscreens in the moderate and higher protection ranges could give the impression that the product was effective for a longer period of time than the actual SPF would allow. Being of the opinion that claims for water resistance should not exceed the times for which the sunscreen would give adequate protection under real circumstances, the Committee decided to limit the length of time which may be claimed for a water-resistant sunscreen. Currently, two test methods are available for determining the water resistance of sunscreen products. The data for showing the equivalence of these methods are limited, and both tests have been included in an Appendix. The equivalence of water resistance and sweat resistance is not established.

As this Standard addresses protection against solar radiation incident upon the surface of the Earth, protection against UV-C does not fall within its scope.

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.

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

FOREWORD

Consumers should understand that, in addition to direct sunlight, UV radiation can also be indirect. Substantial amounts of UV radiation can be reflected from items in the environment, including snow (up to 85%), water (up to 30%), sand (up to 20%), grass (up to 5%) as well as from other solid surfaces and clouds and particles in the sky. This means that you can be sunburned in shade and that the risk of sunburn is greatly increased near snow and water.

The best way to protect against the serious long-term ill effects of the sun, such as premature ageing of the skin and skin cancer, 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. According to present knowledge, sunscreens should not be regarded as the sole means of protecting the body.

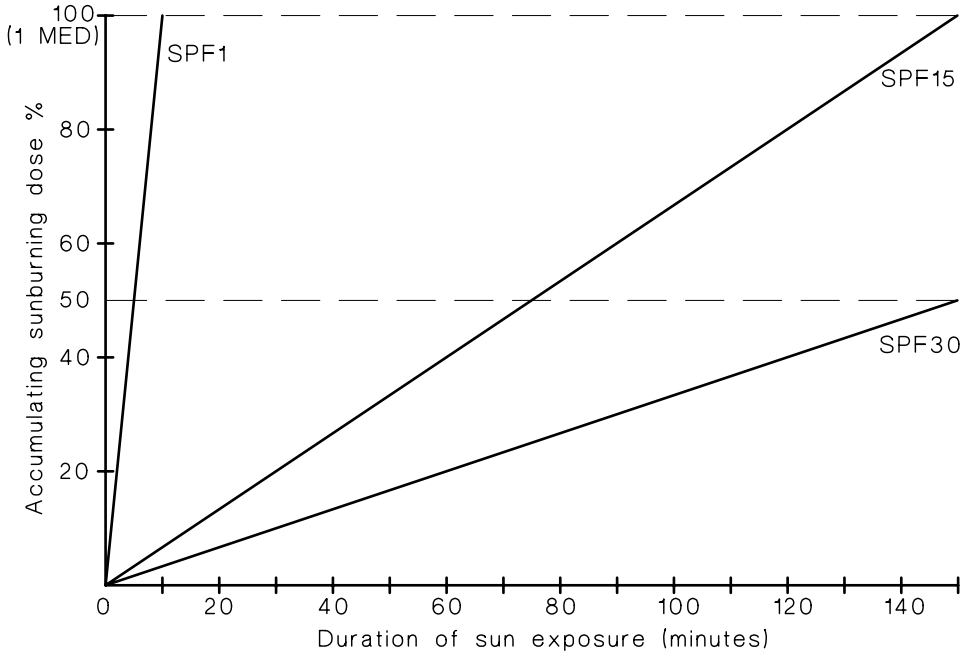
The Sun Protection Factor (SPF) informs consumers of the efficacy of the sunscreen against sunburn and helps them select a product appropriate to their skin sensitivity and exposure to the sun. The SPF is the ratio of the ultraviolet (UV) radiation dose that is required to produce a recognizable constant response on skin (minimum erythema) treated with a sunscreen product compared to that required for untreated skin. Test procedures described in this Standard employ minimum erythema as the constant skin response and ‘solar simulator’ lamps as the UV source.

The term ‘sunblock’ is a misnomer. Sunscreens are filters which prevent varying amounts of sunburning radiation from reaching the skin; however some of the sunburning radiation does get through. This is a continuous process, with skin damage accumulating as long as the skin is exposed to the sun, leading to sunburn if the skin is exposed for long enough. 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 a sunburning dose over time, with or without the protection of a sunscreen, that is the basis for the test method given in this Standard.

The length of exposure to sunlight that will result in a minimum 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, will take approximately 15 times as long to receive the same sunburning dose, i.e 150 minutes. The idealized diagram below compares how that skin receives a sunburning dose of sunlight without the protection of a sunscreen, with the protection of an SPF 15 sunscreen and with the protection of an SPF 30 sunscreen.

It can be seen from the diagram that if unprotected skin receives 100% of a sunburning dose after 10 minutes of exposure, it will receive 6.6% of the sunburning dose in 10 minutes if protected by an SPF 15 sunscreen, 20% in 30 minutes, and 100% in 150 minutes. 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.



NOTES:

1 This diagram is based on a skin that will receive a sunburning dose (minimum erythemal dose, or MED) after 10 minutes exposure to sunlight at summer noon.

2 AT 10 MINUTES:

SPF 1 (no protection)	100% MED
SPF 15	6.6% MED
SPF 30	3.3% MED

IDEALIZED COMPARISON OF PROTECTION PROVIDED BY SUNSCREENS OF INCREASING SPF

Such calculations can never be exactly applied in use, but may 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. 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, this meaning of the SPF numbers should not be misconstrued as a justification to prolong or extend sun exposure.

The examples above show that 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 30 sunscreen has double the protection of an SPF 15 sunscreen.

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, if necessary throughout the world. It is necessary to include statistical requirements in the method to achieve acceptable average results.

Although sunlight may at times be convenient for product testing, it is too variable and unpredictable to be used routinely for assessing large numbers of sunscreen products. In the tropics, it is rare for two consecutive days to be fine and cloudless, but it is even more unusual to find that the UV-B intensity is unchanged. Skin temperature during UV exposure may be an important factor and a wide temperature variation may be caused by natural sunlight. This problem is compounded by intermittent cloud when the total radiation may be as low as 10% (affecting skin temperature), while the UV-B radiation (causing sunburn) may merely be halved. In addition, the results obtained in sunlight are too slow for the practical testing of products with high protection factors.

Historically, some test centres have used long-wave ultraviolet emitting high-pressure mercury lamps, while others have used xenon arc lamps as a source of simulated sunlight, and there were various opinions on whether one of these two UV lamp systems should be preferred. A direct comparison of protection factors obtained with a xenon arc or a mercury sunlamp or sunlight under conditions such as those specified above showed that similar results were achieved for sunscreens with low protection factors, under the same application conditions. However, for sunscreens with high protection factors (15 or over) the results achieved using a mercury lamp were lower than with other sources, which is attributable to the unrepresentatively low UV-A radiation from the mercury sunlamp. A solar simulator with properties that can be achieved by the use of the xenon arc with filters is used in this Standard.

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.

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 solar ultraviolet (UV) radiation.

3 APPLICATION 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.

4 REFERENCED DOCUMENTS The following documents are referred to in this Standard:

AS	
1680	Interior lighting
1680.1	Part 1: General principles and recommendations
2610	Spa pools
2610.2	Part 2: Private spas
AS/NZS	
1580	Paints and related materials—Methods of test
1580.601.1	Method 601.1: Colour—Visual comparison

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

5.1 Broad-spectrum product—a sunscreen product which has been shown, using an in-vitro test method, to provide protection against certain of the sun's UV-A rays as part of the protection of a low, moderate, high or very high protection sunscreen product.

5.2 Category description—the verbal designation of the level of protection given by a grouping of label protection factors.

5.3 Label protection factor—the protection factor indicated on a sunscreen product container.

5.4 Main (or principal) label—the label which shows the name of the product more prominently than any other label.

5.5 May—the use of the word 'may' indicates that the relevant sentence is not a requirement but is optional.

5.6 Mean protection factor—the mean of the protection factors determined on each of the individual test subjects.

5.7 Minimum erythemal dose (MED)—the minimum quantity of radiant energy required to produce a perceptible reddening of human skin (when viewed 16–24 hours after irradiation) following exposure to radiation of a specified wavelength or range of wavelengths. Where the radiation source has constant intensity, MED ratios may be determined by ratios of exposure durations.

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