

SimplyThick Warning

WARNING - NOT intended for use with preterm or infants under 12 months of age. Or children under the age of 12 years with a history of NEC.

Since May 2011, concerns about possible connections between the use of SimplyThick® products and the development of necrotizing enterocolitis (NEC) have led to a warning from the United States Food and Drug Administration (FDA) to not feed or give SimplyThick® brand thickener to babies who were born before 37 weeks post menstrual age.

Subsequent information obtained by the FDA lead them to announce an expanded caution on the use of SimplyThick® brand thickener with any infant.

SimplyThick fully agrees with the FDA recommendations. In addition, after further review, SimplyThick also cautions against the use of SimplyThick with children under the age of 12 with a history of NEC.

Although no definitive link between NEC and SimplyThick® brand products has been found or established, in an abundance of caution, anyone at risk for or with a significant risk factor for developing NEC should not use SimplyThick® products.

In all cases, SimplyThick® should only be used under medical supervision. **Do not self-diagnose.**

Although information provided is believed to be true and accurate, SimplyThick, LLC (ST) cannot anticipate all actual situations and/or conditions of use. ST cannot assure the suitability of SimplyThick® products for any particular situation or that SimplyThick® products will work in every situation. The Food and Drug Administration has not evaluated nor approved any food thickener as a swallowing aid. Do not self-diagnose or self-treat swallowing problems, also commonly termed dysphagia. Swallowing problems and/or dysphagia can be a serious medical condition that should only be treated with proper medical supervision. If you have any questions about use of SimplyThick® products, consult your doctor or physician.

If you have any further questions, if you would like additional information, please call 800-205-7115 or email latestinfo@simplythick.com.