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**parapharma tech**

**NATURE'S HEALTHIER  
THICKENING OPTION**



## Product Specifications

### **PRODUCT**

Gelmix Thickener, a USDA organic thickener for breast milk, formula and other liquids, consists of an off-white fine powder that is odorless, tasteless and smooth when dissolved.

### **USES**

Thickens breast milk, infant formula and other liquids effectively to nectar and honey thick consistencies. Facilitates the retention of nutrients in breast milk and formula that requires thickening, often recommended for otherwise healthy infants with spit-up and vomiting, which are present in conditions such as gastroesophageal reflux (GER).<sup>1</sup> Also thickens other liquids, typically recommended for individuals suffering from swallowing difficulties.

### **INGREDIENTS**

Organic Tapioca Maltodextrin<sup>2</sup>, Organic Carob Bean Gum<sup>3</sup>, Calcium Carbonate<sup>4</sup>

### **SIDE EFFECTS**

Transient gassiness may occur during the first 2 weeks of use, especially for infants under three months of age. Carob bean gum is not absorbed, so stools may have a mild mucous appearance. Gassiness and loose stools typically subside on their own or by decreasing the amount used.

### **CONTRAINDICATIONS**

Not for use with infants under a gestational age of 42 weeks or under six pounds.<sup>5</sup> Do not use for infants with suspected allergy to galactomannans. There are very few cases of allergies to galactomannans reported in academic literature. If an allergic reaction occurs, discontinue use immediately and seek medical attention. Do not use if galactosemia is suspected. Not intended for use with pre-thickened formulas or in addition to other thickening products.

### **MIXING INSTRUCTIONS**

Gelmix dissolves and thickens best in warm liquids, however body temperature will suffice. For best results, warm desired amount of liquid to between 100-120°F. Sprinkle in Gelmix per usage instructions and mix well until Gelmix is completely dissolved. Wait 5 minutes for the mixture to thicken and cool to a safe feeding temperature. Mix again before serving.

Gelmix thickens liquids up to nectar-thick for infants and children under 3 years old, and up to spoon-thick for adults and children over 3. For additional information on thickening liquids with Gelmix, including detailed usage instructions, visit: <http://www.gelmix.com/mixing-instructions/>

<sup>1</sup> "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.

<sup>2</sup> 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.

<sup>3</sup> Carob Bean Gum (also known as Locust Bean Gum) is a galactomannans vegetable gum extracted from the seeds of the carob tree, mostly found in the Mediterranean. Carob Bean Gum, used as a thickening agent and gelling agent, is in the same family as 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. Carob Bean Gum is a GRAS substance (SCOGS) since 1972. CFR Section 184.1343. U.S. Food and Drug Administration.

<sup>4</sup> Calcium Carbonate is added for its anti-caking properties and to improve the consistency of Gelmix.

<sup>5</sup> Study finds Locust Bean Gum safe for its intended therapeutic use in term-born infants to treat uncomplicated regurgitation from birth onwards.

"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.



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## GELMIX QUALITY ASSURANCE

Gelmix is manufactured with the necessary precautions to ensure its safe use with infants. Each batch undergoes strict quality control tests and comes with double tamper proof seals. Parapharma Tech LLC uses a GMP (Good Manufacturing Practice) manufacturing plant that holds a USDA organic certification by Quality Certification Services.

## BENEFITS OF GELMIX THICKENER

- **ADDS 5X LESS CALORIES THAN RICE CEREALS**  
Adds only 4.4 calories per 2-3 ounces!<sup>6</sup>
- **FREE OF COMMON ALLERGENS** Gelmix does not contain corn, wheat, gluten, whey, casein or lactose.<sup>7</sup>
- **THICKENS BREAST MILK** and is not broken down by maternal amylase.
- **DOES NOT DISPLACE NUTRITIONAL BALANCE** of breast milk or formula.
- **DOES NOT CAUSE CONSTIPATION**, as rice cereals commonly do.<sup>8</sup>
- **DOES NOT CONTAIN ARSENIC**, another concern of some infant rice cereals.<sup>9</sup>
- **TASTELESS, ODORLESS AND SMOOTH**, dissolving easily into liquids.

Nutrition Facts	Amount/serving	%DV*	Amount/serving	%DV*
	Serv. Size 1 Scoop (1.2g) Servings Per Container 208 Calories 5 Fat Cal. 0	<b>Total Fat</b> 0g	<b>0%</b>	<b>Total Carb.</b> 1g
	<i>Trans</i> Fat 0g		Fiber <1g	<b>4%</b>
	<b>Sodium</b> 0mg	<b>0%</b>	Sugars 0g	
			<b>Protein</b> 0g	<b>0%</b>
	Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 0%			

**Ingredients:** Organic Tapioca Maltodextrin, Organic Carob Bean Gum, Calcium Carbonate

## SERVINGS PER CONTAINER AND RETAIL PRICING

**Gelmix 8.8 oz Jar** (250 grams) contains 208 servings and thickens up to 624 fluid ounces; MSRP: \$32.95 (plus shipping and handling);<sup>10</sup>

**Gelmix Stick Pack** (2.4 grams) Individual serving packets thicken 4 oz to nectar thick. Sample pack of 5 stick packs on Gelmix.com costs \$5.99

## AVAILABILITY

Gelmix is available at select retailers.

For a current list of retailers visit:

[www.gelmix.com/find-a-store/](http://www.gelmix.com/find-a-store/)

Also available online at

[www.gelmix.com](http://www.gelmix.com)

Retailers, clinics, hospitals, and other institutional health care centers may purchase Gelmix at a wholesale rate.

For more information, visit:

[wholesale.gelmix.com](http://wholesale.gelmix.com)

Not intended to be sold in doctor's offices.

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<sup>6</sup> Based on a weekly comparison of thickening with Gelmix versus thickening with a leading brand of organic rice cereal (using 1 tbs of rice cereal to each oz. of liquid, and an average daily consumption of 28 fl. oz.). Organic rice cereal adds 1470 calories to infant's existing weekly diet, while Gelmix adds only 287.3 calories. Rice cereal adds 367.5 additional grams to infant's existing weekly diet, while Gelmix only adds 78.4 grams.

<sup>7</sup> Suitable for regular infant formulas: Prosobee®, Similac Isomil®, Alimentum®, Nutramigen®, Elecare®, Neocate® and others.

DO NOT USE with pre-thickened formulas, such as Similac for Spit-up® or Enfamil AR®.

<sup>8</sup> Studies have shown that carob bean gum increased bowel movements by an average of one per day. "Effects of Locust Bean Gum in Anti-regurgitant Milk on the regurgitation in uncomplicated gastroesophageal reflux". Miyazakawa, R. et al. Journal of Pediatric Gastroenterology and Nutrition. Vol 38, No 5, 479-483. May 2004.

<sup>9</sup> The presence of arsenic is a growing concern with infant rice cereals. Gelmix contains no arsenic at traceable levels (<10 ppb).

<sup>10</sup> Note that each pharmacy sets individual retail price. This price is comparable to Similac for Spit-up® and Enfamil AR®, even after adding the price for regular formula.



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## WHY GELMIX?

Gelmix is the first and only USDA certified organic thickener specifically formulated for pediatric use in America. Gelmix is increasingly recommended as the preferred thickening option for all ages struggling with food intake.

## COMPARED TO OTHER THICKENERS

**Rice Cereal:** GERD Guidelines by the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) traditionally recommended adding one tablespoon of rice cereal for every ounce of milk or formula, but new AAP guidelines warn that adding rice cereal causes excessive caloric intake.<sup>11</sup> **Each tablespoon of rice cereal adds approximately 15 calories, when a whole ounce of breast milk or formula only contains 20 calories!** Gelmix adds only 2.2 calories per fluid ounce.

The Centers for Disease Control (CDC) issued a warning in 2013 to delay the introduction of cereals until at least 6 months of age.<sup>12</sup> The drawbacks of early introduction of cereals are numerous, including: **predisposition to obesity,<sup>13</sup> constipation,<sup>14</sup> difficult flow through the nipple, and nutrient displacement (the displacement of protein and fat with a considerable amount of carbohydrates).** Additionally, some pediatricians believe that early introduction of solids may predispose infants **for atopic dermatitis.**<sup>15</sup>

2012 Consumer Reports, confirmed by the FDA, **reveal that rice products, including infant cereals, contain high levels of arsenic.** Infant cereals ranged between 97.7 ppb and 329 ppb, which is staggering considering the EPA standard for arsenic in drinking water is <10 ppb.<sup>16</sup> The harmful effects of high arsenic levels have been linked to cancer, heart disease and poor brain function. Gelmix does not contain arsenic.<sup>17</sup>

**Oatmeal:** Fifty percent of infants who develop constipation with rice cereal will still have it with oatmeal.<sup>18</sup> Oatmeal contains gluten and it may trigger food allergies and lead to food sensitization if introduced early. It is also not 100% soluble, so it forms clumps with formula and breast milk.

**NOTE:** Both cereal and oatmeal contain starches that are broken down by the amylase contained in breast milk, and within minutes, they turn into glucose molecules. It is like adding sugar to breast milk. The thickness disappears as the starch is digested.

<sup>11</sup> "Gastroesophageal Reflux: Management Guidance for the Pediatrician," Lightdale, Jenifer R.; Gremse, David A.; Section on Gastroenterology, Hepatology, and Nutrition, *Pediatrics*, Vol. 131, No. 5, May 1, 2013 (published online April 29, 2013); "When to start infants on solid food," Kotz, Deborah, *The Boston Globe*, April 01, 2013 ([www.bostonglobe.com](http://www.bostonglobe.com)).

<sup>12</sup> "Infants Are Fed Solid Food Too Soon, C.D.C. Finds," Quencua, Douglas, *The New York Times*, March 25, 2013 ([www.nytimes.com](http://www.nytimes.com)).

<sup>13</sup> "Maternal feeding practices and childhood obesity: a focus group study of low-income mothers," Baughcum AE, Burklow KA, Deeks CM, Powers SW, Whitaker RC, *Arch Pediatr Adolesc Med*. 1998 Oct; 152(10): 1010-4.

<sup>14</sup> "Difficulty in defecation in infants with gastroesophageal reflux treated with smaller volume feeds thickened with rice cereal," Mascarenhas R, Landry L, Khoshoo V. *Clin Pediatr (Phila)*. 2005 Oct; 44(8): 671-3.

<sup>15</sup> "Timing of solid food introduction in relation to eczema, asthma, allergic rhinitis, and food and inhalant sensitization at the age of 6 years," Zutavern A et al. *Pediatrics*. 2008 Jan; 121(1): e44-52. doi: 10.1542/peds.2006-3553.

<sup>16</sup> "Arsenic in Rice: Full Analytical Results from Rice/Rice Product Sampling," FDA Consumer Health Information; "Arsenic in your food: Our findings show a real need for federal standards for this toxin," Consumer Reports; "FDA Looks for Answers on Arsenic in Rice," FDA Consumer Health Information; "Questions & Answers: FDA's Analysis of Arsenic in Rice and Rice Products" FDA Consumer Health Information; "Arsenic in Drinking Water," United States Environmental Protection Agency.

<sup>17</sup> Every batch of Gelmix is tested for safety, quality and purity. Gelmix shows no traceable amount of Arsenic (<10 ppb).

<sup>18</sup> "Difficulty in defecation in infants with gastroesophageal reflux treated with smaller volume feeds thickened with rice cereal," Mascarenhas R, Landry L, Khoshoo V. *Clin Pediatr (Phila)*. 2005 Oct; 44(8): 671-3.



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## COMPARED TO OTHER THICKENERS (CONT.)

**SimplyThick®:** SimplyThick ingredients include xanthan-gum, sodium acid sulfate, and potassium sorbate. It takes a 15g packet of SimplyThick to thicken 4 ounces to nectar thick.<sup>19</sup> Gelmix only requires a 2.4g packet to thicken 4 ounces to nectar; that's six times less volume than SimplyThick!

SimplyThick underwent a voluntary recall of the product produced at one plant, where conditions were deemed unsanitary to produce the product safely.<sup>20</sup> (Xanthan gum is produced by the fermentation of glucose, sucrose or lactose by the *Xanthomonas campestris* bacterium. It is not a galactomannan like Carob Bean Gum.) In addition, **the FDA issued a warning about SimplyThick® potentially causing Necrotizing Enterocolitis (NEC)** in premature infants due to non-digestible carbohydrates in the lower intestine.<sup>21</sup> NEC is a serious condition that may require surgery, and has a high morbidity and mortality rate. SimplyThick® is no longer recommended for infants.

Parapharma Tech, LLC has prohibited the use of Gelmix Thickener with premature infants since its inception. Gelmix requires a minimum gestational age of 42 weeks and a minimum weight of 6 pounds before its use with infants. Gelmix instructions for use meet current safety guidelines for thickening for its intended use in term-born infants.<sup>22</sup>

**Thick-It®:** Mainly used for the treatment of dysphagia, Thick-It ingredients include modified food starch and maltodextrin. Requires a teaspoon per ounce to thicken to nectar thick, adding 10 calories and 2.3 carbohydrates per ounce.<sup>23</sup> In comparison, Gelmix only adds 2.2 calories and 0.5g carbohydrates per ounce at its maximum usage instructions for nectar thick.

<sup>19</sup> Based on nutritional panel for SimplyThick Nectar Individual Serving Packet.

<sup>20</sup> "SimplyThick, LLC Announces The Voluntary Recall Of Products Manufactured By Thermo Pac, LLC At Their Stone Mountain, GA Food Processing Plant," <http://www.fda.gov/Safety/Recalls/ucm257841.htm>.

<sup>21</sup> "FDA Expands Caution About SimplyThick," <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm256250.htm>.

<sup>22</sup> These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

<sup>23</sup> Based on nutritional panel of Thick-It Original instant food and beverage thickener. Labeling does not disclose source of starch or maltodextrin and may contain corn or other common allergens.