



Missouri Department of Health and Senior Services Advisory Alert

The Missouri Department of Health and Senior Services received the following news release regarding SimplyThick® thickening gel products manufactured in Stone Mountain, Georgia since June 1, 2009.

Simply Thick, LLC Announces the Voluntary Recall of Products Manufactured By Thermo Pac, LLC at Their Stone Mountain, GA Food Processing Plant

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FOR IMMEDIATE RELEASE - June 4, 2011 - St. Louis, MO -- Simply Thick, LLC is announcing a voluntary recall of its SimplyThick® thickening gel products manufactured at a food processing plant located in Stone Mountain, Georgia since June 1, 2009. This plant is currently owned and operated by Thermo Pac, LLC. This voluntary recall is limited to only those products manufactured at the Stone Mountain, Georgia plant. Simply Thick products manufactured at two additional food processing plants are not subject to this voluntary recall.

For information on how to identify the products subject to this voluntary recall, please see the section below: *How To Determine If The Product Was Manufactured At The Stone Mountain GA Plant.*

WHY THE VOLUNTARY RECALL WAS ANNOUNCED

The SimplyThick® thickening gel products manufactured at the Thermo Pac, LLC Stone Mountain plant are being recalled because the U.S. Food and Drug Administration (FDA) advised the company that Thermo Pac, LLC failed to file with the FDA a scheduled process designed to ensure that vegetative cells (harmful bacteria) of possible public health significance are destroyed during the manufacturing process. This failure was discovered during an FDA inspection of the Thermo Pac, LLC Stone Mountain plant conducted from May 23 through June 3, 2011.

HOW TO IDENTIFY THE PRODUCT

Products manufactured at the Stone Mountain, GA plant subject to the voluntary recall were distributed across the United States and Canada through food service distributors, drug distributors, retail outlets (consisting primarily of pharmacies and durable medical equipment suppliers), medical facilities, and directly to consumers.

HOW TO DETERMINE IF THE PRODUCT WAS MANUFACTURED AT THE STONE MOUNTAIN GA PLANT

Products affected are 15 g, 30 g, 120 g and 240 g pouches.

All 15 g pouches are affected

All 30 g pouches are affected

Some 120 g pouches – identified as those with a “TP” in the lot code stamped into the edge of the packet.

Some 240 g pouches – identified as those with a “TP” in the lot code stamped into the edge of the packet.

SimplyThick item numbers affected

ALL 01001, 01005, 01007, 02001, 02005, and 02007

SOME 01004, 02004, 01006 and 02006 – identified as those with a “TP” in the lot code stamped into the edge of the packet.

SimplyThick item numbers are included as part of the UPC barcode on our packaging. The item number is the second group of 5 digits in the UPC barcode.

All products have a code embossed or stamped in the foil. The first 6 digits of that code represent a “best if used by” date in MMDDYY format. ANY date code that falls between 062610 (i.e. June 26, 2010) and 062612 (i.e. June 26, 2012) and contains the letter code “TP” in the code are affected by the recall.

An example of an affected date code is: 0312125TP1. The code breakdown would be the “Best If Used By Date”, 03/12/12 – i.e. March 12, 2012 AND it contains “TP” in the code . A picture of a packet with this date code can be found on our website.

A complete list of affected date codes will be posted on the SimplyThick website at www.simplythick.com/recalleddatecodes¹ within the next day.

Products NOT affected by the recall:

64 oz bottles

Some 120 g pouches – identified as those with a “W” in the lot code stamped into the edge of the packet.

Some 240 g pouches – identified as those with a “W” in the lot code stamped into the edge of the packet.

SimplyThick item numbers NOT affected:

05000, 05005, 05010

SOME 01004, 02004, 01006 and 02006 – identified as those with a “W” in the lot code stamped into the edge of the packet.

SimplyThick item numbers are included as part of the UPC barcode on our packaging. The item number is the second group of 5 digits in the UPC barcode.

Example of a date code NOT affected by recall: 04051211WB. “Best If Used By Date” is 04/05/12 – i.e. April 5, 2012 AND it contains “W” in the code. A picture of a packet with this date code can be found on our website.

SHOULD THE FDA WARNING CONTINUE TO BE FOLLOWED REGARDING PREMATURE BABIES?

Yes. On May 20, 2011, the company notified our customers and medical professionals in Canada and in the United States to follow the FDA’s and the Canadian Food Inspection Agency’s (CFIA) warning not to

give SimplyThick® brand thickener to infants born before 37 weeks gestation who are currently receiving hospital care or have been discharged from the hospital in the past 30 days, pending the results of our, the FDA's and the CFIA's investigations.

At this time, Simply Thick has not been advised by the FDA as to whether there is a relationship between the FDA's previous warning and the FDA's recent discovery that Thermo Pac, LLC failed to file a certain process with the agency.

Until the FDA, the CFIA and our company have completed our investigations, we continue to warn against the use of SimplyThick® brand thickener with infants born before 37 weeks gestation who are currently receiving hospital care or have been discharged from the hospital in the past 30 days regardless of whether or not the product is affected by the recall.

WHAT TO DO IF YOU HAVE PRODUCTS MANUFACTURED AT THE STONE MOUNTAIN GA PLANT THAT ARE SUBJECT TO THE VOLUNTARY RECALL

Anyone who has purchased or who has SimplyThick® thickening gel products manufactured at a food processing plant located in Stone Mountain, Georgia is urged to contact the company directly at 1-800-205-7115 for a full refund or an exchange for product(s) unaffected by the recall. Consumers with questions may contact the company at its toll free number 1-800-205-7115 24 hours a day, or by email at latestinfo@simplythick.com.