

Handling Infant Formula Safely: What You Need to Know



Experts strongly recommend breastfeeding for infants. If that isn't possible, babies will need infant formula. It's extremely important that germs do not get into infant formula because babies do not have fully developed immune systems which puts them at higher risk for infections.

FDA Oversees Infant Formula Manufacturers

All manufacturers of infant formula sold in the United States (U.S.) must register with the U.S. Food and Drug Administration (FDA). Their products must meet the FDA's nutritional quality and safety standards in order to be sold in the U.S.

Nutritional Requirements

Based on the nutritional needs of infants, FDA requires minimum amounts for 30 nutrients. FDA sets maximum amounts for 10 of those nutrients that can be harmful to an infant's growth and development in high amounts, such as Vitamins A and D.

Some infant formulas are made and labeled for infants that have certain medical conditions, such as metabolism issues, low birth weight, or an unusual medical or dietary problem. These specialized formulas do not have to meet these requirements.

Infant Formula Safety

Infant formula manufacturers must follow FDA's Good Manufacturing Practices and other regulations to protect against harmful bacteria, viruses, chemicals, and other risks. If a company wants to sell a new formula or make changes to one that they already sell, they must submit the details to FDA.

The Dangers of *Cronobacter*

Cronobacter is a germ found everywhere around us. It can also live in water and in dry foods, such as:

- Powdered infant formula
- Powdered milk
- Herbal teas
- Starches, like flour or cornstarch

Cronobacter can cause rare but possibly deadly infections in infants, such as *sepsis* (a condition caused by a serious infection in the body) or *meningitis* (swelling of the protective membranes covering the brain and spinal cord, which can cause death or permanent disabilities).

Types of Infant Formula



Powdered

Must be mixed with water according to instructions before feeding



Liquid Concentrate

Must be mixed with an equal amount of water



Ready-to-Feed

Do not add water

Powdered Infant Formula May Get Contaminated with Germs:

In the home: *Cronobacter* can get into powdered infant formula after the container is opened. *Cronobacter* can be found in other foods and live on surfaces like kitchen counters or sinks, and in water. Taking care to avoid cross contamination of bottles, nipples, and utensils during preparation is very important.

In a processing plant: If the manufacturer unintentionally uses ingredients that contain *Cronobacter* to make the formula, or if the formula powder touches a surface that has *Cronobacter*. Infant formula manufacturers must test every batch of infant formula for *Cronobacter* before release for sale.

Preparing and Handling Formula Safely

Preparing Formula—Always wash your hands with soap and water for at least 20 seconds before making formula for your baby.

Cleaning Bottles and Feeding Parts (including breastfeeding pump parts)—Before first use, boil bottles, nipples, caps, rings, and valves for 5 minutes. Afterward, following each use wash them in the dishwasher, if one is available, using hot water and a heated drying cycle (or sanitizing setting). If cleaning the feeding items by hand, wash them in soapy water in a basin used only for formula feeding parts, rinse, and air dry on a paper towel or clean dish towel.

Powdered Infant Formula Containers and Scoops—Powdered infant formula is unlikely to become contaminated if it stays dry. If you want to clean an unopened powdered infant formula container, use a disinfectant wipe or paper towel sprayed with disinfectant to clean the outside of the container and lid before it is opened for the first time. Don't submerge the container or put it under running water. Don't open the container until all surfaces are completely dry. Never clean the inside of the container. If the scoop falls into a sink, on a kitchen counter, or the floor, or is soiled some other way, clean it as you would the baby's bottle. Let it air dry completely before using it.

Water—Always use water from a safe source to mix your infant formula. If you are not sure your tap water, whether from a public drinking water supply or private well, is safe to use for preparing infant formula, contact your local health department.

Bottled Water—Bottled water isn't sterile (free of germs) unless the label says it is. If it is labeled as sterile and is specifically marketed for infants, it must meet FDA requirements for sterility in marketed products. If you use ordinary bottled water to make formula, handle it the same way as safe tap water.

Water Emergencies—If your water supply is cut off by a watermain break or polluted by a hurricane or flood, use bottled water to make formula instead of tap water. If you must use tap water that may be polluted, boil it for one minute (3 minutes at elevations above 6500 feet) to disinfect it and then let it cool in the pot for five minutes to room temperature before adding it to the bottle.

Mixing—Follow the instructions on the product's label. Use the exact amount of water that the label says. Formula with too little water can cause dehydration (harmful loss of body fluid). Formula with too much water will not provide enough nutrition and, if fed to your baby for a long time, may result in slower growth. After adding the water, add the exact amount of formula called for on the label and shake to mix.



Babies at higher risk of getting *Cronobacter* are those:

- Two months and younger, **or**
- With weakened immune systems, **or**
- Born prematurely, **or**
- Who are ill or receiving medical treatment, such as chemotherapy for cancer.

If your baby is at higher risk for *Cronobacter* infections, take these extra steps:

- Consider using liquid ready-to-feed formula, as this is the safest option for formula-fed infants.
- If you can't obtain liquid ready-to-feed formula, consider using a liquid concentrate.
 - If using **liquid concentrate formula** and you are uncertain about the safety of your water source, boil water, let it cool in the pot for five minutes before putting it in the bottle. Add the liquid concentrate, shake to mix and allow the formula to cool to room temperature before feeding your infant.
- If liquid ready-to-feed and liquid concentrate formulas are not available, use powdered infant formula.
 - If using **powdered infant formula**, boil water, let it cool in the pot for 5 minutes, then pour the amount stated on the label into the bottle. Shake to mix and allow the formula to cool to room temperature before feeding your infant.
- Certain metabolic and specialty products include statements on their packaging warning consumers against heating above 100°F, as this could result in a loss of vitamins and nutrients. Therefore, carefully follow the label's instructions included on the packaging for specialty metabolic formulas.
- When cleaning the bottles and other feeding items, such as nipples, caps, rings, and valves, etc.
 - Wash them in a dishwasher using hot water and a heated drying cycle (or sanitizing setting), or
 - Wash them with soapy water in a basin used only for formula feeding parts, rinse, and air dry on a paper towel or clean dish towel.
- Sanitize the feeding items before first use and once daily by:
 - Boiling the loose feeding items in a pot of water for 5 minutes and remove them with clean tongs, or
 - Running them through a dishwasher, if one is available, with hot water and a heated drying cycle (sanitizing cycle), or
 - Steaming in a microwave or a steaming appliance according to the maker's instructions.



Both liquid ready-to-feed formula and liquid concentrate are made to be sterile (without germs) and are the safer options than powdered infant formula for higher risk infants not receiving breast milk.

Storing—Use prepared infant formula within 2 hours. If it is not used immediately, store the bottle in the refrigerator and use it within 24 hours.

Formula Warming—Formula does not need to be warmed. If you prefer it warm, the best way is to place the bottle in a pot of water and heat it on the stove until warm (body temperature). Never use microwave ovens for heating infant formulas because microwaving can allow the bottle to remain cool while hot spots develop in the formula that can burn the baby’s mouth. Before feeding your baby, test the formula’s temperature by putting a few drops on your wrist. It should feel warm, not hot.



After Feeding—Throw away any leftover formula because it now contains the baby’s saliva, which can cause bacteria to grow.

Storing Opened Powdered Infant Formula— The package or container of infant formula must have information on how to store it before and after it is opened. It also must have information on when to throw away prepared formula. Follow the manufacturer’s directions on the label. Once a container of powdered formula is opened, the formula typically needs to be used within one month. Write the date that you opened the formula on the lid. With the lid tight, store in a cool dry place, not in the refrigerator.

“Use By” Date—Don’t use a package or container of infant formula after this date. The manufacturer guarantees the nutrient content and quality of the formula only up to the “use by” date. FDA rules require a “use by” date on every container of infant formula.

Freezing—Freezing is not recommended. It may cause the different parts of the formula to come apart and lower the quality.

Homemade Formula—The FDA advises caretakers to not make or feed their infant homemade infant formula. Homemade infant formula recipes have not been evaluated by the FDA and may lack nutrients vital to an infant’s growth.

Counterfeit (Fake) Formula—Formula products are sometimes taken from normal distribution channels and relabeled to fake the quality or identity of the product. Examples include changing the “use by” date or relabeling the product to hide the true content. This is illegal and can lead to serious health conditions for infants. A wide selection of infant formula is available on the market. If parents have questions about selecting a formula for their infant, they should ask their infant’s healthcare provider.



Formula Changes—Check for any changes in formula color, smell, or taste. If you buy formula by the case, make sure the lot numbers and “use by” dates on the containers and boxes match. Also, check containers for damage, and call the manufacturer’s toll-free number with any concerns or questions. You can also contact FDA at 1-888-SAFEFOOD (1-888-723-3366).