



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Ingredient Summary

Ingredient Name	homosalate
Ingredient ID	53948
Category	Australian Approved Name
Synonyms	Homomethyl salicylate
CAS Number	118-56-9
Availability	<p>Available for use as an Active Ingredient in: Biologicals, Export Only, Listed Medicines, Over the Counter, Prescription Medicines</p> <p>Not available as a Homoeopathic Ingredient in Listed Medicines</p> <p>Available for use as an Excipient Ingredient in: Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, Prescription Medicines</p> <p>Not available as an Equivalent Ingredient in any application</p> <p><i>Please note: Only the name and definition of a substance have been reviewed to allow it to be included in the ingredient repository. The approval for use of the ingredient in therapeutic goods is a decision made by the relevant TGA regulatory area. This approval process may require submission of further information, for example safety data for the ingredient or for the finished goods, to meet legislative and regulatory requirements.</i></p>
Additional Information	

Naming Reference

Reference	Edition/Year/Volume	Page Number(s)	Accessed Online
United States Adopted Name	96		No

Restrictions

Restriction	Applies To
Homosalate is for dermal use only, the concentration of the ingredient is not to exceed 15% and is not to be used in topical products intended for use in the eye.	Over the Counter
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).	Listed Medicines

END OF SUMMARY

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