

Exhibit 6



Cronobacter Home

Cronobacter and Powdered Infant Formula Investigation

Updated May 24, 2022

CDC’s investigation is closed. No additional cases have been identified as part of this investigation. CDC encourages health departments to continue reporting infant *Cronobacter* infections to CDC by emailing cronobacter@cdc.gov. Get updates about FDA’s investigation [↗](#) and learn more about *Cronobacter* prevention, including how to safely prepare and store powdered infant formula.

Fast Facts

- Illnesses: 4
- Deaths: 2
- States: 3 (Minnesota, Ohio, Texas)
- Recall: Yes
- Investigation status: Closed



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Recalled Powdered Infant Formula

FDA has published [a full list of recalled powdered infant formula ↗](#). Check any powdered infant formula you have at home to see if it has been recalled.

On February 28, 2022, Abbott Nutrition recalled one lot of **Similac PM 60/40** powdered formula (Lot # 27032K80 (can) / Lot # 27032K800 (case) manufactured in Sturgis, Michigan. Review these codes on the bottom of the package to find out if the product you have is included in this recall. Parents and caregivers can also enter their product lot code on the company’s [website ↗](#) to check if it is part of the recall. The Similac PM 60/40 recall is in addition to other lots of **Similac**, **Alimentum**, and **EleCare** powdered formula that were recalled on February 17, 2022.

- The February 28 recall was made after a report of the death of an infant with a *Cronobacter sakazakii* infection who consumed Similac PM 60/40 powdered formula from this lot.

Similac, Alimentum, and EleCare powdered formula products recalled on February 17 have all three of these conditions:

- First two digits of the code are 22 through 37, AND
- on the container contains “K8,” “SH,” or “Z2,” AND
- Use-by date is 4-1-2022 (APR 2022) or later.

To find out if the product you have is included in this recall, review product lot code on the bottom of the package. [See the full list of recalled products on FDA’s consumer advisory page](#) .

Advice for Parents and Caregivers

Do not feed your baby any recalled powdered formula.

- If you feed your baby with other types of Similac PM 60/40 powdered formula:
 - Check for the **lot code 27032K800** that is included in the expanded recall. At this time, Similac PM 60/40 with lot code **27032K80 (can) / 27032K800 (case)** is the only type and lot of this specialty formula being recalled.
 - To find out if the product you have is included in this recall, review the product lot code on the bottom of the package and enter it on [Abbott Nutrition’s website](#). [↗](#)
- If you feed your baby with other types of Similac, Alimentum, or EleCare powdered formula:
 - Check to see if your powdered formula is recalled using one of these three ways:
 - Compare the lot code and use-by date on the bottom of the package to the recall information.
 - Visit [Abbott Nutrition’s website](#) [↗](#) and type in the code on the bottom of the package.
 - Call 1-800-986-8540 and follow the instructions provided.
- If you have any recalled powdered formula, immediately stop feeding it to your baby and return it for a refund at the store where you bought it. You can also [return it to Abbott Nutrition](#). [↗](#)
- If you can’t find the code on the powdered formula package, do not use it.
- Parents and caregivers should never dilute powdered infant formula (by adding more water than recommended or another solvent to it) and should not make or feed homemade infant formula to infants.
- Do not buy formula online that comes from outside the United States. This formula could be [counterfeit](#) [↗](#) —for example, it may have fake labels to misrepresent the quality or identity of a formula, the product may not have the proper nutrients or ingredients to feed your baby, or it might have a fake label with a wrong use-by date.
- If you get infant formula through the Women, Infants, and Children (WIC) program, do not throw the formula out. Instead, you should take it to the store for a refund and exchange or call the company at 1-800-986-8540 to help you. WIC recipients should be able to obtain a different brand of similar formula. Call your local WIC clinic for more guidance. Also see:
 - [Information for WIC participants and state agencies](#) [↗](#)
 - [WIC Infant Formula Recall Waivers | Food and Nutrition Service \(usda.gov\)](#) [↗](#)
 - [Toll-Free Numbers for WIC State Agencies](#) [↗](#)
 - [USDA Contact Map](#) [↗](#)
- Check [FDA’s consumer advisory page for additional information](#) [↗](#) if your baby receives medical specialty infant formula.
- Contact your baby’s healthcare provider if:
 - Your baby has symptoms of *Cronobacter* illness (fever and poor feeding, excessive crying, or very low energy).
 - Your regular formula is not available, and you need recommendations on other ways to feed your baby.

Symptoms

- The first symptom of *Cronobacter* infection in infants (0–1 year old) is usually a fever, accompanied by poor feeding, excessive crying, or very low energy. Some infants may also have seizures. Infants with these symptoms should be seen by a medical provider as soon as possible.
- *Cronobacter* bacteria can cause a dangerous blood infection (sepsis) or make the linings surrounding the brain and spinal cord swell (meningitis). Infections in infants usually occur in the first days or weeks of life. Infants 2 months of age and younger are most likely to develop meningitis if they are infected with *Cronobacter*.

What Healthcare Providers/Laboratories Should Do

- If a *Cronobacter* infection is diagnosed by a laboratory culture, CDC encourages clinicians and laboratories to inform their local or state health department.
- *Cronobacter* can be detected in the blood or cerebrospinal fluid (CSF) of patients with meningitis or sepsis caused by these bacteria. *Cronobacter* bacteria grow on routine culture media and microbiological laboratories can detect *Cronobacter* from blood or CSF samples.
- CDC does not recommend testing infants for *Cronobacter* infection unless they have symptoms of meningitis or sepsis, even if they consumed recalled formula.
- CDC does not recommend testing stool for *Cronobacter*. *Cronobacter* infection does not typically cause diarrhea in infants.
- CDC does not recommend testing formula for *Cronobacter* contamination unless an infant has a diagnosed *Cronobacter* infection.



Please contact your [local or state health department](#) if your child has been diagnosed with *Cronobacter* infection and consumed recalled formula.

Description of Cases

On February 10, 2022, CDC was notified of the Food and Drug Administration’s (FDA’s) investigation of consumer complaints of infant illness related to products from Abbott Nutrition in Sturgis, Michigan.

The most recent investigation details are summarized below:

From September 16, 2021, to January 5, 2022, CDC received reports of three *Cronobacter* cases in infants that were later found to be included in FDA’s ongoing investigation. On February 16, 2022, CDC asked clinicians and state and local health departments to provide information on other *Cronobacter* infections associated with infant formula from November 2020 through the present. Since then, CDC has identified one additional case of *Cronobacter* infection in an infant who consumed formula produced at this facility.

- Four infants with *Cronobacter* infections in Minnesota (1), Ohio (2), and Texas (1) consumed formula produced at the Sturgis, Michigan, facility before they got sick.
- Formula types included Similac Sensitive, Similac Pro-total Comfort, Similac Advance, and Similac PM 60/40.
- *Cronobacter* infections may have contributed to the deaths of two infants in Ohio.

CDC performed [whole genome sequencing](#) (WGS) on *Cronobacter* bacteria isolated from two available patient samples to compare them with environmental samples taken at the facility to determine if there is any relation.

At this time, CDC has completed laboratory testing for the two available patient samples. The analysis performed by WGS did not find these samples from patients to be closely genetically related to the multiple strains of *Cronobacter* found in the environmental samples obtained from Abbott Nutrition’s Sturgis, MI facility. Furthermore, WGS showed that bacteria from available patient samples were not closely related to one another. During the course of this investigation, FDA collected additional product samples from the facility and FDA analysis is ongoing.

FDA received one complaint of an infant with a *Salmonella* infection who consumed infant formula from the Sturgis facility. However, there is not enough information available to definitively link this illness to the recalled infant formula. CDC confirmed that this single *Salmonella* illness is not linked to an outbreak. CDC is working with state and local partners to monitor for *Salmonella* illnesses linked to infant formula.





About *Cronobacter*

Cronobacter sakazakii is a bacteria found naturally in the environment and can live in very dry places. The bacteria can live in dry foods, such as powdered infant formula, powdered milk, herbal teas, and starches. *Cronobacter* infection is not reportable in most states, meaning doctors are not required to report cases to their health department. *Cronobacter* illnesses are rare, but when infections happen, they can be deadly for infants. CDC typically receives reports of 2 to 4 infections in infants per year, but the total number of cases that occur in the United States each year is not known.

How *Cronobacter* Bacteria Can Spread

- At a production factory, *Cronobacter* bacteria could get into formula powder if contaminated raw materials are used to make the formula or if the formula powder touches a contaminated surface in the manufacturing environment.
- Powdered infant formula could also become contaminated at home or elsewhere after the container is opened. For example, *Cronobacter* bacteria could get into the formula if formula lids or scoops are placed on contaminated surfaces and later touch the formula or if the formula is mixed with contaminated water or in a contaminated bottle. See more information on how to [safely prepare and store powdered infant formula](#).

See Also

- [FDA Investigation of *Cronobacter* Infections: Powdered Infant Formula \(February 2022\) | FDA](#) 
- [Abbott Recall Notice: US/Puerto Rico](#) 
- [Investigación de la FDA sobre quejas por Cronobacter y Salmonella: Fórmula infantil en polvo \(febrero de 2022\)](#) 
- [Cronobacter Infection and Infants](#)
- [La infección por Cronobacter y los bebés](#)
- [CDC Foodborne Disease Outbreaks Infographic](#)  [PDF – 1 page]