



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Ingredient Summary

Ingredient Name	galactooligosaccharides
Ingredient ID	142918
Category	Australian Approved Name
Synonyms	galacto-oligosaccharides GOS
CAS Number	CAS Number not held on file
Availability	Available for use as an Active Ingredient in: Listed Medicines Not available as a Homoeopathic Ingredient in Listed Medicines Not available as an Excipient Ingredient in any application Not available as an Equivalent Ingredient in any application <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>
Additional Information	

Naming Reference

Reference	Edition/Year/Volume	Page Number(s)	Accessed Online
Compositional Guidelines			Yes - 21 Oct 2021

Restrictions

Restriction	Applies To
Only to be used in a medicine where FrieslandCampina Ingredients B V (Client ID 79530), who applied to have the ingredient included in this Determination, is the sponsor of the medicine or has given written authorisation to the sponsor of a medicine to include the ingredient in the medicine. This paragraph ceases to be a requirement for this ingredient after 1 May 2025. Lactose and glucose are mandatory components of galactooligosaccharides. The route of administration for medicines that contain galactooligosaccharides must be limited to oral. The maximum recommended daily dose of the medicine must not provide more than: (a) 8 g of galactooligosaccharides to individuals aged 0 to 3 years (inclusive); and (b) 16.2 g of galactooligosaccharides to individuals aged 4 years and older. The following warning statement (or words to the same effect) is required on the medicine label: (GOS) 'Not to be taken on the same day with other products containing galactooligosaccharides.'	Listed Medicines

END OF SUMMARY

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