



Australian Government
Department of Health
Therapeutic Goods Administration

Australian regulatory guidelines for sunscreens

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TGA Health Safety
Regulation

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Contents

1.	Introduction	5
2.	Therapeutic sunscreen or cosmetic sunscreen?	7
2.1	Therapeutic sunscreens	7
2.2	Cosmetic sunscreens	7
3.	Regulatory categories of sunscreens	9
3.1	Exempt sunscreens	9
3.2	Listing of therapeutic sunscreens	10
3.3	Registration of therapeutic sunscreens	11
3.4	Responsibility of sponsors to report adverse reactions	11
4.	Labelling and advertising	12
4.1	General	12
4.2	Labelling of immediate container and primary pack	14
4.3	Minimum requirements for small containers	16
4.4	Nanoparticles in sunscreens	16
4.5	Advertisements for therapeutic sunscreens	16
5.	Reproducibility of SPF test results	17
6.	Changes to sunscreens	18
6.1	Changes to active ingredients	18
6.2	Changes to excipients	18
6.3	Other changes	18
7.	Stability testing	19
7.1	Stability test requirements	19
7.2	Establishing stability before listing or registering	19
7.3	Confirming stability and shelf life	19
7.4	Stability protocol requirements	20
7.5	Shelf life determination	20
8.	Manufacture and quality control	22
8.1	Manufacture	22
8.2	Quality control	22
9.	Permitted ingredients	24

9.1	Sunscreening agents permitted as active ingredients_____	24
9.2	Excipients _____	24
10.	New ingredients _____	25
10.1	Naming of new substances _____	25
10.2	New active ingredients_____	25
10.3	Safety data requirements for new actives_____	25
10.4	Justification for not providing particular studies_____	27
10.5	Related studies _____	27
10.6	UV spectral characteristics _____	28
10.7	New excipients _____	28
11.	Glossary of terms and abbreviations _____	31
12.	Bibliography _____	34
	Appendix 1: Labelling checklist_____	36

1. Introduction

These Guidelines replace Chapter 10, 'Sunscreens', in the *Australian Regulatory Guidelines for OTC Medicines* (ARGOM) published in 2003. They have been produced by the Therapeutic Goods Administration (TGA) in consultation with the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the pharmaceutical and cosmetics industries.

The first draft of these Guidelines was published on the TGA web site in May–June 2010 for stakeholder and public consultation. The preparation of the finalised Guidelines has taken into account the comments received as a result of the consultation and also the changes to the Australian and New Zealand Sunscreen Standard (see below).

These Guidelines describe the regulatory requirements and standards for sunscreens and their ingredients in Australia as at the date of publication.

Many of the terms, such as therapeutic sunscreen, cosmetic, cosmetic sunscreen, primary sunscreen, secondary sunscreen, sun protection factor (SPF) referred to in these Guidelines are defined in section 11 '[Glossary of terms and abbreviations](#)'.

The legislation (Acts and regulations), standards and other relevant regulatory documents (Therapeutic Goods Orders, codes, etc.), referred to in these Guidelines are listed along with their sources in section 12 '[Bibliography](#)' at the end of the document. Sunscreens classified as therapeutic goods are, unless exempt, required to be included in the Australian Register of Therapeutic Goods (ARTG) maintained by the TGA before they can legally be marketed in Australia. To be listed, sunscreens must comply with the Australian and New Zealand Sunscreen Standard *AS/NZS 2604 Sunscreen products—Evaluation and classification* in force at the time of listing.

A new Australian and New Zealand Sunscreen Standard, *AS/NZS 2604:2012* which replaces the previous Standard *AS/NZS 2604:1998* has been developed by the Standards Australia and Standards New Zealand in consultation with stakeholders and the public. This was published on 30 May 2012. The Standard and the International Standards Organisation (ISO) standards to which it refers are available for purchase from SAI Global through its web site.

AS/NZS 2604:2012 includes the following significant changes from the previous Standard:

- Adoption of the *ISO 24444:2010 in vivo* test procedure for determining SPF. This is essentially the same as the *in vivo* test procedure in *AS/NZS 2604:1998*, but includes statistical criteria for acceptance of the test results. In most cases the SPF test results obtained according to *AS/NZS 2604:1998* would comply with *ISO 2444:2010*.
- Increase of the maximum SPF that may be claimed on the label of a sunscreen product from SPF 30+ to SPF 50+. A claim of SPF 50+ is allowed only if the mean SPF test result is 60 or higher.
- Limiting of the permitted SPF claims to 4, 6, 8, 10, 15, 20, 25, 30, 40, 50 and 50+ (depending on the SPF test result). Note that a claim of SPF 30+ is not permitted under *AS/NZS 2604:2012*.
- Changing of the SPF ranges for categorisation of protection as 'low' (SPF 4, 6, 8 or 10), 'medium' or 'moderate' (SPF 15, 20 or 25), 'high' (SPF 30, 40 or 50) or 'very high' (SPF 50+).
- Adoption of the *in vitro* test procedure in *ISO 24443:2012* for determining broad spectrum performance. The criteria for broad spectrum performance determined using this test procedure are significantly more stringent than the criteria in *AS/NZS 2604:1998*, and many products complying with that standard would not comply with *ISO 24443:2012*.
- Making 'broad spectrum' performance mandatory for all primary sunscreens and for those secondary sunscreens classified as 'therapeutic sunscreens' and regulated by the TGA.

- Making 'broad spectrum' performance mandatory for cosmetic sunscreens with SPF30 or higher and optional for cosmetic sunscreens with SPF less than 30.

In recognition of this new Standard, Item 7 of Part 1 of Schedule 4, Item 8(g) of Schedule 5, and Item 14 of Schedule 7 of the *Therapeutic Goods Regulations 1990* (the Regulations) have been amended to require sunscreens products listed in the ARTG as from 10 November 2012 to comply with *AS/NZS 2604:2012* rather than *AS/NZS 2604:1998*.

However, regulation 49 of the Regulations allows products listed prior to that date (that come within Item 7 of part 1 of Schedule 4 or are able to be marketed in Australia because they are exempt under Item 8(g) of Schedule 5 of the Regulations) to continue to comply with *AS/NZS 2604:1998*.

Sponsors may make changes to those products (for example, changes to labels or sites of manufacture) provided the changes do not make the product a new product requiring a new listing in the ARTG.

A proposed change to a product will create a new product if it is of the kind referred to in s.16(1A) of the Act (different active ingredients, different quantities of active ingredients or different dosage form) or in regulation 11 of the Regulations (different name, different indications, different excipient or changes are made to or in relation to any restricted ingredients).

If a new listing is required because of such a change, the product concerned will need to comply fully with *AS/NZS 2604:2012*.

At the time the 2012 guidelines were published the majority of sunscreens listed in the ARTG carried claims of SPF30+ and provided broad spectrum protection.

An SPF30+ sunscreen may have originally produced an SPF test of 40 or higher and, therefore, could potentially carry a claim of SPF 40, SPF 50 or SPF 50+ allowed under *AS/NZS 2604:2012*. In most cases the SPF test results (and water resistance test, if relevant) obtained previously would have complied with the statistical requirements of *AS/NZS 2604:2012* and retesting for these parameters would not be necessary. Any such product would, however, need to be retested according to *AS/NZS 2604:2012* and *ISO 24443:2012* for compliance with the requirements for 'broad spectrum' performance. If any such product passed the broad spectrum test, the product could be renamed and relabelled accordingly in compliance with *AS/NZS 2604:2012*. Prior to release into the Australian market it would need to be relisted in the ARTG as a new product with a new AUST L number.

If, on the other hand, the product failed the broad spectrum test in *AS/NZS 2604:2012*, it may be possible for it to be reformulated (for example, by adjusting the quantities of the active ingredients within the allowed limits or adding other approved active ingredients) in order to pass the test. The reformulated product would then need to be retested for SPF (and water resistance, if relevant), renamed and relabelled in full compliance with *AS/NZS 2604:2012* and these Guidelines, and listed in the ARTG as a new product with a new AUST L number. Depending upon the degree of reformulation required, new stability data may also need to be generated to support the shelf life claimed for the reformulated product.

2. Therapeutic sunscreen or cosmetic sunscreen?

2.1 Therapeutic sunscreens

For the purpose of these Guidelines, sunscreens that are regulated as therapeutic goods under the Act and the Regulations and are not classified and regulated as cosmetics (see [subsection 2.2](#)) are referred to as 'therapeutic sunscreens'. Included in this category are:

- primary sunscreens with SPF 4 or more
- secondary sunscreens – except those regulated as cosmetics (see [subsection 2.2](#))
- primary or secondary sunscreens with SPF 4 or more that contain an insect repellent
- sunscreens that are exempt from being listed under the Act because they come within the exemption in Item 8(g) of Schedule 5 of the Regulations.

2.2 Cosmetic sunscreens

Some products contain an ingredient with suncreening properties but the primary purpose of the product is neither suncreening nor therapeutic. These products are regulated as cosmetics by the National Industrial Chemicals Notification & Assessment Scheme (NICNAS) rather than by the TGA as therapeutic goods. In accordance with the *Therapeutic Goods (Excluded Goods) Order No. 1 of 2011*, these products are not regulated under the Therapeutic Goods legislation and are not required to be included in the ARTG. For the purpose of these Guidelines such products are called 'cosmetic sunscreens'. They may also be referred to as 'excluded' sunscreens.

A cosmetic sunscreen product must meet the definition of a cosmetic under the *Industrial Chemicals (Notification and Assessment) Act 1989* and any requirements set out in the current *Cosmetics Standard* and *NICNAS Cosmetics Guidelines*. Requests for regulatory information and enquiries about cosmetic products should be directed to NICNAS.

Section 5 of the *Industrial Chemicals (Notification and Assessment) Act 1989* defines a cosmetic as follows:

'Cosmetic means:

- a. substance or preparation intended for placement in contact with any external part of the human body, including:
 - i. the mucous membranes of the oral cavity; and
 - ii. the teeth;with a view to:
 - iii. altering the odours of the body; or
 - iv. changing its appearance; or
 - v. cleansing it; or
 - vi. maintaining it in good condition; or
 - vii. perfuming it; or
 - viii. protecting it; or
- b. substance or preparation prescribed by regulations made for the purposes of this paragraph; but does not include:
- c. therapeutic good within the meaning of the Therapeutic Goods Act 1989; or
- d. a substance or preparation prescribed by regulations made for the purposes of this paragraph.'

The current *Cosmetics Standard* and the associated *NICNAS Cosmetics Guidelines* should be consulted for guidance on the conditions applying to the following secondary sunscreen products for them to be regulated as cosmetics rather than therapeutic goods:

- a. Make-up products for the face and nails:
 - tinted bases or foundation (liquids, pastes or powders) with sunscreen
 - products (tinted or untinted) intended for application to the lips with sunscreen.
- b. Skin care products:
 - some moisturising products with sunscreen for dermal application, including anti-wrinkle, anti-ageing and skin whitening products
 - some sunbathing products (for example, oils, creams or gels, including products for tanning without sun and after sun care products).

The *Cosmetics Standard* and *NICNAS Cosmetics Guidelines* include specific requirements regarding the presentation and labelling of cosmetic sunscreen products. Sponsors are responsible for ensuring that such products comply with those requirements. Failure to comply with those requirements may make the product concerned a therapeutic good that must be listed or registered in the ARTG.

Other mandatory requirements applying to the labelling of all cosmetic products are set out in *Cosmetic & toiletries ingredient labelling* published by the Australian Competition & Consumer Commission (ACCC).

3. Regulatory categories of sunscreens

Most therapeutic sunscreens marketed in Australia are currently defined as 'listable' therapeutic goods which means that they must be 'listed' in the ARTG. Other sunscreen products must be 'registered' in the ARTG, while others are exempt from registration or listing (see below). General information on listing and registration of therapeutic goods is available on the TGA Internet site. The current regulation of the various categories of sunscreens is summarised in Table 1 below and explained in the text that follows.

Table 1. Summary of the current regulation for the various categories of sunscreens.

Product category	Sub-category	Currently regulated by:
Listable sunscreens	<ul style="list-style-type: none"> Primary sunscreens carrying SPF claims of at least SPF 4 and not greater than SPF 50+ Secondary suncreening products that meet the definition of a therapeutic sunscreen (See subsections 2.1 and 3.2)	Listing in the ARTG under s.26A of the Act
Registrable sunscreens	Sunscreens that make therapeutic claims other than suncreening and/or reduction of risk of skin cancer, solar keratosis, sunspots or premature ageing. (See subsection 3.3)	Registration in the ARTG under s.25 of the Act
Exempt sunscreens	Primary sunscreens with an SPF less than 4 and not containing ingredients of human or animal origin. (See subsections 2.2 and 3.1)	Exempt from the requirement of listing or registration in the ARTG
Cosmetic sunscreens (Excluded sunscreens)	Some secondary sunscreens that are excluded from regulation by the TGA but meet the definition of a cosmetic. (See subsection 2.2)	Regulated by NICNAS and the ACCC as cosmetics and not regulated under the Act

3.1 Exempt sunscreens

A therapeutic sunscreen product is 'exempt' under Item 8(g) of Schedule 5 of the Regulations if:

- the SPF established by testing according to *AS/NZS 2604:2012* is less than 4, and
- the label claims comply with *AS/NZS 2604:2012*, and
- the product does not have an indication for the treatment of a serious disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the *Therapeutic Goods Advertising Code*.

Exempt therapeutic sunscreens do not require registration or listing in the ARTG, but are treated as therapeutic goods in all other respects and must comply with all relevant parts of the Therapeutic Goods legislation, including relevant standards such as the Labelling Order (Therapeutic Goods Order No. 69, and amendments) and the *Therapeutic Goods Advertising Code*.

3.2 Listing of therapeutic sunscreens

The majority of therapeutic sunscreen products require listing in the ARTG in accordance with Item 7 of Part 1 of Schedule 4 of the Regulations.

Information on the listing process using the TGA's Electronic Listing Facility (ELF) and details of what information needs to be provided for listed products are provided in the *Electronic Listing Facility (ELF) User Guide*.

Under Item 7 of Part 1 of Schedule 4 of the Regulations, sunscreen products are eligible for listing where they come within the following description:

'Sunscreen preparations for dermal application (other than preparations for the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code), if:

- a. the claimed sun protection factor has been established by testing according to the method described in Standard *AS/NZS 2604:2012*, as in force from time to time; and
- b. the performance statements and markings on the label comply with that Standard; and
- c. the sunscreen preparation only contains ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act; and
- d. if a determination under paragraph 26BB(1)(b) of the Act specifies requirements in relation to ingredients being contained in the sunscreen preparation—none of the requirements have been contravened

The SPF of therapeutic sunscreens must be determined by testing on human skin in accordance with the sunscreen standard *AS/NZS 2604:2012* which references the International Organisation for Standardisation procedure *ISO 24444:2010 Cosmetics – Sun Protection test methods – In vivo determination of SPF (Sun Protection Factor)*.

Note that, where *in vivo* SPF test results have been produced using the US FDA static SPF test procedure described in *FDA Sunscreen Drug Products for OTC Human Use: Final Monograph*, the individual SPF results may be used to calculate the mean SPF and the label SPF provided they meet the statistical criteria set out in *ISO 24444:2010* as referenced in *AS/NZS 2604:2012*.

Therapeutic sunscreen products may only contain active sunscreens ingredients that are included in the list of sunscreens agents permitted as active ingredients in therapeutic sunscreens (see [subsection 9.1](#)) and are within the maximum concentrations stated in the list.

Sponsors should consider the impact of excipients on the sensitivity of the skin to sunlight and should ensure that the finished product is safe for its intended purpose.

Sunscreen products that make therapeutic claims other than sunscreens (for example, reduction of free radicals in or below the skin, or claims relating to reduction of UV induced immune suppression) and/or contain active therapeutic ingredients that are not included in the list of sunscreens agents permitted as active ingredients (see [subsection 9.1](#)) are not 'listable sunscreen preparations' and must be registered in the ARTG as OTC or prescription medicines depending on the active ingredients contained and therapeutic claims made (see [subsection 3.3](#) for registration of therapeutic sunscreens). [Subsection 4.1](#) lists the therapeutic claims permitted for listed sunscreens.

3.3 Registration of therapeutic sunscreens

Sunscreens that are not 'listable', 'exempt' or 'cosmetic' (excluded) are evaluated by the TGA for quality, safety and efficacy as registered therapeutic goods under section 25 of the Act.

Data to support the quality, safety and efficacy of such products are required as detailed under the relevant chapters of the *Australian Regulatory Guidelines for OTC Medicines* (ARGOM).

Products in this category include:

- products that contain a sunscreen active ingredient that is not included in the list of sunscreens permitted as active ingredients (see [subsection 9.1](#))
- products that make any therapeutic claims other than the sunscreens permitted under section 4 '[Labelling and advertising](#)', or that are for the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 of the *Therapeutic Goods Advertising Code*
- products that contain substances that are scheduled in the SUSMP
- products that contain a sunscreens active ingredient combined with a claimed therapeutic active ingredient that is not a permissible active ingredient in a listed medicine in accordance with section 26BB of the Act
- products that are not otherwise 'listable', 'exempt' or 'excluded'.

3.4 Responsibility of sponsors to report adverse reactions

It is a standard condition of listing or registration of a medicine that the sponsor has an appropriate system of pharmacovigilance and that the sponsor reports to the TGA adverse reactions experienced by users of the sponsor's products. This requirement applies to sponsors of therapeutic sunscreens.

Details of the TGA's requirements for pharmacovigilance and the reporting of adverse reactions can be found on the TGA Internet site.

4. Labelling and advertising

The labelling and advertising of therapeutic sunscreen products included in the ARTG must comply with the relevant requirements of each of the following:

- the Labelling Order, Therapeutic Goods Order No 69 (or any subsequent order amending or replacing TGO 69)
- the *Therapeutic Goods Advertising Code* (as updated from time to time)
- the Australian/New Zealand Standard *AS/NZS 2604:2012 Sunscreen products – Evaluation and classification*
- the current edition of *Required Advisory Statements for Medicine Labels* (RASML).

A check list is provided at the end of this document ([Appendix 1](#)) to assist sponsors in designing their sunscreen labels in accordance with the requirements of the documents listed above. However, the check list is not exhaustive and sponsors are responsible for ensuring that their labelling complies with all of the relevant legislative requirements.

TGO 69, the *Therapeutic Goods Advertising Code* and the RASML do not apply to cosmetic sunscreens.

4.1 General

As required by sections 2 and 3 of the Labelling Order (TGO 69), the label (or labels) must:

- be printed on or firmly and securely attached to the container
- be unlikely to become detached or defaced or illegible during use
- be positioned so that it will not be damaged or removed when the container is opened
- not be obscured by any other label or object
- be printed in English
- be printed in lettering that is clear, distinct and legible, and the height of letters with ascenders or descenders is not less than 1.5 mm (except for the AUST L or AUST R number, which may be 1 mm high).

As prohibited by section 4 of the *Therapeutic Goods Advertising Code*, the labelling must be free from claims, statements or pictures that:

- are likely to arouse unwarranted and unrealistic expectations of the product's effectiveness
- are false, unbalanced, unsubstantiated, misleading or likely to mislead the user
- abuse the trust or exploit the lack of knowledge of consumers or contain language that could bring about fear or distress
- encourage or are likely to encourage inappropriate use
- indicate or imply that the product is infallible, unfailing, magical, miraculous, or effective in all cases
- indicate or imply that the product cannot cause harm
- indicate or imply that other competitor products are harmful or ineffectual

- indicate or imply that the product is endorsed by any government agency, hospital or other facility providing healthcare services, individual healthcare professional or group of healthcare professionals.

Therapeutic sunscreens that are 'listable' are permitted to carry the following coded indications provided that the sunscreen meets the requirements of *AS/NZS 2604:2012* for the indications designated:

1. A broad spectrum sunscreen with an SPF of 30 or higher is permitted to carry the following indications:
 - 'May assist in preventing some skin cancers.'
 - 'May reduce the risk of some skin cancers.'
 - 'Can aid in the prevention of solar keratoses.'
 - 'Can aid in the prevention of sunspots.'
2. A broad spectrum sunscreen with an SPF of 4 or higher is permitted to carry the following indication:
 - 'Can aid in the prevention of premature skin ageing.'

In principle, indications considered appropriate for listed sunscreens are those that can be used safely and effectively without the intervention of a healthcare practitioner. For medicines generally this includes diseases, disorders or conditions that are normally of a benign or self-limiting nature that the average consumer can be expected to evaluate or diagnose accurately. Some indications that relate to a serious disease condition, ailment or defect such as skin cancer are restricted except those allowed above which have been approved by the TGA for therapeutic sunscreens.

The Act requires that, at the time of listing a medicine in the ARTG, a sponsor must certify that it holds the information or evidence to support indications and claims made in relation to the product. All indications and claims must be capable of substantiation – that is, evidence held by the sponsor must adequately demonstrate all indications and claims made for the product are true, valid and not misleading.

Listed medicines are not subject to pre-market evaluation for efficacy at the time of listing. However, data supporting the indications may be requested by the TGA for review after listing of a medicine. Hence, the TGA may request copies of labelling and the results of pre-market SPF, broad spectrum performance, water resistance or stability testing. If requested, it is expected that this information will be available and can be provided to the TGA within a reasonable time of the request.

Therapeutic sunscreens may also carry justified non-therapeutic claims (for example, 'contains Vitamin E', 'contains aloe vera', 'moisturising', 'antioxidant', 'free radical barrier') and information to support such claims may be requested by the TGA for review. If the certification by the sponsor that it holds this information or evidence is incorrect, the TGA can cancel the listing of the product from the ARTG.

The labelling may also carry company logos, other symbols and consumer information provided these do not create confusion for Australian consumers and they do not conflict with the requirements of the Therapeutic Goods legislation, the Labelling Order, the Sunscreen Standard or the Advertising Code.

If the formulation includes a proprietary ingredient, the sponsor should check with the manufacturer or supplier of the proprietary ingredient to ascertain that it does not contain any specified excipients that must be declared on the labels in accordance with TGO 69.

4.2 Labelling of immediate container and primary pack

As required by subsection 3(2) of the Labelling Order and section 7 of the Sunscreen Standard *AS/NZS 2604:2012*, the main label on the container and the main label of the primary pack (for example, carton), if any, must contain all of the following information:

- the product name

Note: The use of the term 'sunblock' is not acceptable as part of a product name (or elsewhere on the label). The term is a misnomer because sunscreens filter to varying degrees but do not completely block the sunburning radiation.

- the name of the dose form, for example, 'cream' or 'lotion'
- the sun protection factor (SPF) of the product preceded by the expression 'Sun Protection Factor' or 'SPF' marked in durable and legible characters and in such colour or colours as to afford a distinct contrast to the background colour and in letters not less than 1.5mm in height

Note: A category description may also be given, for example, 'low / medium or moderate / high / very high protection'.

- [if relevant] the water resistance of the product (in hours or in minutes) established in accordance with *AS/NZS 2604:2012*

Note: The use of the terms 'waterproof' and 'sweat proof' are not acceptable. Sunscreens may be water resistant but none are completely waterproof, and even those with a high water resistance rating will gradually wash off the skin when immersed in water for long enough or through perspiration.

- the statement 'broad spectrum' in letters not larger than those used for the SPF provided that the product meets the criteria of broad spectrum protection from UV (or UVA and UVB) light as defined and measured by *AS/NZS 2604:2012*
- the net quantity of the goods (by volume in mL or weight in g)
- the ARTG listing number preceded by 'AUST L' or registration number preceded by 'AUST R'.

Note: If the container is packed in an outer carton the listing or registration number must be on the main label of that carton and may be, but is not required to be, on the container as well.

All of the following information must be included either on the main label or on a rear or side panel [see subsection 3(3)(c) of the Labelling Order]:

- the names of all sunscreens active ingredients expressed using Australian Approved Names (AAN)

Note: International Nomenclature of Cosmetic Ingredients (INCI) names may also be included in addition to (but not as a substitute for) the AANs.

- the proportions of those ingredients either expressed as a percentage in terms of w/w or w/v or expressed as a weight in a stated weight or volume of the product using metric units of measurement (for example, mg/g or mg/mL).

All of the following information must be included somewhere on the label(s) or container:

- the recommended storage conditions 'store below 25°C' or 'store below 30°C', as applicable
- the batch or lot number of the product, preceded by the batch number prefix using one of the formats specified in subsection 2(1) of the Labelling Order

- the expiry date of the product preceded by the expiry date prefix 'Expiry Date', 'EXPIRY DATE', 'Expiry', 'EXPIRY', 'Expires', 'EXPIRES', 'Exp. Date', 'EXP. DATE', 'Use before', 'USE BEFORE', 'Use By', 'USE BY', 'Exp', or 'EXP'

Note: Terms such as 'Best by' or words to this effect are not acceptable.

- if relevant, the presence in the product (preceded by the word 'contains') of any ingredient listed in the First Schedule to the Labelling Order, including:

- benzoic acid, calcium benzoate, potassium benzoate or sodium benzoate

Note: If the product contains more than one of these substances, they may be grouped under the term 'benzoates'.

- ethanol (if > 3% v/v)
- hydroxybenzoate ester(s) (for example, ethyl, methyl, propyl, sodium ethyl, sodium methyl, sodium propyl hydroxybenzoate)

Note: If the product contains more than one of these substances, they may be grouped under the term 'hydroxybenzoates'.

- peanuts and peanut products (for example, peanut oil, arachis oil)
- sorbic acid or potassium sorbate

Note: If the product contains more than one of these substances, they may be grouped under the term 'sorbates'.

- sulfite, metabisulfite and bisulfite salts and sulfur dioxide

Note: If the product contains more than one of these substances, they may be grouped under the term 'sulfites'.

- tartrazine or 'tartrazine CI 19140'
- any other antimicrobial preservative(s)

- a statement of the purpose or purposes of the product

Notes:

- a. The purpose of the product can generally be made obvious by it being called a 'sunscreen' or 'moisturiser with sunscreen' or 'moisturiser' with an SPF stated on the label.
- b. If (and only if) a therapeutic sunscreen has an SPF of 30 or higher and it provides broad spectrum protection, the label is permitted to include a representation to the effect that the product 'may assist in preventing some skin cancers' or 'may reduce the risk of some skin cancers' provided the label also highlights the need for avoidance of prolonged exposure to the sun and the importance of wearing protective clothing, hats and eyewear (see Gazette notice of 25 September 2002). Other acceptable related claims are 'can aid in the prevention of solar keratoses' and 'can aid in the prevention of sunspots'.
- c. Any broad-spectrum suncreening preparation with an SPF of 4 or higher may also make the claim 'can aid in the prevention of premature skin ageing' or words to that effect.
- d. The labelling of therapeutic sunscreens may also carry justified non-therapeutic claims.

- directions for use of the product

Note: The directions for use for a primary therapeutic sunscreen should include statements to the effect that the product should be applied to the skin in generous amounts over all of the exposed areas 20 minutes before sun exposure, it should be reapplied every two hours or more often when sweating, and should be reapplied after swimming or towelling. The labelling must not contain a claim (for example, 'all day protection') that indicates or implies that the product does not need to be reapplied at regular intervals.

- required warning statements as included in the RASML

Note: The labels of both primary and secondary therapeutic sunscreens should include warning statements to the effect that the product should be kept out of the eyes and should not be used on broken, damaged or diseased skin. Spray-sunscreens should also include a warning not to inhale the product.

Primary therapeutic (but not secondary) sunscreen products should also include warning statements to the effect that prolonged exposure to the sun should be avoided, and it is important to wear protective clothing, hats and eyewear when exposed to the sun.

- the name and address of the sponsor or Australian supplier of the product.

Note: An Australian contact telephone number may also be included.

4.3 Minimum requirements for small containers

In accordance with subsection 3(11) of the Labelling Order, if the immediate container has a capacity of 20mL or less AND the container is enclosed in a primary pack (for example, carton), the primary pack labelling must include all of the information listed above and the labelling on the container must include at least the following information:

- product name (in full or in abbreviated form if there is insufficient room for the full name)
- name of the dosage form
- quantity of product in the container
- batch or lot number preceded by the batch number prefix
- names and quantities of all active ingredients in the product. If there is insufficient room, this information about active ingredients is only required on the label of the primary pack.

4.4 Nanoparticles in sunscreens

Nanoparticulate titanium dioxide and zinc oxide are commonly used in sunscreens. The labels of therapeutic sunscreens are not required to declare the particle sizes of ingredients.

The TGA's policy on the safety of nanoparticulate ingredients in sunscreens is available from the TGA Internet site.

4.5 Advertisements for therapeutic sunscreens

Advertisements for therapeutic sunscreens are required to comply with the Therapeutic Goods Advertising Code.

5. Reproducibility of SPF test results

The in vivo testing of the SPF of a sunscreen product according to the procedure in *ISO 24444:2010* and *AS/NZS 2604:2012* produces a reasonable estimate, but not a highly accurate and precise measure, of the true SPF of the product applied to the skin at a rate of 2 mg/cm². The test data exhibit a considerable inherent variance which needs to be taken into account when interpreting the test results and labelling of the product, and also needs to be taken into account when interpreting the results of any subsequent retesting of the product.

The test procedure in *ISO 24444:2010* and referenced by *AS/NZS 2604:2012* requires the product to be tested on a minimum of 10 subjects and for the arithmetic mean, standard deviation and 95% confidence interval (95% CI) for the mean to be calculated using the formula $95\% \text{ CI} = m \pm t.s/\sqrt{n}$, where:

‘n’ is the number of individual SPF data,

‘m’ is the arithmetic mean of those data,

‘t’ is the value of Student’s t for n-1 degrees of freedom and p=0.05 (double sided), and

‘s’ is the standard deviation of the test data.

There is a 95% probability that the true SPF of the product lies somewhere within the 95% CI.

For the test to be considered valid, the 95% CI must fit within $\pm 17\%$ of the mean and, if not, the product must be tested on further subjects (up to a maximum of 20) until the 95% CI based on the data for all subjects does fit within $\pm 17\%$ of the mean. If testing on 20 subjects does not bring the 95% CI within $\pm 17\%$ of the mean the whole test must be rejected. In practice, use of more than 10 subjects would be necessary only if the coefficient of variation ($CV = s/m$) is greater than 24%, and testing on 20 subjects would only fail if the CV was greater than 37%.

Statistical analysis of the SPF test data submitted to the TGA over recent years in support of SPF claims made for a large range of sunscreen products has shown that the data typically exhibit a relative standard deviation (RSD) or coefficient of variation (CV) in the range 5–20%. Only rarely is the CV less than 5% or greater than 20%. Thus, in the majority of cases, testing on 10 subjects would yield a 95% CI well within the $\pm 17\%$ limits and testing on additional subjects would not be required.

Subsequent retesting of a sunscreen is likely to yield a mean SPF anywhere within the 95% CI from the original testing of the product or even a few SPF units beyond either end of that 95% CI. Consequently, if the original test result was close to the lower limit for a particular SPF claim allowed by the Standard, the retest result could be lower than that lower limit and appear to cast doubt on the validity of the labelled SPF claim. However, it would be necessary to retest the product several times and obtain consistently low mean results before any conclusion could be drawn about the labelled SPF being unjustified.

6. Changes to sunscreens

Details of the requirements and procedures for making changes to the ARTG record of listed therapeutic goods are provided in the ELF User Guide.

6.1 Changes to active ingredients

The addition to or deletion of an active ingredient to a product or a change to the quantity of such an ingredient creates a new therapeutic good requiring an application to be made for a new entry in the ARTG (see subsections 16(1) and 16(1A) of the Act and regulation 11 of the Regulations). If successful, a new AUST L or AUST R number will be assigned to the new product.

6.2 Changes to excipients

The identities of excipients in a sunscreen product and the quantities of 'restricted ingredients' are required to be included in the ARTG record for the product.

Deletion or addition of excipients in a therapeutic sunscreen (other than the permanent removal or addition of a fragrance or colouring agent) creates a new therapeutic good requiring an application to be made for listing or registration in the ARTG as a new product. If successful, a new AUST L or AUST R number will be assigned to the new product.

If the excipient to be added or removed is a fragrance or colouring then, notwithstanding that a new therapeutic good is created, the new product can retain the same AUST L or AUST R number under the *Therapeutic Goods (Groups) Order No. 1 of 2001* (the Grouping Order) provided the new formulation is intended to replace the existing formulation. However, an electronic application must be submitted to change the formulation recorded in the ARTG

Quantities of excipients other than restricted excipients are not required to be included in the ARTG record for listed sunscreens.

Where a change is to be made to the quantity of a restricted excipient and grouping applies in accordance with the Grouping Order subsection 5.1(a)(i) and (ii) and (b) an electronic application must be lodged to change the formulation details recorded in the ARTG. When grouping does not apply, such a change will require a new product application and a new AUST L or AUST R number.

Sponsors should recognise that the SPF and other physical properties of a sunscreen are affected not only by the active ingredients, but also by the base. Therefore, qualitative or quantitative changes in the excipients may adversely affect the SPF. Testing of a changed formulation to confirm its SPF or stability may be required if the changes are likely to affect the emulsion properties or the adhesion of the product to the skin in a way that could alter its sun protection properties.

6.3 Other changes

Changes to the ARTG details of a sunscreen product must be approved by or notified to the TGA (using the ELF system in the case of a listed sunscreen). Whether or not grouping applies, a change to the product name requires approval.

7. Stability testing

7.1 Stability test requirements

Therapeutic sunscreens marketed in Australia must be labelled with an 'expiry' or 'use by' date. That date must be supported by experimental data that support the shelf life of the sunscreen product in the container intended for marketing (or at least a container made of the same materials and with similar shape, size and wall thickness to that of the market container) under the recommended storage conditions (that is, 'Store below 25°C' for product to be stored in air-conditioned premises or 'Store below 30°C' for product to be stored at room temperature). The data must substantiate the physical, chemical and microbiological stability of the product for at least the claimed shelf life.

Sponsors of all therapeutic sunscreen products are expected to have performed stability testing on each product to at least the standard set out in these Guidelines. The claimed shelf life and storage conditions for each product should be derived from the results of the stability testing on that product. Generation of adequate stability data to support the assigned shelf life for a therapeutic sunscreen is the responsibility of the sponsor.

While the stability data supporting the shelf life of a sunscreen product are not required to be submitted to the TGA at the time of listing, they may be requested for review by the TGA at any time. Sponsors should, therefore, ensure that the data are available in a form suitable for submission to the TGA if and when requested.

Stability testing guidelines for sunscreens, *Guidelines for Stability Testing of Sunscreens April 1994*, were developed by the Australian industry peak bodies and accepted by the TGA. They are now incorporated below with some minor amendments to improve clarity and consistency with the stability guidelines for medicines adopted by the TGA (see ARGOM chapter on Quality). This section (7) now supersedes the *Guidelines for Stability Testing of Sunscreens April 1994*.

7.2 Establishing stability before listing or registering

Prior to listing and market launch, the shelf life must be established with real time testing for the whole of the required shelf life or with adequate certainty using accelerated testing (that is, 6-9 months at 10°C or 15°C above the stated maximum storage temperature – see [Table 2](#)) or justified on the basis of supporting stability data for a closely related formulation.

Pre-listing or pre-registration stability testing should be carried out using at least two batches of the formulation intended for marketing manufactured in a manner that closely mirrors the production-scale manufacturing process. A formulation very similar, but not identical, to that intended for marketing formulation may be used provided any differences are very minor and unlikely to affect the physical, chemical or microbiological stability or in-use performance of the product.

The batches tested in stability studies may be pilot-scale but should have been manufactured in a manner sufficiently similar to that of commercial production scale batches that they adequately reflect the properties of the product intended for the market.

7.3 Confirming stability and shelf life

If the shelf life assigned at the time of listing is based on data generated using pilot-scale batches and accelerated studies, the shelf life should subsequently be confirmed by real time studies covering the whole of that shelf life using at least two production-scale batches stored at the

maximum recommended storage temperature. These production scale batches should be tested initially at manufacture and then annually until the end of the shelf life.

7.4 Stability protocol requirements

Physical testing should include at least the following quality parameters: appearance, emulsion stability, absence of crystallisation, odour, viscosity, compatibility with the immediate container and the condition of the inside surface of the container in contact with the product.

Chemical stability testing should include: pH (if water is the continuous phase) and the content of each of the active ingredients assayed using a validated, stability-indicating analytical procedure (for example, HPLC). Active ingredients should remain within the limits 90% to 120% of label claim.

Overages of active ingredients in the formulation are acceptable provided they do not result in concentrations exceeding the limits provided in [subsection 9.1](#).

For water-containing sunscreens, microbiological stability should be confirmed by means of preservative efficacy testing at the start and end of accelerated stability testing and at the end of the shelf life during the subsequent real-time stability testing.

The temperature of storage used in stability studies should be controlled, monitored and logged to ensure the integrity of the results.

The frequency of testing for accelerated studies should be adequate to allow regression and statistical analysis to support extrapolation of the data. Appropriate testing time points would typically be 0, (1 or 2), (3 or 4), (5 or 6), 9 and 12 months (followed by 24 and 30 months, depending on the shelf life required to be justified).

The accelerated stability data should only be extrapolated as in [subsection 7.5](#) if their accuracy, reproducibility and fit around a straight time-line are adequate. A minimum of 4 time-points with a reasonably even spread over the time period concerned are needed for meaningful line-fitting and 95% confidence interval calculations.

7.5 Shelf life determination

For a product exhibiting no discernible changes or trends, a 2-year shelf life for storage conditions of 'store below 30°C' (that is, storage at room temperature in Australia) may be supported by stability data covering 6 months storage at 40°C, and a 3-year shelf life for storage conditions of 'store below 30°C' may be supported by data covering either 9 months at 40°C or 6 months at 45°C.

A shelf life of greater than 3 years should be supported by data from storage at 40°C covering at least half of the shelf life (for example, 2.5 years accelerated data would be required to support a 5-year shelf life).

For a product exhibiting no discernible changes or trends, a 2-year shelf life for storage conditions of 'store below 25°C' (that is, the product should be stored in air-conditioned premises) may be supported by stability data covering 6 months storage at 35°C, and a 3-year shelf life for storage conditions of 'store below 25°C' may be supported by data covering either 9 months at 35°C or 6 months at 40°C.

A shelf life of greater than 3 years should be supported by data from storage at 35°C covering at least half of the shelf life.

Generally, the maximum shelf life permitted for any therapeutic good is 5 years.

Table 2. Shelf life Prediction from short-term testing at elevated temperatures

Temperature above labelled storage conditions	Time period	Test time points	Possible shelf life prediction
+10°C	6 months	0, (1 or 2), (3 or 4), 6 months	2 years
+10°C	9 months	0, (1 or 2), (3 or 4), (5 or 6), 9 months	3 years
+15°C	6 months	0, (1 or 2), (3 or 4), 6 months	3 years

8. Manufacture and quality control

8.1 Manufacture

In accordance with Part 3-3 of the Act and Part 4 of the Regulations, manufacturers of 'listed' or 'registered' therapeutic goods destined for the Australian market or for export from Australia to an overseas market must be licensed or approved by the TGA and must also comply with manufacturing principles as determined by the Minister. These manufacturing principles are set out in the TGA's requirements for good manufacturing practice (GMP).

Where an Australian manufacturer is nominated in an application to list or register a sunscreen, that manufacturer must be licensed by the TGA to manufacture such products and must comply with the TGA's GMP requirements as relevant to sunscreens. Where the product is imported, each nominated overseas manufacturer is expected to comply with a code of GMP equivalent to that applying to Australian manufacturers and the TGA must have issued a GMP clearance for that manufacturer.

Further information on licensing or approval of manufacturers is available on the TGA Internet site.

8.2 Quality control

It is the responsibility of the manufacturer of the finished therapeutic product to ensure the quality of the product and also that of the active ingredients and excipients used in its manufacture.

Section 40(4)(a)(i) of the Act requires the manufacturer to ensure that the product complies with any standard applicable to the product.

In accordance with the definitions in section 3 of the Act, the default standards applying to therapeutic goods registered or listed in the ARTG are the *British Pharmacopoeia (BP)*, *European Pharmacopoeia (Ph Eur)* and *United States Pharmacopoeia-National Formulary (USP-NF)*. Other standards in addition to the pharmacopoeia that apply to sunscreens include relevant Therapeutic Goods Orders made under section 10 of the Act (for example, TGO No. 69 for labelling and TGO No. 77 for microbiological quality).

This means that if there is a monograph for a finished product in one (or more) of the BP, Ph Eur and USP-NF, then the sponsor must ensure that the product will comply with the specifications in that monograph (or at least one of those monographs).

Sunscreen finished products are not the subject of a monograph in the BP, Ph Eur or USP-NF and therefore must be controlled, instead, by appropriate "in house" quality control specifications that control and ensure their identity and relevant physical, chemical and microbiological properties. Test methods must be validated, as appropriate.

Therapeutic sunscreen products in all categories are required to comply with the relevant requirements of sections 8 and 9 of *Therapeutic Goods Order No. 77 Microbiological Standards for Medicines*.

Sunscreen manufacturers are responsible to ensure that batches of product released to the market comply with their specifications.

Subsection 13(5) of the Act requires that, when a finished product is not the subject of a monograph in the BP, Ph Eur or USP-NF, but any of its ingredients is the subject of a monograph in one or more of those pharmacopoeia, that ingredient must comply with at least one of the monographs concerned, unless the Minister has issued an order determining that this

requirement does not apply to the goods concerned. Note that, as at the date these Guidelines were published, no such order exempting sunscreens had been issued by the Minister.

Many of the organic chemicals used as active ingredients in sunscreens are the subjects of monographs in the USP-NF (generally under their International Non-proprietary Names [INNs]) while the inorganic substances titanium dioxide and zinc oxide are the subject of monographs in each of the BP, Ph Eur and USP-NF.

Many of the excipients (including solvents) used in sunscreen products are the subjects of monographs in one or more of the BP, Ph Eur and USP-NF.

Ingredients that are not the subject of a monograph in the BP, Ph Eur or USP-NF must be controlled by appropriate quality control specifications that control and ensure their identity, relevant physical and chemical properties, and purity. Test methods must be validated, as appropriate.

9. Permitted ingredients

9.1 Sunscreening agents permitted as active ingredients

The only sunscreening active ingredients permitted in therapeutic sunscreens are those included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#). Sponsors should consult the Determination for restrictions applying to each ingredient. The labelling must include the Australian Approved Name (AAN) for each active sunscreening ingredient.

Sponsors wanting to market a therapeutic sunscreen product containing a sunscreening active ingredient which is not on the list of permitted substances in therapeutic sunscreens must submit data to establish the safety and efficacy of the ingredient under its proposed conditions of use (see [section 10](#)).

9.2 Excipients

Only those excipients approved by the TGA for use in topical medicines may be used in therapeutic sunscreens. In some cases the TGA has set limits on the amounts of such ingredients and sunscreens must comply with those limits. For more information on the substances that may be used in Listed medicines supplied in Australia and the restrictions applying to their use, please consult the [Therapeutic Goods \(Permissible Ingredients\) Determination](#).

10. New ingredients

The information below should be read in conjunction with the guidelines for the approval of new substances given in the ARGOM section on applications for new substances.

10.1 Naming of new substances

A 'Proposed Name for a Chemical Substance Used in a Therapeutic Good' application form needs to be submitted to the TGA to enable the establishment of an identity and an appropriate 'Australian Approved Name' (AAN) for the substance. Information on the naming of substances and applying for an AAN can be found on the TGA Internet site.

There are no fees for the AAN applications and approval of ingredient names (at the time of publication). However, fees will apply to the evaluation of the data for the new substance and for the listing or registration of the product as specified in the summary of fees and charges available from the TGA Internet site.

10.2 New active ingredients

Sponsors wishing to market a product containing an active ingredient which is not on the [Therapeutic Goods \(Permissible Ingredients\) Determination](#) must submit data to establish the safety and efficacy of the ingredient under its proposed conditions of use.

10.3 Safety data requirements for new actives

Table 3 below lists the topics of relevant guidelines for the types of safety data that are usually required for a new sunscreen active ingredient or new excipient (see also [new excipient section](#)).

The list of relevant European Union (EU) 'non-clinical' guidelines that have been adopted by the TGA can be found on the TGA Internet site. They are not detailed in this Sunscreen Guideline document because there are frequent changes and sponsors should, therefore, consult the current list on the TGA Internet site. These EU guidelines relate to sunscreens because suncreening products (as defined earlier in this Guideline) are treated as therapeutic goods in Australia.

The intention in listing relevant guideline topics is not to set absolute requirements but to assist sponsors in assessing the type and depth of information needed to support an application with the understanding that primary sunscreen products are treated as therapeutic goods in Australia as opposed to 'cosmetics' in Europe.

If a particular guideline is not applicable or other data are available that adequately address the same criteria, alternative approaches based on adequate scientific justification will be considered by the TGA during evaluation of the application, or pre-submission. Relevant human studies are acceptable in the assessment of potential skin irritation and sensitisation using the repeat 'insult patch test' or other relevant validated tests.

Table 3. Safety data normally required for a new sunscreen active ingredient or excipient

Requirements
<p>Photostability</p> <ul style="list-style-type: none"> • UV absorption spectra
<p>Acute toxicity (oral and dermal; animal data)</p>
<p>Local tolerance:</p> <ul style="list-style-type: none"> • skin irritation (animal data and/or human repeat insult patch test - HRIPT) • phototoxicity (animal and/or human data) • eye irritation (animal <i>in vivo</i> or <i>in vitro</i> test)
<p>Allergenicity:</p> <ul style="list-style-type: none"> • skin sensitisation (animal data and/or HRIPT) • photosensitisation (animal and/or human data – HRIPT)
<p>Toxicokinetics:</p> <ul style="list-style-type: none"> • oral and dermal bioavailability • ADME (absorption, distribution, metabolism and excretion) studies <p>Note: An <i>in vivo</i> determination of dermal and oral absorption is needed to establish systemic exposure via both routes and to enable interpretation of the toxicity studies.</p>
<p>Repeat dose toxicity (oral and dermal) at least 3 months</p>
<p>Genotoxicity:</p> <ul style="list-style-type: none"> • <i>In vitro</i> bacterial (Ames) assay • <i>In vitro</i> mammalian cell line assay • <i>In vitro</i> and <i>in vivo</i> chromosome aberration assay <p>Note: Genotoxicity <i>in vitro</i> testing in bacterial, mammalian cell lines, and chromosome aberration assay should include photomutagenicity arm.</p>
<p>Reproductive toxicity</p> <p>Notes:</p> <ol style="list-style-type: none"> For assessment of developmental and fertility effects. Endocrine disruption potential needs to be addressed. This could be examined during the repeat-dose toxicity and/or reproductive toxicity studies.
<p>Carcinogenicity</p> <p>Note: <i>In vivo</i> carcinogenicity and photocarcinogenicity bioassays or a justification for not providing these studies (see below).</p>

Requirements

Interaction potential

Note: Since sunscreen formulations usually contain more than one active ingredient, data on the potential for interaction of the new substance with other UV filters will usually need to be provided.

More details on different safety tests for chemicals for pharmaceutical use can be found at the Internet sites of the following organisations:

- The European Medicines Agency (EMA)
- The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
- The Organisation for Economic Co-operation and Development Guidelines for the testing of chemicals (section 4: Health Effects).

More details on different safety tests for chemicals that are for cosmetic sunscreens used in Europe can be found in The SCCS's *Note for Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 7th Revision 14 December 2010 SCCS/1416/11*.

10.4 Justification for not providing particular studies

In circumstances where particular tests specified in the table above (TGA-adopted European guidelines) are not feasible or appropriate, sponsors should submit a justification for not including these tests in the dossier which is based on sound scientific argument.

In the case of *in vivo* carcinogenicity bioassays, a justification for not including long-term studies could be based around the following issues as they apply to the ingredients or product:

- the expected pattern of use
- results of *in vitro* and *in vivo* genotoxicity assays
- lack of similarity to other molecules with known carcinogenic activity
- low persistence in the skin
- low or no *in vivo* dermal absorption
- lack of photosensitisation or phototoxic potential
- proven photostability
- lack of possible adverse effects on the skin (change to epidermis/dermis)
- length of submitted *in vivo* repeat dose toxicity studies
- lack of adverse activity in local tolerance studies (skin irritation and skin sensitisation).

10.5 Related studies

Other studies that are not currently referenced in EU guidelines may be useful in supporting particular applications. Reference to these studies is included only as a guide. They will not be relevant in all cases, nor should they be seen as a complete list of relevant studies. Examples

include the following studies and referenced Internet sites which may be useful in providing information on the potential of a substance to cause tumours in people:

- studies using appropriate and validated transgenic animal models to test exposure to the substance; information on transgenic models can be found on the OECD or European Centre for the Validation of Alternative Methods (ECVAM) internet sites
- *in vitro* human dermal cell cultures exposed to the substance
- *in vitro* human dermal tumour cell cultures exposed to the substance.

Additionally, the following references may be useful when investigating the use of ingredients with a potential for skin corrosion/irritation:

Non-animal testing strategies for assessment of the skin corrosion and skin irritation potential of ingredients and finished products; M K Robinson *et al*; *Food and Chemical Toxicology*, 40(5), pp 573–592, 2002.

OECD/OCDE, test number: 431 (April 2004) OECD Guidelines for the testing of chemicals; *in vitro* skin corrosion: human skin model test.

10.6 UV spectral characteristics

In addition to the requirements stated in the ARGOM chapter on Quality, sponsors should provide data to establish the UV absorption range of the new substance enabling confirmation of UVA/UVB absorption profile. Data addressing the potential for physical interaction with other commonly used sunscreens should also be provided.

10.7 New excipients

Where a therapeutic sunscreen contains an excipient ingredient which is not in any product currently included in the ARTG for supply in Australia, the excipient must be assessed for use by the TGA. The following information is required as a minimum:

- naming and identification of an ingredient name as an Australian Approved Name (AAN) - this may be finalised while the safety data are being evaluated
- identification of the excipient as a substance included in the Personal Care Products Council International Cosmetic Ingredient Handbook (Dictionary) (the page number and reference should be quoted). There is also an on line subscription service known as wINCI that provides an electronic version of INCI monographs
- assurance that it does not appear in Annex II to the EEC Directive 76/768 list of substances which must not form part of the composition of cosmetic products
- documentary evidence that the excipient has been approved by the appropriate regulatory agency in Sweden, Canada, USA, UK or the Netherlands; or evidence that there have been marketplace sales of comparable products containing the excipient in one of those five countries for at least two years
- acute oral toxicity study
- skin irritation study – animal or alternative study such as HRIPT
- sensitisation study – skin, animal and/or (preferably) HRIPT.

The following additional studies may be requested in individual cases where concern becomes evident at the time of evaluation:

- *in vitro* mutagenicity (for example, an Ames test or other validated alternative test)
- eye irritation study (animal *in vivo* or *in vitro* test)
- *in vitro* or *in vivo* percutaneous absorption test.

All of the above information should be submitted for safety evaluation of the new substance for use in therapeutic sunscreens. Additional studies may be requested in individual cases where concerns become evident at the time of evaluation.

Once the substance is approved (and an AAN has been assigned), it will thereafter be able to be used in other therapeutic sunscreens without the need for further evaluation, but only up to the safety limit that has been approved. Any increase in that safety limit requires submission and approval of a formal application. The substance may also be able to be used in other topically applied medicines (subject to any conditions or limitations) without the need for further evaluation. However, additional data may be required if the characteristics of the substance are considered to change in different formulations or patterns of use in new products or if the substance is to be used outside the stated conditions and/or limitations.

Alternative sources of data on the safety of the excipient will be considered. For example, if the excipient has been assessed by NICNAS or by the US Cosmetic Ingredient Review (CIR) group, the review document may be sufficient in itself. Copies of CIR reviews are available from the Internet site www.cir-safety.org. Copies of NICNAS reviews may be available from the supplier of the excipient.

Required study reports should be submitted in full as well as in summary form (as described in the ARGOM Chapter on Applications). Simple summaries or synopses of studies without the full study reports are not acceptable for assessment.

All studies submitted must be in English or be provided with an accompanying English translation.

The EU guidelines that have been adopted by the TGA for therapeutic goods should be referred to for detailed guidance on the appropriate tests and how they should be conducted. Studies can be rejected as 'invalid' if appropriate and scientifically robust methodology is not followed (for example, low animal numbers, lack of or inappropriate controls).

Proper and comprehensive identification of the substance(s) being tested in all studies is required; laboratory codes, trade names and synonyms must be linked to the substance identified in the new substance application form for the AAN.

Concentrations of the new substance used in all studies must be clearly and unambiguously stated. The intended final concentration of the new excipient in therapeutic goods to be marketed in Australia must be stated; this allows a comparison to establish that the submitted studies were conducted at concentrations to support the proposed levels to be used in marketed goods.

Where a substance is present in the product with the listed purpose of excipient, no therapeutic claims can be listed against its presence.

If a substance with a known active function is classified as an excipient, evidence of excipient function and purpose will be required.

Furthermore, a justification must be provided for the inclusion of that substance as an excipient at a concentration in excess of the concentration typically used for its role as an active ingredient. If that concentration is above the approved safety limit for use in listed products, then the product with that concentration of the substance must be registered.

The concentrations of excipients with a known active function in the formulation must be below the concentration associated with its established active function. If the excipient concentration is above the minimum threshold of active function then the substance should not be classified as an excipient in the product but, instead, should be classified as an active substance in the product and it will be evaluated as an active component of the product. In this case a therapeutic sunscreen containing that substance must be listed or registered on the ARTG.

11. Glossary of terms and abbreviations

Note: Where relevant, references to particular definitions are provided in brackets (...)

ACCC means the Australian Competition and Consumer Commission.

Active ingredient (in relation to a sunscreen) means an active substance included in a sunscreen to protect the skin from ultraviolet (UV) radiation. It is an ingredient in a therapeutic good's formulation that is responsible for its physiological or pharmacological action (see regulation 2 of the Regulations).

Antimicrobial preservative means an ingredient added to a product to inhibit the growth of micro-organisms in the product. (TGO 69).

ARGOM means the Australian regulatory guidelines for OTC medicines

ARTG means the Australian Register of Therapeutic Goods

AS/NZS 2604:2012 means the Australian and New Zealand Standard for Sunscreen Products (2012 edition)

Australian Approved Name (AAN) – The approved name applied to a therapeutic substance, as outlined in the *TGA Approved Terminology for Medicines*, which includes: Approved Biological Substance Names (ABNs); Approved Chemical Substance Names; Approved Herbal Names (AHNs); and Approved Herbal Substances (AHSs).

Batch number means a number, or a combination of numerals, symbols or letters, which is given by a manufacturer to a batch of goods, to uniquely identify that batch and from which it is possible to trace that batch through all stages of manufacture and distribution (TGO 69).

Batch number prefix means the prefix which precedes the batch number and clearly indicates that the number is the batch number. Examples of acceptable batch number prefixes include 'Batch Number', 'BATCH NUMBER', 'Batch No.', 'BATCH NO.', 'Batch', 'BATCH', 'B', '(B)', 'B/N', 'Lot Number', 'LOT NUMBER', 'Lot No.', 'LOT NO.', 'Lot' or 'LOT'; or words or symbols to this effect.

Broad spectrum product means a sunscreen product which has been shown, using the in vitro test method defined in *AS/NZS 2604:2012* to provide protection from the sun's terrestrial UVA and UVB rays (*AS/NZS 2604:2012*).

Category description means the designation of the level of protection given by a grouping of label sun protection factors (*AS/NZS 2604:2012*).

Container means an article (for example, bottle, jar, tube, sachet) that immediately covers the goods, and includes an ampoule, blister pack, bottle, sachet, dial dispenser pack, strip pack, syringe, tube, vial, wrapper or other similar article, but does not include an article intended for ingestion (TGO 69).

Cosmetic (For the full definition, see [subsection 2.2.](#))

Cosmetic sunscreen product means a product containing a sunscreensing ingredient that is regulated as a cosmetic by the *Industrial Chemicals (Notification and Assessment) Act 1989* and by the Cosmetics Standard and is not a therapeutic good (see [subsection 2.2.](#)).

Excipient ingredient (in relation to a sunscreen) means an ingredient of a sunscreen other than an active ingredient. Excipient ingredients may have multiple uses such as fragrance, preservative and/or solvent.

Excipient mix is a Proprietary Ingredient formulation comprised of a mixture of excipient ingredients that may be used in a therapeutic good. Examples include emulsifiers and anti-oxidants.

Excluded sunscreen means a sunscreen product that is not regulated under the *Therapeutic Goods Act 1989* (see the *Therapeutic Goods (Excluded Goods) Order No. 1 of 2011*).

Exempt sunscreen means a sunscreen product that is regulated under the Act but is not required to be registered or listed in the ARTG (see Item 4(g) of Schedule 5 of the Regulations).

Expiry date means the date (month and year) after which the goods should not be used, being a date not more than five years after the date of manufacture (TGO 69).

Expiry date prefix means the prefix which precedes the expiry date, and clearly indicates that the following information is the expiry date. Examples of acceptable prefixes include 'Expiry Date', 'EXPIRY DATE', 'Expiry', 'EXPIRY', 'Expires', 'EXPIRES', 'Exp. Date', 'EXP. DATE', 'Use before', 'USE BEFORE', 'Use By', 'USE BY', 'Exp', or 'EXP' but terms such as 'Best by' or words to this effect are not acceptable (TGO 69).

Fragrance (or perfume) means a substance whose primary purpose is to alter the smell of a therapeutic good.

Ingredients of human or animal origin are those derived directly from a human or animal source. They are also listed in the Regulations.

INCI means International Nomenclature Cosmetic Ingredient.

INN means International Non-proprietary Name.

Label means a display of printed information upon, or securely affixed to, the container and any primary pack containing the goods (TGO 69).

Label Sun Protection Factor (SPF) means the SPF indicated on the label.

Letter height means the height of upper case (capital) letters or lower case letters having an ascender or descender, unless otherwise stated (TGO 69).

Listing or registration number means the combination of numbers, symbols and letters assigned to the goods by the TGA under section 27 of the Act (TGO 69).

Medicine means a therapeutic good that is represented to achieve, or is likely to achieve, its principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal (see subsection 3(1) of the Act).

Minimum Erythema Dose (MED) means the lowest dose of ultraviolet radiation that produces the first perceivable unambiguous erythema with defined borders appearing over most of the field of UV exposure 16-24 hours after UV exposure (*AS/NZS 2604:2012*).

New substance is an ingredient (chemical, herbal or biological) that is currently not used in a medicine for supply in Australia, or is proposed for a new route of administration to the previous use of the ingredient. This ingredient may or may not have an Australian Approved Name.

NICNAS means the National Industrial Chemicals Notification and Assessment Scheme.

Primary pack, in relation to therapeutic goods, means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers (see subsection 3(1) of the Act).

Primary sunscreen product means a product which is represented as being primarily to protect the skin from ultraviolet radiation (*AS/NZS 2604:2012*).

Principal or main label means (a) where there are two or more labels or two or more portions of a single label — that label or portion of the label where the product name is more or most conspicuously shown; or (b) where the product name is equally conspicuous on two or more labels or portions of a label — each such label or portion (TGO 69).

RASML means Required Advisory Statements for Medicine Labels.

Secondary sunscreen product means a product that is represented as having a primary purpose other than sun protection whilst providing some protection of the skin from ultraviolet radiation (*AS/NZS 2604:2012*).

Sun Protection Factor (SPF) means the arithmetic mean of all valid individual SPF values obtained from all subjects in the test (*AS/NZS 2604:2012*). See also, Minimum Erythema Dose (MED).

SUSMP means the *Standard for the Uniform Scheduling of Medicines and Poisons* (previously called the *Standard for the Uniform Scheduling of Drugs and Poisons* [SUSDP]).

TGO 69 – see the Labelling Order.

The Act means the *Therapeutic Goods Act 1989*.

The Labelling Order means Therapeutic Goods Order (TGO) No. 69 – **General requirements for labels for medicines** (or any subsequent order amending or replacing TGO 69).

The Regulations means the *Therapeutic Goods Regulations 1990*.

Therapeutic good includes a good that is represented in any way to be, or that is, whether because of the way in which the good is presented or for any other reason, likely to be taken to be for therapeutic use or for use as an ingredient or component in the manufacture of therapeutic goods (subsection 3(1) of the Act).

Therapeutic sunscreen product means a primary or secondary sunscreen product that meets the definition of a therapeutic good rather than the definition of a cosmetic (see [subsection 2.1](#)).

Therapeutic use means use in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals, or influencing, inhibiting or modifying a physiological process in persons or animals (subsection 3(1) of the Act).

Topical – for sunscreen use means applied to a certain area of the skin for a localised effect.

TSEs means transmissible spongiform encephalopathies.

Ultraviolet radiation (UV) means the terrestrial solar ultraviolet radiation in the range 290–400 nm. Ultraviolet radiation A (UVA) is the terrestrial solar ultraviolet radiation in the range 320–400 nm and ultraviolet radiation B (UVB) is the terrestrial solar ultraviolet radiation in the range 290–320 nm.

UV filter, for the purposes of these Guidelines, means a substance that is exclusively or mainly intended to protect the skin against certain UV radiation by absorption, reflection or scattering of UV radiation.

Water resistant product, for the purposes of these Guidelines, means a sunscreen product which has been shown after designated periods of water immersion, using in vivo Sun Protection Factor test methods to provide protection against certain of the sun's UV rays (*AS/NZS 2604:2012*).

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Appendix 1: Labelling checklist

Note: This check list is not mandatory. It is designed to assist sponsors in designing their labels for therapeutic sunscreens in accordance with the TGA's requirements. It is not exhaustive. Sponsors are reminded that they are responsible for ensuring that their labelling complies with all of the relevant legislative requirements. These labelling requirements do not apply to those secondary sunscreen products categorised as cosmetics.

General	
Is/are the label (or labels):	
• printed on or firmly and securely attached to the container?	
• printed on or firmly and securely attached to the container?	
• unlikely to become detached or defaced or illegible during use?	
• positioned so that it will not be damaged or removed when the container is opened?	
• not obscured by any other label or object?	
• printed in English?	
• printed in lettering that is clear, distinct and legible, and the height of letters with ascenders or descenders is not less than 1.5 mm (except for the AUST L number, which may be 1 mm high)?	
As prohibited by the Therapeutic Goods Advertising Code section 4, is the labelling free from claims, statements or pictures that:	
• are likely to arouse unwarranted and unrealistic expectations of the product's effectiveness?	
• are false, unbalanced, unsubstantiated, misleading or likely to mislead the user?	
• abuse the trust or exploit the lack of knowledge of consumers or contain language that could bring about fear or distress?	
• encourage or are likely to encourage inappropriate use?	
• indicate or imply that the product is infallible, unfailing, magical, miraculous, or effective in all cases?	
• indicate or imply that the product cannot cause harm?	
• indicate or imply that other competitor products are harmful or ineffectual?	

General	
<ul style="list-style-type: none"> indicate or imply that the product is endorsed by any government agency, hospital or other facility providing healthcare services, individual healthcare professional or group of healthcare professionals? 	

Labelling of immediate container and primary pack	
Does the main label contain the following information:	
<ul style="list-style-type: none"> the product name? Note: The use of the term 'sunblock' is not acceptable. 	
<ul style="list-style-type: none"> the name of the dose form, (for example, 'cream', 'lotion', 'stick')? 	
<ul style="list-style-type: none"> the sun protection factor (SPF) of the product preceded by the expression 'Sun Protection Factor' or 'SPF'? Note: A category description may also be given, for example, 'low/moderate or medium/high/very high protection'. 	
<ul style="list-style-type: none"> the fact that the product provides 'broad spectrum' protection from UV light (in letters no larger than the SPF)? 	
<ul style="list-style-type: none"> [if relevant] the water resistance of the product (in hours or minutes)? Note: 'sweat proof' and 'waterproof' are not acceptable claims. 	
<ul style="list-style-type: none"> the contents of the container (volume in mL or weight in g)? 	
<ul style="list-style-type: none"> the ARTG listing or registration number preceded by 'AUST L' or 'AUST R'? Note: If the container is packed in an outer carton the listing number must be on the main label of that carton and may also be but is not required to be on the container. 	
Is the following information included either on the main label or on a rear or side panel:	
<ul style="list-style-type: none"> the names of all active ingredients expressed using Australian Approved Names AND the proportions of those ingredients either expressed as a percentage in terms of w/w or w/v or expressed as a weight in a stated weight or volume of the product using metric units of measurement (for example, mg/g or mg/mL)? 	
Is the following information included somewhere on the label(s) or container:	
<ul style="list-style-type: none"> the batch or lot number of the product preceded by the batch number prefix using one of the formats specified in TGO 69 s2(1)? 	
<ul style="list-style-type: none"> the recommended storage conditions? 	

Labelling of immediate container and primary pack	
<ul style="list-style-type: none"> • if relevant, the presence in the product of benzoates, hydroxybenzoate ester(s), sulfites, or any other antimicrobial preservative(s), sorbates, ethanol (if >3% v/v), peanuts or peanut products (for example, peanut/arachis oil), or any other ingredient included in Schedule 1 of TGO 69? 	
<ul style="list-style-type: none"> • required warning statements? <p>Note: The label for a primary sunscreen should include warning statements to the effect that: prolonged exposure to the sun should be avoided, it is important to wear protective clothing, hats and eyewear when exposed to the sun, and the product should be kept out of the eyes.</p>	
Is the following information included somewhere on the label(s):	
<ul style="list-style-type: none"> • a statement of the purpose or purposes of the product? <p>Notes:</p> <ol style="list-style-type: none"> 1. The purpose of the product is generally made obvious by it being called a 'sunscreen'. 2. If a sunscreen has an SPF of 30 or higher and it provides broad spectrum protection the label is permitted to include claims that the product may assist in preventing some skin cancers or may reduce the risk of some skin cancers provided the label also highlights the need for avoidance of prolonged exposure to the sun and the importance of wearing protective clothing, hats and eyewear. 3. Any broad spectrum sunscreen may also carry a claim that it can aid in the prevention of premature skin ageing. 4. Sunscreens may also carry justified non-therapeutic claims. 	
<ul style="list-style-type: none"> • directions for use of the product? <p>Note: The directions for use for a primary sunscreen should include statements to the effect that the product should be applied in generous amounts over all of the exposed areas 15 to 20 minutes before sun exposure, and again after swimming or towelling. An indication should also be given of how frequently the product should be re-applied during prolonged exposure to the sun.</p>	
<ul style="list-style-type: none"> • the name and address of the sponsor or Australian supplier of the product? <p>Note: An Australian contact telephone number may also be included.</p>	

Special requirements – small containers

If the immediate container has a capacity of 20mL or less AND the container is enclosed in a primary pack (for example, carton):

- | | |
|--|--|
| <ul style="list-style-type: none"> • Does the primary pack labelling include all of the information listed above? | |
| <ul style="list-style-type: none"> • Does the labelling on the container include at least the following information: <ul style="list-style-type: none"> – the product name (in full or in abbreviated form if there is insufficient room for the full name)? – the name of the dosage form? – the quantity of product in the container? – the batch number preceded by the batch number prefix? – the names and quantities of all the active ingredients? <p>Note: If there is insufficient room, the information regarding active ingredients is only required on the label of the primary pack.</p> | |

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Office of Medicines Authorisation	10/10/2012
V1.1	<p>Updated to reflect the changes to the <i>Therapeutic Goods Regulations 1990</i> by removing references to sunscreens with a claimed SPF of <4 that contain certain human or animal derived ingredients</p> <p>Updated the relevant sections by including reference to the recently made Therapeutic Goods (Permissible Ingredients) Determination No.1 of 2015.</p> <p>Updated the table listing the permitted active ingredients by adding the newly approved sunscreen active Tris-biphenyl triazine</p>	Complementary & OTC Medicines Branch – OTC Medicines Evaluation	22/01/2016
V1.2	Updated to remove Table 3 – Permitted active ingredients for therapeutic sunscreens and replace with links to the Therapeutic Goods (Permissible Ingredients) Determination	Complementary and Over the Counter Medicines Branch	30/8/2019

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