Australian Government
Department of Health
Therapeutic Goods Administration

Australian regulatory guidelines for sunscreens

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TGA Health Safety Regulation

Contents

Part A – General information about the regulation of sunscreens

Introduction

The Australian Regulatory Guidelines for Sunscreens (ARGS; the Guidelines) describe the regulatory requirements and standards for sunscreens (and their ingredients) regulated as **therapeutic goods** in Australia by the Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act 1989* (the Act) as at the date of publication.

For the purpose of these Guidelines, sunscreens that are regulated as therapeutic goods under the Act are referred to as '**therapeutic sunscreens**'. Unless excluded, therapeutic sunscreens include:

- Primary sunscreens: Products that are used primarily for protection from UV radiation.
- Some secondary sunscreens: Products with a primary purpose other than sun protection, but which also contain sun screening agents.

Many secondary sunscreen products, such as cosmetic sunscreens, are not considered to be therapeutic goods and are 'excluded' from therapeutic goods legislation.

Sunscreen and insect repellent combination products

Therapeutic sunscreens that also make insect repellent claims must comply with all legislative requirements as for any other therapeutic sunscreen.

In addition, all insect repellents for human use must comply with any requirements of the Australian Pesticides and Veterinary Medicines Authority (APVMA). Refer to APVMA more information.

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

The Australian/New Zealand Sunscreen Standard

The Australian/New Zealand Sunscreen Standard (AS/NZS) 2604 Sunscreen products — Evaluation and classification [as referenced in the *Therapeutic Goods Regulations 1990* (the Regulations) and in the Therapeutic Goods (Excluded Goods) Determination 2018 (Excluded Goods Determination); herein referred to as the **Australian Sunscreen Standard**] details the procedures for testing the performance of all sunscreen products (including therapeutic sunscreens) in Australia. It also provides labelling requirements that need to be applied along with all other applicable legislation relating to labelling for therapeutic sunscreens.

The Australian Sunscreen Standard classifies sunscreens as primary or secondary sunscreen products and further describes them based on their performance e.g. SPF; broad spectrum [protects against the sun's ultraviolet A (UVA) and ultraviolet B (UVB) rays]; and water resistance claims. Table 1 provides the category descriptions based on the SPF for sunscreens. These categories and performance are reflected in the indications that therapeutic sunscreens can make (refer to the Indications permitted for use in listed therapeutic section).

Table 1. Sunscreen category descriptions based on SPF

SPF	SPF claim on label	Description/Level of protection
0-4	NA	NA
4-14	4, 6, 8,10	Low protection
15-29	15, 20, 25	Medium or moderate protection
30-59	30 ,40, 50	High protection
60 or higher	50+	Very high protection

Regulatory categories of sunscreens

In Australia, unless exempt, therapeutic sunscreens must be listed or registered in the Australian Register of Therapeutic Goods (ARTG) before they can legally be marketed in Australia (refer to Medicines and TGA classifications for more information on listed and registered therapeutic goods). Other sunscreens are **exempt** from therapeutic goods legislation or **excluded** from the requirement to be in the ARTG.

Sunscreens not required to be included in the ARTG

Excluded sunscreens

Many **secondary** sunscreen products are not considered to be therapeutic goods and are '**excluded**' from therapeutic goods legislation under the Excluded Goods Determination, for example: cosmetic sunscreens. Refer to table 2 for details of these product types.

Excluded products are not required to be included in the ARTG and are not required to comply with standards applicable to therapeutic goods. These products may fall within the definition of a '***cosmetic***' as defined in the Industrial Chemicals Act 2019 (refer to Glossary of terms and abbreviations).

For information on the regulatory requirements for these products refer to:

- The Australian Industrial Chemicals Introduction Scheme which is responsible for the manufacture and importation of industrial chemicals including ingredients used in cosmetic sunscreens.
- The Australian Competition and Consumer Commission which is responsible for product safety and labelling standards for consumer products including cosmetics.
- The Consumer Goods (Cosmetics) Information Standard 2020 which sets out the mandatory requirements applying to the labelling of all cosmetic products.

This category of sunscreen product will not be considered further in these Guidelines.

Exempt sunscreens

Item 8(g) of Schedule 5 of the Regulations 'exempts' certain therapeutic sunscreens from the requirement to be included in the ARTG – refer to table 2 for details of these product types

While 'exempt' therapeutic sunscreens do not need to be included in the ARTG, these products are considered to be therapeutic goods and therefore must comply with all relevant legislative requirements for therapeutic goods. These include relevant standards such as the most current Labelling Order (Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines) and Advertising Code.

This category of sunscreen product will not be considered further in these Guidelines.

Sunscreens required to be included in the ARTG

Sunscreens classified as therapeutic goods are, unless exempt, required to be included (listed or registered) in the ARTG before they can be marketed legally in Australia.

To supply a therapeutic good in Australia, you must have:

- your own ARTG entry for that therapeutic good; or
- retail arrangements with a sponsor who has an ARTG entry for that therapeutic good.

Listed therapeutic sunscreens

The majority of therapeutic sunscreen products fall under the listed medicines framework and are included in the ARTG in accordance with section 26A of the Act and Item 7 of Part 1 of Schedule 4 of the Regulations. More information about the requirements for listed therapeutic sunscreens can be found in Part B – Information for Listed therapeutic sunscreens.

Registered therapeutic sunscreens

Therapeutic sunscreens that are not exempt or not eligible to be listed in the ARTG require inclusion in the ARTG as registered therapeutic goods under section 25 of the Act. As such, these products must be evaluated for suitability as either over-the-counter (OTC) registered medicines or prescription medicines. Further information can be found in the Australian Regulatory Guidelines for OTC Medicines (ARGOM) or the Australian Regulatory Guidelines for Prescription Medicines, respectively.

Table 2 provides a summary of the current regulation for the various categories of sunscreens.

Table 2. Summary of the current regulation for the various categories of sunscreens

Sunscreen category	Required to be in ARTG?	Product type
Excluded sunscreens	**No** Excluded from therapeutic goods legislation under the Excluded Goods Determination.	Excluded sunscreens are **secondary** sunscreen products that are used, advertised or presented for supply in the following ways: • products intended for application to the lips with sunscreen if the **SPF is 4 or more** • tinted bases and foundations (such as liquids, pastes or powders) with sunscreen if the SPF is 4 or more • moisturising skin care products for dermal application (including anti-wrinkle, anti-aging and skin whitening products), in a pack size no larger

Sunscreen category	Required to be in ARTG?	Product type
		than 300mL or 300g, with sunscreen if the SPF between 4 and 15 • sunbathing skin care products (such as oils, creams, gels, tanning products without sun, and after-sun care products), in a pack size not larger than 300mL or 300g, with an SPF between 4 and 15 Excluded sunscreen products must: • meet the requirements set out in the Australian Sunscreen Standard, including the performance requirements for a broad-spectrum product • not contain any substances included in Schedules 2, 3, 4 or 8 of the Standard for the Uniform Scheduling of Medicines and Poisons
Exempt sunscreens	**No** Exempt [under item 8(g) Schedule 5 of the Regulations] from the requirement to be included in the ARTG	A therapeutic sunscreen is considered 'exempt' from the requirement to be included in the ARTG if: • the SPF established according to the Australian Sunscreen Standard is less than 4 • the label claims comply with the Australian Sunscreen Standard • the product does not have an indication for the treatment of a serious disease, condition, ailment or defect as specified in the most current Advertising Code • the product does not contain ingredients listed in Item 8(g) of Schedule 5 of the Regulations, such as ingredients that are from humans, or particular organs from cows, sheep, goats or mule deer. Note: if the sunscreen contains one of these ingredients, it is not exempt from the requirement to be included in the ARTG

Sunscreen category	Required to be in ARTG?	Product type
Therapeutic sunscreens	**Yes** Required to be listed (under s.26A of the Act) or registered (under s.25 of the Act) in the ARTG	Non-exempt therapeutic sunscreens that are required to be included in the ARTG include: • primary sunscreens carrying SPF claims of more than SPF 4 • some secondary sunscreens (i.e. those secondary sunscreens that are not excluded from therapeutic goods regulation by the Excluded Goods Determination) such as sunbathing and moisturising skin care products with an SPF of over 15 **Listed therapeutic sunscreens** Therapeutic sunscreens may be listed in the ARTG if they: • only make therapeutic indications that are permitted for use in listed medicines(see Ingredients permitted for use in listed therapeutic sunscreens) • only include ingredients that are permitted for use in listed medicines(see Indications permitted for use in listed therapeutic sunscreens) **Registered therapeutic sunscreens** Therapeutic sunscreens require registration in the ARTG if they: • contain an ingredient that is not a permitted ingredient in a listed medicine; and/or • carry higher-level therapeutic indications than those permitted for use in listed medicines

Legislative requirements for all therapeutic sunscreens

To be included in the ARTG, sunscreens must comply with the Australian Sunscreen Standard and with any relevant requirements as prescribed by the Act. General information on how to list or register a therapeutic good can be found in Part B of this document (listed therapeutic goods), and on the TGA website.

There are legal requirements that apply to all therapeutic goods. It is the responsibility of the sponsor to review the relevant regulatory guidance and ensure their product meets all relevant legal requirements. It is also important to note that sponsors have ongoing responsibilities and legal obligations. For more information, refer to Overview of supplying therapeutic goods in Australia on the TGA website.

Requirement to report adverse reactions for therapeutic sunscreens

It is a standard condition of listing or registration of a medicine in the ARTG 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 all therapeutic sunscreens.

Details of the TGA's requirements for pharmacovigilance and the reporting of adverse reactions can be found on the TGA's Pharmacovigilance responsibilities of medicine sponsors website.

Labelling and advertising requirements for of therapeutic sunscreens

The labelling and advertising of therapeutic sunscreens must comply with the relevant requirements of each of the following:

- the most current version of the Labelling Order
- the most current version of the Advertising Code
- the Australian Sunscreen Standard

Non therapeutic claims for therapeutic sunscreens

Therapeutic sunscreens may also carry non-therapeutic claims, providing they are truthful and not misleading, such as:

- cosmetic claims, such as 'moisturising', 'antioxidant', 'free radical barrier'
- insect repellent claims
- content claims, such as 'contains Vitamin E', 'contains 30% more'

The sponsor must be able to substantiate these claims. 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. All insect repellents for human use must comply with any requirements of the APVMA. Refer to APVMA more information.

The labelling of therapeutic sunscreens may carry company logos, other symbols and consumer information provided that these do not create confusion for Australian consumers and they do not conflict with the requirements of the Australian Sunscreen Standard or relevant Therapeutic Goods legislation, such as the current Labelling Order and 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 the most current Labelling Order; and all components in the proprietary ingredient comply with the Permissible Ingredients Determination.

The Labelling Order and the Advertising Code do not apply to **excluded** sunscreens. Rather, mandatory requirements applying to the labelling of all excluded sunscreens that are considered to be cosmetic products are set out in the Consumer Goods (Cosmetics) Information Standard 2020.

Part B – Information for listed therapeutic sunscreens

Legislative requirements for listed therapeutic sunscreens

At the time of listing a sunscreen in the ARTG, a sponsor must certify that their product meets all applicable legislative requirements, which includes certification that the product:

- Only makes certain therapeutic claims selected from the Therapeutic Goods (Permissible Indications) Determination (Permissible Indications Determination), an exclusive list of indications that have been pre-approved by the TGA (see Indications permitted for use in listed therapeutic sunscreens section in this document) and complies with any requirements associated with those indications.
- Only contains low-risk ingredients selected from the Therapeutic Goods (Permissible Ingredients) Determination (Permissible Ingredients Determination), a list of ingredients pre-approved by the TGA (see Ingredients permitted for use in listed therapeutic sunscreens section in this document) and complies with any requirements associated with those ingredients. Information about the data required to support the safety and quality of sunscreen ingredients can be found in the Safety data requirements for new ingredients for use in listed therapeutic sunscreens and Quality data requirements for new ingredients for use in listed therapeutic sunscreens respectively.
- Complies with any applicable standards, including:
    - the claimed SPF of the therapeutic sunscreen must have been established by testing according to the method described in the Australian Sunscreen Standard
    - the performance statements and markings on the label comply with the Australian Sunscreen Standard

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

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 Application and submission user guide: Listed and assessed listed medicines.

Indications permitted for use in listed therapeutic sunscreens

Listed therapeutic sunscreens are only permitted to carry indications that are specified in the Permissible Indications Determination, which is maintained by the TGA (see Appendix 1).

In principle, indications that are considered appropriate for listed therapeutic sunscreens are those that can be applied to products that can be used safely and effectively without the intervention of a healthcare practitioner. Indications permitted for use in listed medicines can relate to 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.

However, as sunscreens are a primary preventative measure against skin cancer for all Australians, in the interests of public health, the TGA has allowed listed therapeutic sunscreens

to make higher level therapeutic claims relating to sunburn and skin cancer as provided below, even though neoplastic disease[1] is generally considered a prohibited representation under the Advertising Code.

In addition, the sunscreen must meet the requirements of the Australian Sunscreen Standard.

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.'

The Act requires that, at the time of listing a medicine in the ARTG, a sponsor must certify that they hold the information or evidence to support indications and claims made in relation to their 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. 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.

Therapeutic sunscreens that make therapeutic indications other than sunscreening (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 Permissible Ingredients Determination, do not fit the criteria of a listed therapeutic sunscreen product. Such products must be included in the ARTG as an OTC or prescription registered therapeutic sunscreen, depending on the active ingredients it contains and therapeutic claims made (see Registered therapeutic sunscreens subsection in this document).

Appendix 1 provides a list of indications permitted for use in listed therapeutic sunscreens at the time of publication.

Ingredients permitted for use in listed therapeutic sunscreens

Listed sunscreen products may only contain low-risk ingredients selected from the Permissible Ingredients Determination, a list of ingredients that have been approved by the TGA. Sponsors should consult the Permissible Ingredients Determination for restrictions applying to each ingredient in their product. The product's label must include the Australian Approved Name (AAN) for each active ingredient.

[1] Paragraph 30(b)(i) of the Advertising Code defines representations that regard the treatment, cure, prevention, diagnosis (including screening), monitoring or susceptibility of, or pre-disposition to, neoplastic disease as a prohibited representation.

If your product contains an ingredient that is not on the Permissible Ingredients Determination, you will need to submit an application to have the safety and quality of the substance evaluated under its proposed conditions of use; please refer to the Applying for a new ingredient to be used in listed therapeutic sunscreens, Safety data requirements for new ingredients for use in listed therapeutic sunscreens and Quality data requirements for new ingredients for use in listed therapeutic sunscreens sections in this document for more information on new ingredients.

Ingredients permitted for use in listed therapeutic sunscreens, that are not restricted to use in sunscreens only, may also be used in other topically applied medicines (subject to any conditions or limitations) without the need for further evaluation. However, additional data to ensure the continued safety of use 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. For example, if a substance has been limited for use in a particular dosage form, such as a cream/lotion, then an application to vary the Permissible Ingredients Determination would be required to provide further safety information that supports its use in an alcohol base.

Active ingredients permitted for use in listed therapeutic sunscreens

A list of active ingredients restricted for use in sunscreen products can be found in Appendix 2. In general, these will be present at significant concentrations in therapeutic sunscreens to be efficacious, and may be expected to interact with human tissues and physiological systems topically (skin, eyes and mucosal surfaces) and systemically (if they penetrate the skin and move into the systemic circulation).

Excipient ingredients permitted for use in listed therapeutic sunscreens

Only excipients approved by the TGA for use in topical medicines may be used in therapeutic sunscreens. Excipient ingredients are not generally considered to be 'inert' and may have effects on human health and safety, even though no therapeutic claims can be listed against their presence. In addition, these ingredients may sometimes make up a significant proportion of the sunscreen. 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.

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.

Nanoparticle ingredients in sunscreens

Nanoparticulate titanium dioxide and zinc oxide are commonly used in sunscreens; however, other ingredients may be used in nanoparticle form if they have been specifically evaluated and approved by the TGA. The labels of sunscreens are not required to declare the particle sizes of ingredients.

The TGA actively monitors local and international research on nanoparticles in sunscreens. A literature review by the TGA on the safety of titanium dioxide and zinc oxide nanoparticles in sunscreens was first published in 2006, and is regularly updated.

Applying for a new ingredient to be used in listed therapeutic sunscreens

The information below should be read in conjunction with the guidelines for the approval of new substances provided in the Applications for new substances in listed medicines: Australian regulatory guidelines and Information required in an evaluation of a substance for use in listed medicines: guidance for sponsors.

A 'Proposed name for a chemical substance (AAN) 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 approved terminology for therapeutic goods webpage.

There are no fees associated with AAN applications and approval of ingredient names. 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 TGA's Schedule of fees and charges webpage.

General requirements for new ingredients for listed therapeutic sunscreens

Sponsors wishing to market a product containing an active or excipient ingredient that is not on the Permissible Ingredients Determination (see Ingredients Permitted for use in listed therapeutic sunscreens) must submit data to establish the safety and quality of the ingredient under its proposed conditions of use. Please refer to Information required in an evaluation of a substance for use in listed medicines: guidance for sponsors for further information.

The safety data for new ingredients need to be comprehensive to ascertain both the short-term (acute) and long-term (chronic) effects on human health and safety from exposure to these ingredients. This is important, given that sunscreen products will be used by people of all ages (infants, children, adults and the elderly); genders (including women of childbearing potential); and could be readily anticipated to be used frequently (daily).

Once the substance is approved, and an AAN has been assigned, it may thereafter be able to be used in other therapeutic sunscreens without the need for further evaluation, but only up to the limit that has been approved. Sponsors wishing to increase the limit imposed by the TGA will need to submit a separate application for further safety evaluation.

Scientific guidelines for ingredient testing for listed therapeutic sunscreens

The TGA closely aligns its regulatory approaches to therapeutic products with those of comparable international regulatory counterparts wherever possible. The list of relevant guidelines that have been adopted by the TGA can be found on the TGA's International scientific guidelines adopted in Australia webpage. These guidelines are not detailed in this document because they are subject to frequent changes. Therefore, sponsors should consult the current list on the TGA website.

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 regarded as 'invalid' if appropriate and scientifically robust methodology is not followed (e.g. low animal numbers, lack of or inappropriate controls).

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.

- Details on different safety tests for **chemicals for pharmaceutical use** can be found on the websites 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).
- Details on different safety tests for **chemicals that are for cosmetic sunscreens used in Europe** can be found in the:
    - Scientific Committee on Consumer Safety's (SCCS) The SCCS notes for guidance for the testing of cosmetic ingredients and their safety evaluation 10th Revision (SCCS/1602/18.)

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 during a pre-submission meeting. 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.

Safety data requirements for new ingredients for use in listed therapeutic sunscreens

Safety data that is required for a new active or excipient ingredient for use in listed medicines, including sunscreens, are included in Table 3 below.

Required study reports must:

- be submitted in full as well as in summary form: simple summaries or synopses of studies without the full study reports are not acceptable for assessment
- be in English or be provided with an accompanying certified English translation.

Proper and comprehensive identification of the substance(s) being tested in all studies is required. The CAS number, laboratory codes, trade names and synonyms must be linked to the substance identified in the new substance application form and the 'Proposed name for a chemical substance (AAN) used in a therapeutic good' application form.

Concentrations of the new substance used in all studies must be clearly and unambiguously stated. The intended final concentration of the new substance in therapeutic goods to be marketed in Australia must be stated as 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.

Table 3. Safety data required for new active or excipient sunscreen ingredients

Requirements	
TOXICOKINETICS	
• oral and dermal bioavailability • ADME (absorption, distribution, metabolism and excretion) studies Note: An *in vivo* determination of dermal and oral absorption is needed to establish systemic exposure via both routes and to enable interpretation of the toxicity studies.	
TOXICITY	
Acute toxicity	• Oral and dermal; animal data • This can be addressed with information obtained from repeat dose toxicity studies
Repeat dose toxicity	• Oral and dermal (at least 3 months) • Inhalation toxicity data may be required if the product is used in a spray dosage form
Genotoxicity	• *In vitro* bacterial (Ames) assay • *In vitro* mammalian cell line assay • *In vivo* chromosome aberration assay • Genotoxicity *in vitro* testing in bacterial, mammalian cell lines, and chromosome aberration assay should include a photomutagenicity arm
Carcinogenicity	• Refer to ICH guidelines • *In vivo* carcinogenicity and photocarcinogenicity bioassays or a justification for not providing these studies (see Justification for not providing particular studies to support the safety of new ingredients for use in listed therapeutic sunscreens section)
Reproductive toxicity	• For assessment of developmental and fertility effects
Local tolerance	
• Skin irritation (animal data and/or human repeat insult patch test - HRIPT) • Phototoxicity (animal and/or human data) • Eye irritation (animal *in vivo* or *in vitro* test) • Skin sensitisation (animal data and/or HRIPT) • Photosensitisation (animal and/or human data – HRIPT)	
Interaction potential	
• 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.	

Safety data requirements for new excipients for use in listed therapeutic sunscreens

Where a therapeutic sunscreen contains an excipient that 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:

- acute oral toxicity study – this can be addressed with information obtained from repeat-dose toxicity studies
- skin irritation study – animal or alternative study such as HRIPT
- sensitisation study – skin, animal and/or 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
- assurance that it does not appear in Annex II to the Regulation (EC) No. 1223/2009 list of substances that 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.

All of the above information should be submitted for a 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.

Justification for not providing particular studies to support the safety of new ingredients for use in listed therapeutic sunscreens

In circumstances where particular tests specified in Table 3 above are not feasible or appropriate, the sponsor should submit a justification based on sound scientific argument for not including these tests in their dossier.

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).

Related studies that may be used to support the safety of new ingredients for use in listed therapeutic sunscreens

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 websites that may be useful in providing information on the potential of a substance to cause tumours in humans:

- 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.

Alternative test methods accepted by the TGA for new ingredients for use in listed therapeutic sunscreens

Major advances in alternative testing methods and new validated methods have been implemented following the introduction of animal testing bans for cosmetic ingredients in Europe and Australia (see the Industrial Chemicals Act 2019). The TGA follows the EMA Guideline on the principles of regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches, which describes the criteria for regulatory acceptance of an alternative testing approach. In addition, the TGA will accept validated test methods that are alternatives to animal testing methods from the following sources:

- OECD Test guidelines for the Chemicals
- The European Commission's Tracking System for Alternative methods towards Regulatory acceptance (TSAR)
- The European Commission's science and knowledge service

Alternative sources of data for listed therapeutic sunscreens

Alternative sources of data on the safety of excipient ingredients will be considered. For example, if the excipient has been assessed by AICIS, the Scientific Committee on Consumer Safety (SCCS), or 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 AICIS reviews may be available from the supplier of the excipient.

Quality data requirements for new ingredients for listed therapeutic sunscreens

Where a therapeutic sunscreen contains an ingredient (active or excipient) that is not in any product currently included in the ARTG for supply in Australia, the ingredient 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 new ingredient as a substance included in the International Cosmetic Ingredient Dictionary and Handbook published by the Personal Care Products Council, available electronically as wINCI (the page number / reference should be quoted)

Photostability of active ingredients for use in listed therapeutic sunscreens

Sponsors should provide data to establish the UV absorption range of a new active ingredient to enable confirmation of its UVA/UVB absorption profile. Data addressing the potential for physical interaction with other commonly used sunscreening agents should also be provided.

Manufacture and quality control of listed therapeutic sunscreens

Manufacture of listed therapeutic sunscreens

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. These goods 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). Guidance specific to sunscreen manufacturing can be found in the Sunscreen manufacturing: Demonstrating compliance with the PIC/S guide to GMP, PE0009-13.

- 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 website.

In addition, subparagraph 40(4)(a)(i) of the Act requires the manufacturer to ensure that the product complies with any standard applicable to the product. It is the responsibility of the finished medicinal product manufacturer to hold evidence that ingredients (active and excipient) used in a product meet the requirements of a default standard, or the established specification as stated in the Release for supply of medicines guidance document.

Quality control – manufacturing of listed therapeutic sunscreens

All sunscreen products released on the Australian market must be manufactured according to the principles of GMP as described in the Sunscreen manufacturing: Demonstrating compliance with the PIC/S guide to GMP, PE 009-13. This document states that all sunscreen products released on the Australian market must be manufactured by pre-approved manufacturers who are responsible for meeting the necessary requirements associated with the raw materials, ingredients and manufacturing process.

Default standards for listed therapeutic sunscreens

Pharmacopoeial Standards

In accordance with the definitions in section 3 of the Act, the default standards applying to therapeutic goods registered or listed in the ARTG include the:

- British Pharmacopoeia (BP)
- European Pharmacopoeia (Ph Eur)
- United States Pharmacopeia-National Formulary (USP-NF).

Non-pharmacopoeial Standards

Other standards that apply to sunscreens include relevant Therapeutic Goods Orders made under section 10 of the Act such as the most current:

- Labelling Order
- Order for Microbiological Standards for medicines

Finished products specifications for listed therapeutic sunscreens

Pharmacopoeial standards

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

Finished sunscreen products that are not the subject of a monograph in the BP, Ph Eur or USP-NF must be controlled 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.

Non-pharmacopoeial standards

Therapeutic sunscreen products in all categories are required to comply with the most current order describing Microbiological Standards for medicines, particularly with regard to the sections regarding the efficacy of antimicrobial preservation of a multidose medicine and microbiological attributes of a non-sterile medicine.

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

Ingredients specifications for listed therapeutic sunscreens

Pharmacopoeial standards

Subsection 13(5) of the Act requires that when a finished product is not the subject of a monograph in a default standard, but any of its ingredients is, 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.

Reproducibility of SPF test results for listed therapeutic sunscreens

The SPF of therapeutic sunscreens must be determined by testing on human skin in accordance with the Australian Sunscreen Standard, which references the International Organisation for Standardisation procedure *ISO 24444 Cosmetics – Sun Protection test methods – In vivo determination of SPF (Sun Protection Factor)* as referenced in the Australian Sunscreen Standard.

In vivo SPF testing protocol for listed therapeutic sunscreens

The *in vivo* testing of the SPF of a sunscreen product according to the procedure in *ISO 24444* referenced in the Australian Sunscreen Standard 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/cm^2. The test data exhibit a considerable inherent variance, which need to be taken into account when interpreting the test results and labelling of the product, and also need to be taken into account when interpreting the results of any subsequent retesting of the product.

Validity of *in vivo* SPF testing results for listed therapeutic sunscreens

The SPF test is considered valid if the 95% CI fits within ±17% of the mean. If this criterion is not met:

- 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 fits within ±17% of the mean.
- If testing on 20 subjects does not bring the 95% CI within ±17% of the mean the whole test must be rejected.
- In practice, the 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 of 5–20%. Only rarely is the CV less than 5% or greater than 20%.

In the majority of cases, testing on 10 subjects would yield a 95% CI well within the ±17% limits and testing on additional subjects would not be required.

Retesting listed therapeutic sunscreens

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.

- If the original test result is close to the lower limit for a particular SPF claim allowed by the Australian Sunscreen 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.

Stability testing of listed therapeutic sunscreens

Stability test requirements for listed therapeutic sunscreens

Therapeutic sunscreens marketed in Australia must be labelled with an '***expiry***' or '***use-by***' date. This must be supported by:

- experimental data supporting 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:
    - '***Store below 25°C***' for products to be stored in air-conditioned premise
    - '***Store below 30°C***' for products 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.

- 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. However, the data 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.

The TGA follows the EMA/ CPMP/ ICH guidelines, which provides direction on the design and conducting of stability studies:

- ICH Q1A (R2) Stability Testing Guidelines: Stability Testing of New Drug substances and Products (CPMP/ICH/2736/99)
- Guideline on Stability Testing: Stability Testing of Existing Active substances and Related Finished Products (CPMP/QWP/122/02 Rev 1)
- ICH Q1E Note for Guidance on Evaluation of Stability Data (CPMP/ICH/420/02)
- ICH Q1B Photostability Testing of New Drug substances and Medicinal Products (CPMP/ICH/279/95).

Establishing stability before market approval for listed therapeutic sunscreens

The shelf life of a sunscreen product must be established with real-time testing for the whole of the required shelf life or with adequate certainty before it can receive market approval and be included in the ARTG. This can be achieved by:

- accelerated testing for 6-9 months at 10°C or 15°C above the stated maximum storage temperature (see Table 4)
- providing a justification based on supporting stability data generated for a closely related formulation.

Table 4 shows the shelf life prediction of a sunscreen product from short-term testing.

Table 4. Shelf life prediction from short-term testing of listed therapeutic sunscreens at elevated temperatures

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

Stability testing should be carried out using at least two batches of the formulation intended for marketing that have been manufactured in a manner that closely mirrors the production-scale manufacturing process.

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

A formulation that is very similar, but not identical, to that intended for marketing formulation may be used provided any differences are:

- very minor
- unlikely to affect the physical, chemical or microbiological stability of the product
- unlikely to affect the in-use performance of the product.

Confirming stability and shelf life for listed therapeutic sunscreens

If the shelf life assigned at the time of listing in the ARTG is based on data generated using pilot-scale batches and accelerated studies, the sponsor will need to:

- confirm the shelf life using real-time studies that encompass the whole of that shelf life using at least two production-scale batches stored at the maximum recommended storage temperature
- test the production-scale batches initially at manufacture and then annually until the end of the shelf life.

Stability protocol requirements for listed therapeutic sunscreens

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

Physical testing of listed therapeutic sunscreens

Physical testing should include at least the following quality parameters:

- appearance
- emulsion stability
- absence of crystallisation
- odour
- viscosity
- compatibility with the immediate container
- the condition of the inside surface of the container in contact with the product.

Chemical testing of listed therapeutic sunscreens

Chemical stability testing should include:

- pH (if water is the continuous phase)
- the content of each of the active ingredients assayed using a validated, stability-indicating analytical procedure (e.g. 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 the Permissible Ingredients Determination.

Microbiological stability testing of listed therapeutic sunscreens

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. It may be useful to monitor chemical stability of preservatives during stability using a stability-indicating validated method.

Accelerated studies of listed therapeutic sunscreens

The frequency of testing for accelerated studies should be adequate to allow regression and statistical analysis to support extrapolation of the data using a minimum of four data points

- Appropriate testing time points are typically 0, (1 or 2), (3 or 4), (5 or 6), 9 and 12 months. This can be followed by further testing at 24 and 30 months, depending on the length of the shelf life that needs to be justified.

The accelerated stability data should only be extrapolated as described in the Shelf life determination for listed therapeutic sunscreens subsection 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% CI calculations.

Shelf life determination for listed therapeutic sunscreens

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

The stability data that is required to support the shelf life of a product with no discernible changes or trends is dependent on the labelled storage conditions.

- Products labelled with storage conditions ***'store below 30°C'*** (i.e. storage at room temperature in Australia) require stability data covering:
    - 6 months storage at 40°C to support a 2-year shelf life
    - either 9 months at 40°C *or* 6 months at 45°C to support a 3-year shelf life
    - data from storage at 40°C covering at least half of the shelf life to support a shelf life greater than 3 years (e.g. 2.5 years accelerated data would be required to support a 5-year shelf life).
- Products labelled with storage conditions ***'store below 25°C'*** (i.e. the product should be stored in air-conditioned premises) require stability data covering:
    - 6 months storage at 35°C to support a 2-year shelf life
    - either 9 months at 35°C *or* 6 months at 40°C to support a 3-year shelf life
    - data from storage at 35°C covering at least half of the shelf life to support a shelf life greater than 3 years.

Changing the ARTG entry of listed therapeutic sunscreens

Details of the requirements and procedures for making changes to the ARTG record of listed therapeutic goods, including sunscreens, are provided in the Changing a listed or assessed listed medicine: application levels and change tables document. Note that some changes may be made through a grouping application, which will not require a change to the AUST L number.

Changes to active ingredients in listed therapeutic sunscreens

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. Such changes require the sponsor to submit an application for a new entry in the ARTG. Please refer to subsection 16(1A) of the Act and regulation 11 of the Regulations. If the application is successful, a new AUST L or AUST R number will be assigned to the new product.

Changes to excipient ingredients in listed therapeutic sunscreens

The identities of excipient ingredients 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 excipient ingredients for listed therapeutic sunscreens

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. Such changes require the sponsor to submit an application for a new entry in the ARTG. If the application is successful, a new AUST L or AUST R number will be assigned to the new product.

Deletion or addition of fragrance or colour for listed therapeutic sunscreens

If the excipient to be added or removed is a fragrance or colouring agent 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 excipient ingredients in listed therapeutic sunscreens

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 will be issued.

Changes that may affect SPF properties of listed therapeutic sunscreens

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.

Other changes to listed therapeutic sunscreens

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.

Glossary of terms and abbreviations

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

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).

AICIS means the Australian Industrial Chemicals Introduction Scheme

ARTG means the Australian Register of Therapeutic Goods

Australian Approved Name (AAN) means the approved name applied to a therapeutic substance, as outlined in the TGA approved terminology for therapeutic goods, which includes: Approved biological names (ABNs); Approved cell and tissue names (ACNs); Approved names for herbal ingredients (AHNs); and Approved herbal substance names (AHSs).

Australian Sunscreen Standard means The Australian/New Zealand Sunscreen Standard (AS/NZS) 2604 Sunscreen products —Evaluation and classification [as referenced in the *Therapeutic Goods Regulations 1990* and in the Therapeutic Goods (Excluded Goods) Determination 2018]

Broad spectrum product means a sunscreen product which has been shown, using the *in vitro* test method defined in the Australian Sunscreen Standard to provide protection from the sun's terrestrial UVA and UVB rays.

Category description means the designation of the level of protection given by a grouping of label sun protection factors (see the Australian Sunscreen Standard).

Container (in relation to therapeutic goods) means the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion (see subsection 3(1) of the Act).

Cosmetic means:

a. a substance or preparation intended for placement in contact with any external part of the human body, including the mucous membranes of the oral cavity and the teeth, with a view to: altering the odours of the body; changing its appearance; cleansing it; maintaining it in good condition; perfuming it; or protecting it.

b. A substance or preparation prescribed by the rules for the purposes of this paragraph, but does not include:

   i. a therapeutic good within the meaning of the *Therapeutic Goods Act 1989*; or

   ii. A substance of preparation prescribed by the rules for the purposes of this paragraph.

   Noting that an ingredient or component of a cosmetic could be an industrial chemical (see section 9 of the *Industrial Chemicals Act 2019*; definition accessed 26 February 2021).

ELF means Electronic Listing Facility.

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.

Excluded sunscreen means a sunscreen product that is excluded from regulation under the *Therapeutic Goods Act 1989* by virtue of the Therapeutic Goods (Excluded Goods) Determination 2018.

Exempt sunscreen means a sunscreen product that is regulated under the *Therapeutic Goods Act 1989* but is not required to be registered or listed in the ARTG (see Item 8 of Schedule 5 of the Regulations).

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

GMP means Good manufacturing practice.

Ingredients of human or animal origin are those derived directly from a human or animal source. These are also listed in Item 8, Schedule 5 of the Regulations.

INN means International Non-proprietary Name.

Label means a display of printed information upon, or securely affixed to, the container, any intermediate packaging and any primary pack containing the medicine (see section 6 of the TGO 92).

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

Listing number means the combination of numbers and letters that are required to be included on the label of therapeutic goods in a manner described in regulation 15 of the Regulations (see section 6 of the TGO 92)

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 name of the medicine is more or most conspicuously shown; or

b. where the name of the medicine is equally conspicuous on two or more labels or portions of a label — each label or portion (see section 6 of the TGO 92).

Medicine means therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human (see subsection 3(1) of the Act).

Minimal Erythemal 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 (the Australian Sunscreen Standard).

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 (the Australian Sunscreen Standard).

Registration number means the combination of numbers and letters that is required to be included on the label of medicines in a manner described in regulation 15 of the Regulations (see section 6 of the TGO 92).

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 *(the* Australian Sunscreen Standard).

Sun Protection Factor (SPF) means the arithmetic mean of all valid individual SPF values obtained from all subjects in the test (the Australian Sunscreen Standard). See also, Minimal Erythemal Dose (MED).

TGO 92 means the Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines.

The Act means the *Therapeutic Goods Act 1989*.

The Advertising Code means the most current Therapeutic Goods Advertising Code

The Labelling Order means the most current Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines

The Regulations means the *Therapeutic Goods Regulations 1990*.

Therapeutic goods means goods that are represented in any way to be, or that are, whether because of the way in which the goods are 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 (see subsection 3(1) of the Act).

Therapeutic sunscreen means a primary or secondary sunscreen product that meets the definition of a therapeutic good rather than the definition of a cosmetic.

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

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

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, 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 (the Australian Sunscreen Standard)

Appendix 1: Indications permitted for use in listed therapeutic sunscreens

Indications permitted for use in listed therapeutic sunscreens at the time of publication are listed in Table 1.

Please note: Table 1 includes only those indications that were included in the Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021. It is the sponsor's responsibility to check the current Permissible Indications Determination to ensure that ingredient information is correct.

Table 1. Indications permitted for use with listed therapeutic sunscreens (as included in the Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021).

Indication	Requirement
Can aid in the prevention of premature skin ageing (sunscreen)	Indication for use in sunscreen products only.
Can aid in the prevention of solar keratosis (sunscreen)	Indication can only be used for sunscreen products with an SPF rating of 30 or higher.
Can aid in the prevention of sunspots (sunscreen)	Indication can only be used for sunscreen products with an SPF rating of 30 or higher.
May assist in preventing some skin cancers (sunscreen)	Indication can only be used for sunscreen products with an SPF rating of 30 or higher.
May reduce the risk of some skin cancers (sunscreen)	Indication can only be used for sunscreen products with an SPF rating of 30 or higher.
SPF 4 Broad spectrum low protection sunscreen	Indication for use in sunscreen products only.
SPF 6 Broad spectrum low protection sunscreen	Indication for use in sunscreen products only.
SPF 8 Broad spectrum low protection sunscreen	Indication for use in sunscreen products only.
SPF 10 Broad spectrum low protection sunscreen	Indication for use in sunscreen products only.
SPF 15 Broad spectrum medium/moderate protection sunscreen	Indication for use in sunscreen products only.
SPF 20 Broad spectrum medium/moderate protection sunscreen	Indication for use in sunscreen products only.

Indication	Requirement
SPF 25 Broad spectrum medium/moderate protection sunscreen	Indication for use in sunscreen products only.
SPF 30 Broad spectrum high protection sunscreen	Indication for use in sunscreen products only.
SPF 40 Broad spectrum high protection sunscreen	Indication for use in sunscreen products only.
SPF 50 Broad spectrum high protection sunscreen	Indication for use in sunscreen products only.
SPF 50 PLUS Broad spectrum very high protection sunscreen	Indication for use in sunscreen products only.

Appendix 2: Active ingredients restricted to use in therapeutic sunscreens

A. Searching the TGA ingredient database

Active ingredients restricted for use in therapeutic sunscreens can be found by searching the TGA ingredient database. This ingredient database is an electronic repository of approved ingredient names for therapeutic substances, and includes the requirements specified for each ingredient in the Permissible Ingredients Determination. The ingredient database also provides additional information for ingredients that is not in the Permissible Ingredients Determination, and allows for searching using:

- CAS numbers (where available); and
- ingredients that are in the Permissible Ingredients Determination, by entering the term 'Listed' and selecting the field 'Listed' (see Figure 1).

Figure 1 - The TGA ingredients database is a public tool to search for ingredients available for selection in therapeutic goods applications. Searches may be performed on CAS Number, or whether they are available for listed medicines (by typing "Listed" and selecting Listed in the dropdown).

From here, the list of ingredients can be exported in excel, xml and HTML formats. At present, restrictions are not visible in the search results table or exported results; however, they can instead be viewed by clicking on the ingredient summary hyperlink in the ingredients database search results (see Figure 2).

Figure 2 – Click on hyperlinks to view restrictions for individual ingredients in the TGA ingredients database.

B. Active ingredients currently restricted for use in therapeutic sunscreens

Active ingredients currently restricted for use in therapeutic sunscreens at the time of publication are listed in Table 1.

Please note: Table 1 includes only those active ingredients that were included in the Therapeutic Goods (Permissible Ingredients) Determination (No. 1) 2021. This Determination is updated regularly; therefore, it is the sponsor's responsibility to check the current Permissible Ingredients Determination to ensure that ingredient information is correct.

Table 1. Active ingredients restricted for use in therapeutic sunscreens (as included in the Therapeutic Goods (Permissible Ingredients) Determination [No. 1] 2021)

Australian Approved Name (AAN)	CAS Number	Synonyms	Maximum concentration
aminobenzoic acid	150-13-0	PABA para-aminobenzoic acid	15%
bemotrizinol	187393-00-6	bemotrizinolum	10%
benzylidene camphor sulfonic acid	56039-58-8	alpha-(2-oxoborn-3-ylidene)toluene-4-sulphonic acid	6% (as acid)
butyl methoxydibenzoylmethane	70356-09-1	BMDM 4-tert-butyl-4'-methoxy dibenzoylmethane avobenzone	5%
camphor benzalkonium methosulfate	52793-97-2	N,N,N-Trimethyl-4-(oxoborn-3-ylidenemethyl)anilinium methyl sulfate camphor benzalkonium sulfate	6%
cinoxate	104-28-9	2-ethoxyethyl para-methoxycinnamate cinoxate anhydrous	6%
diethylamino hydroxybenzoyl hexyl benzoate	302776-68-7		10%
dioxybenzone	131-53-3	benzophenone 8	3%

Australian Approved Name (AAN)	CAS Number	Synonyms	Maximum concentration
disodium phenyl dibenzimidazole tetrasulfonate	180898-37-7	1H-benzimidazole-4,6-disulfonic acid, 2,2'-(1,4-phenylene)bis-, disodium salt bisimidazylate	10%
drometrizole trisiloxane	155633-54-8		10%
ecamsule	90457-82-2	terephthalylidene dicamphor sulfonic acid	10%
ethylhexyl triazone	88122-99-0	octyl triazone	5%
homosalate	118-56-9	homomethyl salicylate	15%
isoamyl methoxycinnamate	71617-10-2	amiloxate isopentenyl-4-methoxycinnamate	10%
menthyl anthranilate	134-09-8	menthyl 2-aminobenzoate 5-methyl-2-(1-methylethyl) cyclohexanol-2-aminobenzoate meradimate anthranilic acid, p-menth-3-yl Ester cyclohexanol, 5-Methyl-2-(1-Methylethyl)-,2-Aminobenzoate menthol anthranilate menthyl o-aminobenzoate	5%
4-methylbenzylidene camphor	36861-47-9	3-(4-methylbenzylidene)-dl-camphor enzacamene neo heliopan 1,7,7-trimethyl-3-[(4-methylphenyl)-methylene]bicyclo[2.2.1]heptan-2-one	4%
methylene bis-benzotriazolyl tetramethylbutylphenol	103597-45-1		10%
octyl methoxycinnamate	5466-77-3	ethylhexyl methoxycinnamate octinoxate	10%
octyl salicylate	118-60-5	ethylhexyl salicylate 2-ethylhexyl salicylate octisalate	5%

Australian Approved Name (AAN)	CAS Number	Synonyms	Maximum concentration
octocrylene	6197-30-4	2-ethylhexyl-2-cyano-3,3 diphenylacrylate	10%
oxybenzone	131-57-7	benzophenone 3	10%
padimate O	21245-02-3	ethylhexyl dimethyl PABA 4-(dimethylamino)benzoic acid 2-ethylhexyl ester	8%
PEG-25 PABA	113010-52-9	ethoxylated ethyl 4-aminobenzoate	4%
phenylbenzimidazole sulfonic acid	27503-81-7	2-phenylbenzimidazole-5-sulfonic acid 2-phenyl-5-sulfobenzimidazole ensulizole	4%
polysilicone-15	207574-74-1	diethylmalonylbenzylidene oxypropene dimethicone dimethicodiethylbenzalmalonate diethylbezylidene malonate dimethicone	10%
sulisobenzone	4065-45-6	benzophenone 4	10%
sulisobenzone sodium	6628-37-1	benzophenone 5	10%
titanium dioxide	13463-67-7	E171 titanium dioxide anhydrous	25%
tris-biphenyl triazine	31274-51-8		10%
trolamine salicylate	2174-16-5	triethanolamine salicylate TEA-salicylate	12%
zinc oxide	1314-13-2	pigment white 4	N/A

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Office of Medicines Authorisation	10/10/2012
V1.1	Updated to reflect the changes to the *Therapeutic Goods Regulations 1990* by removing references to sunscreens with a claimed SPF of <4 that contain certain human or animal derived ingredients. Updated the relevant sections by including reference to the recently made Therapeutic Goods (Permissible Ingredients) Determination No.1 of 2015. Updated the table listing the permitted active ingredients by adding the newly approved sunscreen active Tris-biphenyl triazine	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
V2	Restructured into Parts A and Part B. Removed Australian Sunscreen Standard specific reference and outdated information. New table with Sunscreen SPF categories. Clarification of sunscreen regulatory categories. New information on indications permitted for use in listed medicines. New subsection on adverse reactions. Removed Bibliography and instead provided hyperlinks in document. Updated Glossary. New information on EMA guidelines. Changed NICNAS to AICIS. New subsection on alternative test methods. Removed reference to RASML. New information on searching the ingredient database. Reinstated the table of active ingredients. Updated links to legislation and guidelines: e.g. Therapeutic Goods Orders; Advertising Code; Excluded Goods Determination, ELF user guide. Removed reference to the Cosmetics Standards and the NICNAS Cosmetic Guidelines. Included links to the *Industrial Chemicals Act 2019* and the Consumer Goods (Cosmetics) Information Standard 2020.	Complementary and Over the Counter Medicines Branch	July 2021

Version	Description of change	Author	Effective date
	Updated EEC Directive reference. Updated the SCCS's Note for Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation to the 10th Revision. Removed duplicative information: definitions, labelling information; labelling checklist. Provided links to: pharmacovigilance website, GMP requirements and guidance; TGA approved terminology, schedule of fees and charges		

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