

February 22, 2022

Infant Formula Linked to Cronobacter sakazakii and Salmonella Newport

SUMMARY:

The U.S. Food and Drug Administration (FDA), along with the Centers for Disease Control and Prevention (CDC), are investigating four consumer complaints of infant illness received from September 20, 2021, to January 11, 2022, related to infant formula products from the Abbott Nutrition facility in Sturgis, MI. All of the cases are reported to have consumed powdered infant formula produced at this 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* infection may have contributed to death in one case.

The Indiana Department of Health (IDOH) is issuing a call for cases of *Cronobacter sakazakii* and *Salmonella* Newport that could be associated with powdered infant formula. Please notify the IDOH Enteric Epidemiology Team of any *Cronobacter sakazakii* or *Salmonella* cases among infants who consumed powdered infant formula in the 10 days before illness onset. Onset dates are estimated to range from November 2020 to the present date. No Indiana cases of *Cronobacter sakazakii* or *Salmonella* linked to recalled infant formula have been identified at this time. Testing of recalled infant formula samples may be approved if criteria are met.

Please review the links below for more information about a recall of infant formula due to potential bacterial contamination, including *Cronobacter sakazakii* or *Salmonella* species. Providers should check to ensure they are not distributing recalled infant formula and report any *Cronobacter* or *Salmonella* infections that occur in infants to the IDOH at 317-233-7125.

- Abbott Recall Notice
- FDA Investigation Announcement
- CDC Information on Cronobacter Infection and Infants

Three brands of powdered infant formula were recalled on February 17, 2022, for possible *Cronobacter* contamination. FDA is investigating several consumer complaints about sick infants who were fed powdered formula.

Product and Recall Information:

Recall: <u>https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-</u> recalls-powder-formulas-manufactured-one-plant

Date	Brand Name(s)	Product	Product	Recall Reason	Company
		Description	Туре	Description	Name
02/17/2022	<u>Similac,</u>	Powdered	Food &	Consumer	Abbott
	Alimentum, and	Infant	Beverages	complaints regarding	
	EleCare	Formula	_	Cronobacter	
	(including			sakazakii, Salmonella	
	EleCare Jr.)			Newport	

The FDA advises consumers not to use recalled Similac, Alimentum or EleCare (including EleCare Jr.) powdered infant formulas. Recalled products can be identified by the 7- to 9-digit code and expiration date on the bottom of the package (see image below). Products are included in the recall if they have all three items below:

- 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.

Additional recall information is available on the FDA website. Parents can also enter their product lot code on the company's website to check if it is part of the recall. **Do not feed infants recalled powdered formula.**

Product Images





Product photos, courtesy of U.S. FDA



Cronobacter and Salmonella Infection:

More information on *Cronobacter* and infant formula is available on <u>CDC's website</u>.

Cronobacter sakazakii is commonly found in the environment and a variety of areas in the home. Infection can cause fever, poor feeding, excessive crying or low energy, as well as other serious symptoms. It's important to follow instructions for proper preparation, handling and storage of powdered formulas. Recalled powdered infant formulas have the potential to be contaminated with *Cronobacter*, a bacterium that can cause severe foodborne illness primarily in infants. *Cronobacter* infection may also cause bowel damage and may spread through the blood to other parts of the body. *Cronobacter* infections are rare but are especially high risk for newborn infants

Salmonella are a group of bacteria that can cause gastrointestinal illness and fever called salmonellosis. Most people with salmonellosis develop diarrhea, fever and abdominal cramps. More severe cases of salmonellosis may include a high fever, aches, headaches, lethargy, a rash, blood in the urine or stool, and in some cases, may become fatal.

Information for Healthcare Providers:

- Notify IDOH of any laboratory confirmed cases of *Cronobacter* infection or salmonellosis from November 2020 to present in infants who have consumed infant formula.
- Notify IDOH of any consumer complaints associated with the consumption of infant formula who have corresponding symptoms. IDOH will review and organize specimen collection if determined necessary.

Healthcare providers with suspected or confirmed cases of *Cronobacter* infection or salmonellosis in infants who have consumed infant formula should notify Nicole Stone, senior enteric epidemiologist, at nstone2@isdh.in.gov or 317-234-2898.

Information for Local Health Departments:

Local health departments that are notified or contacted by a parent or caregiver who has an infant who consumed recalled product can follow these steps:

- For infants who consumed the **recalled** product and are **experiencing symptoms** of *Cronobacter* or *Salmonella* infection:
 - o Confirm the product lot information
 - Confirm if they have product left over
 - o Confirm the symptoms the infant has experienced
 - Recommend the infant be treated by a healthcare provider
 - \circ $\;$ Notify IDOH Food Protection Division for product collection and testing
 - Notify IDOH Enteric Epidemiology of the patient (name, DOB, address, symptoms, onset date)



- For infants that consumed the **recalled** product and are **NOT** experiencing any symptoms:
 - Recommend they discard or return recalled product for a different product
 - Do not continue to feed recalled infant formula to their infant
 - If they begin to experience symptoms of *Cronobacter* or *Salmonella* infection, contact their healthcare provider

For Product Testing:

Consumer product sample testing may be approved by the IDOH for the following conditions:

- You or your agency is aware of a consumer complaint regarding an **infant illness** and the illness/complain is associated with the **recalled lots**, or
- You or your agency is aware of a **confirmed** *Cronobacter sakazakii* illness in an infant who **consumed infant formula from one of the recalled lots**

Approved samples may be sent to the IDOH laboratory or to an FDA laboratory for testing. Product information should be obtained even if physical product samples are unavailable. The IDOH will request product and lot information during communications with parents, caregivers, and healthcare providers. Sampling will only occur for recalled lots. Parents who wish to have product tested should also have their child seek consultation with a healthcare provider.

For consultation on product sampling, please contact Kris Gasperic, Consumer Specialist, kgasperic@isdh.in.gov, 317-233-8475.

Information for Parents and Caregivers:

The recall does not include liquid formula products or any metabolic deficiency nutrition formulas. Consumers should continue to use all product not included in the recall. Families receiving WIC assistance can contact their <u>local clinic</u> for breastfeeding support or for questions on their benefits during this recall.

- Parents and caregivers of infants who have used these products and are concerned about the health of their child should contact their child's healthcare provider. 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.
- If your regular formula is not available, contact your child's healthcare provider for recommendations on changing feeding practices.
- Parents and caregivers should never dilute infant formula and should not make or feed homemade infant formula to <u>infants</u>.



 Use prepared infant formula within 1 hour from start of feeding and within 2 hours of preparing it. If your baby does not finish the entire bottle of formula, throw away leftover formula. If you do not plan to use the prepared formula right away, refrigerate it immediately. Use refrigerated formula within 24 hours. If you can't remember how long you have kept formula in the refrigerator,



Image source: CDC

- it is safer to throw it out than to feed it to your baby.
- Clean, sanitize, and store your baby's feeding items and breast pump parts safely to protect your baby from *Cronobacter* and other germs.

