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Therapeutic Goods Administration

Understanding the regulation of therapeutic sunscreens

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Purpose

The TGA regulates sunscreens in Australia that are classified as therapeutic goods to make sure they are safe, efficacious and high quality.

Understanding the regulation of therapeutic sunscreens ('this guidance') explains which sunscreens are regulated by the TGA (therapeutic sunscreens) and which, providing they meet certain requirements, are not regulated by the TGA (e.g. cosmetic sunscreens).

This guidance also provides:

- information on the Australian regulatory requirements for therapeutic sunscreens
- requirements for new sunscreen ingredients
- guidance on how to change an entry in the Australian Register of Therapeutic Goods (ARTG) for a listed sunscreen.

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

Legislation

This guidance explains and references the following legislation:

- Therapeutic Goods Act 1989
- Therapeutic Goods Regulations 1990
- Therapeutic Goods (Excluded Goods) Determination 2018

General information about the regulation of sunscreens

Introduction

In Australia, sunscreens are regulated as either cosmetics or therapeutic goods depending on a number of factors, such as their ingredients, health claims and claimed Sun Protection factor (SPF). The objective of regulation of sunscreens is to ensure their quality, safety, and efficacy to protect consumers from the sun's harmful Ultra-Violet (UV) radiation and reduce the incidence and tragic outcomes of skin cancer.

Sunscreen products are categorised as: 'primary' or 'secondary' in the Australian/New Zealand standard for sunscreens (see 'The Australian/New Zealand Sunscreen Standard'), as below:

1. **Primary sunscreen product:** Product that is represented as being primarily to protect the skin from UV radiation.

2. **Secondary sunscreen product:** Product that is represented as having a primary function other than sun protection whilst providing some protection of the skin from UV radiation.

Many secondary sunscreen products, such as cosmetic sunscreens, are not considered to be therapeutic goods and are “excluded” from therapeutic goods legislation, provided they meet certain criteria (for more information see ‘excluded sunscreens’).

Under the *Therapeutic Goods Act 1989* (the Act)] and supporting legislation, sunscreen products that are regulated as therapeutic goods (‘therapeutic sunscreens’) include:

- All primary sunscreens.
- Some secondary sunscreens: Products, containing sun screening agents, with a primary purpose other than sun protection, but that are not ‘excluded’ (see below) from therapeutic goods legislation e.g. sunbathing and moisturising skin care products with an SPF over 15.

Note

Sunscreen and insect repellent combination products

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

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

Regulatory categories of sunscreens

Excluded sunscreens

Many secondary sunscreen products with a primary purpose other than sun protection are not considered to be therapeutic goods and are “excluded” from therapeutic goods legislation, provided they meet certain criteria. These product types are outlined under the Therapeutic Goods (Excluded Goods) Determination 2018 (Excluded Goods Determination). Examples include moisturisers with an SPF less than 15 and tinted foundations with an SPF up to 50+. Refer to Table 1 for details of these product types.

To be eligible for exclusion, these products must meet certain criteria, such as not containing ingredients included in a schedule to the Poisons Standard and compliance with the AZ/NZ standard for sunscreens.

Excluded products are not required to be included in the ARTG and may meet 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.

Therapeutic sunscreens

Therapeutic sunscreens must be listed or registered in the Australian Register of Therapeutic Goods (ARTG) before they can legally be supplied in Australia (refer to Medicines and TGA classifications for more information on listed and registered therapeutic goods).

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 Schedule 4 Part 1 Item 7 of the Therapeutic Goods Regulations 1990 (the Regulations), excerpt below

Item No.	Therapeutic goods
7	sunscreen preparations for dermal application, if: (a) the claimed sun protection factor has been established by testing according to the method described in Australian/New Zealand Standard AS/NZS 2604:2021, Sunscreen products - Evaluation and classification, published jointly by, or on behalf of, Standards Australia and Standards New Zealand, 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; and (e) the sunscreen preparation only has indications that are covered by a determination under paragraph 26BF(1)(a) of the Act; and (f) if a determination under paragraph 26BF(1)(b) of the Act specifies requirements in relation to the indications—none of the requirements have been contravened

More information about can be found in ‘Specific legislative requirements for listed therapeutic sunscreens’.

Registered therapeutic sunscreens

Therapeutic sunscreens that are not eligible to be listed in the ARTG require inclusion in the ARTG as registered therapeutic goods under section 25 of the Act. These products undergo a full TGA pre-market assessment of their safety, quality and efficacy. Further information on registered medicines can be found in the Australian Regulatory Guidelines for OTC Medicines (ARGOM).

You may wish to request a meeting with the TGA prior to submitting an application for a registered sunscreen. See Pre-submission meetings with the TGA for details on arranging a meeting. There is no fee associated with a pre-submission meeting. The TGA may be able to address any questions proposed for the pre-submission meeting in writing in which case a pre-submission meeting will not be required.

Table 1 provides a summary of the current regulation for the various categories of sunscreens.

Table 1. 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 for application to the lips with **SPF of 4 or more** • tinted bases and foundations (liquids, pastes or powders) with **SPF of 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 than 300mL or 300g, with an SPF between 4 and 15, but not presented as being water resistant • sunbathing skin care products (oils, creams, gels, without sun tanning products, and after-sun care products) in a pack size not larger than 300mL or 300g, with an SPF between 4 and 15 but not presented as being water resistant. Excluded sunscreen products must: • meet the requirements set out in the AS/NZS standard for sunscreens, 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.
Therapeutic sunscreens	**Yes** Required to be listed (under s26A of the Act) or registered (under s25 of the Act) in the ARTG	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 therapeutic sunscreens

Sunscreen category	Required to be in ARTG?	Product type
		(see Indications permitted for use in listed therapeutic sunscreens) and • only include ingredients that are permitted for use in listed medicines (see Ingredients 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 included in the Therapeutic Goods (Permissible Ingredients) Determination (Permissible Ingredients Determination) for use in a listed medicine; and/or • carry therapeutic indications other than those permitted for use in listed therapeutic sunscreens.

Legislative requirements for all therapeutic sunscreens

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.

To be included in the ARTG, sunscreens must comply with the AS/NZS standard for sunscreens and with any relevant requirements as prescribed by the Act.

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 **AS/NZS standard for sunscreens**] details the procedures for testing the performance of **all** sunscreen products (including therapeutic sunscreens and cosmetic sunscreens) in Australia. It also provides labelling requirements that need to be complied with (in addition to all other applicable legislation relating to labelling for therapeutic sunscreens).

The AS/NZS standard for sunscreens 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 2 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 sunscreens).

Table 2. 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

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 webpage.

Labelling and advertising requirements for therapeutic sunscreens

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

- the most current version of the Therapeutic Goods Order No. 92 - Standard for labels of non-prescription medicines (the Labelling Order)
- the most current version of the Therapeutic Goods Advertising Code (the Code)
- the AS/NZS standard for sunscreens.

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 AS/NZS standard for sunscreens or relevant Therapeutic Goods legislation e.g. the current Labelling Order and 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 the most current Labelling Order
- for listed sunscreens, all components in the proprietary ingredient comply with the Permissible Ingredients Determination.

Note

The Labelling Order and the Advertising Code do not apply to **excluded** sunscreens. 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.

Specific 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 therapeutic claims that are permitted for listed therapeutic sunscreens 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 Guidance) and complies with any requirements associated with those indications.
- Only contains low-risk ingredients selected from the Permissible Ingredients Determination a list of ingredients pre-approved by the TGA (see Ingredients permitted for use in listed therapeutic sunscreens) and complies with any requirements associated with those ingredients.
- 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 AS/NZS standard for sunscreens
  - the performance statements and markings on the label comply with the AS/NZS standard for sunscreens.
- Listed medicines are not subject to a pre-market evaluation of efficacy at the time of listing, however, sponsors certify at the time of listing that they have data supporting their medicine's indications. Data supporting the indications may be requested by the TGA for review at any time while the medicine is included in the ARTG. The TGA may request such things as copies of labelling and the results of pre-market testing of SPF, broad-spectrum performance, water-resistance or stability. 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 can only carry indications that are permitted for listed therapeutic sunscreens in the Permissible Indications Determination (see Appendix 1).

In principle, indications that are considered appropriate for listed medicines are those for products that can be safely and effectively used by a consumer without the intervention of a healthcare practitioner. Indications permitted for use in listed medicines can only 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 allows listed therapeutic sunscreens with certain SPF claims to make higher level therapeutic claims (than otherwise permitted for listed medicines) relating to sunburn and skin cancer, even though neoplastic disease[1] is generally considered a prohibited representation under the Advertising Code. These higher-level indications are:

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 compliance review. If the certification by the sponsor that it holds this information or evidence is

[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.

incorrect, the TGA can cancel the listing of the product from the ARTG. Appendix 1 provides a list of indications permitted for use in listed therapeutic sunscreens at the time of publication.

In addition, sunscreens must meet the requirements of the AS/NZS standard for sunscreens.

Therapeutic sunscreens that:

- make therapeutic indications other than sunscreen permitted indications (for example, reduction of free radicals in or below the skin, or claims relating to reduction of UV- induced immune suppression); and/or
- contain ingredients that are not included in the Permissible Ingredients Determination

do not fit the criteria for inclusion in the ARTG as a listed therapeutic sunscreen product. Such products must be included in the ARTG as a registered therapeutic sunscreen (see Registered therapeutic sunscreens).

Note

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’
- 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.

*Therapeutic sunscreens that make insect repellent claims for human use must comply with any requirements of the TGA and the APVMA. Refer to the APVMA for more information.

Ingredients permitted for use in listed therapeutic sunscreens

Listed therapeutic sunscreens may only contain low-risk ingredients selected from the Permissible Ingredients Determination. Sponsors should consult the Permissible Ingredients Determination for restrictions applying to each ingredient in their product. The Australian Approved Name (AAN) for each active ingredient must be included on the product’s label.

If your product contains an ingredient that is not in 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. For more information, refer to the Understanding the application requirements for a new substance in listed medicines (URNS).

Active ingredients permitted for use in listed therapeutic sunscreens

The list of active ingredients restricted for use in therapeutic sunscreens, current at the time of publication of this guidance, is provided in Table 9 of Appendix 3. In general, active ingredients 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

While therapeutic claims cannot be made for excipient ingredients, these ingredients may have effectson human health and safety. In addition, these ingredients may sometimes make up a significant proportion of the sunscreen. Sponsors should consider the impact of exposure of all excipient ingredients 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. Further, a justification must be provided for the inclusion of that substance as an excipient if it is at a concentration in excess of the concentration typically used for its role as an active ingredient. If the concentration of an ingredient is above the approved safety limit for use in listed products, then the product is required to be registered in the ARTG.

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

A nanoparticle ranges from one to 100 nanometres in size (a nanometre is one-millionth of a millimetre) and is invisible to the human eye. Humans are exposed to nanoparticles through the air and water in the form of smoke, dust, ash and fine clays. Nanoparticles are also found in some foods and cosmetics.

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.

> **Note**
>
> 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

Sponsors wishing to market a product containing an active or excipient ingredient that is not in the Permissible Ingredients Determination (see Ingredients permitted for use in listed therapeutic sunscreens) must submit an application for a substance to be used in listed medicines with data to establish the safety and quality of the ingredient under its proposed conditions of use.

An application to include a new active or excipient sunscreen ingredient into the Permissible Ingredients Determination (or to vary the entry of an ingredient already in the Determination) is made under s26BD of the *Therapeutic Goods Act 1989*. This pathway has specific application categories (IN1-4) with varying legislated timeframes and associated fees dependent on the level of TGA de novo evaluation required, and appeal rights.

Applicants can complete the approved online application form titled 'Substance Evaluation,' accessed via the electronic lodgement facility within TGA Business Services in the Applications menu under the heading Listed Medicine. For more information, refer to 'SECTION A – Application process for new substances for use as ingredients in listed medicines' in the URNS and the User guide: Evaluation of substances for use in listed medicines and assessed listed medicines.

An application can also be made via Regulation 16GA to the *Therapeutic Goods Regulations 1990* to have a new sunscreen ingredient evaluated. This can be done by completing a different form titled 'Substance Evaluation,' accessed via the electronic lodgement facility within TGA Business Services in the Applications menu under the heading Non-prescription Medicines. Applications under 16GA are a legacy pathway that was in place prior to the implementation of the s26BD pathway. Applicants should note that unlike applications submitted through the s26BD pathway described above, use of Regulation 16GA does not have legislative timeframes, appeal rights, or mandatory data requirements. Application fees are also based on page count.

TGA *de novo* evaluation may be reduced by providing either quality or safety evaluation reports from Comparable Overseas Bodies (COB). The COB report-based process is a process that allows technical evaluation reports from identified bodies to be used by the TGA. For example, the Australian Industrial Chemical Introduction Scheme (AICIS), Scientific Committee on Consumer Safety (SCCS) and Cosmetic Ingredient Review (CIR) are on the list of COBs. In general, applicants must submit the COB evaluation report(s), the completed COB checklist(s) for substance evaluations and a gap analysis to demonstrate that the information meets the Australian requirements. For full details for submission requirements for the COB-report based process, refer to SECTION B – Submission requirements for the COB report-based process in Using the Comparable Overseas Bodies process for registered complementary medicines, assessed listed medicines and substances in

listed medicines. If an applicant decides not to use this process, such reports can also be provided as supporting information as part of an application.

Irrespective of which pathway applicants use, the TGA evaluates the quality and safety of a substance to the same standard, as all substances must be included in the Permissible Ingredients Determination before they can be used in listed therapeutic sunscreens or listed medicines - see General requirements for new ingredients for listed therapeutic sunscreens.

A 'Proposed name for a chemical substance (AAN) used in a therapeutic good' application form also 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.

Once the substance is approved, and included in the Permissible Ingredients Determination, it may be used in other therapeutic sunscreens if not subject to an ingredient exclusivity period. Sponsors wishing to propose a new role or change the existing requirement for use of a current permitted ingredient will need to submit a separate application for evaluation.

New ingredients included in the Permissible Ingredients Determination may be eligible to receive a 2-year exclusivity period where unauthorised sponsors are prohibited from using an ingredient with market exclusivity. It is the responsibility of the applicant to 'opt in' at the time of making the application. For more information see heading 'After approval of a new ingredient - exclusive use' in the URNS.

General requirements for new ingredients for listed therapeutic sunscreens

The information in this document should be read in conjunction with the URNS.

New applications for sunscreen ingredients are assessed like all other topical substances used in listed medicines based on 'SECTION B – Information requirements' in URNS. Table 3 and Table 5 in this document specify the respective quality and safety data requirements for new ingredients for use in listed therapeutic sunscreens.

Note

If data or information cannot be provided to address a core information requirement, a justification must be provided. See headings 'When a justification needs to be provided', 'Purpose of justifications' and 'What needs to be included in a justification' in the URNS.

There are a few unique requirements relevant to new sunscreen ingredients, and these are discussed under headings ‘Establishing the UV absorption range of new active sunscreen ingredients’, ‘Other safety requirements specific for new substances for use in listed therapeutic sunscreens’ and Appendix 2.

Scientific guidelines for testing of new ingredients 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 International scientific 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. When information does not adhere to a relevant EU or ICH guideline adopted in Australia to establish safety or quality for use in listed sunscreens, a justification must be provided.

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 regulated as therapeutic goods in Australia as opposed to ‘cosmetics’ in some other parts of the world.

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. See heading ‘What needs to be included in a justification’ in the URNS.

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

For a new application for a substance that is **subject to a monograph in a default standard**, applicants need to provide the information described under sub-heading ‘Information required to demonstrate QUALITY for substances subject to a monograph in a default standard’ under ‘SECTION B – Information requirements’ in the URNS.

Quality data for new applications for substances **not subject to a monograph in a default standard** is required to clearly characterise the substance. The amount of information required will vary depending on the purpose of use of the substance. Table 3 lists “core information requirements” that are needed for a quality evaluation of a new listed sunscreen ingredient that is not subject to a monograph in a default

standard. The quality requirements are the same for other listed medicines for dermal use. Guidance can be found under the heading ‘Information required to demonstrate QUALITY for substances not subject to a monograph in a default standard’ under ‘SECTION B – Information requirements’ in the URNS. The headings of each core information requirement in Table 3 correspond with the headings in the URNS.

Specifications (tests and acceptance criteria) that describe the substance and ensure its quality, must be provided in a compositional guideline where there is no corresponding monograph in a default standard. In most cases, the compositional guideline template for chemical entities/synthetic polymers will be appropriate for sunscreen ingredients. If the tests described in the compositional guideline are pharmacopeial methods or involve the sensory organs (i.e. organoleptic or visual observation), then further information for these methods does not need to be provided other than what is included in the compositional guideline. For example, if pharmacopeial methods are used for the identity, assay, and impurities described in the compositional guideline, then applicants can state under the relevant heading in Table 3 to “refer to the compositional guideline”. Other core information requirements not covered in the compositional guideline (such as manufacturing details, certificates of analysis, reference standard, and stability test) must be addressed in the application.

In circumstances where data or information cannot be provided to address a core information requirement in Table 3, for example where particular tests are not feasible, appropriate or necessary, submit a justification based on sound scientific argument for not including this in the dossier. Refer to ‘Dossier preparation’ in the URNS**.** For example, where an excipient ingredient is supplied as a component of a proprietary ingredient (that contains multiple substances) that is only used in very small quantities, it may not be possible to provide many of the quality data information e.g. manufacturing process, impurities and incidental ingredients. In such cases, the applicant may provide an assurance that there are unlikely to be any impurities of safety concern, and this will be considered during evaluation. Ultimately, the appropriateness of the specification for the raw material (input) to ensure purity and safety must be established by the manufacturer.

Table 3. Quality data required for new dermal substances (active and excipient) not subject to a monograph of a default standard

Core information requirement		Dermal active substances[2]	Dermal excipient substances[2]
Description	Description of the substance	ü	ü

[2] Refers to substances that are applied topically for use in listed therapeutic sunscreens.

Core information requirement		Dermal active substances[2]	Dermal excipient substances[2]
Manufacturing details	Description of manufacturing process	ü	ü [3]
	Control of materials	ü	û
	Critical steps & intermediates	ü	û
	Process development	ü	û
	Process validation	ü	û
Characterisation	General properties	ü	ü
	Identity	ü	ü
	Assay	ü	r [4]
	Impurities and incidental constituents	ü	ü
	Reference standard	ü	r [5]
Specifications	Compositional guideline	ü	ü
	Certificates of Analysis (CoA)	2 commercial-scale OR 3 pilot-scale batches	1 commercial-scale OR 2 pilot-scale batches
Stability test	Real-time and accelerated stability testing data[6] for two commercial-scale batches or three pilot scale batches	ü	û

ü: required
û: not required
r : situational, see corresponding footnotes

[3] For chemically derived excipients for dermal use only, only a brief description of manufacturing process required.
[4] An assay test is not a requirement if the excipient is only for use in a formulation for its physical properties (e.g. emulsifier, thickener etc.).
[5] A reference standard is not a requirement for chemically derived excipients for dermal use only.
[6] Stability testing is not required if stress testing data can be provided that demonstrates the absence of degradants.

Establishing the UV absorption range of new active sunscreen ingredients

For new applications for substances intended for use as an active sunscreen ingredient, sponsors should provide data to establish the UV absorption range to enable confirmation of its UVA/UVB absorption profile. This information will determine the specifications of the UV range for the substance to work as an active sunscreen agent. If the new substance is not subject to a monograph in a default standard, this information should be included in the compositional guideline.

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

Safety data is required for a new application for substances for use in listed therapeutic sunscreens. Table 5 lists “core information requirements” that are needed for a safety evaluation of a new listed sunscreen ingredient. The safety requirements are the same for other listed medicines for dermal use. Guidance can be found under the headings ‘Information required to demonstrate SAFETY’ and ‘Substances for dermal use’ under ‘SECTION B – Information requirements’ in the URNS. The headings of each core information requirement in Table 5 correspond with the headings in the URNS.

The safety assessment determines the overall risk associated with a substance based on the level of **exposure** to the substance, and the level of **hazard** (its actual or potential to cause harm) that is intrinsic to that substance. There are different requirements if a substance is not absorbed beyond the superficial barrier of the epidermis (the *stratum corneum*). 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.

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. Conditions may be placed on the use of a new ingredient to ensure appropriate level of risk if it is determined that the hazard posed by the proposed use is beyond that considered acceptable for listed medicines.

In circumstances where data or information cannot be provided to address a core information requirement in Table 5, for example where particular tests are not feasible, appropriate or necessary, submit a justification based on sound scientific argument for not including this in the dossier. Refer to ‘Dossier preparation’ in the URNS**.**

When considering using justification to replace data requirements to support safety, the applicant should consider whether the justification addresses the same safety concerns that the core information requirement would address.

For example, if an ingredient has current and historical use as food as well as its proposed use as a sunscreen/dermal excipient, and the proposed concentration in use is well below the Acceptable Daily Intake value, then the data or information required to demonstrate oral toxicity, or potential toxicity concerns arising from incidental oral ingestion, would not be required. However, local tolerance (such as skin irritation and sensitisation studies) will still need to be addressed, as these risks are not addressed by the ingredient's use as food.

Similarly, even if an ingredient shows skin absorption, further pharmacokinetic and pharmacodynamic studies may not be required if the level absorbed is not likely to impact on the risk due to factors such as quantity absorbed, whether the substance is already expected to be within the system, and history of safe use of the ingredient in similar applications.

Substances that are not absorbed

If a substance does not demonstrate absorption beyond the *stratum corneum*, or scientific justification has been provided to address that the substance is highly unlikely to be absorbed, and does not biologically or chemically react with the skin in a hazardous way,[7] then limited safety data is required. If you are not providing absorption studies, and the substance is highly unlikely to be absorbed, you must provide scientific justification discussing the relevant factors influencing dermal absorption (e.g. molecular weight, lipophilicity etc.). Refer to the heading 'Substances for dermal use' in the URNS for details (p 37 at the time of this publication). If absorption has been demonstrated (or cannot be excluded), then the information required will be similar to other substances that are systemically absorbed.

Determining the safe concentration of substances that are absorbed

If a substance is systematically absorbed, then the TGA uses the Australian Sunscreen Exposure Model (ASEM) to estimate sunscreen exposure to calculate the Systemic Exposure Dose (SED). The SED is then used together with a no observed adverse effect level (NOAEL), where possible, derived from animal studies to calculate Margin of Safety (MoS). The following formula is used to calculate the MoS:

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)}$$

For general sunscreens that are intended to be used over the body, the highest estimated daily sunscreen exposure values below are used to calculate the SED depending on how dermal absorption data for the ingredient is reported. This ensures that risk assessments, when based on the highest usage estimations, also guarantee safety for the average, or lower usage cases where less of the ingredient may be applied to the skin.

[7] Local tolerance studies may be used to demonstrate the substance does not react with the skin.

Table 4. SED calculation

How dermal absorption data is reported	Highest estimated daily sunscreen exposure	How to calculate the SED
Method 1 (%)	673 mg/kg bw/day	SED = 673 mg/kg bw/day x DA_p x C
Method 2 (µg/cm^2)	336 cm^2/kg bw/day	SED = 336 cm^2/kg bw/day x DA_a

C: % concentration of the ingredient used to test dermal absorption
DA_p: % of ingredient absorbed in the dermal absorption study
DA_a: absolute amount in µg/cm^2 of the ingredient bioavailable in dermal absorption study

Because the SED is based on the ASEM highest estimated sunscreen exposure as a proportion of kg body weight per day, risk assessments using this value account for any body weight (i.e. including adults or children). This ensures that risk assessment comprehensively cover the highest exposure for all Australians and ensure ingredients are safe to be used by everyone, no matter their age, weight, or outdoor activity.

For specific sunscreen use scenarios (such as those with application restricted to the face only), the ASEM can be used as a tool to consider usage scenarios. The TGA will give consideration to establishing standardised exposure assumptions for such scenarios and this may be to be included in future guidance.

See APPENDIX 2 for details on how risk assessments are conducted using the ASEM.

Table 5. Safety data required for new dermal substances (active and excipient)

Core information requirement		Dermal active substances[8]	Dermal excipient substances[9]
Systematic literature search	A systematic literature search on the substance; with the search strategy and results with justification for inclusion/exclusion of data	ü	ü
History and pattern of human use	Information on: • Use in therapeutic goods (Australian and International) • Use in food • Traditional use • History of safe use - Summary of overall human exposure from all sources	ü	ü

[8] Refers to substances that are applied topically for use in listed therapeutic sunscreens.

Core information requirement			Dermal active substances[8]	Dermal excipient substances[9]
Biological activity	**Pharmacokinetics**	Pharmacokinetic studies addressing: • Absorption	ü	ü
		• Tissue distribution and storage • Metabolism • Mode and extent of excretion or elimination	r [9]	r [10]
	Pharmacodynamics	For substances that are systemically absorbed (or cannot be excluded), pharmacology information addressing: • Primary pharmacodynamics • Safety pharmacology to study the effects of the substance on the following vital functions: - Central nervous system - Cardiovascular system - Respiratory system • Known pharmacodynamic drug interactions	r [10]	r [11]
Toxicological data		Information from *in vitro* studies, animal studies, human clinical studies or other information (or a combination) addressing: • Maximum daily dosage • Duration of use • Genotoxicity • Carcinogenicity (if continuous use of at least 6 months intended) • Reproductive and developmental toxicity (if there are no restrictions proposed in the application that limit use of the substance for use in pregnant or lactating females, or in a paediatric population < 18	r [11]	r [12]

[9] This information is not required if the substance is for use on unbroken skin only, and is demonstrated to not be absorbed beyond the *stratum corneum*.

[10] This information is not required if the substance is for use on unbroken skin only, is demonstrated to not be absorbed beyond the *stratum corneum,* and does not react with the skin.

[11] This information is not required if the substance is for use on unbroken skin only, is demonstrated to not be absorbed beyond the *stratum corneum,* and does not react with the skin.

Core information requirement		Dermal active substances[8]	Dermal excipient substances[9]
	years)		
	• Local tolerance	ü	ü
	• *In silico* analysis for mutagenicity if potential exposure to other tissues (e.g. oral exposure if substance applied on face).	r [12]	r [12]
Adverse reactions	A list of the nature, severity and frequency of adverse reactions from adverse event databases, clinical trials, or case reports of human poisoning	ü	ü
Substances of human or animal origin	Information on clearance of risk for transmissible spongiform encephalopathy (TSE) if substances of human or animal origin were used during manufacture	ü	ü

ü: required
û: not required
r : situational, see corresponding footnote.

Demonstrating the substance is not carcinogenic

Sunscreens could be used long term (for at least 6 months) and are often encouraged for use (with other sun protection measures such as clothing and seeking shade) throughout most of the year and are not limited to just the summer months in Australia.

[12] This information is only required if genotoxicity data has not been provided.

If the substance has demonstrated to not be absorbed beyond the *stratum corneum* or scientific justification has been provided to address that the substance is highly unlikely to be absorbed, provide an *in silico* analysis for mutagenicity or genotoxicity studies (if available) to address its mutagenic potential. If these studies have not raised concerns, then the substance is not likely to have carcinogenic potential. If the *in silico* analysis for mutagenicity is positive for the substance, then the information required will be similar to other substances that are systemically absorbed.

If the substance is absorbed beyond the *stratum corneum* (or cannot be excluded), then carcinogenicity studies are generally required for substances intended to be used long-term (continuous use for at least 6 months). However, the TGA will not generally consider an application for a new substance ineffective simply because a carcinogenicity study was not provided. If carcinogenicity studies are not provided, applicants need to demonstrate that the substance does not pose a risk of carcinogenicity with a justification. This could be based on the following points. Note: not all the points are required, but these are possible examples that are considered during evaluation:

- 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
- 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 and the lack of pre-neoplastic changes
- lack of evidence for hormonal perturbation
- lack of adverse activity in local tolerance studies (skin irritation and skin sensitisation).

The following studies and referenced websites may also be useful in providing information on the potential of a substance to cause tumours in humans:

- *in vitro* human dermal cell cultures exposed to the substance
- *in vitro* human dermal tumour cell cultures exposed to the substance.

Other safety requirements specific for new substances for use in listed therapeutic sunscreens

For all new applications for sunscreen ingredients

Applicants should provide assurance that a new substance 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.

For new applications for sunscreen active ingredients

Since sunscreen formulations usually contain more than one active ingredient, data addressing the potential for physical interaction of the new substance with other commonly used sunscreen actives identified in the literature search should be provided.

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 applications. For example, 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 test number 431: *in vitro* skin corrosion: reconstructed human epidermis (RHE) test method.

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 (e.g. studies using appropriate and validated transgenic animal models to test exposure to the substance)
- The European Commission's Tracking System for Alternative methods towards Regulatory acceptance (TSAR)
- The European Commission's science and knowledge service
- EU Reference Laboratory for alternatives to animal testing (EURL ECVAM)

Manufacture and quality control 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). All sunscreen products released on the Australian market must be manufactured according to the principles of GMP. Guidance specific to sunscreen manufacturing can be found in the Sunscreen manufacturing: Demonstrating compliance with the PIC/S guide to GMP, PE0009-13. 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.

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.

Default standards for listed therapeutic sunscreens

Pharmacopeial 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-pharmacopeial 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

Ingredients specifications for listed therapeutic sunscreens

Pharmacopeial 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 ingredient(s) 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 this Guidance was 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.

Finished products specifications for listed therapeutic sunscreens

Pharmacopeial 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-pharmacopeial 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.

SPF test results for listed therapeutic sunscreens

The SPF informs consumers of the efficacy of sunscreen against sunburn and helps to select a product appropriate to their skin sensitivity and exposure to the sun.

The SPF of therapeutic sunscreens must be determined by testing on human skin in accordance with the AS/NZS standard for sunscreens, which references the International Organisation for Standardisation (ISO) procedure:

- ISO 24443 Determination of sunscreen UVA photoprotection in vitro
- ISO 24444 Cosmetic—Sun protection test methods—in vivo determination of the SPF

- ISO 16217 Cosmetics—Sun protection test methods—Water immersion procedure for determining water resistance

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 AS/NZS standard for sunscreens, 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 testing for sunscreens is mandatory. All responsibilities related to ongoing stability testing should be defined in a GMP agreement (unless the sponsor, manufacturer and authorised person conducting release for supply are all from the same entity).

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 this Guidance.

- 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.

Note

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 6)
- providing a justification based on supporting stability data generated for a closely related formulation.

Table 6 shows the shelf-life prediction of a sunscreen product from short-term testing.

Table 6. 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.

Note

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

- very minor
- unlikely to affect the physical, chemical or microbiological stability of the product, and
- 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. Stability testing should be conducted on all those parameters that are likely to influence the quality and performance of the sunscreen. Some of the 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 timeline 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 Changing a listed or assessed listed medicine in the Australian Register of Therapeutic Goods (ARTG). 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 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.

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 number will be issued.

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 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 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.

Changes that may affect SPF properties of listed therapeutic sunscreens

Sponsors should recognise that the SPF and other physical properties of a sunscreen are affectednot 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.

Appendix 1: Indications permitted for use in listed therapeutic sunscreens

Indications permitted for use in listed therapeutic sunscreens at the time of publication of this Guidance are listed in Table 7.

Note

Table 7 includes only those indications that were included in the Therapeutic Goods (Permissible Indications) Determination at the time of publication. It is the sponsor's responsibility to check the current Permissible Indications Determination to ensure that indication information is correct.

Table 7. Indications permitted for use in listed therapeutic sunscreens

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.
SPF 25 Broad spectrum medium/moderate protection sunscreen	Indication for use in sunscreen products only.

Indication	Requirement
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: How risk assessments are conducted for ingredients that are systemically absorbed

When considering the risks to human health and safety from the use of substances in therapeutic goods, including sunscreens, it is essential to consider their use in the context of hazard and exposure.

The hazard of a substance is defined by its intrinsic toxicity, characterised by the dosage and its short-term or long-term adverse effects on biological systems, with a critical factor being the identification of a toxicological threshold known as the 'No Observed Adverse Effect Level' (NOAEL) where no adverse effects are observed.

Exposure is the identification and characterisation of the contact between a product or substance and the host, in this case humans. For dermally applied products, the exposure can be either local or both local and systemic.

There are 2 broad areas of risk associated with dermally applied products, including sunscreens:

(1) adverse effects at or around the site of application/administration e.g. irritation and inflammation.

(2) adverse effects related to systemic effects following distribution of substances internally via ingestion, inhalation, or penetration/absorption though the skin, eyes, and other areas of the body.

Local intolerance of a dermally applied product may be thought as time-limited and self-identifiable, i.e. a product can be removed (washed) off the skin or flushed from the eyes, (skin surface removal/sloughing) and a person could readily identify irritation to the eyes, skin, and mucosal surfaces.

On the other hand, the adverse effects of the product on the human body when distributed internally to other tissues and organs and for varying periods of time may not be immediately obvious or not become apparent for many months or years after exposure. The TGA considers the systemic exposure as a critical determinant when considering the inherent risks from contact with dermally applied products, including sunscreens. The risk is assessed using a Margin of Safety (MoS) calculation described below.

Margin of Safety (MoS)

A MoS approach is used to consider the risks to human health and safety of substances. The MoS compares the expected systemic exposure dose (SED) of a substance within the human population to a toxicological threshold, known as the 'No Observed Adverse Effect Level' (NOAEL). The NOAEL is the level at which no specific adverse effects were observed in humans or animals, adjusted for body weight. Typically, the NOAEL is derived from long-term, repeat-dose toxicity studies in animals. As such, the MoS value indicates the likelihood of an adverse health effect occurring under specific exposure conditions.

To correct for the uncertainty in the data, the internationally accepted methodology utilises a correction factor of 10 to account for interspecies differences between animals and humans, and a further correction factor of 10 for intraspecies differences to account for variations in the human population. These factors are multiplied together to arrive at a value of 100. Margins of Safety below 100 are generally considered unacceptable. Moreover, as the MoS increases, the potential risk decreases.

Determining the adequacy of the MoS requires expert judgment, which is typically exercised on a case-by-case basis. This judgment should account for uncertainties in the risk assessment process, such as data completeness and quality, the nature and severity of the adverse effects, and intra/inter species variability. For instance:

- acceptance of lower MoS values may be deemed appropriate when the NOAEL is based upon human toxicological data.
- conversely, a requirement for higher MoS values may arise such as, in situations where the duration of the toxicological study does not adequately reflect the intended duration of exposure, or when MoS is based on a LOAEL in the absence of a NOAEL.[13]

The following formula is used to calculate the MoS:

$$MoS = \frac{NOAEL\ (mg/kg\ bw/day)}{SED\ (mg/kg\ bw/day)}$$

NOAEL may be adjusted for bioavailability to reflect a systemic value, particularly when evaluating dermal exposure risks using a NOAEL derived from an oral study.

Systemic Exposure Dose

SED is the internal exposure dose, which is the amount of an ingredient absorbed through the skin into the systemic circulation. It is the amount expected to enter the blood stream (and therefore be systemically available) per kg body weight and per day. It is expressed in mg/kg body weight (bw)/day, similar to NOAEL.

Determining the SED is based on how much sunscreen is applied to the skin on a daily basis (i.e. the external exposure dose). Applicants can also provide available pharmacokinetic data that will be considered in determining the SED as part of the risk assessment. For instance, dermal absorption factors may be refined further when robust scientific data (i.e. data demonstrating plasma values after dermal application) can be provided.

The TGA has drawn upon the same risk assessment method developed by the SCCS for cosmetic ingredients to calculate the SED and MoS. However, the Australian Sunscreen Exposure Model (ASEM) utilises a different estimated average daily sunscreen exposure (external exposure) for therapeutic sunscreens than is

[13] An additional assessment factor of 3 is included in the MoS calculation in these situations, as per the SCCS Notes for guidance for safety evaluation of cosmetics (12th Revision).

used by the SCCS to calculate the SED and MoS for cosmetics including sunscreens.

How the ASEM was used to calculate sunscreen exposure

The ASEM is a model that calculates the estimated average daily sunscreen exposure using a formula, and the input into that formula is based on Australian expected sunscreen use scenarios.

The ASEM is based on data for skin surface area, age, and body weight for the Australian population. The formula calculates the daily sunscreen exposure by considering how many times it is applied a day, number of days of the year it is applied, and the skin surface area of each body part it is applied to. All these variables can change based on how the sunscreen is used and who it is used by.

For general therapeutic sunscreens meant to be used by the whole population, a highest estimated average daily sunscreen exposure amount was calculated based on the highest use scenarios in the most vulnerable population (toddlers aged 1-2 years). These values, and how to calculate the SED are reproduced in the table below depending on how data is reported from the dermal absorption studies. The respective input values for these variables were described in the public consultation on adopting the ASEM.[14]

For all the calculations for the estimated daily sunscreen exposure for each age group and scenario, and the combinations of the ASEM scenarios (including how Australian skin surface area and body weight data have been used) please refer to Attachment 2 of the ASEM.

Table 8: SED calculation

How dermal absorption data is reported	Highest estimated daily sunscreen exposure	How to calculate the SED
Method 1 (%)	673 mg/kg bw/day	SED = 673 mg/kg bw/day x DA_p x C
Method 2 (µg/cm^2)	336 cm^2/kg bw/day	SED = 336 cm^2/kg bw/day x DA_a

For specific sunscreen use scenarios (such as those with restricted application to the face only), the ASEM can be used as a tool to consider usage scenarios. The TGA will give consideration to establishing standardised exposure assumptions for such scenarios and this may be to be included in future guidance.

[14] Australian Government, Department of Health and Aged Care, Therapeutic Goods Administration (2024). Australian Sunscreen Exposure Model. Consultation on an exposure model for assessing the safety of sunscreen ingredients in Australia. Version 1.0, July 2024.

When to use Method 1 vs Method 2

The choice of dermal absorption factor and method of calculation (i.e. Method 1 vs Method 2) depends on the type and quality of the data available for establishing the dermal absorption potential of the ingredient under consideration. In general, there is no preference for use of Method 1 or Method 2 as the ASEM approach results in the same risk quantification (i.e. same MoS values) irrespective of whether dermal absorption is quantified in µg/cm² (Method 2) or as a percentage (Method 1) when the test formulation is applied at a thickness of 2 mg/cm^2 in the dermal absorption study (compliant with OECD 428 – Guideline for Skin Absorption: in vitro method).

Dermal absorption studies (compliant with OECD 428) typically express results as both an absolute amount (i.e. µg/cm²) and a relative amount (percentage) and stipulate an application rate of 1-5 mg/cm² to mimic realistic human exposure. While 2 mg/cm² is the thickness of applied sunscreen needed to achieve the labelled SPF rating, studies often apply the test formulation at 3, 4, or 5 mg/cm² instead. The SCCS notes for guidance for testing of cosmetic ingredients (12th Rev) also state that *in vitro* measurements using less than 2 mg/cm² are not technically feasible. The SCCS guidance on basic criteria for the in vitro assessment of dermal absorption recommends a 2-5 mg/cm^2 dose of test formulation. This can cause variability in the risk quantification (i.e. MoS calculation) between Method 1 and 2 since the reported absolute amount absorbed will be a different percent of 3, 4, or 5 mg/cm² application rate versus that of a 2 mg/cm² application.[15]

Where an application rate greater than 2 mg/cm^2 is used in the dermal absorption study, the absolute amount (µg/cm²) may be used when calculating the systemic exposure for risk assessments to minimise this variability. This is particularly important since it is known that the efficiency of absorption may remain the same or change as the concentration on the skin increases for some chemicals. For chemicals that penetrate the skin rapidly, the total amount of chemical absorbed increases as the dosage increases. Conversely, for chemicals that penetrate very slowly, the rate of penetration and the surface area exposed will have a greater influence on the systemic absorption dose than the extent of dermal deposition.

Since the efficacy of sunscreen ingredients relies predominantly on their ability to persist on the skin (including the top layers of the skin), they are likely to penetrate very slowly (or ideally not penetrate). Suggesting that the total amount of chemical systemically absorbed may not be proportional to the dermal dose/deposition. Hence using the dermal absorption factor expressed as a proportion (i.e. %) may not be appropriate for some sunscreen ingredients.

[15] See demonstration in Attachment 3 in the Australian Sunscreen Exposure Model. Consultation on an exposure model for assessing the safety of sunscreen ingredients in Australia. Version 1.0, July 2024.

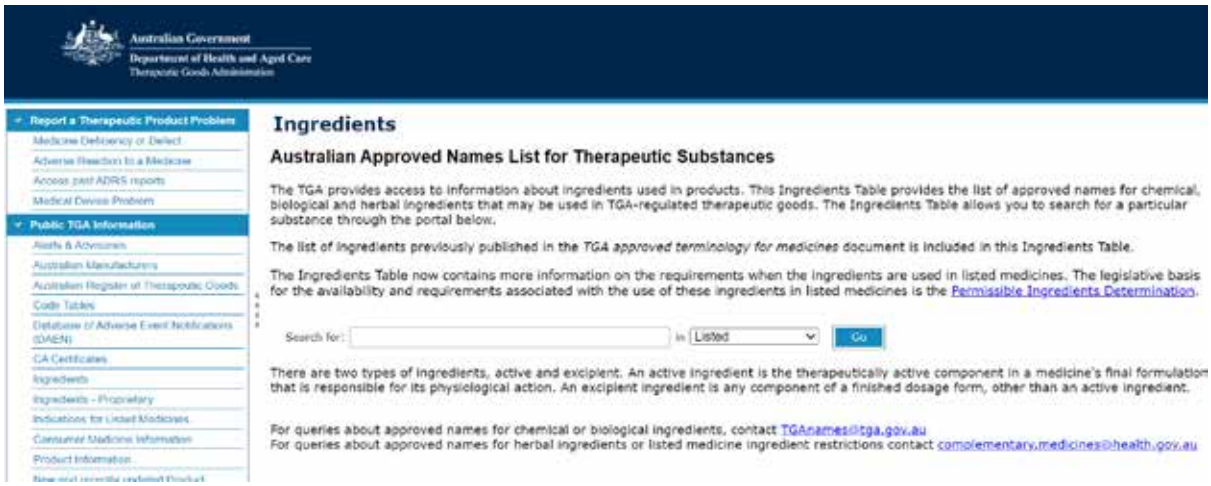
Appendix 3: Active ingredients restricted to use in therapeutic sunscreens

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:

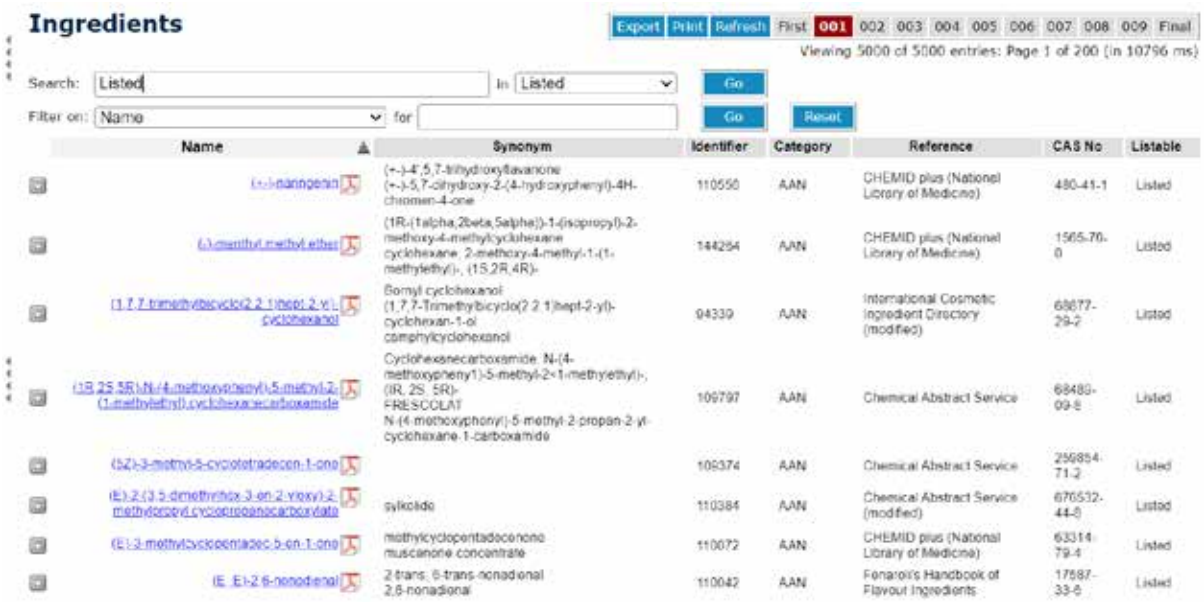
- CAS numbers (where available); and
- ingredients that are in the Permissible Ingredients Determination, by entering the term 'Listed' and selecting the field 'Listed' (see Figure 1).

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 9.

Note

Table 9 includes only those active ingredients that were included in the Therapeutic Goods (Permissible Ingredients) Determination at the time of publication. 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 9. Active ingredients restricted for use in therapeutic sunscreens (at time of publication)

Australian Approved Name (AAN)	CAS Number	Synonyms	Maximum concentration
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%

Australian Approved Name (AAN)	CAS Number	Synonyms	Maximum concentration
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%
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%

Australian Approved Name (AAN)	CAS Number	Synonyms	Maximum concentration
methoxypropylamino cyclohexenylidene ethoxyethylcyanoacetate	1419401-88-9	2-ethoxyethyl (2Z)-2-cyano-2-[3-(3-methoxypropylamino) cyclohex-2-en-1-ylidene]acetate	3%
4-methylbenzylidene camphor	36861-47-9	3-(4-methylbenzylidene)-di-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%
octocrylene	6197-30-4	2-ethylhexyl-2-cyano-3,3diphenylacrylate	10%
oxybenzone	131-57-7	benzophenone 3	10%
padimate O	21245-02-3	ethylhexyl dimethyl PABA 4-(dimethylamino)benzoic acid2-ethylhexyl ester	8%
PEG-25 PABA	113010-52-9	ethoxylated ethyl 4-aminobenzoate	10%
phenylbenzimidazole sulfonic acid	27503-81-7	2-phenylbenzimidazole-5-sulfonic acid 2-phenyl-5-sulfobenzimidazole ensulizole	4%

Australian Approved Name (AAN)	CAS Number	Synonyms	Maximum concentration
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

Glossary

Term	Definition
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.
URNS	means the guidance titled Understanding the application requirements for new substances in listed medicines (formerly, Application requirements for new substances in listed medicines).
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).
AS/NZS standard for sunscreens	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 AS/NZS standard for sunscreens).
Comparable Overseas Body (or COB)	means a competent regulatory authority of a foreign country or a foreign jurisdiction determined by the Secretary for the purposes of regulation 16GJ of the Regulations.
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).

Term	Definition
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).
Dermal substances	means substances that are to be applied topically for use in listed therapeutic sunscreens.
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.
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).

Term	Definition
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 AS/NZS standard for sunscreens).
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.
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 AS/NZS standard for sunscreens).
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

Term	Definition
	represented as having a primary purpose other than sun protection whilst providing some protection of the skin from ultraviolet radiation *(the* AS/NZS standard for sunscreens).
Sun Protection Factor (SPF)	means the arithmetic mean of all valid individual SPF values obtained from all subjects in the test (the AS/NZS standard for sunscreens). 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.

Term	Definition
UV filter	for the purposes of this Guidance, 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 this Guidance, 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 AS/NZS standard for sunscreens).

Revision history

Note: this section is the same as page history on the TGA website.

August 2025

- Document name changes:
  - Australian Regulatory Guidelines for Sunscreens to Understanding the regulation of therapeutic sunscreens.
  - Application requirements for new substances in listed medicines to Understanding the application requirements for a new substance in listed medicines.
- Included information on how requesting for pre-submission meetings prior to lodging an application for registered therapeutic sunscreens.
- Included information about how to determine the safe concentration of substances that may be absorbed using the Australian Sunscreen Exposure Model, including further information in Appendix 2.
- Update to section Safety data requirements for new ingredients for use in listed therapeutic sunscreens:
  - Added additional information that should be considered for safety assessment including importance of clearly stating concentration sought and consideration of both short- and long-term effects.
  - Added clarification that justifications may be acceptable in lieu of some core information categories.
- Removed references to exempt sunscreens.
- Updated reference to the Australian Sunscreen Standard to AS/NZS standard for sunscreens.
- Updated Table 9 to include methoxypropylamino cyclohexenylidene ethoxyethylcyanoacetate, which is a new ingredient listed in the Permissible Ingredients Determination.
- Minor formatting changes including table titles.

May 2023

- Updated to a new template.
- Major change to the sections:
  - Ingredients permitted for use in listed therapeutic sunscreen and Applying for a new ingredient to be used in listed therapeutic sunscreens
    - § updated links to reference to updated guidance documents ‘Application requirements for new substances in listed medicines’ and ‘Guidance on using Comparable Overseas Body reports’.

    - § included option for eligible new ingredients to receive a 2-year exclusivity period.
    - § updated quality and safety data requirements to refer to ‘Application requirements for new substances in listed medicines’ to align the data requirements for all listed medicines ingredients.
    - § added Tables 3 and 4 to specify respective quality and safety core information requirements for a new ingredient to be used in listed therapeutic sunscreens. Rearranged and updated information for consistency.
    - § included the provision of using the COBs-based process.
  - SPF test results for listed therapeutic sunscreens:
    - § Removed details of SPF testing and updated to follow the ISO testing methods.
- Editorial and minor changes to overall text to remove repetitive information.
- Updated links to current documents.
- Images in Appendix 2 replaced with higher resolution examples.
- New terms added to the ‘Glossary of terms and abbreviations’.
- Updates to Table 7: List of active sunscreen ingredients
  - Removed aminobenzoic acid (PABA) to align with removal of ingredient from the Permissible Ingredients Determination.
  - Amended a typographical error for the maximum level of use for PEG-25 PABA to 10%.

July 2021

- 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.

August 2019

- Updated to remove Table 3 – Permitted active ingredients for therapeutic sunscreens and replace with links to the Therapeutic Goods (Permissible Ingredients) Determination,

January 2016

- 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.

October 2012

- Original publication.

Related links

- How sunscreens are regulated in Australia to be effective and safe | Therapeutic Goods Administration (TGA)
- Dossier requirements for non-prescription medicines | Therapeutic Goods Administration (TGA)
- Understand the non-prescription medicine pathways | Therapeutic Goods Administration (TGA)
- Sunscreens - ensuring products are effective and safe for the 2021-22 summer | Therapeutic Goods Administration (TGA)
- What do I require to have a listed medicine in the ARTG? | Therapeutic Goods Administration (TGA)
- TGA publishes updated guidelines for sunscreens | Therapeutic Goods Administration (TGA)

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