



Freeze-dried breast milk: an evidence-based review for providers

Authors: Berkley Luck, PhD; Lauren Figard, PhD

What is freeze-dried breast milk?

Lyophilization, or freeze-drying, works by a simple principle called sublimation, in which water is removed from frozen breast milk by transitioning directly from a solid (ice) to a gas (water vapor). Frozen breast milk is loaded into a specialized chamber which is brought to a very low temperature (-30°F) and a deep vacuum (<500 mTorr). A low heat is used (<75°F) to gradually remove water from breast milk while it is still frozen. This gentle process preserves the structure of molecules and results in retention of the nutritional composition and quality of the milk. The result after freeze-drying is a shelf-stable breast milk powder, which has all of the components of the breast milk without the water. This process is very different than standard "dehydrating" techniques, which use high temperatures to remove water, thereby damaging the nutritional properties of the milk. No chemicals or additives are used in the freeze-drying process.

In what situations may freeze-drying breast milk be useful?

The Academy of Breastfeeding Medicine states that frozen milk can be stored safely for 3 months, but notes that fat, protein, and calories decrease in human milk when frozen for 90 days compared to fresh human milk (1,2). Frozen human milk also has a significant increase in acidity by 3 months due to enzymatic processes that persist during freezer storage, which may result in changes to milk quality (1). The concentration and activity of important bioactive factors such as lactoferrin in human milk have also been shown to be significantly lower in milk frozen for 3 months (3,4). The CDC recommends storage time of 6-12 months for breast milk stored in a typical home freezer which was expressed under very clean conditions (5). This guideline was established to ensure the safety of the milk (i.e. from bacterial contamination), however

does not address the decline in quality of the milk. For this reason, many milk donation organizations suggest use within 3 months due to the degradation of nutritional and immunologic properties that occurs in human milk stored in the freezer (6).

Freeze-drying breast milk extends shelf life, lengthening the useful life of the milk past the original date of expiration if stored in the freezer (7). Freeze-drying is not suggested as an exclusive method of feeding, but rather as a supplement to already established feeding methods. Mothers who are pumping to maintain supply or when they return to work often accumulate expressed breast milk in the freezer. Freeze-drying excess stored milk can therefore promote continued provision of breast milk to infants even after weaning. For example, freeze-dried breast milk powder can be added to solid foods, purees, yogurts, etc. for feeding to older babies and toddlers.

Freeze-drying breast milk is also particularly useful in situations when continued frozen storage becomes impractical or impossible. This may be due to lack of freezer space, travel, relocation, and as a safeguard for power outages (e.g. due to natural disasters). Given the amount of effort and time that a mother invests in storing milk for later use, many wish to utilize the milk that they worked so hard to save.

1. Eglash, A., Simon, L., & The Academy of Breastfeeding Medicine. ABM clinical protocol #8: human milk storage information for home use for full-term infants, revised 2017. *Breastfeed Med* 12, (2017).
2. García-Lara NR et al. Effect of freezing time on macronutrients and energy content of breastmilk. *Breastfeeding Medicine*. 2012;7(4):295-301.
3. Raoof NA, Adamkin DH, Radmacher PG, et al. Comparison of lactoferrin activity in fresh and stored human milk. *J Perinatol* 2016;36:207–209.
4. Rollo DE, Radmacher PG, Turcu RM, et al. Stability of lactoferrin in stored human milk. *J Perinatol* 2014;34: 284–286.
5. Center for Disease Control and Prevention: Proper Storage and Preparation of Breast Milk (2022) Accessed at: https://www.cdc.gov/breastfeeding/recommendations/handling_breastmilk.htm
6. La Leche League. Milk Donation and Sharing (2020) Accessed at: <https://www.llli.org/breastfeeding-info/milk-donation/>
7. Shelf-life testing of freeze-dried human breast milk commissioned on behalf of Milkify performed by Meter Group Inc., USA (2020)

How does Milkify ensure the safety of their process?

Milkify does not pasteurize the milk prior to processing. We operate in a “closed-loop system” with customers receiving back their own breast milk after freeze-drying; we do not buy, sell, or distribute breast milk. We assume full responsibility for ensuring the safety of our process and compliance with regulatory requirements. We advise consumers against using freeze-drying services that operate outside of a dedicated facility (e.g. their home or a shared commercial kitchen space), services offering batch processing in uncontrolled environments, and online instructions for “do-it-yourself” freeze-drying of breast milk. Feeding breast milk powder that was freeze-dried under these circumstances should be avoided due to risks arising from a lack of sanitization, quality control, and oversight.

Facility

Freeze-drying breast milk should be performed in a safe and controlled environment. Milkify is fully cGMP-compliant (Good Manufacturing Practice as defined by the FDA Food Code, 21CFR110) and adheres to all applicable guidelines set forth by the Centers for Disease Control and Prevention (CDC) and the Human Milk Banking Association of North America (HMBANA) for the safe handling of breast milk. We have several safety and quality assurance measures in place, including:

- Ensuring cold-chain transport by using pharmaceutical-grade insulated coolers to ship milk to our facility
- Quality control checkpoints including time/temperature controls at each step of the process
- Strict personnel policies relating to safe handling
- Consistent adherence to sanitization procedures and protocols
- Regular environmental testing of our facility and equipment to ensure that sanitization practices are effective at preventing contamination during processing. We routinely test for the following pathogens:
 - Total aerobic plate counts
 - Coliform/ E. Coli
 - Yeast/mold
 - Listeria monocytogenes

- Bacillus cereus
- Salmonella
- Staphylococcus aureus

Breast milk is stored frozen at all times while in the Milkify facility. Commercial deep freezers are remotely monitored for temperature and power outages. Our facility is equipped with back-up generators to power our freezers in case of outages.

Process

Our process is designed with safety in mind from beginning to end. Our process includes the following safeguards:

- **Closed loop system**

A “closed-loop” system with customers receiving back their own breast milk after freeze-drying (i.e. no donors and no buying or selling of breast milk). Each bag is labeled with the customer’s name and a tracking number. The bags are individually weighed and logged, along with any other information written on the bags (expression date, dietary notes, vaccine/medication information). The milk is stored in a labeled, enclosed bin in our deep freezers until freeze-drying.

- **SafeDry™ contact-free processing**

Mikify’s proprietary SafeDry™ technology ensures that the milk is processed in the safest possible way. We use specially engineered lyophilization pouches that vent during freeze-drying to allow water vapor to escape, while protecting each individual bag of milk from contamination or contact with any equipment. By processing each bag of milk individually, we eliminate the need to pool milk onto trays (which introduces contamination risks). The powder from each bag is then packaged under a sterile laminar flow hood without contact from any additional utensil (no scoops, etc.).

- **100% chemical-free**

Absolutely no chemicals or additives are used in the freeze-drying process. The only thing removed from the milk is the water.

- **Gentle heat**

From start to finish, the milk remains frozen while in our facility – there is absolutely no thawing. The very low heat used in the process (about 75°F or room temperature) is unlikely to cause nutrient degradation or protein denaturation.

- **Quality control testing**

As part of our final quality control check, we measure the water activity (“dryness”) of each batch of milk that we process. This ensures that the milk is dry enough when packaged to prevent microbial growth and remain shelf-stable for 3 years.

- **High barrier packaging**

The freeze-dried breast milk powder is packaged in food-safe, high-barrier packaging. Each pouch of powder has a custom label which indicates how much water to add back to rehydrate the milk to its original consistency. We are in compliance with the packaging regulations for infant food set forth by the U.S. Food and Drug Administration (FDA).

What effect does freeze-drying have on the nutritional properties of breast milk?

Published research studies support the nutritional quality and safety of freeze-dried breast milk. Freeze-drying is an effective way of preserving macronutrients, micronutrients, and other unique bioactive components of breast milk (see Table 1).

Table 1: Effect of lyophilization on breast milk properties: a summary of published research

Breast milk component	Biological significance	Effect of lyophilization	Refs
Nutrients			
Total fat content and fatty acid profiles	Major source of calories	No significant change	1, 2
Arachidonic acid (AA), docosahexaenoic acid (DHA), eicosapentaenoic acid (EPA)	Fatty acids important for immune function and neuronal development	No significant change	2
Protein	Source of amino acids, digestive and immune functions	No significant change	3
Bioactive components			
Human milk oligosaccharides (HMOs) and HMO profiles	Prebiotics, stimulate infant immune system, block pathogen binding/entry	No significant change	4
Vitamin C	Antioxidant	Mild reduction (~31%)	5
Catalase	Antioxidant	No significant change	5
Leptin, Adiponectin	Hormones involved in appetite and metabolic regulation	No significant change	6
Hepatocyte Growth Factor	Growth factor involved in intestinal development	No significant change	6
Lipase	Enzyme involved in fat metabolism	No significant change	6
Glycoproteins	Involved in immune function; block pathogen binding/entry	No significant change	7
Antibodies: IgA, IgG and IgM	Involved in immune function, IgA blocks pathogen binding and entry	Slight reduction (25% IgA, and 20% IgG and IgM)	8
Lysozyme	Enzyme with bactericidal properties	No significant change	5

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Are there potential risks associated with using freeze-dried breast milk?

Microbial

No pasteurization is performed prior to freeze-drying, therefore safe pumping and storage practices are necessary to ensure the safety of the milk. Milkify provides detailed instructions on storage and use based on current CDC guidance. (see: <https://www.milkify.me/breast-milk-handling-safety> and <https://www.milkify.me/how-to-use>). Powdered breast milk should be stored and prepared properly in order to prevent contamination with *Cronobacter* and other bacteria that can cause serious illness if precautions are not taken. Milkify has strict cleaning and sanitization procedures performed daily and between all batches which are in compliance with the FDA Food Code (21CFR110.35). Regular environmental testing is also performed to ensure that sanitization procedures are effective at preventing the introduction of bacterial contaminants during processing.

Osmolarity

Powdered breast milk must be reconstituted correctly to ensure that osmolarity of the milk is not altered. The correct volume of water and detailed rehydration and use instructions are printed on each bag. There are no published contraindications for using freeze-dried breast milk in correctly reconstituted form for healthy infants, as a supplement in solid foods, or for continued provision of breast milk after weaning. Clinical trials have not been performed however, so freeze-dried breast milk is not recommended for premature or immune-compromised infants unless under supervision of a physician. Further research needs to be performed to assess the osmolar safety of using whole freeze-dried breast milk as a fortifier, however all human milk fortifiers currently in use in a hospital setting (and approved by the FDA) utilize lyophilization as part of their process to preserve the human milk used to make the fortifier.

Nutritional

All available studies have found that freeze-drying preserves many vital molecules present in breast milk (see Table 1). However, breast milk is comprised of thousands of

unique compounds, and detailed studies of molecular changes to each class of molecule have not yet been performed.

Is breast milk freeze-drying covered by insurance/HSAs/employer benefits?

Breast milk processing is not yet covered by most insurance plans, however many FSA/HSA providers will reimburse for the cost of the service. Moms traveling or moving for work are usually able to receive full or partial employer reimbursement for the cost of the service.

What regulatory requirements exist for freeze-drying services in the U.S.?

The FDA does not regulate breast milk freeze-drying services at the time of writing due to the nature of the “closed-loop” system, in which the service provider does not buy, sell, or distribute breast milk as a food or pharmaceutical product. The milk is returned in freeze-dried form to the mother that supplied it. However, Milkify is in full compliance with FDA Title 21 regulations relating to Good Manufacturing Practices for food manufacturing (21CFR110). Human milk fortifiers (which are already approved by the FDA for use in hospital settings) utilize lyophilization as part of their process to preserve the nutritional value of the milk. The FDA does regulate the types of packaging that can come into contact with food intended for infants, and Milkify’s packaging is fully compliant with these regulations.