

FDA Investigation of Cronobacter and Salmonella Complaints: Powdered Infant Formula (February 2022)

Do not use certain powdered infant formulas produced at Abbott Nutrition's Sturgis, MI facility

The FDA, along with CDC and state and local partners are investigating four consumer complaints of infant illness related to products from Abbott Nutrition's Sturgis, MI facility received from 9/6/2021 to 12/18/2021. All of the cases are reported to have consumed powdered infant formula (IF) produced from Abbott Nutrition's Sturgis, MI facility. These complaints include three reports of *Cronobacter sakazakii* infections and one report of *Salmonella* Newport infection in infants. All four cases related to these complaints were hospitalized and *Cronobacter* may have contributed to a death in one case.

FDA has initiated an onsite inspection at the facility. Findings to date include several positive *Cronobacter* results from environmental samples taken by FDA, and adverse inspectional observations by FDA investigators. A review of the firm's internal records also indicate environmental contamination with *Cronobacter sakazakii* and the firm's destruction of product due to the presence of *Cronobacter*.

FDA is issuing this advisory to alert consumers to avoid purchasing or using certain powdered infant formula produced in the Sturgis, MI facility.

This is an ongoing investigation and the firm is working with the FDA to initiate a voluntary recall of potentially affected product. FDA is continuing to investigate and will update this advisory should additional consumer safety information become available.

Recommendation

The FDA is advising consumers not to use Similac, Alimentum or EleCare powdered infant formulas if:

- the first two digits of the code are 22 through 37 and
- the code on the container contains K8, SH, or Z2, and
- the expiration date is 4-1-2022 (APR 2022) or later.

The code is printed on the product packaging near the expiration date (see product image below).

Additional information on products made by Abbott Nutrition is available on their website:

<https://abbottnutrition.com/infant-and-new-mother> (<https://abbottnutrition.com/infant-and-new-mother>) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Products that do not contain the information listed above are not impacted by this advisory. This advisory does not include liquid formula products or any metabolic deficiency nutrition formulas. Consumers should continue to use all product not covered by this advisory.

Products made at the Sturgis facility can be found across the United States and were likely exported to other countries as well.

These powdered infant formulas have the potential to be contaminated with *Cronobacter*, a bacterium that can cause severe foodborne illness primarily in infants. *Cronobacter* infections are rare but are especially high risk for newborn infants (see symptoms below).

Parents and caregivers should never dilute infant formula and [should not make or feed homemade infant formula to infants \(/food/alerts-advisories-safety-information/fda-advises-parents-and-caregivers-not-make-or-feed-homemade-infant-formula-infants\)](/food/alerts-advisories-safety-information/fda-advises-parents-and-caregivers-not-make-or-feed-homemade-infant-formula-infants).

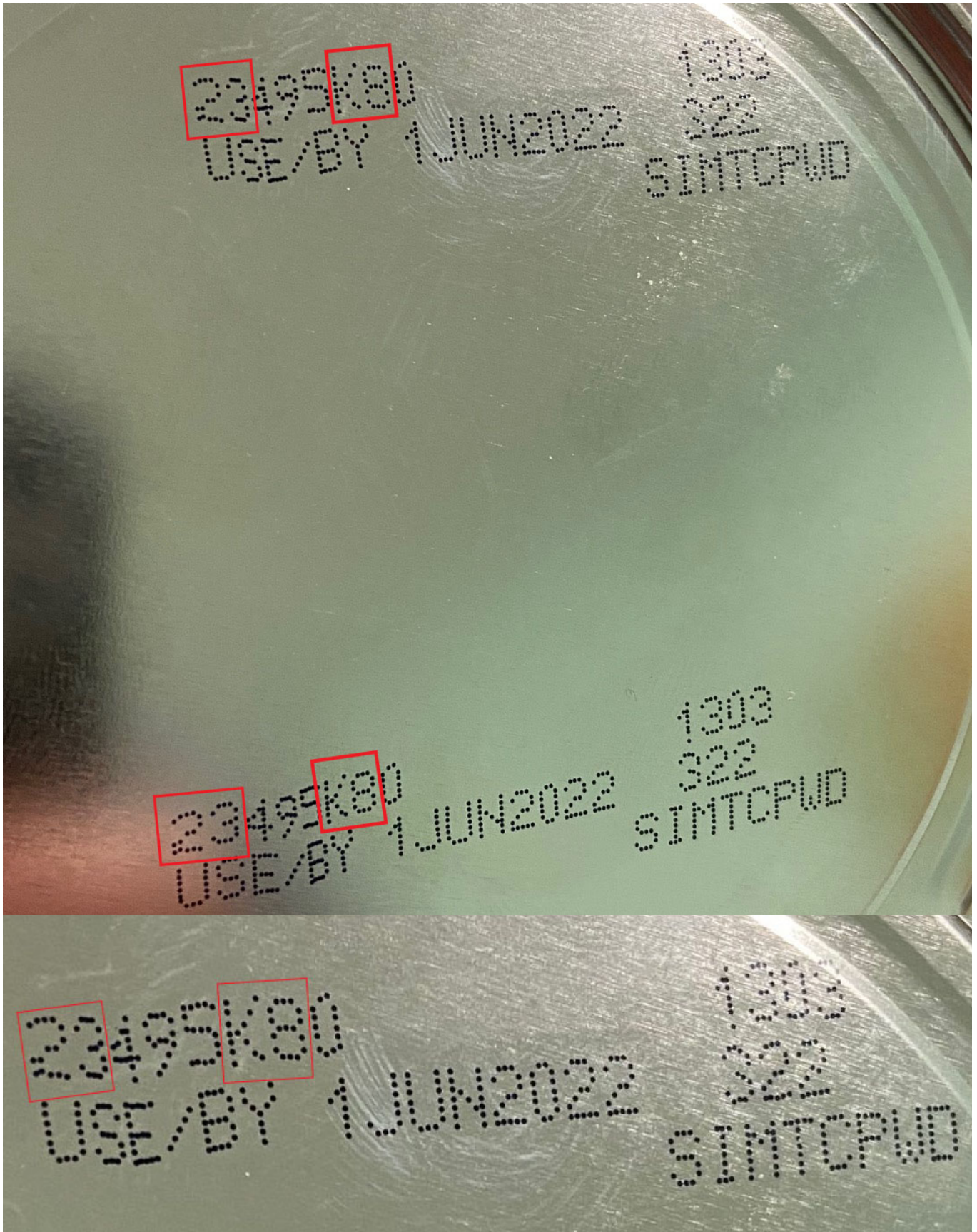
If your regular formula is not available, contact your child's healthcare provider for recommendations on changing feeding practices.

More [information on *Cronobacter* and infant formula \(https://www.cdc.gov/cronobacter/infection-and-infants.html\)](https://www.cdc.gov/cronobacter/infection-and-infants.html) is available on CDC's website.

Cronobacter 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 child is experiencing any of these symptoms, you should notify your child's healthcare provider and seek medical care for your child immediately. Healthcare providers and health departments are encouraged to report any confirmed cases of *Cronobacter sakazakii* to CDC.

Product Images



Case Counts

Total Adverse Events: 4 (3 *Cronobacter*, 1 *Salmonella*)

Hospitalizations: 4

Reported Deaths: 1*

Adverse Event Dates: 9/6/2021 – 12/18/2021

States with Adverse Events: MN (1), OH (1), TX (2)

Product Distribution: Nationwide and International

*One death has been reported but has not been confirmed to be solely attributable to *Cronobacter* infection.

Useful Links

- [Cronobacter Infection and Infants \(CDC\)](https://www.cdc.gov/cronobacter/infection-and-infants.html) (<https://www.cdc.gov/cronobacter/infection-and-infants.html>)
- [What is Salmonella?](/food/foodborne-pathogens/salmonella-salmonellosis) (</food/foodborne-pathogens/salmonella-salmonellosis>)
- [Food Safety Tips for Consumers & Retailers During an Outbreak](/food/outbreaks-foodborne-illness/food-safety-tips-consumers-retailers-during-outbreak-foodborne-illness) (</food/outbreaks-foodborne-illness/food-safety-tips-consumers-retailers-during-outbreak-foodborne-illness>)
- [Who to Contact](#)

Who to Contact

Consumers who have symptoms should contact their health care provider to report their symptoms and receive care.

To report a **complaint** or **adverse event** (illness or serious allergic reaction), you can

- Call an FDA [Consumer Complaint Coordinator](/safety/report-problem-fda/consumer-complaint-coordinators) (</safety/report-problem-fda/consumer-complaint-coordinators>) if you wish to speak directly to a person about your problem.
- Complete an [electronic Voluntary MedWatch form](https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm) (<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>) online.
- Complete a [paper Voluntary MedWatch form](/media/85598/download) (</media/85598/download>) that can be mailed to FDA.

Submit Questions/Get Assistance (<https://www.fda.gov/fcic>)

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