Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Clarification and updates to the regulation of sunscreens

Consultation paper

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Introduction

Skin cancer is a major health issue in Australia. The age-standardised rate of melanoma in Australia increased from 46 cases per 100,000 persons in 2000 to an estimated 55 cases per 100,000 persons in 2021. Exposure to UV can be moderated by protective behaviours, such as: wearing a hat, using sunscreen, wearing protective clothing and seeking shade[1].

The primary objective of regulation of sunscreens in Australia is to ensure their quality, safety and efficacy with a view to protecting consumers from the sun's harmful UV radiation and reducing the incidence and tragic outcomes of skin cancer. Many Australians use sunscreen every day of their lives, sometimes over large areas of their body surface. It is important, therefore, that sunscreens used in Australia are safe, effective and of good quality.

About this consultation

The Therapeutic Goods Administration (TGA) is seeking public comment on potential clarification and updates to the regulation of sunscreens.

A number of documents are referred to in this consultation paper; the abbreviations used for these documents are provided in Table 1 below.

The potential regulatory clarification and updates include:

1. Adoption of the 2021 Sunscreen Standard which specifies the current testing and labelling requirements for sunscreens.
2. Removal of the category of 'exempt' sunscreens and previous transitional arrangements (from the Regulations) which enables sunscreen products with less than SPF4 (that were supplied in the market prior to 9 November 2012) to comply with the superseded 1998 Sunscreen Standard and be exempt from the requirement to be included in the ARTG.
3. Clarification of the indications (therapeutic uses) that sunscreens can make. Three options are proposed for stakeholder consideration.

The purpose of the consultation is to seek stakeholder feedback on any positive or negative impacts the proposed amendments may have on businesses and/ or consumers. This information will be used to help inform the Government's decision on whether or not to implement any of the proposals by amending the relevant legislation.

While feedback on all issues is welcome from all stakeholders, consumers and health professionals will likely be more interested in issue 3, as issues 1 and 2 are more technical. If a topic is not of interest, stakeholders do not need to provide a response.

We invite you to provide your feedback by answering the questions in this consultation paper in Citizen space https://consultations.tga.gov.au/medicines-regulation-division/updates-to-regulation-of-sunscreens by 31 May 2023.

We will consider all feedback received before a Government decision is made to implement the proposed changes . If you have any questions about the proposals or this consultation, please email: complementary.medicines@health.gov.au

Table 1: List of abbreviations used in this document

Document and terms	Abbreviation
Australian/New Zealand Standard Sunscreen products - Evaluation and classification AS/NZS 2604:1998	1998 Sunscreen Standard

[1] www.aihw.gov.au/reports/australias-health/natural-environment-and-health

Document and terms	Abbreviation
Australian/New Zealand Standard Sunscreen products - Evaluation and classification AS/NZS 2604:2012	2012 Sunscreen Standard
Australian/New Zealand Standard Sunscreen products - Evaluation and classification AS/NZS 2604:2021 Amd 1:2022	2021 Sunscreen Standard
Australian Register of Therapeutic Goods	ARTG
Australian Regulatory Guidelines for Sunscreens	ARGS
Electronic Listing Facility	ELF
Standard for the Uniform Scheduling of Medicines and Poisons	Poisons Standard
Sun Protection Factor	SPF
Therapeutic Goods Act 1989	the Act
Therapeutic Goods (Therapeutic Goods Advertising Code) Instrument 2021	Advertising Code
Therapeutic Goods (Excluded Goods) Determination 2018	Excluded Goods Determination
Therapeutic Goods (Permissible Indications) Determination (No. 1) 2021	Permissible Indications Determination
Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2023	Permissible Ingredients Determination
Therapeutic Goods Regulations 1990	the Regulations

Proposals discussed in this consultation

Proposal 1

Standards Australia have recently published the 2021 Sunscreen Standard, which replaces the 2012 Sunscreen Standard[2]. The TGA is proposing to adopt the 2021 Sunscreen Standard by updating the therapeutic goods legislation to include references to this standard and removing references to all previous Sunscreen Standards.

Proposal 2

The 1998 Sunscreen Standard permitted sunscreens to have label claims of less than SPF4. Provisions and previous transitional arrangements in the Regulations (which occurred when the 2012 Sunscreen Standard was adopted by the TGA) exempt sunscreen products with less than SPF4 from the requirement to be included in the ARTG and enables these goods to be available for supply without complying with the 2012 Sunscreen Standard (that is, they can comply with the superseded 1998 Sunscreen Standard).

As the 2012 Sunscreen Standard and 2021 Sunscreen Standard do not permit sunscreens to be labelled with a SPF of less than 4, the TGA proposes to remove these exemption provisions when the 2021 Sunscreen Standard is adopted, given that all sunscreens will be required to comply with the 2021 Sunscreen Standard (and there will be no grandfathering arrangements whereby sunscreens can continue to comply indefinitely with previously published sunscreen standards). The effect of this will be those products with less than SPF4 will need to comply with the 2021 Sunscreen Standard, meaning they cannot make any claims relating to sun screening.

[2] Standards Australia published a Sunscreen Standard in 2021. This was not adopted by the TGA as we were aware this publication would be amended in 2022.

Proposal 3

Primary and secondary sunscreens are restricted to only using indications permitted for sunscreen use (as included in the Permissible Indications Determination). This restriction was intentional. Recently, sponsors have requested to use indications for their sunscreens that are permitted for other listed medicines, however, these indications are not available in the Electronic Listing Facility (ELF) for sunscreen sponsors to select.

The TGA is seeking feedback on options for clarifying the indications that are appropriate for listed sunscreens to use.

Current regulation of sunscreens in Australia

The TGA regulates sunscreens in Australia that are classified as therapeutic goods to make sure they are safe, efficacious and high quality. Sunscreens that are regulated as therapeutic goods under the Act are referred to as 'therapeutic sunscreens' by the TGA.

Sunscreens fall into two categories: 'primary' sunscreens and 'secondary' sunscreens. The Australian therapeutic goods legislation relies on the definition of primary and secondary sunscreens as set out in the Sunscreen Standard (as adopted by the TGA) which are reproduced below:

- **Primary sunscreen product:** Product that is represented as being primarily to protect the skin from UV radiation.
- **Secondary sunscreen product**: Product that is represented as having a primary function other than sun protection while providing some protection of the skin from UV radiation, for example:
    - Skin care
        (a) Moisturising products for face, hands and body that are secondary sunscreen products for dermal application, including anti-wrinkle, anti-ageing and skin-whitening products
        (b) Sunbathing products that are secondary sunscreen products (e.g. oils, creams or gels) including products for tanning without sun, and 'after-sun' skin care products.
    - Colour cosmetic products that are secondary sunscreen products and are either tinted base or foundation (make-up), or products intended for application to the lips (tinted or untinted).

Primary sunscreens are regulated by the TGA as therapeutic goods. Secondary sunscreens may, depending on their presentation and their SPF, also be regulated as therapeutic goods. However, many secondary sunscreen products are not considered to be therapeutic goods and are '**excluded**' from therapeutic goods legislation. These product types are outlined under the Excluded Goods Determination (excerpt provided at **Attachment 1**).

Secondary sunscreens that are/are not regulated by the TGA are broadly summarised below:

- Secondary sunscreens that **are** regulated by the TGA as therapeutic goods include moisturisers with sunscreen having a SPF greater than 15.
- Secondary sunscreens that **are not** regulated as therapeutic goods (providing they do not contain ingredients in Schedules 2, 3, 4 or 8 of the Poisons Standard) include:
    - products applied to the lips with any SPF
    - tinted bases and foundations with any SPF
    - moisturisers with a SPF of up to 15 in a pack size no larger than 300mL/300g that do not make any therapeutic claims other than reducing premature ageing from sun exposure
    - preparations that contain a screening substance but make no reference to sun protection and make no therapeutic claims

- sunbathing products (e.g. products for tanning without sun and after-sun skin care products) with a SPF of between 4 and 15 in a pack size no larger than 300mL/300g that do not make any therapeutic claims other than those relating to premature ageing from sun exposure.

Unless **exempt** from the requirement, sunscreens that are considered therapeutic goods must be included in the ARTG to be supplied, imported or exported in Australia. Most sunscreens are eligible for listing in the ARTG, in accordance with the criteria of Schedule 4, Part 1, item 7 of the Regulations, shown in the excerpt below:

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

If a sunscreen does not meet the eligibility criteria for listing in the ARTG provided by Schedule 4 of the Regulations (e.g. it contains ingredients that are not permitted for use in listed medicines), then it is required to be included in the ARTG as registered goods and undergo a full pre-market evaluation of safety, quality and efficacy. There are currently no registered sunscreens included in the ARTG.

Listed sunscreens are not pre-market evaluated by the TGA. Instead, they are included in the ARTG under section 26A of the Act, based on a number of sponsor certifications that their therapeutic good meets all legislative requirements. An excerpt from the Act providing sponsor certifications under 26A of the Act is provided at **Attachment 2**. Among the certifications, a sponsor of a listed sunscreen certifies that the sunscreen:

- only contains ingredients included in the Permissible Ingredients Determination
- only contains indications included in the Permissible Indications Determination
- conforms to every standard applicable to the medicine (e.g. the Sunscreen Standard)
- conforms with the Advertising Code
- is compliant with the principles of Good Manufacturing Practice
- has evidence (held by the sponsor) supporting all indications and claims.

Listed sunscreens must comply with the Australian and New Zealand Sunscreen Standard adopted by the TGA. Standards Australia publishes the Sunscreen Standard which provides the testing and labelling requirements for sunscreens marketed in Australia. The 2012 Sunscreen Standard is the standard currently adopted by the TGA, as referenced in the Regulations and in the Excluded Goods Determination.

Listed sunscreens can be the subject of a compliance review at any time the product remains in the ARTG. If it is found that the sponsor's certifications are incorrect, the listed sunscreen can be cancelled from the ARTG.

Proposal 1: Adoption of the new sunscreen standard

Background

The 2012 Sunscreen Standard is currently adopted by the TGA, as referenced in the Regulations and in the Excluded Goods Determination.

The Sunscreen Standard details the procedures for testing the performance of all sunscreen products in Australia. It also provides required label statements for sunscreen products.

In December 2022, Standards Australia published the 2021 (amended) Sunscreen Standard which replaced the previous Sunscreen Standard. The main changes in the final 2021 Sunscreen Standard compared to the 2012 Sunscreen Standard are:

- adoption of the ISO standards 24444:2019 and 16217:2020 for determining sun protection factor and water resistance
- adoption of ISO 24443:2021 - Determination of sunscreen UVA photoprotection in vitro
- a new flow chart to assist product owners determine what part of the standard is applicable to primary or secondary sunscreens
- introduction of labelling instructions for the application of aerosol and pump pack sunscreens.

For details of the changes between the 2012 Sunscreen Standard and the 2021 Sunscreen Standard, refer to **Attachment 3**.

Proposal

The primary objective of regulation of therapeutic sunscreens in Australia as therapeutic goods by the TGA is to ensure their quality, safety and efficacy with a view to protecting consumers from the sun's harmful UV radiation and reducing the incidence and tragic outcomes of skin cancer. The requirement that these products comply with the most recent Sunscreen Standard is a vital part of the assurance of quality, safety and efficacy.

The TGA is proposing to adopt the 2021 Sunscreen Standard by removing any references to previous sunscreen standards (the 1998 Sunscreen Standard[3] and the 2012 Sunscreen Standard) and replacing with references to the 2021 Sunscreen Standard in the following pieces of therapeutic goods legislation:

- Item 7 of Schedule 4 to the Regulations
- Items 14 and 15 of Schedule 1 to the Excluded Goods Determination
- Items 5 and 10 of Schedule 2 to the Excluded Goods Determination

Adoption of the 2021 Sunscreen Standard will mean that sponsors of therapeutic sunscreens will be required to comply with:

- ISO standard 24444:2019 Sun protection test methods - in vivo determination of the sun protection factor
- ISO 16217:2020 Water immersion procedure for the determination of water resistance
- ISO Standard 24443:2021 Determination of sunscreen UVA photoprotection in vitro
- Label instructions for the application of aerosol and pump pack sunscreens.

[3] The 1998 Sunscreen Standard is referenced in the Excluded Goods Order as part of the transitional arrangements when the 2012 Sunscreen Standard was adopted.

Transition considerations

The adoption of the 2021 Sunscreen Standard is proposed to commence on 1 January 2024.

It is the TGA's understanding from informal consultation that industry is already preparing to transition to the new requirements. However, industry has requested a transition time to enable sponsors to meet the new testing requirements.

The TGA is proposing a staggered transition to enable an earlier transition to the new labelling requirements for aerosol and pump pack sunscreens, as these changes represent an essential improvement in the safety of these products. The proposed transition times are, upon commencement of the adoption of the 2021 Sunscreen Standard on 1 January 2024:

- immediate commencement for all new sunscreen products
- 3-year transition for sunscreens already in the market to comply with new testing requirements (ending 31 December 2027)
- 1-year transition for aerosol and pump pack sunscreens already in the market to comply with the new labelling requirements (ending 31 December 2024) (note: aerosol and pump pack sunscreens will have a 3-year transition to comply with new testing requirements, as for other sunscreens).

It is the TGA's intention that all sunscreens will need to comply with the 2021 Sunscreen Standard at the end of the transition period. That is, all previous transition arrangements enabling certain sunscreens to comply with previous Sunscreen Standards will no longer apply.

Consultation questions on Proposal 1

These questions can be answered in Citizen space https://consultations.tga.gov.au/medicines-regulation-division/updates-to-regulation-of-sunscreens.

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1. For sunscreen sponsors: Will adoption of the 2021 Sunscreen Standard, including adoption of the latest ISO testing methods, have any significant impacts on your business? If yes, please advise what those impacts would be.

2. For sunscreen sponsors: Is your business in a position to adopt the 2021 Standard earlier, i.e. before it is adopted into legislation by the TGA? If yes, please advise of any issues this may cause for you.

3. For sunscreen sponsors: Do you agree that all new sunscreens should be required to comply with the 2021 Standard from the adoption commencement date?

4. For all stakeholders: Do you support a transition period of 3 years for sunscreens already in the market to comply with new testing requirements? If no, why not?

5. For all stakeholders: Do you support a transition period of 1 year for aerosol and pump pack sunscreens to comply with new labelling requirements ? If no, why not?

6. For all stakeholders: Do you have any other comments or feedback about the proposed amendment to the Regulations and Excluded Goods Determination?

Proposal 2: Removal of exemption provisions

Background

Sunscreens classified as therapeutic goods are, unless exempt, required to be included in the ARTG before they can legally be marketed in Australia. The ARTG is maintained by the TGA.

Subregulation 12(1) of the Regulations provides that therapeutic goods mentioned in Schedule 5 are exempt from the operation of parts of the Act, as below:

- Subparagraph 8(g)(i) of item 8 in Schedule 5 to the Regulations exempts sunscreens with less than SPF4 from the requirement to be included in the ARTG (Part 3-2 of the Act), provided that they comply with the adopted Sunscreen Standard; do not contain ingredients derived of certain animal parts; and do not refer to the treatment, cure, prevention, diagnosis or monitoring of, or testing susceptibility of persons to, a disease, condition, ailment or defect.
- Item 14 in Schedule 7 to the Regulations exempts sunscreens with less than SPF4 from manufacturing requirements (part 3-3 of the Act) when tested as per the adopted Sunscreen Standard.

The relevant excerpts from the Regulations in relation to exemption provisions for sunscreens are provided at **Attachment 4.**

Issue

The 1998 Sunscreen Standard allowed sunscreens to make SPF claims of less than 4. The 2012 Sunscreen Standard and recently published 2021 Sunscreen Standard do not permit sunscreens to include a SPF on their label that is less than 4, so it is not possible for a sunscreen to include a label claim of less than 4 and be compliant with either of these Sunscreen Standards. Therefore, the above exemption provisions are no longer fit for purpose.

However, due to concerns regarding potential shortage of sunscreens (as a result of the increased testing requirements in the 2012 Sunscreen Standard) when the 2012 Sunscreen Standard was adopted by the TGA, transition arrangements were provided (regulation 49 refers), allowing existing exempt products in the market to continue to be marketed in Australia and comply with the 1998 Sunscreen Standard. These transition arrangements did not provide an end date, so the provisions remain in effect today.

As these exempt products are not in the ARTG, the TGA has no visibility of how many of these products remain on the market. However, initial investigation indicates there are likely only to be a limited number of insect repellent/sunscreens still being marketed under these transition provisions.

When the TGA adopts the 2021 Sunscreen Standard, indefinite transition arrangements are not proposed. That is, all relevant therapeutic goods will be required to comply with the 2021Sunscreen Standard at the end of a finite, appropriate transition period.

It is proposed to recommend to Government that exemption provisions from the Regulations that apply to sunscreens with a SPF of less than 4 be repealed:

- Schedule 5 item 8 paragraph (g)
- Schedule 7 item 14
- Regulation 49

The proposed transition times upon commencement of the amendment to the regulations (anticipated to be January 2024) are:

- immediate commencement for all new sunscreen products
- a 3-year transition period for existing products in the market

Consultation questions on Proposal 2

These questions can be answered in Citizen space https://consultations.tga.gov.au/medicines-regulation-division/updates-to-regulation-of-sunscreens.

7. For sunscreen sponsors: Will the removal of exemption provisions for sunscreens with less than SPF4 have any significant impacts on your business? If yes, please advise what those impacts are.

8. For all stakeholders: Do you have any comments or feedback about Proposal 2?

Proposal 3: Clarification of indications permitted for sunscreens

Background

Most sunscreens are included in the ARTG via the low risk listed medicine pathway. Listed sunscreens are included in the ARTG without TGA pre-market evaluation as they may only contain pre-approved permitted ingredients and use pre-approved permitted indications. This is a streamlined regulatory pathway that allows early market access for sunscreen products.

Listed sunscreens are only permitted to carry indications that are specified in the Permissible Indications Determination, which is an instrument made under section 26BF of the Act and updated from time to time.

The Permissible Indications Determination includes low-level indications that do not refer to the prevention, treatment or cure of a serious disease. However, as sunscreens are a primary preventative measure against skin cancer for all Australians, in the interests of public health an exception has been made in legislation to allow sunscreens to make high-level indications referring to the prevention of skin cancer (otherwise only allowed in registered therapeutic goods). Other therapeutic goods making such high-level indications require registration in the ARTG and a full TGA pre-market evaluation of their quality, safety and efficacy.

The Permissible Indications Determination lists all the indications relating to skin. Sixteen indications refer to use in sunscreens only and are reproduced in Table 2 below.

Table 2: Permitted indications for sunscreen products only

Indication	Type of evidence	Other requirements
Can aid in the prevention of premature skin ageing (sunscreen)	Scientific	Indication for use in sunscreen products only.
Can aid in the prevention of solar keratosis (sunscreen)	Scientific	Indication can only be used for sunscreen products with a SPF rating of 30 or higher.
Can aid in the prevention of sunspots (sunscreen)	Scientific	Indication can only be used for sunscreen products with a SPF rating of 30 or higher.
May assist in preventing some skin cancers (sunscreen)	Scientific	Indication can only be used for sunscreen products with a SPF rating of 30 or higher.
May reduce the risk of some skin cancers (sunscreen)	Scientific	Indication can only be used for sunscreen products with a SPF rating of 30 or higher.
SPF10 Broad spectrum low protection sunscreen	Scientific	Indication for use in sunscreen products only.
SPF15 Broad spectrum medium/moderate protection sunscreen	Scientific	Indication for use in sunscreen products only.
SPF20 Broad spectrum medium/moderate protection sunscreen	Scientific	Indication for use in sunscreen products only.
SPF25 Broad spectrum medium/moderate protection sunscreen	Scientific	Indication for use in sunscreen products only.
SPF30 Broad spectrum high protection sunscreen	Scientific	Indication for use in sunscreen products only.
SPF4 Broad spectrum low protection sunscreen	Scientific	Indication for use in sunscreen products only.
SPF40 Broad spectrum high protection sunscreen	Scientific	Indication for use in sunscreen products only.

Indication	Type of evidence	Other requirements
SPF50 Broad spectrum high protection sunscreen	Scientific	Indication for use in sunscreen products only.
SPF50 PLUS Broad spectrum very high protection sunscreen	Scientific	Indication for use in sunscreen products only.
SPF6 Broad spectrum low protection sunscreen	Scientific	Indication for use in sunscreen products only.
SPF8 Broad spectrum low protection sunscreen	Scientific	Indication for use in sunscreen products only.

Listed sunscreens can include claims that are not therapeutic (e.g. cosmetic or insect-repellent claims) on their label/advertising and these are not required to be in the ARTG entry for the product. Section 26A of 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. The sponsor must hold evidence to demonstrate all indications and claims made for the product are true, valid and not misleading. Information to support such claims may be requested by the TGA for review. The TGA can cancel the listing of the product from the ARTG if any certifications made by the sponsor are incorrect.

While sunscreens can include non-therapeutic claims on their label, it has been a long-standing policy in the TGA (as reflected in the ARGS since 2010) that if a sunscreen makes indications other than the indications listed above, then the product is required to be registered on the ARTG and undergo a pre-market evaluation for safety, quality and efficacy. When the Permissible Indications Determination came into effect, ELF was designed so that sunscreen products could only use the above indications, consistent with the TGA's long-standing policy.

Recently, sponsors of listed sunscreens have requested to use other indications included in the Permissible Indications Determination that are not marked as 'sunscreen' or with the requirement 'indication for use in sunscreen products only'. However, ELF does not enable this.

The requirement in column 4 of table 12 of the Permissible Indications Determination that sunscreen-specific indications are 'for use in sunscreen products only' or 'can only be used for sunscreen products (with certain SPF ratings)' indicates that sunscreen-specific indications cannot be used for non-sunscreen products. However, the Permissible Indications Determination does not explicitly indicate that sunscreen products cannot use other non-sunscreen-specific indications.

Therefore, in consideration of requests for sponsors to be able to use other non-sunscreen indications, the TGA has proposed 3 options to clarify the appropriate indications that sunscreens should be permitted to make without pre-market assessment.

Option 1: Clarify that listed sunscreens can only use indications permitted for sunscreens (current situation)

Option 1 proposes to make necessary regulatory amendments that clarify that listed sunscreens can only use permitted indications currently specified for sunscreens, consistent with the TGA's current and long-standing policy and reflective of the importance of the sun protection function of these products. Guidance will also be updated to:

- explain what non-therapeutic claims (e.g. cosmetic claims) can be included on a sunscreen label
- clarify that sunscreens above SPF30 can make high-level sun screening claims, and sunscreens less than SPF30 can only make a permitted indication relating to the reduction or premature aging from UV exposure.
- clearly state that if a sunscreen makes other indications (other than sun screening) then they have to be pre-market evaluated by the TGA for safety, quality and efficacy, i.e. registered.

Reasons for this option

- Sunscreens are an important health measure in Australia and can refer to prevention of skin cancer, unlike any other listed medicine. Having other non-sunscreen indications (e.g. 'Reduce symptoms of nappy rash', 'Improve hair growth') may dilute the important health message that these products should be used for the prevention of skin cancer.
- Sunscreen active ingredients in the Permissible Ingredients Determination were assessed for safety in the context of use in sunscreens. There may be unintended consequences when these ingredients are used for other purposes and at frequencies and doses different to sunscreen use that have not been considered as part of their safety assessment. For example, sunscreens with UV filters provide protection from exposure to the sun's radiation. Having indications other than sun screening will potentially lead to people applying UV filters to their skin when there is no risk of sun exposure (e.g. when they are indoors or at night). There may be unintended consequences from increased and unnecessary use of UV filters which have not been assessed for use in that context.
- It is important to ensure that sunscreens are used according to the directions on the label and are applied in a way that they will be effective. Many people may apply them too sparingly and not frequently enough, and consequently do not receive the benefits they are designed to deliver. Using other indications is likely to lead to confusion about the appropriate way to use sunscreens and could lead to unacceptable presentation (confusing or misleading as to the proper use of the goods under subsection 3(5) of the Act).
- Having multiple indications on a product label may require multiple different directions for use, which may be confusing for people and lead to inappropriate use of the product for UV protection. An example may be a formulation that reduces the occurrence of eczema and is directed for localised topical use, rather than the required liberal use as a sunscreen when exposed to the sun.

Reasons against this option

- Secondary therapeutic sunscreens have limited permitted indications available.
- May limit innovation and marketing advantage for sunscreen sponsors to distinguish their products from other sunscreens.

Option 2: Allow listed sunscreens to use any permitted indications relating to dermal application

Option 2 proposes to make necessary regulatory amendments to enable listed sunscreens to use all permitted indications specified for dermal use in addition to sunscreen indications. That is, all indications included in Table 12 of the Permissible Indications Determination (see **Attachment 5** for the full list).

This option would be subject to sponsors holding appropriate evidence that the non-sunscreen ingredients used to achieve these additional therapeutic benefits do not interfere or affect the SPF and/or performance claims (broad spectrum and water resistance) for the sunscreen.

Reasons for this option

- This will enable innovation and marketing advantage for sunscreen sponsors to distinguish their products from other sunscreens.

Reasons against this option

- Sunscreens are an important health measure in Australia and can refer to prevention of skin cancer, unlike any other listed medicine. Having other non-sunscreen indications (e.g. 'Reduce symptoms of nappy rash', 'Improve hair growth') may dilute the important health message that these products should be used for the prevention of skin cancer.
- Sunscreen active ingredients in the Permissible Ingredients Determination were assessed for safety in the context of how sunscreens are used e.g. for use when skin is exposed to the sun.

There may be unintended consequences when these ingredients are used for other purposes, with increased frequency of use and at increased dosages, that have not been considered as part of their safety assessment. For example, having indications other than sun screening will potentially lead to people applying UV filters to their skin when there is no risk of sun exposure (e.g. when they are indoors or at night). There may be unknown consequences from this increased and unnecessary use of UV filters.

- It is important to ensure that sunscreens are used according to the directions on the label and are applied in a way that they will be effective. Many people apply them too sparingly and not frequently enough, and consequently do not receive the benefits they are designed to deliver. Using other indications is likely to lead to confusion about the appropriate way to use sunscreens and could lead to unacceptable presentation (confusing or misleading as to the proper use of the goods under subsection 3(5) of the Act).
- Having multiple indications on a product label may require multiple different directions for use, which may be confusing for people and lead to inappropriate use of the product for UV protection. An example may be a formulation that reduces the occurrence of eczema and is directed for localised topical use, rather than the required liberal use as a sunscreen when exposed to the sun.
- There is an overlap of cosmetic claims and therapeutic indications e.g. 'Relieve dry skin' could be considered a cosmetic claim or a therapeutic indication dependent on overall product presentation. The inclusion of these types of indications in the ARTG entries for therapeutic sunscreens could lead to further confusion for product owners regarding whether their secondary sunscreen is a therapeutic or a cosmetic good and accordingly when it is required to be included in the ARTG.

Option 3: Allow listed sunscreens to use additional specified permitted indications relating to dermal application

Option 3 proposes to make necessary regulatory amendments to enable listed sunscreens to use additional specified permitted indications related to dermal use. That is, listed sunscreens will be able to use a subset of the indications included in table 12 of the Permissible Indications Determination (see Table 3 below for the proposed subset) in addition to the sunscreen-specific permitted indications.

These indications have been selected because they could have a similar level of skin exposure when used as a sunscreen. Indications that imply damaged, broken or inflamed skin have not been included because this could result in increased systemic absorption which may not have been assessed for sunscreen ingredients. Indications referring to relieving or preventing skin redness, or soothing the skin, have not been included as this could be confusing for the consumer if the product is to be applied to damaged/sunburnt skin or if it is to be applied before sun exposure to prevent redness/irritation from sunburn.

This option would be subject to sponsors holding appropriate evidence that the non-sunscreen ingredients used to achieve these additional therapeutic benefits do not interfere or affect the SPF and/or performance claims (broad spectrum and water resistance) for the sunscreen.

The proposed indications are provided in Table 3 below.

Table 3: Proposed subset of dermal indications for use in therapeutic sunscreens

Indication	Type of evidenc	Other requirements
Decrease/reduce/relieve skin dryness	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
Helps enhance/improve skin elasticity	Scientific	

Indication	Type of evidenc	Other requirements
Helps enhance/improve/promote/increase skin firmness	Scientific or Traditional	
Helps enhance/improve/promote/increase skin hydration	Scientific or Traditional	
Helps enhance/promote skin health	Scientific or Traditional	
Helps reduce occurrence of skin dryness	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
Maintain/support skin elasticity	Scientific or Traditional	
Maintain/support skin firmness	Scientific or Traditional	
Maintain/support skin health	Scientific or Traditional	
Maintain/support skin hydration	Scientific or Traditional	

Reasons for this option

- Option 3 will enable innovation and marketing advantage for sunscreen sponsors to distinguish their products from other sunscreens.
- These indications are unlikely to lead to systemic absorption of sunscreen ingredients as they relate to normal intact skin.

Reasons against this option

- Sunscreens are an important health measure in Australia and can refer to prevention of skin cancer, unlike any other listed medicine. Having other non-sunscreen indications that may be considered cosmetic claims (e.g. 'support skin firmness') may dilute the important health message that these products should be used for the prevention of skin cancer.
- Sunscreen active ingredients in the Permissible Ingredients Determination were assessed for safety in the context of use in sunscreens. Although these indications are unlikely to lead to increased exposure of sunscreen ingredients as they relate to normal intact skin, there may still be unintended consequences when these ingredients are used for other purposes and at frequencies and doses different to sunscreen use that have not been considered as part of their safety assessment. For example, having indications other than sun screening will potentially lead to people applying UV filters to their skin when there is no risk of sun exposure (e.g. when they are indoors or at night). This is more likely when those indications refer to relieving skin dryness, firming the skin, improving skin elasticity, etc.
- It is important to ensure that sunscreens are used according to the directions on the label and are applied in a way that they will be effective. Many people may apply them too sparingly and not frequently enough, and consequently do not receive the benefits they are designed to deliver. Using other indications is likely to lead to confusion about the appropriate way to use sunscreens and could lead to unacceptable presentation (confusing or misleading as to the proper use of the goods under subsection 3(5) of the Act).

- Given there is an overlap of cosmetic claims and therapeutic indications (e.g. 'Relieve dry skin' could be considered a cosmetic claim or a therapeutic claim dependent on product presentation) this could lead to significant confusion regarding whether a secondary sunscreen is a therapeutic good or a cosmetic good.

Consultation questions on Proposal 3

These questions can be answered in Citizen space https://consultations.tga.gov.au/medicines-regulation-division/updates-to-regulation-of-sunscreens.

Questions for all stakeholders:

9. Which is your preferred option?
   - Option 1
   - Option 2
   - Option 3

   Please describe why this is your preferred option.

10. Do you have an alternative option you would like to put forward?

11. Do you have any other comments on Proposal 3?

Attachments

Attachment 1: Excerpt from Excluded Goods Order

Section 5 of the Therapeutic Goods (Excluded Goods) Determination 2018 provides that for subsection 7AA(1) of the Act, the goods specified in Schedule 1 of this instrument are excluded goods for the purposes of the Act. Items 14 and 15 of Schedule 1 include the following goods:

Therapeutic Goods (Excluded Goods) Determination 2018

Schedule 1 Item14	products intended for application to the lips, that contain sunscreen, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of secondary sunscreen product in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of secondary sunscreen product in AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iii) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012; and (iv) the product must meet the performance requirements for a broad-spectrum product set out in clause 6.3 of AS/NZS 2604: 2012 and Table 1 in clause 5.2 of AS/NZS 2604: 2012
Schedule 1 Item15	tinted bases and foundations, such as liquids, pastes or powders, that contain sunscreen, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of secondary sunscreen product in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of secondary sunscreen product in AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iii) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012; and (iv) the product must meet the performance requirements for a broad-spectrum product set out in clause 6.3 of AS/NZS 2604: 2012 and Table 1 in clause 5.2 of AS/NZS 2604: 2012

Section 6 of the Excluded Goods Determination provides that for subsection 7AA(2) of the Act, the goods specified in Schedule 2 of this instrument, when used, advertised, or presented for supply in a way specified in that Schedule are excluded goods for the purposes of the Act. Items 5,9 and 10 of Schedule 2 include the following goods:

Schedule 2 Item 5	moisturising skin care products, that contain sunscreen, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, for dermal application, including anti-wrinkle, anti-ageing and skin whitening products, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of secondary sunscreen	when the product: (a) is not advertised or presented for supply as having a sun protection factor of more than 15; and (b) is not advertised or presented for supply as being water-resistant; and (c) if the product is not stable for at least 36 months – includes an expiry date on its label; and (d) has a pack size not larger than 300mL or 300g; and

	product in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of secondary sunscreen product in AS/NZS 2604:2012; and (ii) the product meets the performance requirements for a broad-spectrum product set out in clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012; and (iii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iv) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012	(e) except in the manner provided below, does not have any therapeutic claims made in relation to it, including claims about skin cancer; and therapeutic claims made in relation to the product are limited to those in relation to premature ageing in connection with sun exposure, and are only made if the product meets the performance requirements for broad-spectrum product set out in: (a) clause 7.2 of AS/NZS 2604:1998; or (b) both clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012
Schedule 2 Item 9	preparations containing a sunscreening substance, if the primary purpose of the preparation is neither protection from solar radiation nor another therapeutic purpose	when the preparation is not advertised or presented for supply with: a statement of claimed sun protection factor; or a description of a claimed sun protection factor; or a reference to another therapeutic use in respect of the preparation
10	sunbathing skin care products, such as oils, creams, gels, tanning products without sun and after-sun care products, that contain sunscreen with a sun protection factor of at least 4 and not more than 15, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of secondary sunscreen product in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of secondary sunscreen product in AS/NZS 2604:2012; and (ii) the product meets the performance requirements for a broad-spectrum product set out in clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012; and (iii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iv) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012	when the product: (a) is not advertised or presented for supply as having a sun protection factor of more than 15; and (b) is not advertised or presented for supply as being water-resistant; and (c) if the product is not stable for at least 36 months – includes an expiry date on its label; (d) has a pack size not larger than 300mL or 300g; and (e) except in the manner provided below, does not have any therapeutic claims made in relation to it, including claims about skin cancer; and therapeutic claims made in relation to the product are limited to those in relation to premature ageing in connection with sun exposure, and are only made if the product meets the performance requirements for broad-spectrum product set out in: (a) clause 7.2 of AS/NZS 2604:1998; or (b) both clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of ASNZS 2604:2012

Attachment 2: Excerpt from 26 A of the Act

Certifications made by listed medicine sponsors

(2) The applicant must certify that:
- (a) the medicine is eligible for listing; and
- (b) the medicine is safe for the purposes for which it is to be used; and
- (c) the presentation of the medicine is not unacceptable; and
- (ca) the medicine does not contain an ingredient that is not specified in a determination under paragraph 26BB(1)(a); and
- (cb) if a determination under paragraph 26BB(1)(b) specifies requirements in relation to ingredients being contained in the medicine—none of the requirements have been contravened; and
- (d) the medicine conforms to every standard (if any) applicable to the medicine; and
- (da) both of the following are complied with in relation to the medicine:
  - (i) the applicable provisions of the Therapeutic Goods Advertising Code;
  - (ii) the other requirements (if any) relating to advertising applicable under Part 5-1 or under the regulations; and
- (e) if the medicine has been manufactured in Australia—each step in the manufacture of the medicine has been carried out by a person who is the holder of a licence to carry out that step; and
- (f) the medicine complies with all prescribed quality or safety criteria that are applicable to the medicine; and
- (fa) the medicine's specifications comply with any requirements that are prescribed by the regulations for the purposes of this paragraph and that are applicable to the medicine; and
- (fb) the medicine's label:
  - (i) complies with any requirements that are prescribed by the regulations for the purposes of this subparagraph and that are applicable to the medicine; and
  - (ii) does not make a claim that is inconsistent with any claim made by the applicant in relation to the medicine in, or in connection with, the application; and
- (fba) if the medicine's label contains one or more indications—each indication:
  - (i) is covered by a determination under paragraph 26BF(1)(a); and
  - (ii) is proposed to be accepted in relation to the inclusion of the medicine in the Register; and
- (fc) the applicant holds information or evidence showing the medicine's specifications will be maintained under the conditions set out on the medicine's label until the medicine's expiry date; and
- (fd) each indication proposed to be accepted in relation to the inclusion of the medicine in the Register is covered by a determination under paragraph 26BF(1)(a); and
- (fe) if a determination under paragraph 26BF(1)(b) specifies requirements in relation to an indication proposed to be accepted in relation to the inclusion of the medicine in the Register—none of the requirements have been contravened; and
- (g) the medicine does not contain substances that are prohibited imports for the purposes of the Customs Act 1901; and
- (h) all the manufacturers of the medicine are nominated as manufacturers in the application; and
- (i) the applicant has, with manufacturers of the medicine who are manufacturers of the prescribed kind, written agreements containing such matters as are prescribed; and
- (j) both:
  - (i) the applicant holds information or evidence to support any claim (other than a claim that is an indication) proposed to be accepted in relation to the inclusion of the medicine in the Register; and
  - (ii) the information or evidence complies with any requirements specified in a determination under subsection (2B); and
- (ja) both:
  - (i) the applicant holds information or evidence to support each indication proposed to be accepted in relation to the inclusion of the medicine in the Register; and
  - (ii) the information or evidence complies with any requirements specified in a determination under subsection (2B); and
- (k) the information included in or with the application is correct.

(2A) The applicant must also certify any other matters prescribed by the regulations for the purposes of this subsection.

Attachment 3: Changes to the Sunscreen Standards

2021 Sunscreen Standard compared to 2012 Sunscreen Standard

2012 Sunscreen Standard	2021 Sunscreen Standard
ISO 24444:2010 cosmetic -Sun protection test methods-in vivo determination of the SPF.	ISO 24444:2019 cosmetic -Sun protection test methods-in vivo determination of the SPF
ISO 24443:2012 Determination of sunscreen UVA photoprotection in vitro	ISO 24443:2021 Cosmetics — Determination of sunscreen UVA photoprotection in vitro
	ISO 16217:2020 Water immersion procedure for the determination of water resistance
	New label instructions for the application of aerosol and pump pack sunscreens.
	New flow chart for determining requirements for secondary and primary sunscreens.

Changes in ISO 24444:2010 compared to ISO 24444:2019 cosmetic - Sun protection test methods -in vivo determination of the SPF.

Topic	ISO 24444:2010	ISO 24444:2019
Definition of minimal erythema response (MED) criteria has been revised.	Lowest dose of ultraviolent radiation (UVR) that produces the first perceptible unambiguous erythema with define boarders appearing over most of the field of UV exposure, 16h to 24 h after UV exposure	Lowest erythemal effective radiant exposure (Her) that produces the first perceptible unambiguous erythema with define boarders appearing over more than 50% of UV exposure subsite, 16h to 24 h after UV exposure
Selection of test subject	Test subjects included in the SPF test shall be only phototypes I, II or III according to Fitzpatrick[7] or shall have an ITA° value > 28° by colorimetric methods	Test subject shall have ITA° at least 28° by colorimetric method. Colorimetric ITA values and skin colour categories are defined by the colorimetric descriptors of Chardon using CIE lab colour space (Annex A) (Fitzpatrick skin type selection not included)
Source of ultraviolent radiation Apparatus and material -	The intensity of the beam shall be as uniform as possible. The minimum beam irradiance, at any sub-site, shall be no more than 10 % lower than the maximum beam irradiance at any sub-site.	Includes more detailed information and limits. Uniformity of beam shall be measured depending on the solar simulator type using either UV sensitive film or UV sensor method. UV film densitometry: Exposure dose of the UV sensitive film shall be calibrated to achieve film darkening to a density in the mid-range of the scale. Uniformity shall be >90%. UV Radiometer method: UV radiometer sensor used to sample the beam intensity at multiple sites. Multiple output device. New test methods are provided to determine the uniformity of the beam of both large and small beam size solar stimulator. A requirement for uniformity greater than or equal to 90% has been added.
Total Irradiance	Total irradiance shall not exceed 1 600 W/m2. The calibrated criteria for the solar simulator not included.	Total irradiance shall not exceed 1 600 W/m2. The output of the solar simulator shall be measured with broad spectrum sensor (capable of measuring between 280-1600nm) calibrated against the standard reference.

Topic	ISO 24444:2010	ISO 24444:2019
The test subject is based on the individual typology angle (ITA°)	Value characterizing the skin colour of the subject.	Value characterizing the skin colour of the subject as measured by skin contact reflectance spectrophotometer or skin colourimeter. The test subject is based on the individual typology angle (ITA°) with the average of test panel to be within the range 41°-55° with minimum of three subjects with in two of the three ITA° ranges.
		The ITA° is used to define the range of unprotected MED doses for the provisional or the test day unprotected MED determination.
Reference standard sunscreens added to validate SPF test panels	P2, P3, P7. Expected SPF<SPF20 any of the P2, P3 or P7 reference standard can be used. Expected SPF> SPF 20 one of the P2 or P3 standard is used.	Three new reference standard sunscreens (P5, P6 and P8) are added to validate SPF test panels for products with SPF equal to 25 or higher. SPF claim <24: P2 or P3 SPF> 25 but less than SPF 50: P5 of P6 (on at least 5 subjects) and P2 or P3 on remaining subjects. SPF>50: P8 (on at least 5 subjects) and P2 or P3 on the remaining subjects.
		Sunscreen application procedure has been described in greater detail.
Addition of Annex	Not present	An informative Annex F is added with photographic examples of erythema responses with guidelines for grading.
	Not present	The reporting table in Annex G and requirement in Clause 11 have modified to provide more complete information on the results of the testing.
		Bibliography is updated.

Changes in ISO 24443:2021Determination of sunscreen UVA photoprotection in vitro compared to ISO 24443:2012

- Acceptance of module and introduction of sandblasted PMMA (polymethylmethacrylate) plates, according to specifications described in Annex D.
- Product application fitted to 1,2 mg/cm2 for sand blasted plates.
- Description of application gesture according to tested products.
- Introduction of a new high UVA PF standard P8 in addition to S2 in the ISO-24443-2012.
- Introduction of critical length calculation.
- Calculation of coefficient ‘C’ accepted from in vivo screening SPF, with specific conditions based on SEM and percentage of variability and new range proposed from 0,6 to 1,6.
- Pre-Irradiation dose should be limited at a maximum of 36J/cm2 (UVA-PF0 maximum 30).
- Additional capabilities – Sandblasted PMMA plates P8 reference standard.
- The acceptable time for water immersion is 4hrs as described in the AS/NZS 2604 update.

Changes to ISO 16217: 2020 Water immersion procedure for the determination of water resistance

The process used is mostly described in ISO 24444. Australia retains the 4hr water test period and claim and, continue to determine SPF after immersion as the SPF value to use for labelling SPFs.

Attachment 4: Legislative excerpts relating to exempt sunscreens

Schedule 5—Therapeutic goods exempt from the operation of Parts 3-2 and 3-2A of the Act

Column 1 Item No.	Column 2 Therapeutic goods
8	the following goods, unless the goods are for the treatment, cure, prevention, diagnosis or monitoring of, or testing susceptibility of persons to, a disease, condition, ailment or defect: ……. (g) sunscreen preparations for dermal application, if: (i) the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:2012, as in force from time to time; and (ii) the performance statements and markings on the label comply with that Standard; and (iii) the sun protection factor stated on the label is less than 4, unless the preparations include ingredients of human origin, or of animal origin if the ingredient consists of, or is derived from, any of the following parts of cattle, sheep, goats or mule deer: (A) adrenal; (B) brain; (C) cerebrospinal fluid; (D) dura mater; (E) eye; (F) ileum; (G) lymph nodes; (H) pineal gland; (I) pituitary; (J) placenta; (K) proximal colon; (L) spinal cord; (M) spleen; (N) tonsil

Schedule 7—Therapeutic goods exempt from the operation of Part 3-3 of the Act unless supplied as pharmaceutical benefits

Column 1 Item No.	Column 2 Therapeutic goods
14	sunscreen preparations for dermal use that: (a) are packaged in containers the labels of which include a statement that the preparations have a sun protection factor below 4 or the equivalent category description; and (b) when tested as described in Standard AS/NZS 2604:2012, as in force from time to time, are established to have a sun protection factor below 4 or the equivalent category description

Attachment 5: Permitted indications relating to skin

Excerpt from the Permissible Indications

Table 12—Indications relating to skin

Indications relating to skin

Column 1	Column 2	Column 3	Column 4
Item	**Indication**	**Type of evidence**	**Other requirements**
1	Aids/assists healing of minor skin pressure sores (decubitus ulcers/bedsores)	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
2	Antimicrobial for minor cuts and abrasions	Scientific or Traditional	Product presentation must not imply or refer to serious infections.
3	Antipruritic/Relieves itchy skin	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
4	Antiseptic for minor cuts and abrasions	Scientific or Traditional	Product presentation must not imply or refer to serious infections.
5	Can aid in the prevention of premature skin ageing (sunscreen)	Scientific	Indication for use in sunscreen products only.
6	Can aid in the prevention of solar keratosis (sunscreen)	Scientific	Indication can only be used for sunscreen products with a SPF rating of 30 or higher.
7	Can aid in the prevention of sunspots (sunscreen)	Scientific	Indication can only be used for sunscreen products with a SPF rating of 30 or higher.
8	Cleanse minor skin wound/cuts/scratches/abrasions	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
9	Counterirritant	Traditional	
10	Decrease/reduce skin sensitivity	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
11	Decrease/reduce/relieve burning/tingling associated with facial cold sores	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
12	Decrease/reduce/relieve blisters	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
13	Decrease/reduce/relieve bruise pain	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
14	Decrease/reduce/relieve bruise swelling	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
15	Decrease/reduce/relieve congested skin pores	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
16	Decrease/reduce/relieve itchy/prickling skin associated with mild eczema/dermatitis	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional. Product presentation must only refer to mild eczema.
17	Decrease/reduce/relieve numbness associated with chilblains	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
18	Decrease/reduce/relieve oily skin	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
19	Decrease/reduce/relieve pimples	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.

20	Decrease/reduce/relieve prickling sensation associated with chilblains	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
21	Decrease/reduce/relieve prickly heat skin rash	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
22	Decrease/reduce/relieve scalp flaking/scaling	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
23	Decrease/reduce/relieve scalp itching/irritation/redness	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
24	Decrease/reduce/relieve skin burning/itching associated with athlete's foot/tinea	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
25	Decrease/reduce/relieve skin chafing	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
26	Decrease/reduce/relieve skin dryness	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
27	Decrease/reduce/relieve skin irritation	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
28	Decrease/reduce/relieve skin peeling/cracking	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
29	Decrease/reduce/relieve skin redness	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
30	Decrease/reduce/relieve skin scaling/crusty skin	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
31	Decrease/reduce/relieve symptoms of acne blackheads	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
32	Decrease/reduce/relieve symptoms of athlete's foot/tinea	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
33	Decrease/reduce/relieve symptoms of boils	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
34	Decrease/reduce/relieve symptoms of chickenpox	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
35	Decrease/reduce/relieve symptoms of chilblains	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
36	Decrease/reduce/relieve symptoms of cradle cap	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
37	Decrease/reduce/relieve symptoms of dandruff	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
38	Decrease/reduce/relieve symptoms of facial cold sores	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
39	Decrease/reduce/relieve symptoms of insect bite/sting	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
40	Decrease/reduce/relieve symptoms of medically diagnosed shingles	Scientific or Traditional	Label statement: If symptoms persist or worsen talk to your medical practitioner. Product presentation must only refer to medically diagnosed shingles.
41	Decrease/reduce/relieve symptoms of mild eczema/dermatitis	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional. Product presentation must only refer to mild eczema.
42	Decrease/reduce/relieve symptoms of mild psoriasis	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional. Product presentation must only refer to mild psoriasis

43	Decrease/reduce/relieve symptoms of mild, superficial skin fungal infections	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional. Product presentation must only refer to mild fungal infection.
44	Decrease/reduce/relieve symptoms of nappy rash	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
45	Enhance/improve healing of minor skin wound/cuts/scratches/abrasions	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
46	Enhance/improve healthy skin flora	Scientific or Traditional	
47	Enhance/improve/promote healing of bruises	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
48	Enhance/improve/promote healing of facial cold sores	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
49	Enhance/improve/promote skin healing	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
50	Enhance/improve/promote skin repair/healing	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
51	Helps decrease/reduce/relieve swelling associated with chilblains	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
52	Helps decrease/reduce/relieve symptoms of minor skin wounds (cuts, scratches and abrasions)	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
53	Helps enhance/improve skin elasticity	Scientific	
54	Helps enhance/improve skin internal structure	Scientific or Traditional	
55	Helps enhance/improve skin strength	Scientific or Traditional	
56	Helps enhance/improve/promote/increase skin firmness	Scientific or Traditional	
57	Helps enhance/improve/promote/increase skin hydration	Scientific or Traditional	
58	Helps enhance/promote skin health	Scientific or Traditional	
59	Helps enhance/promote skin regeneration	Scientific or Traditional	
60	Helps healing of mild skin burn/sunburns	Scientific or Traditional	If product is indicated for skin burn, Label statement: Immediate treatment of burns should be application of cold water for ten minutes (or words to that effect). If product is indicated for skin burn, Label statement: Only to be used for minor burns after initial first aid treatment, medical advice should be sought for serious burns. Product presentation must only refer to 'mild' burns.
61	Helps improve appearance of skin stretch marks	Scientific or Traditional	
62	Helps maintain/support skin pH balance	Scientific	Label statement: If symptoms persist, talk to your health professional.
63	Helps protect skin elastin from breaking down	Scientific	

64	Helps reduce occurrence of blackheads	Scientific or Traditional	
65	Helps reduce occurrence of congested skin pores	Scientific or Traditional	
66	Helps reduce occurrence of facial cold sores	Scientific or Traditional	
67	Helps reduce occurrence of nappy rash	Scientific or Traditional	
68	Helps reduce occurrence of pimples	Scientific or Traditional	
69	Helps reduce occurrence of skin dryness	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
70	Helps reduce occurrence of skin pressure sores/bedsores	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
71	Helps reduce occurrence of skin scar tissue	Scientific or Traditional	
72	Helps reduce occurrence of skin stretch marks	Scientific or Traditional	
73	Helps reduce occurrence of symptoms of acne	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
74	Helps reduce occurrence of symptoms of dandruff	Scientific or Traditional	
75	Helps reduce occurrence of symptoms of eczema/dermatitis	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
76	Helps reduce/relieve warts	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
77	Maintain/support healthy skin flora	Scientific or Traditional	
78	Maintain/support skin elasticity	Scientific or Traditional	
79	Maintain/support skin firmness	Scientific or Traditional	
80	Maintain/support skin health	Scientific or Traditional	
81	Maintain/support skin hydration	Scientific or Traditional	
82	Maintain/support skin integrity/structure	Scientific or Traditional	
83	Maintain/support skin regeneration	Scientific or Traditional	
84	Maintain/support skin repair/healing/regeneration	Scientific or Traditional	
85	Maintain/support wound healing	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
86	May assist in preventing some skin cancers (sunscreen)	Scientific	Indication can only be used for sunscreen products with a SPF rating of 30 or higher.
87	May reduce the risk of some skin cancers (sunscreen)	Scientific	Indication can only be used for sunscreen products with a SPF rating of 30 or higher.
88	Reduce occurrence of skin chaffing	Scientific or Traditional	
89	Reduce scar tissue	Scientific or Traditional	

90	Relieve hot skin	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
91	Relieve minor skin eruptions	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
92	Relieve red skin rash	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
93	Relieve symptoms of acne	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
94	Soothe skin	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
95	Soothe/relieve mild skin burn/sunburns	Scientific or Traditional	If product is indicated for skin burn, Label statement: Immediate treatment of burns should be application of cold water for ten minutes (or words to that effect). If product is indicated for skin burn, Label statement: Only to be used for minor burns after initial first aid treatment, medical advice should be sought for serious burns. Product presentation must only refer to 'mild' burns.
96	Soothe/relieve skin inflammation	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
97	Soothes/relieves heat rash	Scientific or Traditional	Label statement: If symptoms persist, talk to your health professional.
98	SPF 10 Broad spectrum low protection sunscreen	Scientific	Indication for use in sunscreen products only.
99	SPF 15 Broad spectrum medium/moderate protection sunscreen	Scientific	Indication for use in sunscreen products only.
100	SPF 20 Broad spectrum medium/moderate protection sunscreen	Scientific	Indication for use in sunscreen products only.
101	SPF 25 Broad spectrum medium/moderate protection sunscreen	Scientific	Indication for use in sunscreen products only.
102	SPF 30 Broad spectrum high protection sunscreen	Scientific	Indication for use in sunscreen products only.
103	SPF 4 Broad spectrum low protection sunscreen	Scientific	Indication for use in sunscreen products only.
104	SPF 40 Broad spectrum high protection sunscreen	Scientific	Indication for use in sunscreen products only.
105	SPF 50 Broad spectrum high protection sunscreen	Scientific	Indication for use in sunscreen products only.
106	SPF 50 PLUS Broad spectrum very high protection sunscreen	Scientific	Indication for use in sunscreen products only.
107	SPF 6 Broad spectrum low protection sunscreen	Scientific	Indication for use in sunscreen products only.
108	SPF 8 Broad spectrum low protection sunscreen	Scientific	Indication for use in sunscreen products only.
109	Vulnerary/wound healing	Traditional	Label statement: If symptoms persist, talk to your health professional.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	COMB/TGA	24 April 2023

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