

Sunscreen Regulation In Australia



Presentation March 2026

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SciPharm Pty Ltd

Overview !



New TGA Info Structure !



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

An overview of therapeutic sunscreens

Start here to get an overview of how your product is regulated and helpful information to support your journey.

Australian Regulatory Guidelines for Listed Medicines (ARGLM)

The ARGLM will help you navigate the regulatory requirements for listed medicines in Australia. This includes requirements for applications, safety, ingredients, labelling and advertising.

Last updated: 13 January 2026

On this page

[Regulation basics](#)

[Sunscreens](#)

... navigates to...



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration



Understanding the regulation of therapeutic sunscreens

This guidance explains how sunscreens are regulated in Australia and the requirements for sunscreens (and their ingredients) regulated by us.

(This guidance was previously known as Australian Regulatory Guidelines for Sunscreens).

Published: 1 August 2025

Sunscreen or Not ?

1. IS THE PRODUCT A SUNSCREEN?

IF IT MEETS ALL OF THE BELOW CRITERIA IT IS CONSIDERED A SUNSCREEN

- a) has components to absorb, reflect or scatter UV rays AND
- b) is intended for application to skin AND
- c) is intended to protect against erythema or UV induced damage AND
- d) has a SPF of at least SPF 4

NO

AS/NZ 2604
Does not apply for this
product

YES

AS/NZS 2604 Decision Flow

2. IS THE PRODUCT A PRIMARY SUNSCREEN?

IF IT MEETS ALL OF THE BELOW CRITERIA IT IS A PRIMARY SUNSCREEN

- a) primary purpose is to protect the skin from UV radiation
- b) overall presentation is to protect against exposure to UV radiation
- c) for application to face, body, hands or lips

NO

5

YES

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Primary or Secondary Sunscreen ?

2. IS THE PRODUCT A PRIMARY SUNSCREEN?

IF IT MEETS ALL OF THE BELOW CRITERIA IT IS A PRIMARY SUNSCREEN

- a) primary purpose is to protect the skin from UV radiation
- b) overall presentation is to protect against exposure to UV radiation
- c) for application to face, body, hands or lips

NO

Secondary

YES

Primary

AS/NZS 2604 **Classification** sets Regulation !

Secondary Sunscreens

4. IS THE PRODUCT A SECONDARY SUNSCREEN – COLOUR COSMETIC AND/OR LIP?

IF IT MEETS ALL OF THE BELOW CRITERIA IT IS A SECONDARY SUNSCREEN – COLOUR COSMETIC AND/OR LIP

- a) for application to face, body or hands OR lips
- b) a primary purpose that is as a tinted base or a tinted foundation or tinted makeup or a lip product (tinted, untinted, lipstick, barrier cream , flavoured lip product, lip "paint" or lipgloss)
- d) is not a primary sunscreen

YES

Section 4.2 Table 1 columns 1,2,3 and 6 apply
Section 5.1, 5.2 and 5.3 (Mandatory for SPF 30 to 50+ or optional for SPF 4 to SPF 29) apply for testing.
Sections 6.1 and 6.3 apply with Section 6.3.1 (a) to (c) applying.
Section 6.3.2 Optional labelling may also apply

Secondary Sunscreens



Australian Government

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Excluded goods orders, determinations and specifications

Therapeutic Goods (Excluded Goods) determinations and specifications.

Last updated: 11 November 2022

- * Still requires SPF and Broad Spectrum test and compliance
- * Labelling requirements of AS/NZS 2604 still apply

Products at the Margins

Moisturisers



Products at the Margins

Colour Cosmetics - Tinted Sunscreen



AUSTL 468607
Cancelled 7/25

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Products at the Margins

Stick Form



Appropriate AS/NZS 2604 Requirements

Tested SPF	Label SPF Claim	AS/NZS Category Description	Broad Spectrum Claim		
			Primary Sunscreen	Secondary Sunscreen	
				Skin Care	Colour or Lip
1 to 3	Not Allowed		Not Allowed	Not Allowed	Not Allowed
4 to 14	4,6,8,10	Low Protection	Compulsory	Compulsory	Optional
15 to 29	15,20,25	Medium or Moderate Protection	Compulsory	Compulsory	Optional
30 to 59	30,40,50	High Protection	Compulsory	Compulsory	Compulsory
60 or higher	50 plus	Very High Protection	Compulsory	Compulsory	Compulsory

AS/NZS 2604 **Classification** sets Regulation !

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Water Resistance only for Primary Sunscreens

SPF Range	Allowable Maximum
At least 4 but less than 8	No claim
At least 8 but less than 15	40 min
At least 15 but less than 30	2 h
At least 30 or above	4 h

AS/NZS 2604 **Classification** sets Regulation !

... back to the URTS!



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Understanding the regulation of therapeutic sunscreens

Version 4.0, August 2025

5 URTS Parts to Regulation

- * Pharmaceutical Grade GMP
AS/NZS 2604 Compliance
AUST L Listing
Therapeutic Advertising Code
Poison Regulations ?

Parts to Regulation

1. Pharmaceutical Grade GMP



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Interprets PIC/S clauses as appropriate

Manufacturing sunscreen and complying with Good Manufacturing Practice (GMP)

Was separate GMP Code - now PIC/s PE009-13 - since 2018

5 Parts to Regulation

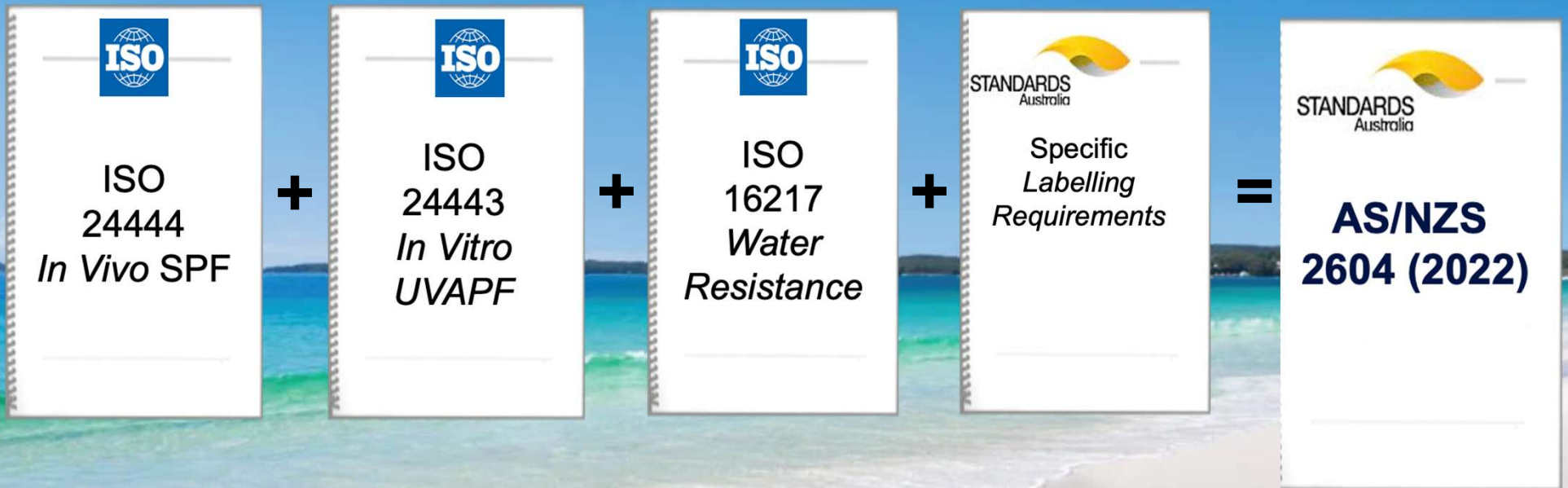
2.

AS/NZS Compliance



Parts to Regulation

2. AS/NZS 2604:2021(2)



AS/NZS 2604 Pre-dates TGA

5 Parts to Regulation

2.

AS/NZS Compliance



Parts to Regulation

3.

AUST L

- * Approved Actives
Approved Excipients
Stat Dec and on line
Test Lab Exclusions

3. *Reliance on Test Lab*

Advice for sunscreen sponsors and manufacturers: Acceptance of additional SPF testing information

Last updated: 23 September 2025

Parts to Regulation

4. Therapeutic Advertising Code

Labelling and advertising for therapeutic sunscreens

Information on how to ensure your therapeutic sunscreen meets labelling, packaging, and advertising standards.

Must be labelled and advertised in a clear, truthful, and accurate way.

Product name, Australian Register of Therapeutic Goods (ARTG) number, ingredients,

Advertising must not make false or misleading claims.

The Sponsor responsible for ensuring all communications comply with Australian laws.

Parts to Regulation

5. Approved UV Actives = 28



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Safety Review of Seven Active Sunscreen Ingredients

Butyl methoxydibenzoylmethane (avobenzene), ethylhexyl triazone, homosalate, octocrylene, octyl methoxycinnamate (octinoxate), oxybenzone and phenylbenzimidazole sulfonic acid (PBSA)

Review of Sunscreen ACTIVES

TGA

AUGUST 2024 : Australian Sunscreen Exposure Model Consultation

Advisory Committee on Medicines Scheduling
Advisory Committee on Chemicals Scheduling

SEPT 2025: ACMS/ACCS Joint meeting











Outcome?

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Summary of TGA Publications

August 2025 to March 2026

-  Advice for sunscreen sponsors and manufacturers/ Acceptance of additional SPF testing information | .pdf
-  Application and market authorisation for therapeutic sunscreens | Therapeutic Goods Administration (.pdf
-  Australian Regulatory Guidelines for Listed Medicines (ARGLM) | Therapeutic Goods Administration (TG.pdf
-  australian-regulatory-guidelines-for-sunscreens.pdf
-  Follow-up TGA statement on CHOICE SPF sunscreen report | Therapeutic Goods Administration (TGA).pdf
-  Labelling and advertising for therapeutic sunscreens | Therapeutic Goods Administration (TGA).pdf
-  Manufacturing for therapeutic sunscreens | Therapeutic Goods Administration (TGA).pdf
-  Monitoring and compliance for therapeutic sunscreens | Therapeutic Goods Administration (TGA).pdf
-  Supply and distribution for therapeutic sunscreens | Therapeutic Goods Administration (TGA).pdf
-  TGA statement on sunscreen labelling practices | Therapeutic Goods Administration (TGA).pdf
-  Therapeutic sunscreens | Therapeutic Goods Administration (TGA).pdf
-  Understanding the regulation of therapeutic sunscreens | Therapeutic Goods Administration (TGA).pdf

TGA Recalls 2025-6

19 Reliance on SPF results from a questionable lab

7 Emulsion Instability : Separation of Zinc Oxide

20+ ? Separate and Distinct Goods

TGA Hot Issues

TGA statement on sunscreen labelling practices

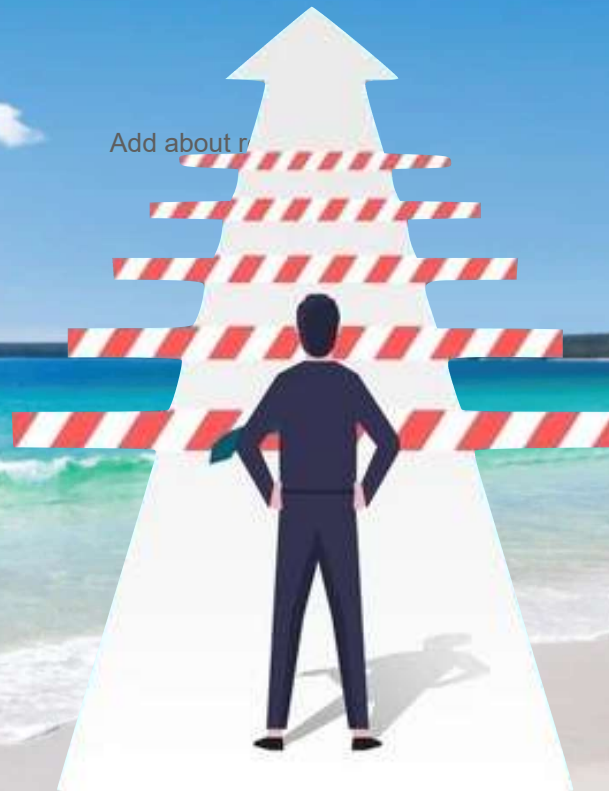
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**For 2026: TGA also flagging...
Extensive Review of the entire category**

Review announcement VERY IMMINENT

Next discussion ComTech 12th May 2026

Complex and Fraught with Challenges!



Add about r

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