

**simplythick**<sup>®</sup>

Simply Different, Simply Better.

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## Why SimplyThick<sup>®</sup> gel is a safer choice than a powder thickener<sup>1</sup>

Many people want to know why they should use SimplyThick<sup>®</sup> gel when there are powders that are “just as good.”

The simplest answer is that SimplyThick<sup>®</sup> gel is the safe choice.

In the 1990s, the U.S. Food and Drug Administration (FDA) examined the safety of over-the-counter (OTC) drugs containing large concentrations of water-soluble gums. FDA found that undissolved, unhydrated gums— powder thickeners— could present a risk of esophageal obstruction and blockage if not properly mixed or if mixed with inadequate amounts of liquid. That risk occurred because during the process of dissolving, these gum particles swell and can form nearly undissolvable masses. FDA stated that when *“products containing a high level of one of these gums are used by individuals who have difficulty in swallowing, or when such products are taken with an inadequate amount of water or other fluid, there is a risk that the product will swell and form a viscous adhesive mass that can block the throat or esophagus.”*<sup>2</sup>

Fully dissolved and fully hydrated water-soluble gums like the xanthan gum used in SimplyThick<sup>®</sup> gel have no similar issue. The water-soluble gum



thickener in the SimplyThick<sup>®</sup> gel is already fully dissolved, hydrated, and is in solution. Because it is fully dissolved and hydrated, the gum thickener present in SimplyThick<sup>®</sup> gel cannot swell and does NOT present a risk of forming an adhesive mass.

Not a big deal? FDA has also said the following about dry products containing high concentrations of water-soluble gum:

*“Esophageal obstruction and asphyxiation due to orally-administered...products containing water-soluble gums...as active ingredients are significant health risks when these products are taken without adequate fluid or when they are used by individuals with esophageal narrowing or dysfunction, or with difficulty in swallowing.”*<sup>3</sup>

*continued on back*

*“The problem with esophageal blockage associated with the use of water-soluble, gum-containing... products has been limited to those products marketed in the unhydrated form. Products that are marketed in a dry or incompletely hydrated state (intended to be dissolved in water by the consumer prior to ingesting...) have the potential for causing obstruction if the product is taken with inadequate fluid or it is taken by individuals with swallowing or other throat problems.”<sup>4</sup>*



And here is what FDA has said about products containing fully hydrated water-soluble gums:

*“The agency agrees that water-soluble, gum-containing products that are marketed in a fully hydrated form (e.g., in a solution) do not pose any significant risk of esophageal obstruction.... The problem with esophageal blockage associated with the use of water-soluble, gum-containing products has been limited to those products marketed in the unhydrated form.”<sup>5</sup>*

## **SimplyThick<sup>®</sup> gel. Fully hydrated. Safe.**

<sup>1</sup> Powders generally are labeled with appropriate directions for use that if properly followed would avoid the issues discussed above. FDA heard that message during the rulemaking process but was not persuaded that the directions are wholly sufficient. “(T)he agency believes a warning will decrease the extent to which these products could be misused by some individuals with possible adverse consequences...The agency therefore concludes that it is appropriate to require the warning for all dosage forms of OTC drug products containing water-soluble gums as active ingredients in dry or incompletely hydrated form” 58 FR 45197 (August 26, 1993).

<sup>2</sup> 58 FR 45194 (August 26, 1993). While this rulemaking involved OTC products, the scientific and medical principles involved are generally applicable to any water-soluble gums ingested by humans.

<sup>3</sup> 55 FR 45782, 45784 (October 23, 1990); 58 FR 45194, 45200 (August 26, 1993).

<sup>4</sup> 58 FR 45194, 45196 (August 26, 1993).

<sup>5</sup> 58 FR 45194, 45196 (August 26, 1993).

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