



21 August 2025

(25-5213)

Page: 1/3

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: AUSTRALIA If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: Department of Health, Disability and Ageing (through the Therapeutic Goods Administration)
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], Other:
4. Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable): <ul style="list-style-type: none">• Homosalate• Oxybenzone• Benzophenone
5. Details of notified document(s) (title, number of pages and languages, means of access): Consultation paper: Proposed amendments to the Poisons Standard in relation to homosalate, oxybenzone and benzophenone; (19 page(s), in English) Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request: https://consultations.tga.gov.au/tga/scheduling-pre-meeting-sunscreen-substances-sep-25/user_uploads/pre-meeting-public-notice---joint-41---homosalate-oxybenzone-benzophenone---sep-2025-1.pdf
6. Description of content: The Therapeutic Goods Administration (TGA) has initiated a public consultation on proposed amendments to the Poisons Standard , aimed at enhancing the regulation of certain sunscreen ingredients and related substances. These proposals have been developed to ensure the safe use of chemicals in therapeutic and cosmetic sunscreens, while maintaining consistency across Australian jurisdictions. The consultation focuses on three substances: <ul style="list-style-type: none">• Homosalate• Oxybenzone• Benzophenone (as an impurity/degradant) These substances are being considered for rescheduling based on emerging scientific evidence and international regulatory trends. The proposed amendments include options for: <ul style="list-style-type: none">• 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

The proposed amendments have been referred to the Joint Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS) at a meeting to be held on 17 September 2025. Following the public consultation and subsequent recommendations and advice from the Joint ACMS-ACCS, the delegate of the Secretary of the Department of Health, Disability and Ageing will make an interim decision. The 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 consultation was open to public comment until 12 August 2025, and all submissions will inform the delegate's interim decision.

- 7. Objective and rationale, including the nature of urgent problems where applicable:** The proposed amendments to the Poisons Standard aim to improve consumer safety and product transparency by regulating the use of homosalate, oxybenzone, and benzophenone in sunscreen products. These changes are based on updated safety reviews and international regulatory developments.

The measure ensures that products containing these substances are appropriately labelled and restricted to safe concentrations, thereby reducing potential health risks from prolonged exposure. It supports informed consumer choice and aligns with global best practices in chemical safety.

This approach balances public health protection with minimal disruption to trade and industry. It allows for continued use in products that meet safety thresholds. ; Protection of human health or safety

- 8. Relevant documents:**

Safety Review of 7 active ingredients in therapeutic Sunscreens [Safety review of seven active sunscreen ingredients](#)

Safety review of Benzophenone [Safety review of benzophenone | Therapeutic Goods Administration \(TGA\)](#)

Evaluation statement on homosalate (AICIS) [Benzoic acid, 2-hydroxy-, 3,3,5-trimethylcyclohexyl ester \(Homosalate\) - Evaluation statement - 16 December 2024](#)

Evaluation statement on Benzophenone (AICIS) [Methanone, diphenyl- \(Benzophenone\) - Evaluation statement - 26 June 2025](#)

- 9. Proposed date of adoption:** To be determined; A proposed date will be published with the Interim Decision.

Proposed date of entry into force: To be determined; A proposed date will be published with the Interim Decision.

- 10. Provision of comments**

Final date for comments: 5 October 2025 (45 days from notification)

[] 60 days from notification

A 45-day period is considered appropriate in this instance, as an Interim Decision is not expected until at least October 2025. Stakeholders will have a second opportunity to provide input during the public consultation following the Interim Decision, prior to any Final Decision being made.

Contact details of agency or authority designated to handle comments regarding the notification:

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