



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

CONSULTATION DOCUMENT:

**Proposed revisions to Chapter 10
'Sunscreens' in the *Australian Regulatory
Guidelines for OTC Medicines (ARGOM)***



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Sunscreens

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X.1 Introduction

Australia has the highest rate of skin cancer in the world¹. Many Australians use sunscreen every day of their lives, sometimes over large areas of their body surface. Therefore, it is important that sunscreens used in Australia are safe, effective and of acceptable quality.

This chapter describes the regulatory requirements for therapeutic sunscreens and their ingredients in Australia. It is also designed to encourage innovation, improvement in sunscreen product formulation and international best practice.

Many of the terms, such as *therapeutic sunscreen*, *cosmetic*, *cosmetic sunscreen*, *primary sunscreen*, *secondary sunscreen*, *sun protection factor (SPF)* referred to in this chapter are defined in the section entitled 'Glossary of terms and abbreviations' given at the end of this chapter.

The legislation (acts, regulations, therapeutic goods orders, codes, etc.), standards and other relevant regulatory documents referred to in this chapter are listed in footnotes indicating their sources) in the Bibliography at the end of this chapter.

X.2 Therapeutic sunscreen or cosmetic sunscreen?

X.2.1 Therapeutic sunscreens

For the purpose of these guidelines, sunscreens that are regulated as therapeutic goods under the *Therapeutic Goods Act 1989 (The Act)* and *Therapeutic Goods Regulations 1990* and are not regulated as cosmetics (see section X.2.2 below) will be referred to as '*therapeutic sunscreens*'. Included in this category are:

- primary sunscreens with SPF 4 or more
- secondary sunscreens; except those regulated as cosmetics (see below)
- primary or secondary sunscreens with SPF 4 or more that contain an insect repellent, and
- products containing sunscreens with SPF less than 4 are currently defined as listable sunscreen products when they contain certain human or animal parts and are not exempt from registration or listing under *Schedule 5 Item 8 (g) (Therapeutic Goods Regulations 1990)* Schedule 4, Part 1, Item 7). [Note: it is intended that these will become excluded products.]

X.2.2 Cosmetic sunscreens

Some products that contain an ingredient with sunscreens properties where the primary purpose of the product is neither sunscreens nor therapeutic are regulated as cosmetics by the National Industrial Chemicals Notification & Assessment Scheme (NICNAS)² rather than by the TGA as therapeutic goods. In accordance with the *Therapeutic Goods (Excluded Goods) Order No. 1 of 2008*, these products are not regulated under the Therapeutic Goods legislation and are not required to be listed on the Australian Register of Therapeutic Goods (ARTG). For the

¹ Marks R (2002). The changing incidence and mortality of melanoma in Australia. Recent results. *Cancer Res.* 160: 113-21.

² <http://www.nicnas.gov.au>

purpose of these guidelines such products are called ‘*cosmetic sunscreens*’. They may also be referred to as ‘*excluded*’ sunscreens.

A cosmetic sunscreen product must meet the definition of a cosmetic under the *Industrial Chemicals (Notification and Assessment) Act 1989* and any requirements set out in the *Cosmetics Standard 2007*³ and the *NICNAS Cosmetics Guidelines 2007*⁴ in order to be regulated as a cosmetic. Requests for regulatory information and enquiries about cosmetic products should be directed to NICNAS⁵.

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

Cosmetic means:

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

Note: An ingredient or component of a cosmetic could be an industrial chemical.

The *Cosmetics Standard 2007* and the associated *NICNAS Cosmetics Guidelines 2007* classify the following secondary sunscreen products as cosmetics:

- (a) *Makeup products for the face and nails:*
- *Tinted bases or foundation (liquids, pastes or powders) with sunscreen;*
 - *Products intended for application to the lips with sunscreen.*
- (b) *Skin care products:*
- *Moisturising products with sunscreen for dermal application, including anti-wrinkle, anti-ageing and skin whitening products with a sun protection factor of not more than 15 and*

³ Available from <http://www.nicnas.gov.au>

⁴ Available from <http://www.nicnas.gov.au>

⁵ <http://www.nicnas.gov.au>

does not carry a claim of water-resistance and has a pack size of not more than 300mL or 300g;

- Sunbathing products (e.g. oils, creams or gels, including products for tanning without sun and after sun care products) with a sun protection factor of at least 4 and not more than 15 and does not carry a claim of water-resistance and has a pack size of not more than 300mL or 300g.

Note: Moisturising or sunbathing products with an SPF of less than 15 are not cosmetics if they carry a claim of water resistance and/or they have a pack size of more than 300mL or 300g.

The *Cosmetics Standard 2007* and *NICNAS Cosmetics Guidelines 2007* include specific requirements regarding the presentation and labelling of cosmetic sunscreen products and sponsors are responsible to ensure that such products do comply with those requirements (or with the requirements of any subsequent edition of these documents). Failure to comply with those requirements may make the product concerned a therapeutic good that must be listed or registered in the ARTG.

X.3 Regulatory categorisation of sunscreens

Most sunscreens marketed in Australia are currently listed as ‘listable’ therapeutic goods. However, some sunscreen products are exempt from registration or listing and some must be ‘registered’ in the ARTG. General information on listing and registration of therapeutic goods is available on the TGA website⁶.

The current regulation of the various categories of sunscreens is summarised in the table below and explained in the text that follows.

Product category	Sub-category	Currently regulated by:
Listable sunscreens	<ul style="list-style-type: none"> • Primary sunscreens carrying SPF claims of at least SPF 4 and not greater than SPF 30+. • Secondary suncreening products that meet the definition of a therapeutic sunscreen. <p>Primary or secondary sunscreens that contain ingredients of human or animal origin and carry any SPF claim (See X.2.1 and X.3.2)</p>	Listing in the ARTG
Registerable sunscreens	<p>Sunscreens that make therapeutic claims other than suncreening and/or reduction of risk of skin cancer, solar keratosis, sunspots or premature ageing. (See X.3.3)</p>	Registration in the ARTG
Exempt sunscreens	<p>Primary sunscreens with an SPF less than 4 and not containing ingredients of human or animal origin (See X.2.2 and X.3.1)</p>	Exempt from the requirement of listing or registration in the ARTG.

⁶ <http://www.tga.gov.au/meds/summary.htm>

Product category	Sub-category	Currently regulated by:
Cosmetic sunscreens	Some secondary sunscreens that are excluded from regulation by the TGA but meet the definition of a cosmetic. <i>(See X.2.2)</i>	Regulated by NICNAS and the ACCC as a cosmetic

X.3.1 Exempt sunscreens

Therapeutic sunscreen products are ‘exempt’ in accordance with Schedule 5, Part 8(g) of the *Therapeutic Goods Regulations 1990* when:

- the claimed SPF established by testing according to AS/NZS 2604:1998 (or subsequent edition) is less than 4, and
- the product does not contain ingredients of human origin or of animal origin as listed below in section X.3.2, and
- the label claims comply with AS/NZS 2604:1998 (or subsequent edition).

Exempt therapeutic sunscreens do not require registration or listing in the ARTG or manufacture in Good Manufacturing Practice (GMP) licensed premises, but are treated as therapeutic goods in all other respects and must comply with all relevant parts of the Therapeutic Goods legislation, including:

- the Labelling Order (*Therapeutic Goods Order 1990*, 59, and amendments)
- the *Therapeutic Goods Advertising Code*, and
- AS/NZS 2604:1998 (or subsequent edition).

Exempt sunscreen products can only contain active ingredients that are included in the list of approved *sunscreening agents permitted active ingredients* (see section X.10 below) and are within the maximum concentrations stated in the list.

X.3.2 Listing of therapeutic sunscreens

The majority of therapeutic sunscreen products require listing in the ARTG in accordance with Schedule 4, Part 1, Item 7 of the *Therapeutic Goods Regulations 1990*. Information on the listing process using the TGA’s Electronic Listing Facility (ELF) can be found on the TGA website⁷ and details of what information needs to be provided for listed products are provided in the *Electronic Listing Facility (ELF) User Guide*⁸.

In accordance with Schedule 4 of the *Therapeutic Goods Regulations, 1990*, sunscreen products are eligible for listing where they meet the following criteria:

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

- the claimed sun protection factor has been established by testing according to the method described in Standard AS/NZS 2604:1998, as in force from time to time; and*
- the performance statements and markings on the label comply with that Standard; and*

⁷ <http://www.tga.gov.au/online/elf.htm>

⁸ <http://www.tga.gov.au/docs/html/elfuserg.htm>

(c) the sun protection factor stated on the label is:

- (i) 4 or greater; or
- (ii) less than 4 and the preparations include an ingredient of human origin, or 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) cerebro-spinal 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.⁹

Applications for listing of therapeutic sunscreen products that contain material of human or animal origin as above must include a pre-clearance certificate regarding minimizing the risk of transmitting transmissible spongiform encephalopathies (TSEs) issued by the TGA's Office of Laboratories and Scientific Services. More details regarding the requirements for minimizing the risk of transmitting TSEs for therapeutic goods can be found on the TGA website⁹.

Therapeutic sunscreen products can only contain active sunscreens ingredients that are included in the list of *sunscreening agents permitted as active ingredients* (see section X.10) and are within the maximum concentrations stated in the list.

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

Substances that are scheduled in the *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) are not permitted in *listed* therapeutic goods including sunscreen preparations. However, sponsors should seek advice from the TGA as to whether such substances can be included in *registered* sunscreens. An example of a substance that is not permitted in listed therapeutic sunscreens because it is included in the SUSDP is hydroquinone (and its derivatives).

Sunscreen products that make therapeutic claims other than sunscreening (e.g. reduction of free radicals in or below the skin or claims relating to reduction of UV induced immune suppression) and/or contain active therapeutic ingredients that are not included in the list of *sunscreening agents permitted as active ingredients* are not 'listable sunscreen preparations' and must be registered as OTC medicines in the ARTG (see below for registration of therapeutic sunscreens).

X.3.3 Registration of therapeutic sunscreens

Sunscreen products that are not 'listable', 'exempt' or 'cosmetic' (excluded) are evaluated by the TGA for quality, safety and efficacy as registrable goods under the provisions of Schedule 10 of the *Therapeutic Goods Regulations 1990*. Data to support the quality, safety and efficacy of such products are required as detailed under the relevant chapters of the *Australian Regulatory Guidelines for OTC Medicines* (ARGOM).

Products in this category include:

- products that contain a sunscreen active ingredient that is not included in the list of *sunscreening agents permitted as active ingredients* (see section X.10)

⁹ <http://www.tga.gov.au/docs/html/tse supp.htm>

- products that make therapeutic claims other than suncreening
- products that contain substances that are scheduled in the SUSDP
- products that contain a sunscreening active ingredient combined with a claimed therapeutic active ingredient that is not a permissible active ingredient in a listed medicine in accordance with section 26BB of the *Therapeutic Goods Act 1989*
- products that are not otherwise 'listable', 'exempt' or 'excluded'.

X.4 Labelling of therapeutic sunscreens

The labelling of therapeutic sunscreen products must comply with the relevant requirements of each of the following:

- the Labelling Order, *Therapeutic Goods Order No 69* (or any subsequent order amending or replacing TGO 69)
- the *Therapeutic Goods Advertising Code 2007* (as updated from time to time)
- the Australia/New Zealand Standard AS/NZS 2604: 1998 (or subsequent edition) *Sunscreen products – Evaluation and classification*
- the current edition of *Required Advisory Statements for Medicine Labels* (RASML).

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

X.4.1 General

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

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

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

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

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

Therapeutic sunscreens that are ‘listable’ are permitted to carry the following coded indications provided that the sunscreen meets the requirements of AS/NZS 2604:1998 for the indications designated

- (SUNSC1) A broad spectrum suncreening preparation of SPF30+: “May assist in preventing some skin cancers.”
- (SUNSC2) A broad spectrum suncreening preparation of SPF30+: “May reduce the risk of some skin cancers.”
- (SUNSC3) A broad spectrum suncreening preparation of SPF30+: “Can aid in the prevention of solar keratoses.”
- (SUNSC4) A broad spectrum suncreening preparation of SPF30+: “Can aid in the prevention of sunspots.”
- (SUNSC5) A broad spectrum suncreening preparation of SPF4 or greater: “Can aid in the prevention of premature skin ageing.”
- (BROADS): “Broad Spectrum Sunscreen”

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

The *Therapeutic Goods Act 1990* (the Act) requires that, at the time of listing a medicine in the ARTG, a sponsor must hold the information or evidence to support indications and therapeutic claims made in relation to the product. All indications and claims must be capable of substantiation – that is, evidence held by the sponsor must adequately demonstrate all indications and claims made for the product are true, valid and not misleading.

Listed medicines are not subject to pre-market evaluation for efficacy at the time of listing. However, data supporting the claimed indications may be requested by the TGA for review after listing of a listed medicine.

Therapeutic sunscreens may also carry justified non-therapeutic claims and these additional claims are not required to be evaluated by the TGA.

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 excipient that must be declared on the labels in accordance with TGO 69.

X.4.2 Labelling of immediate container and primary pack

As required by section 3(2) of the *Labelling Order* and the *Sunscreen Standard AS/NZS 2604:1998*, the main label on the container and the main label of the primary pack (e.g. carton), if any, must contain all of the following information:

- the product name
[Note: The use of the term ‘sunblock’ is not acceptable as part of a product name (or elsewhere on the label). The term is a misnomer because sunscreens filter to varying degrees but do not completely block the sunburning radiation (see AS/NZS 2604:1998, page 5)]
- the name of the dose form, e.g. cream or lotion
- the sun protection factor (SPF) of the product preceded by the expression ‘Sun Protection Factor’ or ‘SPF’ and in letters at least 25% of the size of the largest letters on the main label and not less than 1.5 mm in height
[Note: A category description may also be given, e.g. ‘low/moderate or medium/high/very high protection’.]
- [if relevant] the water resistance of the product (in hours or in minutes)
[Note: The use of the term ‘waterproof’ is not acceptable. Sunscreens may be water resistant but none are completely waterproof, and even those with a high water resistance rating will gradually wash off the skin when immersed in water for long enough or through perspiration.]
- [optional] the statement (if true) that the product provides ‘broad spectrum’ protection from UV light
- the net quantity of the goods (by volume in mL or weight in g)
- the ARTG listing number preceded by ‘AUST L’ or registration number preceded by ‘AUST R’
[Note: If the container is packed in an outer carton the listing or registration number must be on the main label of that carton and may be, but is not required to be, on the container as well.]

Note that AS/NZS 2604:1998 has particular requirements for the labelling of sunscreens:

- specifications for the declaration of the sun protection factor (SPF) and the category of sun protection (e.g. low, medium, high, very high protection)
- a limit of ‘30+’ or ‘30 plus’ as the highest SPF claim that can be made for a sunscreen
- limitations on ‘*broad spectrum*’ claims
- limitations on the use of ‘*water resistant*’ claims.

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

- the names of all sunscreens active ingredients expressed using Australian Approved Names (AAN)
[Note: International Nomenclature of Cosmetic Ingredients (INCI) names may also be included in addition to the AANs.]
- the proportions of those ingredients either expressed as a percentage in terms of w/w or w/v or expressed as a weight in a stated weight or volume of the product using metric units of measurement (e.g. mg/g or mg/mL).

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

- the batch or lot number of the product, preceded by the batch number prefix using one of the formats specified in TGO 69 section 2(1)
- the recommended storage conditions ‘store below 25°C’ or ‘store below 30°C’, as applicable

- the expiry date of the product preceded by the expiry date prefix ‘Expiry Date’, ‘EXPIRY DATE’, ‘Expiry’, ‘EXPIRY’, ‘Expires’, ‘EXPIRES’, ‘Exp. Date’, ‘EXP. DATE’, ‘Use before’, ‘USE BEFORE’, ‘Use By’, ‘USE BY’, ‘Exp’, or ‘EXP’.
[Note. Terms such as ‘Best by’ or words to this effect are not acceptable.]
- if relevant, the presence in the product (preceded by the word ‘contains’) of any ingredient listed in the First Schedule to the *Labelling Order*, including:
 - benzoic acid, calcium benzoate, potassium benzoate or sodium benzoate
[Note. If the product contains more than one of these substances, they may be grouped under the term ‘benzoates’.]
 - ethanol (if > 3% v/v)
 - hydroxybenzoate ester(s) (e.g. ethyl, methyl, propyl, sodium ethyl, sodium methyl, sodium propyl hydroxybenzoate).
[Note. If the product contains more than one of these substances, they may be grouped under the term ‘hydroxybenzoates’.]
 - peanuts and peanut products (e.g. peanut oil, arachis oil)
 - sorbic acid or potassium sorbate
[Note. If the product contains more than one of these substances, they may be grouped under the term ‘sorbates’]
 - sulfite, metabisulfite and bisulfite salts and sulfur dioxide
[Note. If the product contains more than one of these substances, they may be grouped under the term ‘sulfites’.]
 - tartrazine or ‘tartrazine CI 19140’
 - any other antimicrobial preservative(s)
- a statement of the purpose or purposes of the product
[Notes.
 1. The purpose of the product can generally be made obvious by it being called a ‘sunscreen’ or ‘moisturiser with sunscreen’ or ‘moisturiser’ with an SPF stated on the label.
 2. If (and only if) a therapeutic sunscreen has an SPF of 30+ and it provides broad spectrum protection, the label is permitted to include a representation to the effect that the product ‘*may assist in preventing some skin cancers*’ or ‘*may reduce the risk of some skin cancers*’ provided the label also highlights the need for avoidance of prolonged exposure to the sun and the importance of wearing protective clothing, hats and eyewear (see *Gazette* notice of 25 September 2002¹⁰). Other acceptable related claims are ‘*can aid in the prevention of solar keratoses*’ and ‘*can aid in the prevention of sunspots*’.
 3. Any broad-spectrum suncreening preparation may also make the claim ‘*can aid in the prevention of premature skin ageing*’ or words to that effect.]
 4. The labelling of therapeutic sunscreens may also carry justified non-therapeutic claims.]
- directions for use of the product
[Note. The directions for use for a primary therapeutic sunscreen should include statements to the effect that the product should be applied in generous amounts over all of the exposed areas 15 to 20 minutes before sun exposure, and again after swimming or towelling.]
- required warning statements as included in the RASML
[Note. The labels of both primary and secondary therapeutic sunscreens should include warning statements to the effect that the product should be kept out of the eyes. Primary therapeutic (but not secondary) sunscreen products should also include warning statements to the effect that prolonged exposure to the sun should be avoided, and it is important to wear protective clothing, hats and eyewear when exposed to the sun.]
- the name and address of the sponsor or Australian supplier of the product.
[Note: An Australian contact telephone number may also be included.]

¹⁰ www.tga.gov.au/advert/exsunscreens.htm

Currently, the maximum SPF claim permitted in Australia is *30 plus* (30+). SPF claims expressed as numbers greater than 30 are currently not permitted in Australia.

X.4.3 Minimum requirements for small containers

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

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

[Note: AS/NZS 2604:1998 section 8.3 allows containers of not more than 20 mL or 25g to be labelled with text (other than the SPF) that is not less than 1mm in height. However, TGO 69, which was issued after AS/NZS 2604:1998 and overrides that Standard requires that the letter height for all text on the label of a therapeutic good must be not less than 1.5mm in height except for the registration or listing number which must be not less than 1mm. In addition, TGO 69 defines a 'small container' as having a capacity of 20mL whereas AS/NZS 2604:1998 section 3(11) defines a small container as having a capacity of not less than 25mL or 25g. Therapeutic sunscreen products must comply with the requirements of TGO 69.]

X.5 SPF testing and reproducibility of results

The SPF declared on the label of therapeutic sunscreens should be determined by testing on human skin in accordance with the sunscreen standard AS/NZS 2604:1998.

[Note: Other *in vivo* SPF testing procedures that are regarded by the TGA as giving equivalent static SPF results and that may be used instead of the procedures in AS/NZS 2604:1998 are:

- *Cosmetics – Sun Protection test methods – In vivo determination of SPF (Sun Protection Factor) ISO 24444-2009*. International Organisation for Standardisation, Geneva, and
- *FDA Sunscreen Drug Products for OTC Human Use: Final Monograph*. Federal Register Vol. 64 No. 98 Friday May 21, 1999 / Rules and Regulations 27666-27693.]

In vivo SPF testing has a considerable variance which needs to be taken into account when interpreting results and labelling a sunscreen product. As the test is a clinical trial with testing on human skin, the results obtained provide a reasonable estimate (but not a highly precise measure) of the true SPF of a sunscreen product.

Statistical analyses by the TGA of the SPF test data submitted to the TGA in support of SPF claims made for a large range of sunscreen products have shown that the individual test data typically exhibit an underlying coefficient of variation (CV) of 10-15% and estimates of the SPF based on the means of 10 individual tests typically have a CV of 5-25%. Consequently, the

mean test result may lie anywhere in a range extending as much as 15% either side of the true SPF of the product.

AS/NZS 2604:1998 goes only part of the way in addressing the problems caused by this variability in test results by requiring that the mean result obtained is reduced to the next whole number. For example, a mean test result of 24.5 would be reduced to 24 and the product labelled accordingly. However, the true SPF of the product concerned could be anywhere between about 21 and 28 and subsequent retesting could yield a result anywhere between about 19 and 32.

Calculations based on the typical variabilities and distributions of SPF test data submitted to the TGA have shown that, in order to have at least 95% confidence that a sunscreen has a true SPF equal to or greater than that claimed on the label and that retesting according to AS/NZS 2604:1998 will not yield a mean SPF lower than that claimed on the label, the TGA recommends that the label claim should be calculated as described in the US 'FDA method'¹¹, as follows:

1. Calculate the unrounded mean (m) and standard deviation (s) from the individual SPF test data
2. Calculate the lower 95% single sided confidence limit, $CL = m - t.s/\sqrt{n}$, where 'n' is the number of individual SPF data (normally 10 for AS/NZS 2604:1998) and 't' is the value of Student's t for n-1 degrees of freedom and $p=0.05$ (single sided).
3. Finally, round CL down to the nearest whole number 'Z' and label the product with an SPF claim of not more than Z.

For example, a sunscreen product is tested on 10 subjects and yields a mean result of 24.5 with a standard deviation of 3.1. In this case, $CL = 24.5 - 1.833 \times 3.1 \div \sqrt{10} = 22.7$ and $Z = 22$. The maximum SPF that should be claimed for this product is 22 (rather than 24 as allowed by AS/NZS 2604:1998).

According to AS/NZS 2604:1998 an original unrounded SPF test result of 31.0 or greater supports the maximum permissible label claim of SPF30+. However, using the calculation method described above, it can be shown that the original unrounded test result needs to be at least 33-35 (depending on the variance in the test data) to ensure that the true SPF is at least 31 and that subsequent retesting according to AS/NZS 2604:1998 is unlikely to indicate an SPF of less than 31.

It is the sponsor's responsibility to ensure that, if retested during its shelf life, the product SPF will still be compliant with the label SPF. The TGA may request results of post-market testing which should be provided within 3 months from the date of such a request.

¹¹ FDA Sunscreen Drug Products for OTC Human Use: Final Monograph. Federal Register Vol. 64 No. 98 Friday May 21 1999. Rules and Regulations 27666-27693.

X.6 Changes to therapeutic sunscreens

Details of the requirements and procedures for making changes to the ARTG record of listed therapeutic goods are available from the TGA web site¹².

X.6.1 Changes to active ingredients

The addition or deletion of an active ingredient or a change to the quantity of such an ingredient makes the product a new therapeutic good requiring a new entry in the ARTG. Consequently, a new product application should be submitted to the TGA and a new AUST L or AUST R number will need to be assigned.

X.6.2 Changes to excipients

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

Deletion or addition of excipients in a therapeutic sunscreen (other than the permanent removal or addition of a fragrance or colouring agent) make the product a new therapeutic good which needs to be listed or registered in the ARTG as a new product. Consequently, a new product application should be submitted to the TGA and a new AUST L or AUST R number will need to be assigned.

In accordance with the *Therapeutic Goods (Grouping) Order No. 1 of 2001*, a fragrance or colouring may be added or removed from a sunscreen formulation provided the new formulation is intended to replace the existing formulation. In this situation the product, although technically a new product, is allowed to retain the same AUST L number as the old formulation. However, an electronic application must be lodged to change the formulation recorded in the ARTG.

Quantities of excipients other than restricted excipients are not required to be included in the ARTG record for listed sunscreens. Where a change is to be made to the quantity of a restricted excipient (and grouping applies in accordance with the Grouping Order section 5.1(a)(i) and (ii) and (b)) an electronic application must be lodged to change the formulation details recorded in the ARTG. When grouping does not apply, such a change will require a new product application and a new AUST L or AUST R number.

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

X.6.3 Other changes

Changes to the ARTG details of a sunscreen product must be approved by or notified to the TGA (using the electronic listing facility (ELF) system in the case of a listed sunscreen). A change to the product name requires approval when grouping applies (i.e. the only change is the proprietary name and the new product is to replace the existing product). Otherwise, if grouping

¹² <http://www.tga.gov.au/cm/elf3productchanges.pdf>

does not apply, a new product application and a new AUST L or AUST R number will be required.

X.7 Stability testing of therapeutic sunscreens

X.7.1 Stability test requirements

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

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

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

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

This section (X.7) now supersedes the *Guidelines for Stability Testing of Sunscreens April 1994*.

The following is a summary of the TGA’s requirements for establishing and confirming the shelf life of a listed therapeutic sunscreen:

X.7.2 Establishing stability before listing or registering with the TGA

1. Prior to listing and market launch, the shelf life may be established with real time testing for the whole of the required shelf life or with adequate certainty using accelerated testing (i.e. 6-9 months at 10°C or 15°C above the stated maximum storage temperature – see table below) or justified on the basis of supporting stability data for a closely related formulation.
2. Pre-listing or pre-registration stability testing should be carried out using at least two batches of the formulation intended for marketing manufactured in a manner that closely

mirrors the production-scale manufacturing process. A formulation very similar, but not identical, to that intended for marketing formulation may be used provided any differences are small and unlikely to affect the physical, chemical or microbiological stability or in-use performance of the product.

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

X.7.3 Confirming stability and ongoing real time stability studies

If the shelf life assigned at the time of listing is based on data generated using pilot-scale batches and accelerated studies, the shelf life should subsequently be confirmed by real time studies covering the whole of that shelf life using at least two production-scale batches stored at the maximum recommended storage temperature. These production scale batches should be tested initially at manufacture and then annually until the end of the shelf life.

X.7.4 Stability protocol requirements and interpretations

1. Physical testing should include at least the following quality parameters: appearance, emulsion stability, absence of crystallisation, odour, viscosity, compatibility with the immediate container and the condition of the inside surface of the container in contact with the product.
2. Chemical stability testing should include pH (if water is the continuous phase) and the content of each of the active ingredients assayed using a validated, stability-indicating analytical procedure (e.g. HPLC). Active ingredients should remain within the limits 90% to 120% of label claim.
3. Overages of active ingredients in the formulation are acceptable provided they do not result in concentrations exceeding the limits provided in section X.10 below.
4. 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.
5. The temperature of storage used in stability studies should be controlled, monitored and recorded to ensure the integrity of the results.
6. The frequency of testing for accelerated studies should be adequate to allow regression and statistical analysis to support extrapolation of the data. Appropriate testing time points would typically be 0, (1 or 2), (3 or 4), (5 or 6), 9 and 12 months (followed by 24 and 30 months, depending on the shelf life required to be justified).
7. The accelerated stability data should only be extrapolated as in points 8 and 9 below if their accuracy, reproducibility and fit around a straight time-line are adequate. A minimum of 4 time-points with a reasonably even spread over the time period concerned are needed for meaningful line-fitting and 95% confidence interval calculations.

8. For a product exhibiting no discernable changes or trends, a 2-year shelf life for storage conditions of ‘store below 30°C’ (i.e. storage at room temperature in Australia) may be supported by stability data covering 6 months storage at 40°C, and a 3-year shelf life for storage conditions of ‘store below 30°C’ may be supported by data covering either 9 months at 40°C or 6 months at 45°C. A shelf life of greater than 3 years should be supported by data from storage at 40°C covering at least half of the shelf life (e.g. 2.5 years accelerated data would be required to support a 5-year shelf life).
9. For a product exhibiting no discernable changes or trends, a 2-year shelf life for storage conditions of ‘store below 25°C’ (i.e. the product should be stored in air-conditioned premises) may be supported by stability data covering 6 months storage at 35°C, and a 3-year shelf life for storage conditions of ‘store below 25°C’ may be supported by data covering either 9 months at 35°C or 6 months at 40°C. A shelf life of greater than 3 years should be supported by data from storage at 35°C covering at least half of the shelf life.
10. Generally, the maximum shelf life permitted for any therapeutic good is 5 years.

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

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

X.8 Microbial content and preservative efficacy of therapeutic sunscreens

Therapeutic sunscreen products in all categories are expected to comply with the relevant requirements of Therapeutic Goods Order No. 77 *Microbiological Standards for Medicines*, (section 8) for preservative efficacy according to the *British Pharmacopoeia* and section 9 for microbiological quality according to the *British, European or United States Pharmacopoeia*.

X.9 Manufacturers of therapeutic sunscreens

Manufacturers of ‘listed’ or ‘registered’ therapeutic sunscreens must be licensed or approved by the TGA. 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. 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/approval is available on the TGA website¹³.

¹³ <http://www.tga.gov.au/manuf/index.htm#all>

Manufacturers of sunscreens are required to comply with the *Australian Code of GMP for Therapeutic Goods – Sunscreen Products* which is available from the TGA web site¹⁴. As from July 2010 the Australian Code will be replaced by the *PIC/S Guide for Good Manufacturing Practice for Medicinal Products* available from the TGA web site¹⁵

It is the responsibility of the manufacturer of the finished product to ensure that the quality of the suncreening active ingredients and the excipients used in manufacturing the finished product are acceptable for use in therapeutic products. If a British Pharmacopoeia, or European Pharmacopoeia or United States Pharmacopoeia/National Formulary monograph exists for an ingredient in the suncreening product, that ingredient should comply with that monograph or one of those monographs.

X.10 Sunscreening agents permitted as active ingredients

The only sunscreening active ingredients permitted in therapeutic sunscreens are those included in the table below, and must be within the maximum concentration stated in the list.

The labelling should include the Australian Approved Name (AAN) for each active sunscreening ingredient. Some AANs have changed and sponsors should ensure that their labelling is amended accordingly (see note at the end of the table).

Sponsors wanting to market a sunscreen product containing a sunscreening active ingredient which is not on the list of permitted substances in therapeutic sunscreens must submit data to establish the safety and efficacy of the ingredient under its proposed conditions of use (see X.11).

Australian Approved Name (AAN)	Synonym / Abbreviations / Trade Names / INCI Name / CAS Number	Maximum Concentration
Amiloxate*	Isoamyl methoxycinnamate [previous AAN] Isoamyl p-methoxycinnamate [INCI name] Isoamyl-4-methoxycinnamate Isopentenyl-4-methoxycinnamate CAS No: 71617-10-2	10%
Avobenzone*	Butyl methoxy dibenzoylmethane [previous AAN] [INCI name] BMDM 4-tert-butyl-4'-methoxy dibenzoylmethane 1-(4 tert butylphenyl)-3(4-methoxyphenyl)-propane-1,3-dione CAS No: 70356-09-1	5%

¹⁴ <http://www.tga.gov.au/docs/html/gmpsunsc.htm>

¹⁵ <http://www.tga.gov.au/manuf/picsgmpmed.htm>

Australian Approved Name (AAN)	Synonyms / Abbreviations / Trade Names / INCI Name / CAS Number	Maximum Concentration
Bemotrizinol	Bis-ethylhexyloxyphenol methoxyphenol triazine [INCI name] Bemotrizinolum Tinosorb S CAS No: 187393-00-6	10%
Benzylidene camphor sulfonic acid [= INCI name]	alpha-(2-Oxoborn-3-ylidene)toluene-4-sulphonic acid Meroxyl SL CAS No: 56039-58-8	6%
Camphor benzalkonium methosulfate [= INCI name]	N,N,N-Trimethyl-4-(oxoborn-3-ylidenemethyl)anilinium methyl sulfate Meroxyl SO CAS No: 52793-97-2	6%
Cinoxate [= INCI name]	2-Ethoxyethyl para-methoxycinnamate CAS No: 104-28-9	6%
Diethylamino hydroxybenzoyl hexyl benzoate [= INCI name]	Benzoic acid, 2-[4-(diethylamino)-2-hydroxybenzoyl]-hexyl ester Uvinul A Plus CAS No: 302776-68-7	10%
Dioxybenzone	Benzophenone 8 [INCI name] CAS No: 131-53-3	3%
Disodium phenyl dibenzimidazole tetrasulfonate [= INCI name]	1H-Benzimidazole-4,6-disulfonic acid, 2,2'-(1,4-phenylene)bis-, disodium salt Bisimidazylate Neo Heliopan AP CAS No: 18089-17-7	10%
Drometrizole trisiloxane [= INCI name]	2-(2H-Benzotriazol-2-yl)-4-methyl-6[2-methyl-3-[1,3,3,3-tetramethyl-1-(trimethylsilyl)oxy]-disiloxanyl]-propyl-phenol Silatrione Meroxyl XL CAS No: 155633-54-8	15%
Ecamsule	1,3-bis(4-methylphenyl)-2,2,4,4-tetraphthalylidene dicamphor sulfonic acid [INCI name] Meroxyl SX CAS No: 90457-82-2; 92761-26-7	10%
Enzacamene	4-Methylbenzylidene camphor [previous AAN] [INCI name] 3-(4-Methylbenzylidene)-dl-camphor CAS No:36861-47-9; 38102-62-4	4%
Octyl triazone* [= INCI name]	Octyl triazone [previous AAN] 2,4,6-Trianalino-(p-Carbo-2'-ethylhexyl-1'oxy)-1,3,5-triazine CAS No: 88122-99-0	5%
Homosalate [= INCI name]	Homomenthyl salicylate 3,3,5-Trimethylcyclohexyl 2-hydroxybenzoate CAS No:118-56-9	15%

Australian Approved Name (AAN)	Synonyms / Abbreviations / Trade Names / INCI Name / CAS Number	Maximum Concentration
Menthyl anthranilate [= INCI name]	Menthyl 2-aminobenzoate 5-Methyl-2-(1-methylethyl) cyclohexanol-2-aminobenzoate Meradimate CAS No: 134-09-8	5%
Methylene bis-benzotriazolyltetramethylbutylphenol [= INCI name]	2,2'-Methylene-bis-6-(2H-benzotriazol-2-yl)-4-(tetramethylbutyl)-1,1,3,3-phenol Tinosorb M CAS No: 103597-45-1	10%
Octinoxate*	Octyl methoxycinnamate [previous AAN] Ethylhexyl methoxycinnamate [INCI name] CAS No: 5466-77-3	10%
Octisalate*	Octyl salicylate [previous AAN] Ethylhexyl salicylate [INCI name] 2-Ethylhexyl salicylate CAS No: 118-60-5	5%
Octocrylene [= INCI name]	Octocrilene 2-cyano-3,3-diphenyl acrylic acid, 2-ethylhexyl ester 2-Ethylhexyl-2-cyano-3,3 diphenylacrylate CAS No: 6197-30-4	10%
Oxybenzone	Benzophenone 3 [INCI name] 2-Benzoyl-5-methoxyphenol CAS No: 131-57-7	10%
Padimate O	Ethylhexyl dimethyl PABA [INCI name] 2-Ethylhexyl 4-aminobenzylaminobenzoate Octyl dimethyl PABA CAS No: 21245-02-3; 58817-05-3	8%
PEG-25 PABA [= INCI name]	Ethoxycylated ethyl 4-aminobenzoate PEG25 PABA CAS No: 113010-52-9; 116242-27-4	10%
Phenylbenzimidazole sulfonic acid [= INCI name]	2-Phenylbenzimidazole-5-sulfonic acid 2-Phenyl-5-sulfobenzimidazole Ensulizole CAS No: 27503-81-7	4%
Polydimethicone-15 [= INCI name]	Dimethicodiethylbenzalmalonate Diethylbezylidene malonate dimethicone Diethylmalonylbenzylidene oxypropene dimethicone Parsol SLX CAS No: 207574-74-1	10%
Sulisobenzone	Benzophenone 4 [INCI name] 5-Benzoyl-4-hydroxy-2-methoxybenzene sulphonic acid CAS No: 4065-45-6	10%

Australian Approved Name (AAN)	Synonyms / Abbreviations / Trade Names / INCI Name / CAS Number	Maximum Concentration
Sulisobenzone sodium	Benzophenone 5 [INCI name] 5-Benzoyl-4-hydroxy-2-methoxybenzene sulphonic acid, sodium salt CAS No: 6628-37-1	10%
Titanium dioxide [= INCI name]	E171 CAS No: 13463-67-7	25%
Trolamine salicylate*	Triethanolamine salicylate [previous AAN] TEA-salicylate [INCI name] CAS No: 2174-16-5	10%
Zinc oxide [= INCI name]	Pigment white 4 CAS No: 1314-13-2	No limit

* Note: The AANs of the 7 substances marked with an asterisk have changed. Sponsors should amend their labels accordingly at the next print run or by 1 July 2013 (whichever date comes sooner).

X.11 New ingredients in sunscreens

X.11.1 Naming of new substances

A 'Proposed Name for a Chemical Substance Used in a Therapeutic Good' application form needs to be submitted to the TGA to enable the establishment of an identity and an appropriate 'Australian Approved Name' (AAN) for the substance. Information on the naming of substances and applying for an AAN can be found on the TGA website¹⁶.

There are no fees for the AAN applications and approval of ingredient names (at the time of publication). However, fees will apply to the evaluation of the data for the new substance and for the listing or registration of the product as specified in the summary of fees and charges available from the TGA website¹⁷.

X.11.2 New actives in sunscreens

Sponsors wishing to market a product containing an active ingredient which is not on the list of approved sunscreens agents (listed in the table above) must submit data to establish the safety of the ingredient under its proposed conditions of use.

In addition, guidelines for the approval of new substances are given in the ARGOM chapter on Safety and Efficacy of New substances. The subsection below describes the specific requirements for safety data that apply to new sunscreen active ingredients and should be read in conjunction with ARGOM chapter on Safety and Efficacy of New Substances and the ARGOM chapter on Quality.

¹⁶ www.tga.gov.au/docs/html/aan.htm

¹⁷ Fees and charges: <http://www.tga.gov.au/docs/html/feesach.htm>

X.11.3 Safety data requirements for new actives in therapeutic sunscreens

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

The list of relevant EU ‘non-clinical’ guidelines that have been adopted by the TGA can be found on the TGA website¹⁸. They are not detailed in this guideline document because there are frequent changes and sponsors should, therefore, consult the current list on the TGA web site. These EU guidelines relate to sunscreens because suncreening products (as defined earlier in this guideline) are treated as therapeutic goods in Australia.

The intention in listing relevant guideline topics is not to set absolute requirements, but to assist sponsors in assessing the type and depth of information needed to support an application with the understanding that primary sunscreen products are treated as therapeutic goods in Australia as opposed to ‘cosmetics’ in Europe. If a particular guideline is not applicable or other data are available that adequately address the same criteria, alternative approaches based on adequate scientific justification will be considered by the TGA during evaluation of the application. 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.

Type of safety data
Photostability - UV absorption spectra
Acute toxicity (oral and dermal)
Local tolerance - skin irritation - phototoxicity - eye irritation
Allergenicity - skin sensitisation - photosensitisation
Toxicokinetics ^a - oral & dermal bioavailability (exposure) - ADME studies
Repeat dose toxicity (oral & dermal) – 3 to 6 months data
Genotoxicity - photomutagenicity
Reproductive toxicity ^{c, d}
Carcinogenicity ^e - photocarcinogenicity
Interaction potential Since sunscreen formulations usually contain more than one active ingredient, data on the potential for interaction of the new substance with other UV filters will usually need to be provided.

¹⁸ <http://www.tga.gov.au/docs/html/euguidead.htm>

Type of safety data

- (a) An *in vivo* determination of dermal and oral absorption is needed to establish systemic exposure via both routes and to enable interpretation of the toxicity studies.
- (b) Genotoxicity testing in bacterial and mammalian cell lines, photomutagenicity test in bacteria, photomutagenicity in a chromosomal aberration test and an *in vivo* chromosome aberration assay.
- (c) For assessment of developmental and fertility effects.
- (d) Endocrine disruption potential needs to be addressed. This could be examined during the repeat-dose toxicity and/or reproductive toxicity studies.
- (e) *In vivo* carcinogenicity and photocarcinogenicity bioassay or a justification for not providing these studies (see below).

More details on different safety tests for chemicals for pharmaceutical use can be found at the following websites:

The European Medicines Agency:

<http://www.emea.europa.eu/htms/human/humanguidelines/background.htm>

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH):

<http://www.ich.org/cache/compo/276-254-1.html>

The Organisation for Economic Co-operation and Development Guidelines for the Testing of Chemicals (Section 4: Health Effects):

http://www.oecd.org/document/40/0,3343,en_2649_34277_37051368_1_1_1_1,00.html

More details on different safety tests for chemicals that are for cosmetic sunscreen used in Europe can be found in *The SCCP's Note for Guidance for the Testing of Cosmetic ingredients and their Safety Evaluation 6th Revision 29 December 2006* at the following website:

http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_03j.pdf.

X.11.4 Justification for not providing particular studies

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

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

- the expected pattern of use
- results of *in vitro* and *in vivo* mutagenicity assays
- lack of similarity to other molecules with known carcinogenic activity
- low persistence in the skin
- low *in vivo* absorption
- lack of photosensitisation or phototoxic potential
- proven photostability
- lack of possible adverse effects on the skin (change to epidermis/dermis)
- length of submitted *in vivo* repeat dose toxicity studies
- lack of adverse activity in local tolerance studies (skin irritation and skin sensitisation).

X.11.5 Related studies

Other studies that are not currently referenced in EC guidelines may be useful in supporting particular applications. Reference to these studies is included only as a guide. They will not be relevant in all cases, nor should they be seen as a complete list of relevant studies. Examples include the following studies and referenced websites which may be useful in providing information on the potential of a substance to cause tumours in people:

- studies using appropriate and validated transgenic animal models to test exposure to the substance; information on transgenic models can be found on the OECD^{19,20} and European Centre for the Validation of Alternative Methods (ECVAM) websites²¹
- *in vitro* human dermal cell cultures exposed to the substance
- *in vitro* human dermal tumour cell cultures exposed to the substance.

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

- Non-animal testing strategies for assessment of the skin corrosion and skin irritation potential of ingredients and finished products; M K Robinson *et al*; Food and Chemical Toxicology, 40(5), pp 573-592, 2002
- OECD/OCDE, test number: 431 (April 2004) OECD Guidelines for the testing of chemicals; *in vitro* skin corrosion: human skin model test.

X.11.6 UV spectral characteristics

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

X.11.7 New excipients in therapeutic sunscreens

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

1. Naming and identification of an ingredient name as an Australian Approved Name (AAN)
2. Identification of the excipient as a substance included in the *CTFA International Cosmetic Ingredient Dictionary and Handbook* (the page number and reference should be quoted)
3. Assurance that it does not appear in Annex II to the EEC Directive 76/768 list of substances which must not form part of the composition of cosmetic products
4. Assurance that the excipient has been used or permitted in Sweden, Canada, USA, UK or The Netherlands; or (less desirably) assurance by the applicant that there have been market-place sales of comparable products containing the excipient in one of those five countries for at least two years

¹⁹ <http://www.oecd.org/dataoecd/43/38/40830957.pdf>

²⁰ Reference: Novel systems for the study of human diseases; OECD Proceedings; OECD Online Bookshop Code 931998021P1 (Page 400)

²¹ European Centre for the Validation of Alternative Methods: <http://ecvam.jrc.it/>

5. Acute oral toxicity: e.g. an *in vivo* limit test – or alternative method
6. Skin irritation study – animal or alternative method
7. Sensitisation study – skin; animal or alternative method

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

8. *In vitro* mutagenicity (e.g. an Ames test or other validated alternative test)
9. Eye irritation study
10. *In vitro* percutaneous absorption test.

All of the above information should be submitted for safety evaluation of the new substance for use in therapeutic sunscreens. Additional studies may be requested in individual cases where concerns become evident at the time of evaluation. Once the substance is approved (and an AAN has been assigned), it will thereafter be able to be used in other therapeutic sunscreens without the need for further evaluation. The substance may also be able to be used in other topically applied non-prescription medicines (subject to any conditions or limitations) without the need for further evaluation. However, additional data may be required if the characteristics of the substance are considered to change in different formulations or patterns of use in new products or if the substance is to be used outside the stated conditions and/or limitations.

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

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

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

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

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

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

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

X.12 Glossary of terms and abbreviations

In this document references to particular definitions are provided in brackets (...):

ACCC - the Australian Competition and Consumer Commission.

Active ingredient means an active substance included in a sunscreen to protect the skin from ultraviolet (UV) radiation. It is an ingredient in a therapeutic goods formulation that is responsible for its physiological or pharmacological action (Therapeutic Goods Act, 352F).

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

ARGOM – *Australian Regulatory Guidelines for Over-the-Counter Medicines*

ARTG – Australian Register of Therapeutic Goods

AS/NZS 2604: 1998 - The Australian and New Zealand Standard for Sunscreen Products

Australian Approved Name (AAN) – The approved name applied to a therapeutic substance, as outlined in the *TGA Approved Terminology for Medicines*, which includes:

- Approved Biological Substance Names (ABNs)
- Approved Chemical Substance Names
- Approved Herbal Name (AHNs) and
- Approved Herbal Substances (AHSs).

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

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

Broad-spectrum product means a sunscreen product which has been shown, using the *in vitro* test method defined in *AS/NZS 2604: 1998* to provide protection against certain UV-A rays of the sun as part of the protection of a low, moderate or medium, high or very high protection sunscreen product (*AS/NZS 2604: 1998*).

Category description means the designation of the level of protection given by a grouping of label sun protection factors (*AS/NZS 2604: 1998*).

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

Cosmetic (For the full definition see Section X.2.2 above.)

Cosmetic sunscreen product means a product containing a sunscreensing ingredient that is regulated as a cosmetic by the *Industrial Chemicals (Notification and Assessment) Act 1989* and by the *Cosmetics Standard 2007* and is not a therapeutic good.

Excipient ingredient means an ingredient of a sunscreen other than an active ingredient. Excipient ingredients may have multiple uses such as fragrance, preservative, solvent etc.

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

Excluded sunscreen means a sunscreen product that is not regulated under the Therapeutic Goods legislation and are not required to be listed or registered in the Australian Register of Therapeutic Goods (ARTG).

Exempt sunscreen means a sunscreen product that is not required to be listed in the Australian Register of Therapeutic Goods (ARTG) because the SPF is less than 4.

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

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

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

Ingredients of human or animal origin are those derived directly from a human or animal source. They are also listed in the *Therapeutic Goods Regulations 1990*.

INCI means International Nomenclature Cosmetic Ingredient.

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

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

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

Listing or registration number means the combination of numbers, symbols and letters assigned to the goods by the TGA under Section 27 of the *Therapeutic Goods Act 1989* (TGO 69).

Mean Sun Protection Factor (SPF) is the mean sun protection factor rounded down to the nearest whole number (*AS/NZS 2604: 1998*).

Medicine means a therapeutic good that is represented to achieve, or are likely to achieve, its principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal (*Therapeutic Goods Act, 1989, section 3(1)*).

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. This criterion for the use of New Substance applies to all Proprietary Ingredients other than flavours, fragrances, printing inks and adhesives.

NICNAS - National Industrial Chemicals Notification & Assessment Scheme.

Primary pack, in relation to therapeutic goods, the complete pack in which the goods, or the goods and their container, are to be supplied to consumers (Therapeutic Goods Act, 1989) section 3(1)).

Primary sunscreen product means a sunscreen product which is represented on the label as being primarily to protect the skin from certain harmful effects of the sun's UV rays (AS/NZS 2604: 1998).

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

RASML - Required Advisory Statements for Medicine Labels

Secondary sunscreen product means a sunscreen product which is represented on the label as protecting the skin from certain harmful effects of the sun's UV rays while fulfilling another primary function (AS/NZS 2604: 1998).

Sun Protection Factor (SPF) means the ratio of UV radiation dose required to produce a recognizable erythema on skin that has been protected with a sunscreen product to the dose required on unprotected skin under the same conditions (AS/NZS 2604: 1998).

SUSDP - Standard for the Uniform Scheduling of Drugs and Poisons.

The Act means the *Therapeutic Goods Act 1989*

The Labelling Order is *Therapeutic Goods Order (TGO)* 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 249, 250, 251, 252, 253, 254, 255, 256, 257, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 306, 307, 308, 309, 310, 311, 312, 313, 314, 315, 316, 317, 318, 319, 320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330, 331, 332, 333, 334, 335, 336, 337, 338, 339, 340, 341, 342, 343, 344, 345, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 363, 364, 365, 366, 367, 368, 369, 370, 371, 372, 373, 374, 375, 376, 377, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 395, 396, 397, 398, 399, 400, 401, 402, 403, 404, 405, 406, 407, 408, 409, 410, 411, 412, 413, 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 442, 443, 444, 445, 446, 447, 448, 449, 450, 451, 452, 453, 454, 455, 456, 457, 458, 459, 460, 461, 462, 463, 464, 465, 466, 467, 468, 469, 470, 471, 472, 473, 474, 475, 476, 477, 478, 479, 480, 481, 482, 483, 484, 485, 486, 487, 488, 489, 490, 491, 492, 493, 494, 495, 496, 497, 498, 499, 500, 501, 502, 503, 504, 505, 506, 507, 508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528, 529, 530, 531, 532, 533, 534, 535, 536, 537, 538, 539, 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 560, 561, 562, 563, 564, 565, 566, 567, 568, 569, 570, 571, 572, 573, 574, 575, 576, 577, 578, 579, 580, 581, 582, 583, 584, 585, 586, 587, 588, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 603, 604, 605, 606, 607, 608, 609, 610, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 624, 625, 626, 627, 628, 629, 630, 631, 632, 633, 634, 635, 636, 637, 638, 639, 640, 641, 642, 643, 644, 645, 646, 647, 648, 649, 650, 651, 652, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 668, 669, 670, 671, 672, 673, 674, 675, 676, 677, 678, 679, 680, 681, 682, 683, 684, 685, 686, 687, 688, 689, 690, 691, 692, 693, 694, 695, 696, 697, 698, 699, 700, 701, 702, 703, 704, 705, 706, 707, 708, 709, 710, 711, 712, 713, 714, 715, 716, 717, 718, 719, 720, 721, 722, 723, 724, 725, 726, 727, 728, 729, 730, 731, 732, 733, 734, 735, 736, 737, 738, 739, 740, 741, 742, 743, 744, 745, 746, 747, 748, 749, 750, 751, 752, 753, 754, 755, 756, 757, 758, 759, 760, 761, 762, 763, 764, 765, 766, 767, 768, 769, 770, 771, 772, 773, 774, 775, 776, 777, 778, 779, 780, 781, 782, 783, 784, 785, 786, 787, 788, 789, 790, 791, 792, 793, 794, 795, 796, 797, 798, 799, 800, 801, 802, 803, 804, 805, 806, 807, 808, 809, 810, 811, 812, 813, 814, 815, 816, 817, 818, 819, 820, 821, 822, 823, 824, 825, 826, 827, 828, 829, 830, 831, 832, 833, 834, 835, 836, 837, 838, 839, 840, 841, 842, 843, 844, 845, 846, 847, 848, 849, 850, 851, 852, 853, 854, 855, 856, 857, 858, 859, 860, 861, 862, 863, 864, 865, 866, 867, 868, 869, 870, 871, 872, 873, 874, 875, 876, 877, 878, 879, 880, 881, 882, 883, 884, 885, 886, 887, 888, 889, 890, 891, 892, 893, 894, 895, 896, 897, 898, 899, 900, 901, 902, 903, 904, 905, 906, 907, 908, 909, 910, 911, 912, 913, 914, 915, 916, 917, 918, 919, 920, 921, 922, 923, 924, 925, 926, 927, 928, 929, 930, 931, 932, 933, 934, 935, 936, 937, 938, 939, 940, 941, 942, 943, 944, 945, 946, 947, 948, 949, 950, 951, 952, 953, 954, 955, 956, 957, 958, 959, 960, 961, 962, 963, 964, 965, 966, 967, 968, 969, 970, 971, 972, 973, 974, 975, 976, 977, 978, 979, 980, 981, 982, 983, 984, 985, 986, 987, 988, 989, 990, 991, 992, 993, 994, 995, 996, 997, 998, 999, 1000.

Therapeutic good includes a good that is represented in any way to be, or that is, whether because of the way in which the good is presented or for any other reason, likely to be taken to be for therapeutic use or for use as an ingredient or component in the manufacture of therapeutic goods (Therapeutic Goods Act, 1989, section 3(1)).

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

Therapeutic use means use in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals, or influencing, inhibiting or modifying a physiological process in persons or animals (Therapeutic Goods Act, 1989, section 3(1)).

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

TSEs - transmissible spongiform encephalopathies

Ultraviolet radiation (UV) means the solar ultraviolet radiation in the range 290–400 nm. Ultraviolet radiation A (UVA) is the solar ultraviolet radiation in the range 320–400 nm and ultraviolet radiation B (UVB) is the solar ultraviolet radiation in the range 290–320 nm (AS/NZS 2604: 1998).

Water resistant product means a sunscreen product which has been shown after designated periods of water immersion, using *in vivo* Sun Protection Factor test methods to provide protection against certain of the sun's UV rays (AS/NZS 2604: 1998).

Other definitions that may not be described here can be found on the following TGA websites:

- <http://www.tga.gov.au/docs/html/aan.htm>
- <http://www.tga.gov.au/web/glossary.htm>
- http://www.tga.gov.au/docs/pdf/forms/notifpi_guide.pdf

X.13 Bibliography

*Australian Code of GMP for Therapeutic Goods – Sunscreen Products*²²

Australia/New Zealand Standard AS/NZS 2604:1998 *Sunscreen products – Evaluation and classification*²³

*Cosmetics Standard 2007*²⁴

Personal Care Products Council *International Cosmetic Ingredient Dictionary and Handbook*²⁵

EEC Directive 76/768 Annex II: *List of substances which must not form part of the composition of cosmetic products*²⁶

*Electronic Listing Facility (ELF) User Guide*²⁷

*Industrial Chemicals (Notification and Assessment) Act 1989*²⁸

*NICNAS Cosmetics Guidelines 2007*²⁹

*PIC/S Guide for Good Manufacturing Practice for Medicinal Products – 15 January 2009*³⁰

*Required Advisory Statements for Medicine Labels (RASML)*³¹

*Standard for the Scheduling of Drugs and Poisons (SUSDP)*³²

*TGA Approved Terminology for Medicines*³³

*Therapeutic Goods Act 1989*³⁴

*Therapeutic Goods Advertising Code*³⁵

*Therapeutic Goods (Groups) Order No. 1 of 2001*³⁶

*Therapeutic Goods (Excluded Goods) Order No. 1 of 2001*³⁷

*Therapeutic Goods Order No. 69 - General requirements for labels for medicines*³⁸

*Therapeutic Goods Order No. 77 - Microbiological standards for Medicines*³⁹

*Therapeutic Goods Regulations 1990*⁴⁰

²² <http://www.tga.gov.au/docs/html/gmpsunsc.htm>

²³ Available from Standards Australia through SAI Global Ltd at <http://www.saiglobal.com/shop/script/search.asp>

²⁴ Available from <http://www.nicnas.gov.au>

²⁵ Published by Personal Care Product Council Inc. 1101 17th Street, NW, Suite 300, Washington DC 20036-4702, USA

²⁶ <http://ec.europa.eu/enterprise/cosmetics/cosing/index.cfm?fuseaction=search.results&annex=II&search>

²⁷ <http://www.tga.gov.au/docs/pdf/elfuserg.pdf>

²⁸ Available from <http://www.comlaw.gov.au>

²⁹ Available from <http://www.nicnas.gov.au>

³⁰ <http://www.tga.gov.au/manuf/picsgmpmed.htm>

³¹ <http://www.tga.gov.au/meds/rasml.pdf>

³² <http://www.tga.gov.au/ndpsc/susdp.htm>

³³ <http://www.tga.gov.au/docs/html/aan.htm>

³⁴ Available from <http://www.comlaw.gov.au>

³⁵ <http://www.tga.gov.au/advert/tgac/htm>

³⁶ <http://www.tga.gov.au/legis/tgogroups0101.htm>

³⁷ <http://www.tga.gov.au/legis/tgeg0801.htm>

³⁸ <http://www.tga.gov.au/docs/html/tgo/tgo69.htm>

³⁹ <http://www.tga.gov.au/legis/tgo/tgo77.pdf>

⁴⁰ Available from <http://www.comlaw.gov.au>

Appendix 1: Labelling Checklist for Therapeutic Sunscreens Entered on the ARTG

Notes.

1. This check list is not mandatory but is designed as a tool to assist sponsors in designing their sunscreen labels in accordance with the TGA's requirements.
2. It is not exhaustive and sponsors are responsible for ensuring that their labelling complies with all of the relevant legislative requirements.
3. It does not apply to those secondary sunscreen products categorised as cosmetics in accordance with the *Cosmetic Standard 2007* and the *NICNAS Cosmetics Guidelines 2007*.

Product:

General **Yes**

Is/are the label (or labels):

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

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

- are likely to arouse unwarranted and unrealistic expectations of the product's effectiveness?
- are false, unbalanced, unsubstantiated, misleading or likely to mislead the user?
- abuse the trust or exploit the lack of knowledge of consumers or contain language that could bring about fear or distress?
- encourage or are likely to encourage inappropriate use?
- indicate or imply that the product is infallible, unfailing, magical, miraculous, or effective in all cases?
- indicate or imply that the product cannot cause harm?
- indicate or imply that other competitor products are harmful or ineffectual?
- indicate or imply that the product is endorsed by any government agency, hospital or other facility providing healthcare services, individual healthcare professional or group of healthcare professionals?

Labelling of Immediate Container and Primary Pack

Yes

Does the main label contain the following information:

- the product name?
Note: The use of the term 'sunblock' is not acceptable.]
- the name of the dose form, (e.g. 'cream, lotion, stick')?
- the sun protection factor (SPF) of the product preceded by the expression 'Sun Protection Factor' or 'SPF' and in letters at least 25% of the size of the largest letters on the main label and not less than 1.5 mm in height?
Note. A category description may also be given, e.g. 'low/moderate or medium/high/very high protection'.
- [If relevant] the water resistance of the product (in hours or minutes)?
- [Optional] the fact that the product provides 'broad spectrum' protection from UV light?
- the contents of the container (volume in mL for a liquid or weight in g for a solid or semi-solid product)?
- the ARTG listing or registration number preceded by 'AUST L' or 'AUST R' ?
Note: If the container is packed in an outer carton the listing number must be on the main label of that carton and may also be but is not required to be on the container.

Is the following information included either on the main label or on a rear or side panel:

- the names of all active ingredients expressed using Australian Approved Names AND the proportions of those ingredients either expressed as a percentage in terms of w/w or w/v or expressed as a weight in a stated weight or volume of the product using metric units of measurement (e.g. mg/g or mg/mL)?
Note: The TGA Sunscreen guidelines include a list of the active ingredients permitted in sunscreens marketed in Australia

Is the following information included anywhere on the label(s) or container:

- the batch or lot number of the product preceded by the batch number prefix using one of the formats specified in TGO 69 s2(1)?
- the recommended storage conditions?
- the expiry date preceded expiry date prefix using one of the formats specified in TGO 69 s2(1)?

Is the following information included anywhere on the label(s):

Yes

- if relevant, the presence in the product of benzoates, hydroxybenzoate ester(s), sulfites, or any other antimicrobial preservative(s), sorbates, ethanol (if >3% v/v), peanuts or peanut products (e.g. peanut/arachis oil), or any other ingredient included in Schedule 1 of TGO 69?

- a statement of the purpose or purposes of the product?

Notes:

1. The purpose of the product is generally made obvious by it being called a 'sunscreen'.
2. If a sunscreen has an SPF of 30+ and it provides broad spectrum protection the label is permitted to include claims that the product may assist in preventing some skin cancers or may reduce the risk of some skin cancers provided the label also highlights the need for avoidance of prolonged exposure to the sun and the importance of wearing protective clothing, hats and eyewear.
3. Any broad spectrum sunscreen may also carry a claim that it can aid in the prevention of premature skin ageing.
4. Sunscreens may also carry justified non-therapeutic claims.

- directions for use of the product?

Note. The directions for use for a primary sunscreen should include statements to the effect that the product should be applied in generous amounts over all of the exposed areas 15 to 20 minutes before sun exposure, and again after swimming or towelling. An indication should also be given of how frequently the product should be re-applied during prolonged exposure to the sun.

- required warning statements?

Note. The label for a primary sunscreen should include warning statements to the effect that:

1. prolonged exposure to the sun should be avoided and
2. it is important to wear protective clothing, hats and eyewear when exposed to the sun, and
3. the product should be kept out of the eyes.

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

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

Special Requirements – Small Containers

If the immediate container has a capacity of 20 mL or less AND the container is enclosed in a primary pack (e.g. carton):

Does the primary pack labelling include all of the information listed above?

Does the labelling on the container include at least the following information:

- the product name (in full or in abbreviated form if there is insufficient room for the full name)?
- the name of the dosage form?
- the quantity of product in the container?
- the batch number preceded by the batch number prefix?
- the names and quantities of all the active ingredients?

Note. If there is insufficient room, this information regarding active ingredients is only required on the label of the primary pack.