AS 2604—1983
UDC 614.875

Australian Standard 2604—1983

SUNSCREEN PRODUCTS — EVALUATION AND CLASSIFICATION

S/S
By
AS 2604 (1985)

STANDARDS ASSOCIATION OF AUSTRALIA
Incorporated by Royal Charter

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 7 December 1982 and published on 5 April 1983.

The following interests are represented on Committee CS/42:

Australian Cancer Society
Australian Consumers Association
Australian College of Dermatologists
Australian Federation of Consumer Organizations Inc.
Australian Pharmaceutical Manufacturers Association
Australian Society of Cosmetic Chemists
Cosmetic and Toiletry Manufacturers Association of Australia
Department of Health (Commonwealth)
Department of Health, N.S.W.
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 81164.

AUSTRALIAN STANDARD

SUNSCREEN PRODUCTS—EVALUATION AND CLASSIFICATION

AS 2604—1983

First published 1983

PUBLISHED BY THE STANDARDS ASSOCIATION OF AUSTRALIA,
STANDARDS HOUSE, 80 ARTHUR STREET, NORTH SYDNEY, N.S.W.

ISBN 0 7262 2882 6

PREFACE

This standard was prepared by the Association's Committee on Sunscreen Agents following a request from the Commonwealth Department of Health.

The committee was asked to prepare a method for evaluating the performance of sunscreen products under conditions that duplicate the in-use situation as closely as possible.

The committee was unable to reach a consensus concerning broad spectrum products. Consequently broad spectrum products are not dealt with in this standard. The committee intends, as a priority, to devote further time to this matter.

This standard sets out a method of evaluating the performance of sunscreen products in terms of their ability to prevent sunburn on human skin and describes the requirements for labelling sunscreen products in such a way that the information obtained by testing will be meaningful to most consumers.

It is emphasized that consumers will need to use this 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 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.

The procedures described in this standard provide guidelines which should add some certainty and reproducibility to the methods of determining protection factors. All phases of the methods are described as closely as practicable, so far as existing facilities and available information and knowledge permit.

Following publication of the standard the committee intends to review the situation within two years as further experience is gained in the *in-vivo* testing of sunscreen products.

CONTENTS

STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
SUNSCREEN PRODUCTS — EVALUATION AND CLASSIFICATION

FOREWORD

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 UV radiation dose between skin treated with a sunscreen product and untreated skin, required to produce a recognizable constant skin response. The test procedures described in this Standard employ minimum erythema as the constant skin response and 'solar simulator' lamps as the UV source.

The test procedures relate to the protection from UV radiation in a simple situation which is unaccomplicated by processes such as sweating, swimming or similar activities. The tests are not intended simply to determine the strongest sunscreen products, but provides some comparative information about the protective powers of the products.

For a number of reasons, including variations 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.

The committee decided against the use of natural sunlight as the source of UV radiation in the test method. Although sunlight may at times be convenient for sunburn tests, 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, this is rare enough, 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 remain above 50 percent. 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 as to 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 Europe appears to prefer the 'Ultravitalux' lamp while the U.S.A. favours a xenon arc as a solar simulator. The committee accepted the use of a solar simulator with properties that can be met using a xenon arc with filters.

The committee believes that if this standard is used as a basis for legislation, an interim period should be allowed for the collection of additional data by manufacturers who have used the 'Osram Ultravitalux' or other radiation sources.

SPECIFICATION

1 SCOPE. This standard both sets out procedures for determining the performance of sunscreen products, in terms of their protection factors, using artificial sunlight as the ultraviolet (UV) source and human volunteers as subjects for skin response evaluation, and specifies labelling requirements for these products.

2 APPLICATION. This standard applies to sunscreen products represented as being suitable for application essentially to large surface areas of the body primarily to protect the skin from burning caused by the sun's ultraviolet rays.

Consequently this standard is not necessarily applicable to every cosmetic product that contains an UV light absorber. As examples, neither a lip-balm containing an UV light absorber or an aftershave containing an UV light absorber necessarily fall within the scope of this standard. However where claims of sunscreen activity are made for such products their labelling should be compatible with this standard.

Products with a mean protection factor of less than 2.0 shall not be regarded as sunscreen products.

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

3.1 Minimum erythemal dose (MED)—the quantity of radiant energy required to produce the first detectable reddening of fair human skin following exposure to a specified wavelength or range of wavelengths. When the UV source has constant intensity, MED ratios may be determined by ratios of exposure durations.

3.2 Solar simulator—a lamp system that produces artificial or simulated sunlight (as described in Appendix D).

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

3.4 Should—the use of the world 'should' indicates that a requirement is advisory.

3.5 May—the use of the word 'may' indicates that a requirement is optional.

3.6 Protection factor—a factor as described in Clause 5.

3.7 Mean protection factor—a factor as described in Clause 7.9.1.

3.8 Label protection factor—a factor as described in Clause 7.9.3

4 CLASSIFICATION. Sunscreen products shall be classified with the appropriate category description according to their mean protection factors as follows:

Range of mean protection factors	*Category description*
15 and over	Maximum protection sunscreen
8 to under 15	High protection sunscreen
4 to under 8	Moderate protection sunscreen
2 to under 4	Minimum protection sunscreen

The category description shall appear on the product (see Clause 8(a)).

The appropriate label protection factor may appear on the product (see Clause 8 (b)).

NOTE: The method of calculation for assigning category descriptions and, where required, label protection factors, is described in Clauses 7.9.2 and 7.9.3 respectively.

5 PRINCIPLE. The protection factor (PF) of a sunscreen product shall be determined from the minimum erythemal dose (MED) of skin that has been protected with the sunscreen product and from the MED of an adjacent area of unprotected skin, under specified conditions (see Clause 7) by means of the following relationship where the UV source has constant intensity:

$$\text{Protection factor} = \frac{\text{Exposure duration for minimum erythema in protected skin}}{\text{Exposure duration for minimum erythema in unprotected skin}}$$

NOTE: For experimental considerations concerning the determination of protection factors, see Appendix A.

6 REFERENCE PRODUCT. A reference sunscreen product is described in Appendix B. This product may be used if required to verify test procedures.

7 TEST PROCEDURES.

7.1 General Principles. The MED of the (untreated) subject at the test site is first determined. An experienced tester can often predict an MED for a particular lamp distance and subject but, where necessary, one or more sets of trial exposures must be made and after 16 h to 24 h read to determine the approximate MED without exposing the subject to excessive radiation. Exposures are made on one or more small subsite areas at measured exposure times.

On the basis of this predicted or approximate value, the MED is determined more precisely by a set of exposures which span a dose range of approximately 0.6 to 1.5 of the MED. Usually these doses are administered the day before the product is tested but they may be administered at the same time. When administered the day before, the result, the MED, not only provides the denominator for calculating the PF but, when multiplied by the expected or likely value of the product's PF, provides an estimate for the longer exposure needed to assess the product.

The product is assessed by exposing a set of small subsite areas adjacent to the untreated areas, after application of the product. Times of exposure are selected to bracket the estimate above. When read 16 h to 24 h later, the MED for the treated skin is divided by the MED for untreated skin to give the PF.

7.2 Selection of Test Subjects.

7.2.1 *General.* Test subjects shall be fair-skinned male or female volunteers drawn from any of skin types 1, 2 or 3 (see Clause 7.2.2). A questionnaire shall be completed for each volunteer (by means of a personal interview). A suitable questionnaire is described in Appendix C. Volunteers with a history of abnormal response to medication, UV radiation or allergies to topically applied cosmetics shall be excluded. Volunteers taking photo-toxic or photosensitizing medication shall be excluded. All other medication being taken shall be recorded.

NOTE: The National Health and Medical Research Council recommends that informed consent should be obtained from each test subject.