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FDA issues warning for potentially contaminated infant formula

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Melissa Jenco, News Content Editor

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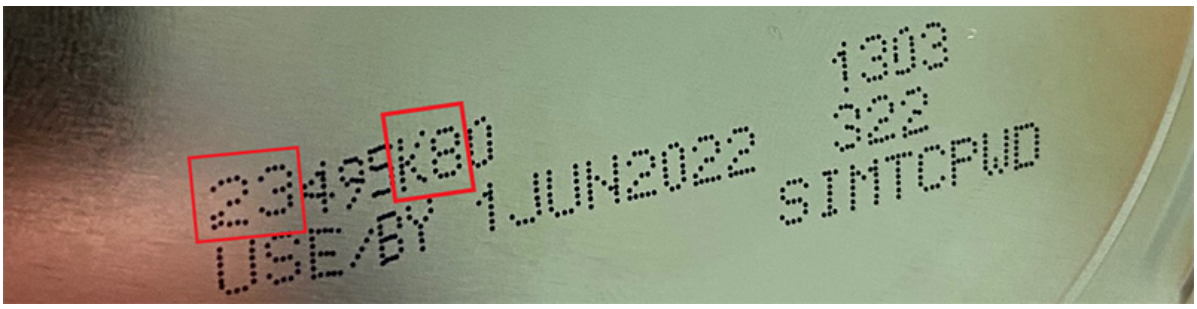
Federal health officials are warning families not to use certain lots of Similac, Alimentum and EleCare powdered infant formula while they investigate complaints of bacterial infections.

The warning comes after reports of four infants in three states becoming ill with *Cronobacter sakazakii* and *Salmonella* Newport infections, according to the Food and Drug Administration (FDA). All four were hospitalized and one died, although the death has not been confirmed to be solely due to the infection.

The impacted Similac, Alimentum and EleCare formulas from Abbott Nutrition were produced at the company's Sturgis, Mich., facility and distributed nationwide as well as to other countries. The FDA has found *Cronobacter* in environmental samples at the facility and noted in the firm's internal records. Officials are working with Abbott to initiate a voluntary recall of the products.

Consumers who have the powdered formula should look for the code printed on the product packaging near the expiration date. They should not use the formula if it meets three criteria:

- 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.



“As this is a product used as the sole source of nutrition for many of our nation’s newborns and infants, the FDA is deeply concerned about these reports of bacterial infections,” FDA Deputy Commissioner for Food Policy and Response Frank Yiannas said in a news release. “We want to reassure the public that we’re working diligently with our partners to investigate complaints related to these products, which we recognize include infant formula produced at this facility, while we work to resolve this safety concern as quickly as possible.”

Liquid formula products, metabolic deficiency nutrition formulas and other products not included in the advisory can still be used. The FDA recommends speaking with a child’s health care provider for recommendations if their regular formula is not available. Parents should never dilute infant formula or make their own.

Cronobacter bacteria can cause sepsis or meningitis. Symptoms include poor feeding, irritability, temperature changes, jaundice, grunting breaths and abnormal movements. *Cronobacter* also may cause bowel damage. *Salmonella* can cause gastrointestinal illness and fever. Severe infections also may include aches, headaches, lethargy, rash and blood in the urine or stool.

Infants who have symptoms of a bacterial infection should contact their health care provider. To report a complaint or adverse event, call an FDA consumer complaint coordinator or complete an electronic voluntary MedWatch form.

The Centers for Disease Control and Prevention also is investigating *Cronobacter sakazakii* case in children who consumed powdered formula in the 10 days prior to getting sick. Clinicians who have cared for these infants since November 2020 should email cronobacter@cdc.gov.

Resources

- FDA warning on powdered infant formulas
- Information about the recall for families from HealthyChildren.org
- Information from the Centers for Disease Control and Prevention on *Cronobacter* infection