Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Ingredient Summary

Ingredient Name	Ocimum tenuiflorum
Ingredient ID	83282
Category	Approved Herbal Name
Synonyms	Holy basil Sacred basil Ocimum sanctum
CAS Number	CAS Number not held on file
Availability	Available for use as an Active Ingredient in: Export Only, Listed Medicines, Over the Counter, Prescription Medicines Also available for use as a Homoeopathic Ingredient in Listed Medicines Available for use as an Excipient Ingredient in: Prescription Medicines Not available as an Equivalent Ingredient in any application *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.*
Additional Information	

Naming Reference

Reference	Edition/Year/Volume	Page Number(s)	Accessed Online
Medicinal Plant Names Services			Yes - 07 Sep 2018

Restrictions

Restriction	Applies To
When the plant part is oil or distillate, eugenol is a mandatory component of Ocimum tenuiflorum. When the concentration of eugenol in the preparation is more than 25%, the nominal capacity of the container must not be more than 25 millilitres and the following warning statements must be included on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect); and - (NTAKEN) 'Not to be taken'. When the concentration of eugenol in the preparation is more than 25% and the nominal capacity of the container is more than 15 millilitres but less than or equal to 25 millilitres, the medicine must have a child resistant closure and restricted flow insert fitted on the container. When the concentration of eugenol in the preparation is more than 25% and the nominal capacity of the container is no more than 15 millilitres, the medicine must have a restricted flow insert fitted on the container. When the preparation is for topical use in the mouth, the preparation may not contain more than 5 mL of eugenol and the concentration of eugenol in the	Listed Medicines

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product must not be greater than 25%.	

END OF SUMMARY

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