



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

SAFETY NOTICE

TGA Safety Review Reference: Safety review of 4-methylbenzylidene camphor |
Therapeutic Goods Administration (TGA)

Dear Healthcare Professional,

Subject: Findings of the TGA safety and risk review of a sunscreen ingredient

The Therapeutic Goods Administration (TGA) has reviewed the safety of 4-methylbenzylidene camphor (4-MBC), a chemical used to protect the skin from UV rays. A search of published literature has identified some effects on animals with the use of this ingredient when used over long periods of time and in very high concentrations. These risks are only theoretical to humans. The risks bear no comparison to the significant risk to human health from sun exposure.

Risk

4-methylbenzylidene camphor is used in sunscreens to protect the skin from ultraviolet (UV) damage.

The review of published literature conducted by the TGA identified some reported effects of this chemical in animal studies when consumed or exposed to chronic, high doses. Importantly, these studies have not been conducted in human clinical studies and/or trials. Given that this ingredient has been shown to be absorbed through the skin, these effects in animals are considered to pose a theoretical risk to humans, risks that would be associated with high levels of frequent sunscreen use over a lifetime. Patients may seek your advice if it is safe to use sunscreen that contain this chemical.

Importantly, the advice to consumers, to you and your patients, remains that the proven benefits of sunscreen in preventing skin cancer continue to far outweigh any theoretical risks.

Points for Consideration

1. UV radiation is a well-established carcinogen to humans. Australians have the highest rates of skin cancer and melanoma in the world. The effective use of sunscreen, as part of the 5 SunSmart (5S) practices (Slip, Slop, Slap, Seek, Slide), should continue.
2. The TGA regulates sunscreens that are primarily for UV protection as therapeutic goods. They are listed on the Australian Register of Therapeutic Goods and need to be safe, effective (SPF testing) and manufactured under Good Manufacturing Practice to assure their quality. When 4-methylbenzylidene

camphor is used as an active ingredient, it is required to be on the product label.

3. The TGA identified risks based on information from animal data, not human studies. They are theoretical only and based on a conservative approach the TGA uses to ensure that risks from use of therapeutic sunscreens in the community are low.
4. The TGA has not banned this ingredient and is not recalling any products.
5. The TGA modelled the amount of sunscreen applied to the skin for the safety assessments based on the recently adopted Australian Sunscreen Exposure Model.
 - The Australian Sunscreen Exposure Model considers sunscreen use by the high-end user (instead of an average user) to assess safety from frequent, prolonged use. It is based on high exposure levels in toddlers (children aged 1-2 y.o) that have a high skin-surface-area to body weight ratio. It is based on the average daily sunscreen use for the body. This ensures assessments account for use by the population including the average child and adult sunscreen user, as well as more regular users.

What the TGA is doing

- **The TGA is potentially undertaking consideration if any risk mitigation steps via the standard scheduling process are needed. This process will consider the risks and benefits for use of this ingredient in sunscreen (both therapeutic and cosmetic).**

Further Information

For more information or to report any adverse events, please contact the TGA at info@tga.gov.au or visit our website at www.tga.gov.au.

Thank you for your prompt attention to this important public health consideration. The TGA is committed to ensuring the safety and well-being of all Australians and appreciates your cooperation in addressing the same.

Sincerely,



Professor Robyn Langham AM

Chief Medical Adviser

Therapeutic Goods Administration

Date: 27 August 2026