

SimplyThick FDA Warning Expanded

The Food and Drug Administration (FDA) wants parents, caregivers and health care professionals to be aware that infants of any age may face an increased risk of developing a life-threatening condition if fed a thickening product called SimplyThick.

In May 2011, FDA advised against feeding SimplyThick to infants born before 37 weeks gestation because it could cause NEC. (Gestational, or post-menstrual, age is calculated from the first day of the last menstrual period, which is about two weeks before ovulation.)

After issuing that warning, FDA conducted an extensive review of reports of health problems potentially tied to SimplyThick. Its findings, published recently in *The Journal of Pediatrics*, included the discovery that among almost two dozen infants ultimately found to develop NEC after ingesting SimplyThick was a baby born at full term—not a premature baby. The other 21 infants, however, were born prematurely. The infants ranged from about 24 to 48 weeks post-menstrual age when they became sick. Half of the infants developed NEC in the hospital, while half developed the condition at home following discharge from the hospital. Fourteen required surgery. Silverman and Klontz are among the authors of the report that concluded that further study is warranted to establish if there is a link between NEC and SimplyThick and other thickening agents. Parents are told that they should contact their child's health care provider before using SimplyThick.

Late Onset Necrotizing Enterocolitis in Infants following Use of a Xanthan Gum-Containing Thickening Agent; *The Journal of Pediatrics*; 11 May 2012; pgs 354-356

You may report side effects related to using SimplyThick to FDA's MedWatch by completing and submitting the report online: www.fda.gov/MedWatch/report.htm⁴;

Thickeners

***Simply Thick Gel:** This is a Xanthan Gum based product. It may be used with any liquid, including breastmilk, and is a consistent, reliable thickener. It does not add calories but does increase volume of liquid.

***Thick and Clear:** This is a Cellulose Gum based, powder product. It may be used with any liquid, including breastmilk, and is a consistent, reliable thickener. This product contains calories. This product is recommended for use in children who do not tolerate Simply Thick gel or in newborns who are unable to receive Simply Thick gel, secondary to FDA guideline. This product contains sodium. This product does not currently have age restrictions or age recommendations for use. It is not readily available in the retail market, but may be ordered on-line via medical supply companies.

Thick and Easy: This is a modified corn starch product that also includes maltodextrin. It comes in a powdered form and may be used with all types of liquids, except breastmilk. It continues to thicken (past goal thickness) over time and therefore it is difficult to keep the consistency of the beverage constant. This product contains calories, 3.3 kcal/gm of product (nectar is 15 kcal/packet and honey is 25 kcal/packet). Infants have reduced ability to digest corn starch until approximately 9 months of age. Per manufacturer's recommendation, this product is intended for children ages 3 years and older.

Thick It: This is a Modified Corn Starch based product. It comes in a powdered form and may be used with all types of liquids, except breastmilk. It continues to thicken (past goal thickness) over time and therefore it is difficult to keep the consistency of the beverage constant. This product contains calories. This product does not currently have age restrictions for use; however, infants have reduced ability to digest corn starch until approximately 9 months of age.

***ThickenUp:** This is a Modified Corn Starch based product. It comes in a powdered form and may be used with all types of liquids, except breastmilk. It continues to thicken (past goal thickness) over time and therefore it is difficult to keep the consistency of the beverage constant. This product contains calories. Not for use under 1 year of age per package instructions.

***ThickenUp Clear:** This product is a powdered form of xanthan gum. It may be used with any liquid, including breastmilk, and is a consistent, reliable thickener. Per package instruction this product is intended for children ages 3 years and older. Ingredients include Maltodextrin, xanthan gum, potassium chloride. 1 scoop= 3.7 calories.

***Rice Cereal:** The main ingredient is Rice Flour. *It is an unreliable thickener as beverages thickened with this product tend to become thinner over time when the rice cereal separates from the liquid. It is not recommended to use as a thickener.* This product adds calories (~5 calories per teaspoon). Per the American Academy of Pediatrics, this product is not recommended for infants less than 4-6 months of age.

*Available at Le Bonheur