1993 ED.
(1986 ED. WILL REMAIN CURRENT)

AS 2604—1986
UDC 614.875:614.898

Australian Standard®
2604—1986

SUNSCREEN PRODUCTS—EVALUATION AND CLASSIFICATION

[Title allocated by Defence Cataloguing Authority:
SUNBURN PREVENTATIVE PREPARATION (Evaluation and Labelling) . . . . . NSC 6508]

STANDARDS ASSOCIATION OF AUSTRALIA
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This Australian standard was prepared by Committee CS/42, Sunscreen Agents. It was approved on behalf of the Council of the Standards Association of Australia on 27 May 1986 and published on 4 August 1986.

The following interests are represented on Committee CS/42:

Australasian College of Dermatologists
Australian Cancer Society Inc.
Australian Consumers Association
Australian Pharmaceutical Manufacturers Association
Australian Society of Cosmetic Chemists
Cosmetic, Toiletry and Fragrance Association of Australia
Department of Health
Department of Health, New South Wales
Health Commission of Victoria
Pharmacy Guild of Australia
Proprietary Association of Australia
Sydney Hospital
University of Queensland

This standard was issued in draft form for comment as DR 84280.

AUSTRALIAN STANDARD

SUNSCREEN PRODUCTS—EVALUATION AND CLASSIFICATION

AS 2604—1986

First published 1983
Second edition.....1986

PUBLISHED BY THE STANDARDS ASSOCIATION OF AUSTRALIA
STANDARDS HOUSE, 80 ARTHUR ST, NORTH SYDNEY, N.S.W.
ISBN 0 7262 4278 0

PREFACE

This edition of this standard was prepared by the Association's Committee on Sunscreen Products, to supersede AS 2604—1983.

This standard carries forward from AS 2604—1983 a method of evaluating the performance of sunscreen products in terms of their ability to limit solar erythema on human skin and describes the requirements for labelling sunscreen products so that the information obtained by testing will be meaningful to most consumers.

It is emphasized that consumers will need to use the information sensibly because of the number of variables involved. The information gives a guide to the individual user as to how long one may remain exposed to sunlight before becoming sunburnt. However, it will not promise a precise result for each individual or indicate the precise range of the ultraviolet (UV) spectrum against which the product provides protection.

Reproducible test methods for evaluating some of the other properties attributed to sunscreen products, such as the promotion of tanning, are not to the committee's knowledge available at the present time in the context of simple test methods using a response on human skin as the yardstick.

This edition of the standard has been expanded to clarify the requirements for sunscreen products which perform more than one purpose, such as a cosmetic product containing a sunscreen agent. This edition also contains guidance for the testing of both broad-spectrum and water resistant sunscreen products.

The committee is well aware of the difficulties of obtaining absolute data concerning the effects of UV-A on the skin. Consequently various methods of evaluating broad-spectrum products were considered by the committee. A method using hairless mice and a method using human volunteers were both rejected. At length the alternative of using an *in vitro* procedure was accepted. However, in view of the present level of knowledge and the evolving climate of scientific opinion the committee decided to provide guidance on the testing of broad-spectrum products rather than specifying exact requirements at this stage of development.

Essentially, there are two test methods available for determining the water-resistance of sunscreen products. The data for showing the equivalence of these methods is limited. Consequently, both tests, have been included for guidance only in an appendix. At this stage of development, neither test could be included as a requirement of this standard.

It is the committee's intention to review this standard during 198- or as additional information and test data become available.

CONTENTS

FOREWORD

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 and to back this up by using sun-hats, adequate clothing, and umbrellas, where appropriate. According to present knowledge, sunscreens should not be regarded as the sole means of protecting the body.

The need for a simple, quantitative method for determining the protective power of sunscreen products has led to the development of an experimentally determined 'protection factor'. The protection factor is the ratio of the ultraviolet (UV) radiation doses that are required to produce a recognizable constant skin response in skin that has been treated with a sunscreen product and in 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 tests are not intended simply to rank sunscreen products. For a number of reasons, including variation in skin types, consumers require a range of sunscreen products with different protective powers and comparative information so that they can as far as possible select the best product for a particular situation.

It is a fairly simple matter to perform evaluations by exposing ordinary skin to sunlight. Unfortunately, there are so many variable factors which contribute significantly to the result that such 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, if two consecutive days happen to be fine and cloudless, it is rare, but it is even more unusual to find that the UV-B intensity is unchanged. Skin temperature during UV exposure is an important factor and a wide variation may be expected in natural sunlight. This problem is compounded by intermittent cloud when the total radiation may be as low as 10 percent (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.

Some test centres have used 'Osram Ultravitalux' lamps while others have used xenon arc lamps as a source of simulated sunlight. Although there have been various opinions on whether one of these two UV lamp systems should be preferred, there does not appear to be a direct comparison of protection factors obtained with a xenon arc or a mercury sunlamp or sunlight under conditions such as those specified above. At present, some European countries appear to prefer the 'Ultravitalux' lamp while the USA favours a xenon arc as a solar simulator. A solar simulator with properties that can be achieved by the use of a xenon arc with filters is used in this standard.

As the role of UV-A, visible, and infra-red radiation in the production of skin damage generally is the subject of some controversy and research, this standard will be reviewed as new data becomes available.

STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
SUNSCREEN PRODUCTS—EVALUATION AND LABELLING

1 SCOPE. This standard sets out procedures for determining the performance of sunscreen products in terms of their mean protection factors. It also provides guidance on the testing of both broad-spectrum and water-resistant sunscreen products. This standard also specifies appropriate detail of labelling requirements.

2 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 rays. It applies to both primary and secondary sunscreen products as defined.

3 REFERENCED DOCUMENTS. The following documents are referred to in this standard:

AS 2610 Spa Pools
Part 2—Private Spas

Cosmetic Ingredient Dictionary Cosmetic, Toiletry and Fragrance Association Inc (USA).

Directives of the European Economic Community.

4 DEFINITIONS. For the purposes of this standard, the following definitions apply:

4.1 Minimum erythemal dose (MED)—the minimum quantity of radiant energy required to produce the first detectable reddening of fair human skin 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.

4.2 Solar simulator—a lamp system that produces artificial sunlight.

NOTE: A solar simulator is described in Appendix D.

4.3 Shall—the use of the word 'shall' indicates that a requirement is mandatory.

4.4 Should—the use of the word 'should' indicates that the relevant sentence is not a requirement but is advisory.

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

4.6 Primary sunscreen product—a sunscreen product which is represented on the primary display panel as being primarily to protect the skin from certain harmful effects of the sun's rays.

4.7 Secondary sunscreen product—a sunscreen product which is represented on the label as protecting the skin from certain harmful effects of the sun's rays while fulfilling another primary function.

4.8 Broad-spectrum product—a sunscreen product which provides protection against certain of the sun's UV-A rays in addition to that of a moderate, high, or maximum protection sunscreen product.

4.9 Protection factor—the ratio of UV radiation dose required to produce recognizable skin erythema on skin that has been protected with a sunscreen product to the dose required on unprotected skin under the same conditions.

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

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

4.12 Sun protection factor (SPF)—an alternative term for protection factor.

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

5 CLASSIFICATION OF SUNSCREEN PRODUCTS.

5.1 Types. Sunscreen products shall be either primary sunscreen products or secondary sunscreen products.

Primary and secondary products may be further classified on the basis of their performance as broad-spectrum or water resistant products where appropriate.

5.2 Category description. Primary and secondary sunscreen products shall be classified for the purposes of labelling according to their mean protection factors (determined in accordance with Appendix A) as follows:

Category description	Mean protection factor
Maximum protection sunscreen	15 or more
High protection sunscreen	At least 8 but less than 15
Moderate protection suncreen	At least 4 but less than 8
Minimum protection sunscreen	At least 2 but less than 4

NOTE: Sunscreen products are not required to be classified by determining their mean protection factors after a test for water-resistance, though use of these values is an acceptable alternative for the proprietor.

6 PERFORMANCE REQUIREMENTS.

6.1 Primary and secondary sunscreen products. When tested in accordance with Appendix A, primary and secondary sunscreen products shall have a mean protection factor of not less than 2.

6.2 Broad-spectrum products. When tested in accordance with Appendix A, broad-spectrum products shall have a mean protection factor of not less than 4. For guidance only, provisional test methods for determining the UV transmission of broad-spectrum products are given in Appendix F.

6.3 Water-resistant products. For guidance only, provisional test methods for water-resistance are given in Appendix G.