

## **Baby Formula recalled due to potential cross contamination**

## ByHeart voluntarily recalls certain infant formula products

The U.S. Food and Drug Administration recently announced that ByHeart, a formula manufacturer, voluntarily recalled certain infant formula products. The USDA is working closely with the FDA to monitor this developing situation and are ready to respond if the impact of the recall evolves. Parents and caregivers of infants who have purchased this product should follow instructions provided by ByHeart in their letter to consumers.

ByHeart has voluntarily recalled five batches of its Whole Nutrition Infant Formula, Milk Based Powder with Iron for 0-12 Months in 24 oz containers due to concern of potential cross contamination with *Cronobacter sakazakii*. The formula under voluntary recall was distributed directly to consumers in the U.S. and can be identified by the number on the bottom of the can. The product batches that have been recalled should be printed with a use by date of 01 JAN 24 or 01JUL 24. Those batches are as follows:

- 22273 C1
- 22276 C1
- 22277 C1
- 22278 C1
- 22280 C1

ByHeart has advised that one test sample collected from a third-party packaging facility tested positive for *Cronobacter sakazakii*. Per the company, all product packaged that day, and the first production on the next day was isolated for destruction and not distributed. Out of an abundance of caution, ByHeart is now recalling all product produced during the entire run. No distributed ByHeart product has tested positive for the bacteria.

Parents and caregivers of infants who have used this product and are concerned about the health of their child should contact their health care provider. Those caregivers who currently possess the recalled formula should dispose of it. Per ByHeart, no consumer complaints have been received that would indicate illness from Cronobacter. If an infant has already consumed all of the formula, there is no reason for concern, and no additional action is needed.

ByHeart is setting up a webpage <u>here</u> with additional information about its measures. Should customers have any other questions or want to find out if the product they have is included in the voluntary recall, please email <u>notices@byheart.com</u> or text ByHeart at 1-909-506-2354. The company will also be reaching out directly to all customers via email who purchased orders from these identified batches.

Additional Information:

- <u>Cronobacter</u> bacteria can cause severe, life-threatening infections (sepsis) or meningitis (an inflammation of the membranes that protect the brain and spine). Symptoms of sepsis and meningitis may include poor feeding, irritability, temperature changes, jaundice (yellow skin and whites of the eyes), grunting breaths and abnormal movements. Cronobacter infection may also cause bowel damage and may spread through the blood to other parts of the body.
- If your infant is experiencing symptoms related to Cronobacter infection, contact your health care provider to report their symptoms and receive immediate care. To report an illness or adverse event, you can
  - Call an **FDA Consumer Complaint Coordinator** if you wish to speak directly to a person about your problem.
  - Complete an **electronic Voluntary MedWatch form** online.
  - Complete a **paper Voluntary MedWatch form** that can be mailed to the FDA.

December 2022