



# CARING SOLUTIONS

## IS GELMIX SAFE FOR USE IN CANADA?

Gelmix is a USDA certified organic thickener specifically formulated for pediatric use, and safe for infants over 42 weeks gestational age. It is recommended for both breast milk and formula when thickening for spit-up and swallowing difficulties. The thickening agent in Gelmix is organic carob (locust) bean gum, and research has concluded that it is safe for use with term-born infants (see links to research on page 2).

For more information on pediatric thickeners see: Duncan, Daniel R., Kara Larson, and Rachel L Rosen. "[Clinical Aspects of Thickeners for Pediatric Gastroesophageal Reflux and Oropharyngeal Dysphagia](#)".

Health Canada and the Canada Food Inspection Agency acknowledge that all of the ingredients in Gelmix (*Organic Tapioca Maltodextrin, Organic Carob Bean Gum, and Calcium Carbonate*) are recognized as **generally safe by the FDA**, and both Locust (Carob) Bean Gum and Calcium Carbonate are **on Health Canada's "List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents"**.

## INGREDIENTS IN GELMIX

Listed below is information about the individual ingredients that comprise Gelmix, as well as links to FDA publications affirming that they are all generally recognized as safe.

**Organic Tapioca Maltodextrin** is an easily digestible polysaccharide used as a food additive and is derived from tapioca. Maltodextrin is widely used in infant formulas, though often it is derived from corn. Gelmix does not contain corn or other common allergens.

**Carob Bean Gum (also known as Locust Bean Gum)** is a galactomannans vegetable gum extracted from fenugreek gum, guar gum, and tara gum. It has been used in Europe as an infant milk thickener to address digestive issues since the 1950s.

**Calcium carbonate** ( $\text{CaCO}_3$ ) is an odorless, tasteless, non-toxic powder or crystal that occurs in nature. It is an antacid that works by lowering the amount of acid in the stomach.

FDA Title 21 FDA, Direct Food Substances Affirmed as Generally Recognized As Safe:

[Sec. 184.1444, Maltodextrin](#)

[Sec. 184.1343 Locust \(carob\) bean gum](#)

[Sec. 184.1191 Calcium carbonate](#)



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## RESEARCH ON THE USE OF LOCUST BEAN GUM IN INFANTS

In order to provide a level of assurance of the safety of Gelmix for use with infants, links to research on the safety of locust bean gum for use with term-born infants are provided below:

[“Locust bean gum safety in neonates and young infants: An integrated review of the toxicological database and clinical evidence,”](#) Leo Meunier et al, Regulatory Toxicology and Pharmacology, Oct 2014, Vol. 70, Issue 1, p. 155-169.

Study concludes that locust bean gum is safe for its intended therapeutic use in term-born infants to treat uncomplicated regurgitation from birth onwards.

[“Effect of formula thickened with reduced concentration of locust bean gum on gastroesophageal reflux,”](#) Acta Paediatrica. Miyazawa R, Tomomasa T, Kaneko H, Arakawa H, Morikawa A. June 2007;96(6):910-914. Available from: Academic Search Complete, Ipswich, MA.

Study finds that formula thickened with locust bean gum reduced the number of regurgitations without affecting gastric emptying delay in very young infants.

[“Effects of Thickened Feeding on Gastroesophageal Reflux in Infants: a Placebo-Control Crossover Study Using Intraluminal Impedance,”](#) Tobias G. Wenzl et al, Pediatrics, 2003, 111: e355-e359.

Study finds thickening of formula feedings with carob bean gum as an efficient therapy for uncomplicated GER in infants.

[“Use of a new thickened formula for treatment of symptomatic gastroesophageal reflux in infants,”](#) Borrelli O, Salvia G, Campanozzi A, Franco MT, Moreira FL, Emiliano M, Campanozzi F, Cucchiara S. Ital J Gastroenterol Hepatol. 1997 Jun;29(3):237-42.

Study shows that formula thickened with locust bean gum is superior to those traditionally thickened with added rice flour, in the conservative treatment of infants with gastroesophageal reflux.