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

Consultation: Proposed amendments to the Poisons Standard in relation to homosalate, oxybenzone and benzophenone – Joint ACMS-ACCS #41 meeting, September 2025

8 July 2025

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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 September 2025 meeting of the Joint Advisory Committees on Medicines and Chemicals Scheduling (Joint ACMS-ACCS #41). Submissions must be received by close of business 12 August 2025.

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 meeting of the Advisory Committee on Medicines Scheduling (ACMS), meeting of the Advisory Committee on Chemicals Scheduling (ACCS), or a joint meeting of these two committees.

This consultation closes on 12 August 2025.

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 2019, the United States Food and Drug Administration (FDA) reviewed of the safety of sunscreen ingredients. The FDA identified 12 ingredients, including homosalate and oxybenzone, where additional data is required to consider them as generally recognised as safe and effective (GRASE).[1]

In 2021, the European Commission's Scientific Committee on Consumer Safety (SCCS) also reviewed sunscreen ingredients. In its review, the SCCS could not conclude that that the levels of oxybenzone and homosalate present in sunscreens sold in Europe were completely safe. Since January 2025, the European Union (EU) has placed restrictions on the maximum amount of homosalate and oxybenzone that can be present in various cosmetic sunscreens.

The EU also placed similar restrictions on another ingredient, benzophenone, which breaks down from octocrylene. Since November 2023, use of benzophenone in cosmetic products is prohibited within the EU.

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).

The *Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2025* currently lists 30 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 then Medicines Evaluation Committee.

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).

Most products containing sunscreen ingredients in the Australian market can be broadly categorised based on the intended pattern of use. These are:

- General or regular body sunscreen products – for application to the whole body including each arm, leg, front of the body, back of the body and face (including the neck and ears)
- Face sunscreen products – for application to the face (including the neck and ears)
- Lip products

The TGA has considered the developments overseas and has been reviewing the safety of the sunscreen ingredients. The TGA has released a safety review of 7 active ingredients in therapeutic sunscreens (TGA Safety Review). These ingredients were prioritised on the basis of availability of nonclinical safety data, their reported use in higher number of sunscreen products marketed in Australia and the safety signals reported overseas. The TGA has also assessed the risks of benzophenone as a degradant in sunscreens (TGA Safety Review of Benzophenone).

[1] In the US, over-the-counter medicines and therapeutic ingredients need to meet the standards of and comply with monographs established by the FDA to be considered GRASE.

The reviews were conducted following the TGA's development of an Australian Sunscreen Exposure Model (ASEM) in July 2024, the release of a literature review of 7 active ingredients used in sunscreens on 4 February 2025 and an initial review of benzophenone as part of the low-negligible risk changes to the Permissible Ingredients Determination in December 2023. 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 TGA safety review recommends restrictions on the maximum concentrations and use in therapeutic sunscreens for homosalate, oxybenzone and benzophenone.

In addition, the Australian Industrial Chemicals Introduction Scheme (AICIS) published an evaluation statement on homosalate on 16 December 2024 and an evaluation statement on benzophenone on 26 June 2025. These statements recommend listing homosalate and benzophenone in the Poisons Standard with restrictions on the concentration of these substances in cosmetic products that include sunscreen ingredients.

The Poisons Standard is a legislative instrument that can create controls on substances used in both therapeutic and cosmetic products. 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 **homosalate**, **oxybenzone** and **benzophenone.**

The proposed amendments include options for:

- restrictions on the maximum concentration of these substances in 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 reports and the AICIS Evaluation statements. 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 that may incorporate one or more of the options (with modification) for each substance.

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 amendments referred for advice to the Joint ACMS-ACCS meeting #41

1.1 Homosalate

Proposed amendments

The Delegate is proposing several options to amend the current Poisons Standard in relation to homosalate. Each option proposes a new CAUTION (Schedule 5) entry for homosalate 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 in Listed medicines.

These are proposed following the findings and recommendations in the TGA Safety Review and the AICIS evaluation statement.

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

Description

The TGA Safety Review concluded homosalate can be deemed low-risk and appropriate for use in all sunscreen preparations for long-term daily use at a concentration up to 0.28%. AICIS concluded that for the combined use of face cream and lip balm, a homosalate concentration of 4.35% poses a low risk for systemic adverse effects.

This option provides one consistent upper limit for exempting all homosalate sunscreen products from the Poisons Standard. However, this option results in a lower maximum concentration in cosmetic preparations than calculated by the AICIS risk evaluation.

Proposed amendments

Schedule 5 – New entry

HOMOSALATE in therapeutic sunscreens and cosmetic preparations **except** in preparations containing 0.28% or less of homosalate.

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

Description

The TGA Safety Review concluded homosalate can be deemed low-risk and appropriate for use in therapeutic sunscreens for long-term daily use when limited to products for face and hand application up to certain concentrations. The review recommended reducing the maximum concentration of homosalate in the sunscreen products depending on the type of product and directions for use. The review calculated that a homosalate concentration of 0.68% in therapeutic sunscreens applied daily to the face and hands to be of low risk for all users. AICIS concluded that for the combined use of face cream and lip balm, a homosalate concentration of 4.35% poses a low risk for systemic adverse effects.

This option provides different upper limits exempting homosalate from the Poisons Standard based on sunscreen type and site of application. This option distinguishes between cosmetic and therapeutic sunscreens and limits homosalate use to products for the face and hands. The Permissible Ingredients Determination might also be amended to restrict the concentration in specified therapeutic sunscreen preparations separately to any changes to the scheduling of homosalate in the Poisons Standard.

Proposed amendments

Schedule 5 – New entry

HOMOSALATE in therapeutic sunscreen and cosmetic preparations **except**:

(a) in therapeutic sunscreen preparations for application to the face and hands containing 0.68% or less of homosalate; or

(b) in cosmetic preparations for application to the face and hands containing 4.35% or less of homosalate.

Option 3: Schedule 5 entry with exemptions based on age, use and application site

Description

The TGA Safety Review concluded homosalate can be deemed low-risk and appropriate for use in sunscreen preparations for long-term daily use when used by adults and when limited to products for face and hand application up to certain concentrations. The review recommended reducing the maximum concentration of homosalate in sunscreen products depending on the type of product and directions for use. The review calculated a homosalate concentration of 2.7% in therapeutic sunscreens applied daily to the face and hands to be of low risk to adults. This is a higher maximum concentration than Option 2. AICIS concluded that for the combined use of face cream and lip balm, a homosalate concentration of 4.35% poses a low risk for systemic adverse effects.

This option provides different upper limits exempting homosalate from the Poisons Standard based on age, sunscreen type and site of application. This option applies to all sunscreen products and limits higher concentrations of homosalate to products for the face and hands for use by adults. This option treats all products consistently but results in a lower maximum concentration in cosmetic preparations than calculated by the AICIS risk evaluation. The Permissible Ingredients Determination might also be amended to further restrict the concentration in specific therapeutic sunscreen preparations separately to any changes to the scheduling of homosalate in the Poisons Standard.

Proposed amendments

Schedule 5 – New entry

HOMOSALATE in therapeutic sunscreens and cosmetics preparations **except** in preparations:

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

(b) for application to the face and hands; and

(c) containing 2.7% or less of homosalate.

Key uses

Homosalate is commonly used as a UV filter in sunscreens, and other cosmetics such as face cream and lip balms. It is also used as fragrance and skin conditioner in a variety of personal care products. Homosalate is used in these products at concentrations of 4-15% with the highest concentrations of the substance being present in therapeutic sunscreens.[2] Preliminary data supplied by the industry indicates that the majority of sunscreens in the Australian market contain either homosalate and/or octocrylene. The AICIS evaluation statement noted that cosmetic preparations currently available contain up to 10% homosalate.

[2] AICIS (2024) Benzoic acid, 2-hydroxy-, 3,3,5- trimethylcyclohexyl ester (Homosalate) Evaluation Statement. Accessed 14 April 2025

CAS Number

118-56-9

Alternative names

Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester; cyclohexanol, 3,3,5-trimethyl-, salicylate; homomenthyl salicylate; salicylic acid, 3,3,5-trimethylcyclohexyl ester; salicylic acid, *m*-homomenthyl ester.

Australian regulations

- According to the TGA Ingredient Database, homosalate is available for use as an active ingredient in: Biologicals, Export Only, Listed Medicines, Over the Counter, Prescription Medicines.
- As of 26 June 2025, there were 471 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain homosalate as an active ingredient. All of these are listed medicines of which 65 are for export only.
- According to the Therapeutic Goods (Permissible Ingredients) Determination No.2 of 2025, homosalate is permitted to be included in listed medicines as follows:

Item	Ingredient name	Purpose	Specific requirements
2573	Homosalate	A, E	For use as an active ingredient only in sunscreens for dermal application. For use as an excipient only in topical medicines for dermal application. Not to be included in medicines intended for use in the eye. The concentration in the medicine must not be more than 15%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (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 E = excipient for a medicine meaning an ingredient that is not an active ingredient or a homoeopathic preparation ingredient			

- The TGA prescribing medicines in pregnancy database does not include homosalate.
- There are no warning statements pertaining to homosalate in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 26 June 2025, there were 711 reports of adverse events for products containing homosalate as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 703 reports where homosalate was the single suspected medicine.
- As of 26 June 2025, there were no products containing homosalate as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).

- Homosalate is listed on the Australian Inventory of Industrial Chemicals as Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester.

International regulations

- Under the US Food and Drug Administration (FDA) Federal Food, Drug, and Cosmetic Act Code of Federal Regulations Title 21, the maximum authorised concentration of the chemical is 15% for sunscreen drug products for over the counter human use. Industry guidance published by the FDA in 2019 determined that there was insufficient information to classify homosalate as an active ingredient in sunscreens as generally recognized as safe and effective (GRASE).
- The EU introduced new requirements on homosalate in cosmetic products on 1 January 2025. Under the new requirements cosmetic products containing homosalate and not complying with the conditions (maximum 7.34% in face products – not permitted in propellent spray products) shall not be placed on the EU market. The European Commission database for information on cosmetic substances and ingredients database allows homosalate to be used in products as a UV absorber or filter and as a fragrance.
- The Canadian (Health Canada) Drug Product Database lists 116 products containing homosalate that are approved and available for over-the-counter sale in Canada.
- In New Zealand, homosalate is listed in the New Zealand Cosmetic Products Group Standard Schedule 8 list of UV filters which are permitted in cosmetic products. The maximum authorised concentration in finished cosmetic products is 10%.
- The Japan Ministry of Health and Welfare's Standards for Cosmetics (Ministry of Health and Welfare Notification No.331 of 2000) restricts homosalate use under a group entry. The entry in "Appendix 4: The ingredients restricted in all types of cosmetics" states that total concentration of homosalate in cosmetics has a concentration limit of 10%.
- The chemical is listed in the ASEAN Cosmetic Directive Annex VII – List of permitted UV filters which are permitted in cosmetic products. The maximum authorised concentration in finished products is 10%.

1.2 Oxybenzone

Proposed amendments

The Delegate is proposing the following options to amend the current Poisons Standard in relation to oxybenzone. Each option proposes a new CAUTION (Schedule 5) entry for oxybenzone 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 in Listed medicines.

These are proposed in view of the findings and recommendations in the TGA Safety Review. AICIS has not conducted an evaluation of oxybenzone in cosmetic preparations. However, the EU has restricted oxybenzone in face, hand and lip products at a maximum concentration of 6.0% oxybenzone whereas whole body products are limited to a maximum concentration of 2.2% oxybenzone.

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

Description

The TGA's Safety Review concluded oxybenzone can be deemed low-risk and appropriate for use in all sunscreen preparations for daily use at a concentration up to 1% for all users.

This option provides one consistent upper limit exempting oxybenzone from the Poisons Standard for all product categories.

Proposed amendments

Schedule 5 – New entry

OXYBENZONE in therapeutic sunscreens and cosmetic preparations **except** in preparations containing 1% or less of oxybenzone.

Option 2: Schedule 5 entry with exemptions based on concentration and application site

Description

The TGA's Safety Review concluded oxybenzone can be deemed low-risk and appropriate for use in therapeutic sunscreens for long-term daily use when limited to products for face and hand application up to a certain concentration. The review recommended reducing the maximum concentration of oxybenzone in the sunscreen products depending on the type of product and directions for use and calculated that an oxybenzone concentration of 2.5% in therapeutic sunscreens applied to the face and hands daily for all users to be of low risk.

This option provides different upper limits exempting oxybenzone from the Poisons Standard based on product type (sunscreen or cosmetic) and limits oxybenzone to use in face and hand products. For cosmetic preparations, the concentration restrictions that apply in the EU are proposed. The Permissible Ingredients Determination might also be amended to restrict the concentration in specified therapeutic sunscreen preparations separately to any changes to the scheduling of oxybenzone in the Poisons Standard.

Proposed amendments

Schedule 5 – New entry

OXYBENZONE in sunscreens and cosmetic preparations **except**:

(a) in therapeutic sunscreen preparations for application to the face and hands containing 2.5% or less oxybenzone; or

(b) in cosmetic preparations for application to the face and hands containing 6.0% or less oxybenzone.

Option 3: Schedule 5 entry with exemptions based on age, concentration and application site

Description

The TGA's Safety Review concluded oxybenzone can be deemed low-risk and appropriate for use in therapeutic sunscreens for long-term daily use when used by adults and when limited to products for face and hand application up to a certain concentration. The review recommended reducing the maximum concentration of oxybenzone in sunscreen products depending on the type of product and directions for use and calculated an oxybenzone concentration of 9.8% in therapeutic sunscreens applied to the face and hands of adult users daily to be of low risk. This is a higher maximum concentration than Option 2.

This option provides different upper limits exempting oxybenzone from the Poisons Standard based on age, sunscreen type and site of application. This option applies consistently to all sunscreen and cosmetic products and limits higher concentrations of oxybenzone to adult use in products for the face and hands. However, this option applies a higher maximum concentration to cosmetic preparations than in the EU. The Permissible Ingredients Determination might also be amended to further restrict the concentration in specific therapeutic sunscreen preparations separately to any changes to the scheduling of oxybenzone in the Poisons Standard.

Proposed amendments

Schedule 5 – New entry

OXYBENZONE in therapeutic sunscreens and cosmetics preparations **except** in preparations:

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

(b) for application to the face and hands; and

(c) containing 9.8% or less of oxybenzone.

Key uses

There is limited data on oxybenzone usage in Australia. In the EU it is used in cosmetic and sunscreen products as a UV filter at up to 6% concentration in ready for use preparations.

Industry consultation has indicated that oxybenzone is not currently used in sunscreen products available on the Australia market. This is likely due to a move away from oxybenzone for alternative 'reef safe' ingredients.

CAS Number

131-57-7

Alternative names

2-Hydroxy-4-methoxybenzophenone; Methanone, (2-hydroxy-4-methoxyphenyl)phenyl-

Australian regulations

- According to the TGA Ingredient Database, oxybenzone is available for use as an active ingredient in: Biologicals, Export Only, Listed Medicines, Over the Counter, Prescription Medicines.
- As of 26 June 2025, there were 39 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain oxybenzone as an active ingredient. These include 37 listed medicines (2 are for export only) and 2 over-the-counter medicines.
- According to the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2025, benzophenone is permitted to be included in listed medicines as follows:

Item	Ingredient name	Purpose	Specific requirements
3635	OXYBENZONE	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. The concentration in the medicine must not be more than 10%. When used in primary sunscreen products, the following warning statements are required on the label: - (AVOID) 'Avoid prolonged exposure in the sun' (or words to this effect); and - (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 oxybenzone
- There are no warning statements pertaining to oxybenzone in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 26 June 2025, there were 857 reports of adverse events for products containing oxybenzone as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 846 reports where oxybenzone was the single suspected medicine.
- As of 26 June 2025, there were 3 products containing oxybenzone as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- In 2010-2020 there were no adverse experiences recorded for oxybenzone in the APVMA Adverse Experience Reporting Program database (AERP)
- Oxybenzone is listed on the Australian Inventory of Industrial Chemicals as Methanone, (2-hydroxy-4-methoxyphenyl)phenyl-.

International regulations

- In the US, the FDA monograph for Sunscreen Drug Products for Over-the-Counter Human Use allows use of oxybenzone at up to 6% concentration. Oxybenzone is available for use as a pesticide according to the United States Environmental Protection Agency's (US EPA) Office of Pesticides Programs.
- The EU limits use of oxybenzone as a UV filter in cosmetics and sunscreen products to a 6% maximum concentration for face, hands, and lip products, excluding propellant and pump spray products. Products for use on whole body, or in propellant and pump spray products, cannot exceed 2.2% oxybenzone. All other cosmetic preparations are allowed a maximum of 0.5% oxybenzone. This is consistent with the most recent Scientific Committee on Consumer Safety (SCCS) *Opinion on Benzophenone-3* (Oxybenzone) finalised in March 2021.[3]
- The European Chemicals Agency (ECHA) classifies oxybenzone as a health hazard (GHS07) and as hazardous to the environment (GHS09). Chemicals containing oxybenzone require the following warning label:
- *"Warning!* According to the classification provided by companies to ECHA in **CLP notifications** this substance is toxic to aquatic life with long lasting effects, is very toxic to aquatic life, causes serious eye irritation, causes skin irritation and may cause respiratory irritation."
- According to the Canadian (Health Canada) Drug Product Database there are 14 products currently approved for sale containing oxybenzone. The Canadian Primary Sunscreen Monograph restricts oxybenzone as an ingredient in non-prescription sunscreens to less than 6% oxybenzone.
- In Japan, oxybenzone is allowed in cosmetic preparations (including sunscreens) up to a 5% concentration, except in cosmetic preparations not used for mucosa and to be washed away which have no upper limit.[4]

[3] health.ec.europa.eu/system/files/2022-08/sccs_o_247.pdf

[4] The Japan Ministry of Health and Welfare's Standards for Cosmetics (Ministry of Health and Welfare Notification No.331 of 2000); accessed 26 June 2025.

1.3 Benzophenone

Proposed amendments

The Delegate is proposing a new CAUTION (Schedule 5) entry amendment to the current Poisons Standard in relation to benzophenone. Products containing substances that are covered by a Schedule 5 entry require a Caution signal word on the main label and cannot be in Listed medicines.

This follows the findings and recommendations in the TGA Safety Review of Benzophenone and the AICIS evaluation statement.

Description

The TGA Safety Review noted that the presence of benzophenone in sunscreen arises as an impurity in the manufacture of products containing octocrylene, and from the degradation of octocrylene into benzophenone as the product ages.

The TGA's Safety Review concluded that the maximum allowable benzophenone concentration in therapeutic sunscreens should not exceed 383 ppm (0.0383%). This concentration would apply whether benzophenone is present as an impurity or is formed as a degradation product and should not be exceeded before the product expiry date.

The AICIS evaluation statement concluded that "given the identified potential long term systemic health hazards, the evidence indicates that there is a risk to the public following repeated, long-term exposure to the chemical that requires management" and also recommended that the concentration of benzophenone be restricted.

The EU has prohibited the inclusion of benzophenone as an ingredient in cosmetic products and the AICIS evaluation on benzophenone noted that the use of air care products (such as scented candles) containing 0.3% benzophenone would provide exposures similar to the tolerable daily intake set by the European Food Safety Authority.

This proposal would create a new Schedule 5 entry for benzophenone when used as a fragrance in cosmetics, therapeutic preparations and candles. It would also provide a consistent exemption from scheduling when benzophenone is present in a therapeutic or cosmetic sunscreen product below a specific concentration. The Permissible Ingredients Determination might also be amended separately to any changes to the scheduling of benzophenone in the Poisons Standard.

Proposed amendment

Schedule 5 – New entry

BENZOPHENONE in

(a) cosmetic and therapeutic preparations when present as a fragrance; or

(b) sunscreen preparations **except** when present as an impurity or degradant at 0.0383% or less of benzophenone; or

(c) air care products **except** when containing 0.3% or less benzophenone

Appendix F, clause 4 (Warning statements and safety directions) – New entry

Item	Poison	Warning statement item number and statement	Safety direction item number and statement
40	BENZOPHENONE—in air care products	-	9 – Use only in well-ventilated area

Key uses

Benzophenone has reported cosmetic uses in personal care products including fragrances, body lotion, face cream, hand cream, makeup, deodorant, nail products, hair products and body wash. However, available information indicates that the use of benzophenone in personal care products is not widespread.

CAS Number

119-61-9

Alternative names

Methanone, diphenyl-; Diphenylmethanone; Diphenyl ketone

Australian regulations

- According to the TGA Ingredient Database, benzophenone is available for use as an:
  - active ingredient in Biologicals, Export Only, Over the Counter and Prescription Medicines
  - excipient ingredient in Biologicals, Devices, Listed Medicines, Over the Counter and Prescription Medicines
- As of 26 June 2025, there were no medicine active on the Australian Register of Therapeutic Goods (ARTG) that contain benzophenone.
- According to the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2025, benzophenone is permitted to be included in listed medicines as follows:

Item	Ingredient name	Purpose	Specific requirements
807	BENZOPHENONE	E	Permitted for topical use only in combination with other permitted ingredients as a fragrance. The total concentration of fragrance proprietary excipient formulations containing benzophenone must not be more than 1% of the total medicine.
E = excipient for a medicine meaning an ingredient that is not an active ingredient or a homoeopathic preparation ingredient.			

- The TGA prescribing medicines in pregnancy database does not include benzophenone.
- There are no warning statements pertaining to benzophenone in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 26 June 2025, there were no report of adverse events for products containing oxybenzone.
- As of 26 June 2025, there were no product containing oxybenzone listed on the Public Chemical Registration Information System Search (PubCRIS).
- In 2010-2020 there were no adverse experiences recorded for oxybenzone in the APVMA Adverse Experience Reporting Program database (AERP)
- Benzophenone is listed on the Australian Inventory of Industrial Chemicals as Methanone, diphenyl-.

International regulations

- Benzophenone is listed on the Health Canada Cosmetic Ingredient Hotlist - List of Ingredients that are Restricted for Use in Cosmetic Products, with a maximum concentration permitted of 3%.
- In the EU, benzophenone is listed on EU Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 - Annex II - List of Substances Prohibited in Cosmetic Products and only trace level of benzophenone can be present in a product as an impurity and/or degradation product of octocrylene.
- Similarly, in New Zealand, benzophenone as an impurity and/or degradation product of octocrylene must be kept at trace level (Cosmetic Products Group Standard (Amendment) Notice 2024).
- The US FDA has prohibited the use of benzophenone as a food additive and as a plasticiser in rubber articles intended for repeated use in contact with food (Food Additive Regulations; Synthetic Flavoring Agents and Adjuvants). In California, benzophenon is listed in Proposition 65 – a list of chemicals known to cause cancer, birth defects or other reproductive harm – and businesses must warn people of any intentional exposure to benzophenone unless the exposure is sufficiently low to not cause cancer.
- Benzophenon is included as a footnote to the octocrylene listing on the ASEAN Cosmetic Directive Annex VII - List of UV filters which cosmetic products may contain. Benzophenone as an impurity and/or degradation product of octocrylene shall be kept at trace level.

How to respond

Submissions must be provided by the closing date of 12 August 2025 through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next meeting of the Advisory Committee on Medicines Scheduling (ACMS), meeting of the Advisory Committee on Chemicals Scheduling (ACCS), or a joint meeting of these two committees.

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 on 12 August 2025.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au