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WHAT TO KNOW ABOUT THE POWDERED INFANT FORMULA RECALL

If you use powdered infant formula, be aware certain Similac, Alimentum and EleCare products have been recalled and should not be used.

The U.S. Food and Drug Administration (FDA) is investigating consumer complaints of bacterial infections in four infants who consumed powdered infant formula produced in Abbott Nutrition's facility in Sturgis, Michigan. All four infants were hospitalized, and the bacterial infection may have contributed to the death of two patients.

The FDA has published a [full list of recalled brands](#). Recalled products should no longer be available for sale; however, check the packaging if you have them in your home to determine if they are included in the recall.

The FDA also provides additional information for parents and caregivers of infants receiving medical specialty infant formula and individuals using certain medical foods.

Because infant formula is the only source of nutrition for many newborns and infants, the FDA understands and shares the concerns parents and caregivers may have.

As the FDA continues its investigation, you can visit its [website](#) for additional information. This article includes information and resources from the consumer website.

Which powdered infant formula products have been recalled?

Abbott Nutrition has recalled certain powdered infant formula products produced at its Sturgis, Michigan, facility. Products from that facility can be found across the United States, and some were exported to other countries. Here's how you can tell if you have any of those products.

The FDA recommends consumers look at the lot code, a multidigit number on the bottom of a container of Similac, Alimentum and EleCare powdered infant formula. Do not use the product if all of the following are present:

- The first two digits of the code are 22-37
- The container code contains K8, SH or Z2
- The expiration date is 4-1-2022 or later

In addition to the products described above, Abbott Nutrition has recalled Similac PM 60/40 with a lot code of 27032K80 (can)/27032K800 (case).

You can also enter your product lot code on the [company's website](#) to check if it is part of the recall.



Powdered Abbott products that don't have the code and expiration noted above are not included in the recall. Liquid formula products are not subject to recall. At this time, Similac PM 60/40 with lot code 27032K80 (can)/27032K800 (case) is the only type, and lots of this specialty formula are recalled.

What infections have been reported, and what symptoms should I look for?

All four cases involve [Cronobacter sakazakii](#) infection. Cronobacter bacteria can cause severe, life-threatening infections (sepsis) or meningitis (inflammation of the membranes that protect the brain and spine). Cronobacter infections are rare but are an especially high risk for newborns.

Symptoms of Cronobacter infection include poor feeding, irritability, temperature changes, jaundice, grunting breaths or abnormal body movements.

If your infant is experiencing symptoms related to Cronobacter infection, contact your child's health care provider to report their symptoms and receive immediate care.

When and where were the illnesses?

Illnesses occurred in Minnesota, Ohio and Texas between Sept. 6, 2021, and Jan. 4, 2022.

I'm having a hard time finding formula. What is the FDA doing to help?

The FDA is aware the recall has created new concerns about the availability of certain types of infant formula, particularly given the overall strains on supply chains experienced during the COVID-19 pandemic.

The agency continues to take several significant actions to help increase the current supply of infant formula in the United States. In fact, other infant formula manufacturers are meeting or exceeding capacity levels to meet current demand.

The FDA is working with Abbott Nutrition to better assess the recall impacts and understand the production capacity at other Abbott facilities that produce some of the impacted brands. The agency is also working with Abbott on the safe resumption of production at the Sturgis, Michigan, facility. As Abbott Nutrition initiated its recall, the FDA intensified outreach to other infant

formula manufacturers to inquire about their capacity and potential impacts. The FDA will continue the discussion with Abbott Nutrition and other infant formula manufacturers and consider all tools available to support the supply of infant formula products.

Are homemade formulas an alternative?

No. The FDA [advises parents and caregivers not to make or feed homemade formula to infants](#). Homemade infant formula recipes have not been evaluated by the FDA and may lack nutrients vital to an infant's growth.

What should I know about medical specialty infant formula and certain medical foods?

The Abbott Nutrition facility that produces recalled infant formulas also manufactures metabolic and other medical specialty infant formulas for infants with inborn errors of metabolism and other medical needs as well as medical foods. Except for one lot of Abbott Similac PM 60/40, these products have not been recalled because the FDA has determined that the risk of not having these specialty products available would significantly worsen underlying medical conditions. For many of these patients, the risk of life-threatening adverse effects from restricted access to these critical products is likely greater than the risk of consuming products produced at the facility.

The FDA wants to be sure that parents and caregivers who use these specialty products know that there may be some risk of Cronobacter contamination. If possible, parents and caregivers should work with their medical provider to consider whether comparable products may be appropriate. If comparable alternative products are not available or appropriate, parents and caregivers should follow [updated advice from the Centers for Disease Control and Prevention \(CDC\) on how to reduce the risk of Cronobacter contamination](#) during formula preparation, whether that contamination comes from the product itself or other contamination sources in the home.

Examples of medical and specialty products include Glutarex-1, Glutarex-2, Cyclinex-1, Cyclinex-2, Hominex-1, Hominex-2, I-Valex-1, I-Valex-2, Ketonex-1, Ketonex-2, Phenex-1, Phenex-2, Phenex-2 Vanilla, Pro-Phree,

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Propimex-1, Propimex-2, ProViMin, Calcilo XD, Tyrex-1, Tyrex-2, and Similac PM 60/40.

It is important to note that these specialty infant formulas and medical foods are not sold in traditional retail stores. These products often require a prescription and are sold through specialty pharmacies and other specialty distribution channels such as medical product suppliers.

Parents and caregivers of infants and children using these products should contact their child's health care provider if they have questions about the use of these products.

Additionally, the FDA has informed Abbott Nutrition that the agency has no objection to the company immediately releasing the product to individuals needing urgent, life-sustaining supplies of the specialty and metabolic formulas listed in the link below on a case-by-case basis. Abbott has confirmed with the FDA that the company will consider releasing these products on a case-by-case basis, depending on product availability and the severity of the individual's need. Patients and caregivers seeking access to these products should contact Abbott directly to request that a product be made available by calling 1-800-881-0876. Please see the [FDA Investigation of Cronobacter Infections: Powdered Infant Formula \(February 2022\)](#).

What else should I know?

Parents and caregivers should never dilute infant formula. Consumers also should avoid buying formula online that comes from outside the United States, as it has the potential to be counterfeit.

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

If you get infant formula through [WIC](#), 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.

Additional resources

- [Infant Formula: Safety Do's and Don'ts](#), FDA Consumer Update
- [FDA Investigation of Cronobacter Infections: Powdered Infant Formula \(February 2022\)](#), FDA webpage
- [Cronobacter Infection and Infants](#), CDC webpage

Source: FDA