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

# Consultation: Proposed amendments to the Poisons Standard in relation to 4-methylbenzylidene camphor (4-MBC) – Joint ACMS-ACCS #45 meeting, November 2026

11 September 2026

**Confidentiality**

All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission form. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission form.

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# About this consultation

Subdivision 3D.2 of the *Therapeutic Goods Regulations, 1990* (the Regulations) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the *Therapeutic Goods Act, 1989* (the Act) to amend the current Poisons Standard or decides to amend the Poisons Standard on his or her own initiative and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice.

In accordance with regulation 42ZCZK of the Regulations, the Secretary invites public submissions on scheduling proposals referred to the NOVEMBER 2026 meetings of the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS) in a joint session (Joint ACMS-ACCS #45). Submissions must be received by close of business **12 October 2026**.

Submissions should be provided through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next joint meeting of the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS).

**This consultation closes on 12 October 2026.**

We aim to provide documents in an accessible format. If you're having problems using this document, please contact medicines.scheduling@health.gov.au.

# Preamble

Australia has the highest rates of skin cancer in the world with around 2,000 people dying each year from skin cancer. Sunscreens provide one of the best ways to protect yourself from the sun's ultraviolet (UV) rays which can cause skin cancer. Many Australians use sunscreens daily. This is why sunscreens need to be regulated in Australia to ensure they are safe, effective and of good quality.

Sunscreens contain substances that either absorb or reflect UV rays and prevent most UV rays from penetrating the skin and damaging skin cells.

In Australia, sunscreens are divided into 2 categories: therapeutic sunscreens and cosmetic sunscreens. Therapeutic sunscreens include primary sunscreens (used primarily for protection from UV rays) and some secondary sunscreens (used mainly for other purposes but contain sun screening agents, for example, sunbathing and moisturising skin care products with an SPF of over 15). Therapeutic sunscreens are regulated by the Therapeutic Goods Administration (TGA).

Cosmetic sunscreens are the majority of the secondary sunscreen products. They are not considered to be therapeutic goods and are 'excluded' from the therapeutic goods legislation. Examples are lipsticks and lip balms that contain sunscreen with an SPF of 4 or more. Ingredients in cosmetic sunscreens are regulated by the Australian Industrial Chemicals Introduction Scheme (AICIS).

Sunscreen products that are considered to be industrial uses are defined in under the Therapeutic Goods (Excluded Goods) Determination 2018 (TGA 2018). These include the following products that contain sunscreen:

- products applied to the lips (such as lipsticks and lip balms)
- tinted bases and foundations (including liquids, pastes and powders)
- moisturising skin care products
- sunbathing skin care products.

The Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2026 currently lists sunscreen active ingredients approved for use in Australia. The safety of these ingredients has been examined by various means, including the assessment of toxicological data, utilisation of overseas regulatory reports, and consideration by committees such as the Medicines Evaluation Committee.

4-MBC is currently permitted at a maximum concentration of 4% in topical therapeutic sunscreen and cosmetic preparations in Australia. Personal care products (cosmetics) are also able to contain 4-MBC.

In 2015, a proposed order by the FDA stated that 4-methylbenzylidene camphor (4-MBC), a sunscreen active ingredient, is not "generally recognized as safe and effective" (GRASE) for use in over-the-counter (OTC) sunscreens, which is not because of proven risk but due to insufficient safety and efficacy data.[1] Consequently, products containing 4-MBC would be considered misbranded unless further evidence is provided to support its use.

In the European Union (EU), 4-MBC in cosmetic products is being phased out, due to concerns about its potential as an endocrine disruptor. Since 1 May 2025, products containing 4-MBC cannot be placed on the EU market, and since 1 May 2026, they cannot be sold within the EU. Additionally, 4-MBC has been removed from Annex VI of the EU Cosmetics Regulation, which lists approved UV filter.[2] In the UK, new cosmetic products containing 4-MBC cannot be released into the market since 15 July 2026, and products containing 4-MBC cannot be sold from 15 January 2027.

Health Canada currently permits the use of 4-MBC at concentrations up to 4%.[3]

Recently, the TGA has assessed the risks of 4-MBC as an active ingredient in therapeutic sunscreens (Safety Review of 4-Methylbenzylidene Camphor; the Safety Review). The TGA has considered

[1] Over-the-Counter Sunscreen Drug Products-Regulatory Status of Enzacamene; accessed 8 September 2026.

[2] COMMISSION REGULATION (EU) 2024/996; accessed 8 September 2026.

[3] DRAFT: GUIDANCE DOCUMENT Sunscreen Monograph, Health Canada; accessed 8 September 2026.

national and international safety assessment reports, and peer reviewed publications investigating the safety and toxicokinetics of 4-MBC, where available.

The review was conducted following the TGA's development of an Australian Sunscreen Exposure Model (ASEM) in July 2024. The ASEM model is based on current sun protection practices and recommendations in Australia, estimating how much sunscreen Australians use, rather than relying on international models that may not reflect Australia's unique environment and practices. The model was subject to targeted and public consultation in 2024 before it was adopted in January 2025. The model incorporates evidence-based data on sunscreen application frequency and quantity, highlighting that Australians apply sunscreen more often and in larger amounts than populations in other countries.

Considering the higher use of sunscreens in Australia on a daily basis, the Safety Review recommends regulatory controls for 4-MBC to restrict its use and permitted concentration in therapeutic sunscreens.

The Poisons Standard is a legislative instrument that can create controls on substances used in both therapeutic and cosmetic products. Currently, 4-MBC is not specifically scheduled in the current Poisons Standard.

To ensure the highest standards of safety for long-term and frequent use of all sunscreens, the delegate of the Secretary of the Department of Health, Disability and Ageing (the Delegate) is proposing to amend the Poisons Standard in relation to 4-MBC.

The proposed amendments include options for:

- restrictions on the maximum concentration of 4-MBC in all sunscreens
- restrictions based on application to parts of the body
- restrictions based on age of the consumer

Each option should be considered in conjunction with the TGA Safety Review and the ASEM.

Additionally, the Delegate received 2 applications to amend the Poisons Standard to prohibit the use of 4-MBC in therapeutic goods and cosmetic products.

The Delegate is seeking public comments on the proposed amendments for further consideration at the joint meeting of the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS). Following the public consultation and subsequent recommendations and advice from the Joint ACMS-ACCS, the Delegate will make an interim decision.

**Neither the TGA nor the Delegate have formed a view at this time as to which options should be implemented or are preferred.**

The benefits of sunscreen in preventing sunburn and skin cancers are well established. Australians should continue to protect themselves from the sun by following the 5 SunSmart S's – slip, slop, slap, seek, slide – the protective measures include seeking shade, wearing a hat, wearing protective clothing and eyewear and using sunscreen.

# 1 Proposed amendment referred for scheduling advice to the Joint ACMS-ACCS meeting #45

## 1.1 4-methylbenzylidene camphor (4-MBC)

### Delegate's proposal

The Delegate is proposing 2 options to amend the current Poisons Standard in relation to 4-MBC. Each option proposes a new CAUTION (Schedule 5) entry for 4-MBC unless the product meets certain exemption criteria. Products containing substances that are covered by a Schedule 5 entry require a CAUTION signal word on the main label and cannot be used in Listed medicines.

**Option 1: Schedule 5 entry with a general exemption up to a specific concentration**

*Proposed amendments*

**Schedule 5 – New Entry**

4-METHYLBENZYLIDENE CAMPHOR in therapeutic sunscreens and cosmetic preparations **except** in preparations containing 0.39% or less of 4-methylbenzylidene camphor

*Delegate's reasons for Option 1*

The Safety Review concluded that 4-MBC can be deemed low-risk and appropriate for use in general therapeutic sunscreens for daily use at a concentration up to 0.39%.

This option provides one consistent upper limit for 4-MBC for exempting cosmetics and therapeutic sunscreens from the Poisons Standard. This option treats all products consistently.

**Option 2: Schedule 5 entry with exemptions based on age, use and application site**

*Proposed amendments*

**Schedule 5 – New Entry**

4-METHYLBENZYLIDENE CAMPHOR in therapeutic sunscreens and cosmetic preparations **except**:

a) in therapeutic sunscreens for application to the face and hands containing 0.95% or less of 4-methylbenzylidene camphor; or

b) in therapeutic sunscreens for application to the face and hands

   (i) containing 3.8% or less of 4-methylbenzylidene camphor; and

   (ii) for use by persons aged 18 years and over; or

c) in cosmetic preparations for application to the face and hands containing 3.3% or less of 4-methylbenzylidene camphor

*Delegate's reasons for Option 2*

Specific use sunscreens are likely to be used differently by consumers, such as daily application to specific parts of the body, compared with the use pattern for general sunscreens which are applied to all parts of the body. This option provides different upper limits for exempting 4-MBC from the Poisons Standard, based on age, sunscreen type and application site.[4]

[4] Concentrations of 4-MBC that can deemed low-risk depending on the user group, site of application and use pattern can be found in the Safety Review.

The Safety Review estimated that 4-MBC in therapeutic sunscreens can be deemed low-risk:

- at a maximum concentration of 0.95%
- in products intended for daily use by the whole family
- when limited to application to face or face and hand only.

For therapeutic sunscreens intended for daily use by adults, 4-MBC can be deemed low-risk:

- at a maximum concentration of 3.8%
- when limited to application to face or face and hand only.

Based on the available information, 4-MBC is most likely to be present in face creams and foundations and secondary sunscreen products like hand creams and lip balms. Based on combined exposure from these products which may be used on the same day, a maximum concentration of 3.3% 4-MBC in cosmetics is considered to be acceptable.

## Applicants' proposal

Two private applicants submitted applications to amend the scheduling of 4-MBC. Both the applications proposed the same amendments i.e. to create a new entry for 4-MBC to warrant prohibition of sale, supply and use (Schedule 10) when used in therapeutic goods or cosmetic products. Therefore, both the proposals are being considered together as Option 3.

**Option 3. Prohibiting use of 4-MBC in therapeutic sunscreens and cosmetics**

*Proposed amendments*

**Schedule 10 – New Entry**

4-METHYLBENZYLIDENE CAMPHOR in therapeutic goods or cosmetic products.

*Applicants' reasons for this proposal*

The applicants stated that 4-MBC is a confirmed endocrine disruptor and its genotoxicity cannot be excluded. The EU Scientific Committee on Consumer Safety (SCCS, 2022)[5], the UK Scientific Advisory Group on Chemical Safety (SAG-CS) and the European Chemicals Agency (ECHA, 2021)[6,7] have all concluded that 4-MBC disrupts both the thyroid and estrogen systems. Effects include decreased thyroxine (T4), increased thyroid stimulating hormone (TSH) thyroid gland enlargement, estrogenic stimulation of breast cancer cells *in vitro*, and reproductive developmental effects in animal studies. The SCCS also concluded that 4-MBC's genotoxic potential cannot be ruled out.

The applicants submitted that, unlike dose-dependent toxicity that can be mitigated by limiting concentration, the potential endocrine disrupting properties of 4-MBC arise from a mechanism that cannot be adequately characterised with a threshold dose given the current state of genotoxicity evidence. The SCCS and SAG-CS have concluded that that a maximum safe concentration cannot be determined due to insufficient toxicological data and confirmed endocrine disrupting properties.

The applicants also argued that no warning label can appropriately address the fundamental inability to establish a safe dose for a substance with confirmed endocrine disrupting activity and unresolved genotoxicity. Sunscreens are used by the general public including vulnerable populations (children, pregnant women, individuals with thyroid disorders) without medical supervision. Risk communication via labelling is inherently limited in this consumer context. Further, current recommended pattern of

[5] European Commission. Scientific Committee on Consumer Safety (SCCS). Final Opinion on 4-Methylbenzylidene Camphor (4-MBC). SCCS/1640/21. 2022.

[6] UK Office for Product Safety and Standards. Scientific Advisory Group on Chemical Safety of Non-Food Consumer Products (SAG-CS). Opinion 18: 4-Methylbenzylidene Camphor in Cosmetic Products. 2025.

[7] European Chemicals Agency (ECHA). Assessment of endocrine disrupting properties: 4-Methylbenzylidene Camphor (4-MBC). 2021.

use (frequent reapplication to large body surface areas) makes it impossible to control consumer exposure through labelling guidance alone.

Approximately 33 or more countries have taken regulatory action. The EU has banned 4-MBC in all cosmetics under Regulation (EU) 2024/996 (effective 2025-2026)[8]. The UK enacted a ban effective July 2026. The US FDA classified 4-MBC as not GRAS and effective since 2015.[9] China has removed it from permitted UV filters in January 2026.[10]

The ASEM, adopted in January 2025, shows Australian consumers apply sunscreens more frequently and in greater quantities than European populations, resulting in higher systemic 4-MBC exposure. Australia has acted less while its consumers are exposed more.

The applicants claim that over 20 alternative UV filters approved in Australia fully replicate the UV protection provided by 4-MBC. The 88% of ARTG-listed sunscreens that already omit 4-MBC demonstrate that effective products can be formulated without it. The EU and China completed their transitions without any reported impact on sunscreen availability or efficacy.

## CAS Number

36861-47-9

## Alternative names

1,7,7-Trimethyl-3-[(4-methylphenyl)methylene]-bicyclo[2.2.1]heptan-2-one

Enzacamene

3-(4-Methylbenzylidene)-dl-camphor

Neo Heliopan

## Key uses / expected use

Sunscreen products, cosmetic products, and fragrances

## Australian regulations

- According to the TGA Ingredient Database, 4-MBC is:
  - available for use as an active ingredient in: Biologicals, Export Only, Listed Medicines, Over the Counter, and Prescription Medicines.
  - available for use as an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines.
  - not available as a Homoeopathic Ingredient in Listed Medicines.
  - not available as an Equivalent Ingredient in any application.
- As of 25 August 2026, there were 107 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain 4-MBC as an active ingredient. These include 95 listed medicines and 12 listed medicines which are export only.
- According to the Therapeutic Goods (Permissible Ingredients) Determination No.2 of 2026, 4-MBC is permitted to be included in listed medicines as follows:

[8] European Commission. Commission Regulation (EU) 2024/996 of 3 April 2024 amending Annexes II and VI to Regulation (EC) No 1223/2009. Official Journal of the European Union. 2024

[9] US Food and Drug Administration. Sunscreen Drug Products for Over-the-Counter Human Use: Proposed Rule. Federal Register. 2019;84(38):6204–6275.

[10] National Medical Products Administration (NMPA), China. Updated List of Permitted UV Filters in Cosmetics. January 2026

| Item | Ingredient name | Purpose | Specific requirements |
|---|---|---|---|
| 268 | 4-METHYLBENZYLIDENE CAMPHOR | A | Only for use as an active ingredient in sunscreens for dermal application and not to be included in medicines intended for use in the eye.<br>The concentration in the medicine must not be more than 4%.<br>The following warning statements are required on the label:<br>- (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and<br>- (SUNPRO) 'Wear protective clothing - hats and eyewear when exposed to the sun' (or words to this effect). |
| A = active ingredient for a medicine has the same meaning as in the Regulations | | | |

- The TGA prescribing medicines in pregnancy database does not include 4-MBC.
- There are no warning statements pertaining to 4-MBC in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 4 September 2026, there were no products containing 4-MBC as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- 4-MBC is listed in the AICIS Australian Inventory of Industrial Chemicals.

## International regulations

- European Chemicals Agency (ECHA) has classified 4-MBC as a Substance of Very High Concern under REACH due to endocrine disrupting properties (Article 57(f) - human health).
- Under the Cosmetic Products Regulation (Annex II – Prohibited Substances), products containing 4-MBC must not be made available in the European Union (EU) from 1 May 2026, as this list covers substances prohibited in all cosmetic products.
- In the European Commission database for information on cosmetic substances and ingredients (CosIng - Cosmetics Ingredients) database, the function of 4-MBC is listed including light stabilizer, UV absorber, and UV filter.
- In New Zealand Inventory of Chemicals (NZIoC), 4-MBC is listed as not individually approved but may be used under an appropriate group standard with similar GHS classification and toxicity data. According to the Chemical Classification and Information Database (CCID), 4-MBC is also classified under:
  - Classification Aquatic Acute 1 - H400: Very toxic to aquatic life, and
  - Classification Aquatic Chronic 1 - H410: Very toxic to aquatic life with long lasting effects.
- On 12 January 2026, China's National Medical Products Administration (NMPA) issued Announcement No. 6 of 2026, incorporating revised standards into the Cosmetic Safety Technical Standards - STSC 2015. 4-MBC was removed from the list of permitted UV filters and added to the list of prohibited substances. The implementation will be from 1 January 2027. Prior to this update, 4-MBC had been permitted in Chinese cosmetics at a maximum concentration of 4%.
- 4-MBC is not listed in the Health Canada Drug Product Database, Canada's Pest Management Regulation Agency, New Zealand Medsafe Medicines Classification Database, European Union Pesticides Database, United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA).

# How to respond

Submissions must be provided by the closing date of **12 October 2026** through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next joint meeting of the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS).

# What will happen

All public submissions will be published on the TGA website at Public submissions on scheduling matters, unless marked confidential or indicated otherwise in the submission coversheet (see Privacy information).

Following consideration of public submissions received before the closing date and advice from the expert advisory committee/s, decisions on the proposed amendments will be published as interim decisions on the TGA website: Scheduling delegate's interim decisions & invitations for further comment.

**Therapeutic Goods Administration**

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