Freeze-drying your breast milk: safety and nutrition considerations to share with your health provider

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Authors: Berkley Luck, PhD; Lauren Figard, PhD; Allyson Ward, MSN, NNP-BC

KEY POINTS

- **Freeze-drying is an effective way to preserve macronutrients, micronutrients, and other unique bioactive components in a mother's own milk.**
- **Milkify's process includes temperature controls and process controls designed to prevent harmful bacterial growth, the introduction of contamination from equipment, and cross-contamination between milk from different clients.**
- **Freeze-dried human milk is not suggested as an exclusive method of feeding, but rather as a supplement to already established feeding methods.**
- **Milkify is cGMP-certified for processing human milk (SGS #US23/00000165) and is an FDA- registered food facility (#16969346312).**

WHAT IS FREEZE-DRIED BREAST MILK?

Lyophilization, or freeze-drying, works by a simple principle called sublimation, in which water is removed from frozen human (breast) milk by transitioning directly from a solid (ice) to a gas (water vapor). Frozen milk is loaded into a specialized chamber which is brought to a deep vacuum (<100 mTorr) and very low temperature (-40°F) A low heat is used to gradually induce sublimation or the removal of water from the milk while it is still frozen. This preserves the structure of molecules and results in retention of the nutritional composition and quality of the milk. The temperature used is dependent on the service provider – Milkify uses a gentle heat (<98°F). The result after freeze-drying is a shelf-stable breast milk powder – these are the solid components of the milk without water. This process is very different than standard "dehydrating" techniques, which use high temperatures to remove water, which can damage the nutritional and bioactive properties of the milk. No chemicals or additives are used in the process.

IN WHAT SITUATIONS MAY FREEZE-DRIED BREAST MILK BE USEFUL?

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 (1). When packaged properly, freeze-dried breast milk has an extended shelf life, lengthening the useful life of the milk past the original date of expiration if stored in the freezer (2). Milkify originally developed the 3-year expiration benchmark for freeze-dried breast milk based on our proprietary critical control limits and extensive testing with a third-party lab (Addium, Inc.).

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. Breast milk stored in powdered form is convenient for caretakers and the extended shelf-life of the milk can also prove useful for feeding to older babies and toddlers. For example, freeze-dried breast milk powder can be added to solid foods, purees, yogurts, etc. Freeze-drying excess stored milk can therefore promote continued provision of breast milk to infants even after weaning.

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 extend the amount of time that they are able utilize the milk.

1. 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
2. Shelf-life testing of freeze-dried human breast milk commissioned on behalf of Milkify performed by Meter Group Inc., USA (2021)

SAFETY OF FREEZE-DRIED BREAST MILK

The safety of freeze-dried breast milk is entirely dependent on the process used. Process controls are needed to prevent both the introduction of contamination from equipment and cross-contamination between milk from different clients. Due to the lack of current U.S. regulation for this growing industry, there is a concern that many service providers are operating with unsafe practices and undefined quality control standards (i.e. home-operators). Parents and care teams should perform careful diligence before choosing a company to freeze-dry breast milk. **Milkify is (at the time of writing) the only U.S.-based company that is cGMP-certified and registered with the FDA as a food processor.**

There are several ways to freeze-dry breast milk, however every piece of equipment (blenders, powder dispensers) or utensil (scoops, bowls, spatulas, trays) that touches the milk during processing could introduce contamination. Types of improper handling before freeze-drying could include thawing the milk, handling without gloves, using a blender to mix the milk into a slushy, or letting the milk contact any utensils or equipment in its frozen state. Breast milk should never be thawed prior to freeze-drying, as unsafe temperatures could allow for microbial growth. After freeze-drying, the breast milk powder has to be packaged - improper handling during this step can also result in cross-contamination if sterile techniques are not used. Powder dispensers are used by large scale food-processers to evenly distribute equal volumes of powder quickly into many bags. Powder dispensers are notoriously hard to clean, and should not under any circumstance be used in a breast milk freeze-drying operation.

Consumers are advised against using freeze-drying services that operate outside of a dedicated facility (e.g. their home, shared commercial kitchen space, or third-party processing facilities), services offering batch processing (where milk is pooled on open trays for processing), 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.

Powdered breast milk must also be reconstituted correctly to ensure the correct nutrient/water balance of the milk. The service provider must provide data-backed rehydration ratios for proper at home usage of the freeze-dried milk.

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 physician supervision is recommended if used for feeding premature or immune- compromised infants.

ABOUT MILKIFY

CERTIFICATIONS

Milkify is the only FDA-registered and cGMP-certified breast milk freeze-drying service in the U.S. Milkify's facility is inspected yearly in-person by a trained GMP compliance officer (SGS), who issued the cGMP certification (current Good Manufacturing Practices) for food, as defined by the FDA in 21 CFR 117, subpart B. GMP standards address design, construction, and maintenance of the facility and equipment, facility sanitation and sanitary operations, as well as production and process control, and personnel hygiene and training. Milkify is also registered with the FDA as a human food processor (#16969346312).

FACILITY AND EQUIPMENT

The Milkify processing facility is located at 2501 Central Parkway B-18, Houston, Texas 77092. All operations are performed in-house and we do not outsource any operations to third-party processors. The Milkify facility houses laboratory-grade clean room equipment (ISO5 laminar flow hoods) for all processing operations and a full suite of quality control and nutritional testing equipment. The professional freeze-drying systems at the Milkify facility allow for precision control of processing parameters (this is not possible with table-top freeze-drying units).

Breast milk is stored frozen at all times while in the Milkify facility. Commercial deep freezers are remotely monitored for temperature and power outages and the facility is equipped with back-up generators to power the freezers in case of outages. Regular environmental testing of the facility and equipment ensure that sanitization practices are effective at preventing contamination during processing, and routine tests are performed for all major food-borne pathogens in addition to *Cronobacter sakazakii.*

PROCESS AND TEAM

Milkify operates in a “closed-loop system” with clients receiving back their own breast milk after freeze-drying - Milkify does function as a donor milk bank and does not buy, sell, or distribute breast milk. The process used at Milkify is designed to prevent the risks of contamination at all points in the process, and is therefore different from traditional freeze-drying techniques. Here’s how:

- **Patented Contact-Free Process**

  Milkify is the only company to have a completely contact-free process from start to finish (absolutely no contact with equipment or utensils at any point in the process). Milkify does not pool milk on open trays for processing. Each bag of frozen milk provided to Milkify is processed individually inside a specially designed freeze-drying pouch which allows water vapor to escape while protecting the milk from potential contamination via equipment. This also allows for the milk remains labeled with the client's name and tracking numbers even while in the freeze-dryer. The pouches that protect the breast milk during processing and packaging at Milkify are specially manufactured and the process has not been licensed out to any other companies in the U.S.

- **Individual bag tracking and processing**

  Every bag of breast milk is tracked from start to finish using a unique bag ID. Each bag is individually weighed - this information is logged, along with any other information written on the bags (expression date, dietary notes, vaccine/medication information). This information is transferred to the final pouch of powder, enabling the retention of important information about individual bags of milk.

- **No thawing**

  From start to finish, the milk remains frozen while in the Milkify facility. Transfer from the lactation bag to the customized freeze-drying pouch is performed while the milk is frozen, eliminating the need for thawing.

- **Shelf life testing**

  The expiration date of freeze-dried breast milk processed and packaged by Milkify is 3 years from the date of freeze-drying. Milkify's shelf-life testing was performed by Addium (formerly Meter Group). Milkify uses laboratory grade testing equipment (the Aqualab3 water activity meter) to test the moisture content of every batch of freeze-dried breast milk before packaging. This ensures that the milk is dry enough to prevent microbial growth and remain shelf-stable with no refrigeration for 3 years. No oxygen/moisture absorbers are used in packaging by Milkify.

- **Sterile handling**

  Our highly-trained staff uses sterile techniques in ISO5 cleanroom workstations to ensure that no contamination is introduced during the pre-freeze drying or the packaging steps of our process. We pack every bag individually (no powder dispensers). Milkify's processing team is supervised by trained research laboratory personnel. Only these highly trained personnel with active food safety certifications process the milk and follow strict protocols regulating personnel hygiene, personal protective gear, and equipment sanitization to ensure that the milk is handled safely from start to finish.

NUTRITION OF FREEZE-DRIED BREAST MILK

All available studies have found that freeze-drying preserves vital macronutrients present in breast milk. 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. Both our own in-house testing and 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 Tables 1 and 2).

Table 1: Macronutrient composition of rehydrated breast milk powder samples

Nutrient	Rehydrated milk Milkify (g/100mL) n=150**	Reference values[1] – Term milk (g/100mL)
Fat	3.9 ± 0.8	3.5
Carbohydrates	7.8 ± 0.7	8.2
True Protein	0.9 ± 0.3	0.9
	Rehydrated milk Milkify (kcal/100mL) n=150**	**Reference values [1] – Term milk (kcal/100mL)**
Calories	72.2 ± 6.4	67.5

*Average +/- SD.
**Accurate rehydration to 87% water is vital to ensuring these concentrations. Milkify data via Miris Human Milk Analyzer.
(1) American Academy of Pediatrics Committee on Nutrition. Appendix A. In: Kleinman RE, Greer FR, eds. Pediatric Nutrition. 8th ed. Itasca, IL: American Academy of Pediatrics; 2019:1505-1508.

Table 2: 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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SHELF LIFE OF FREEZE-DRIED BREAST MILK

The shelf life of freeze-dried breast milk is the time that it is expected to remain free from microbial growth. Since breast milk is not sterile (and is not pasteurized), if there is too much moisture left in breast milk powder prior to packaging, microbes will be able to grow. Excess moisture can actually cause the freeze-dried breast milk to spoil within just a few weeks or months. The use of oxygen/moisture absorber packets is not a substitute for an actual shelf-life analysis, which is dependent on the type of packaging used and therefore varies by service provider.

There is no industry standard for the shelf life of freeze-dried breast milk because it is completely dependent on how it is processed and how it is packaged after freeze-drying, which varies by service provider. The shelf life of freeze-dried breast milk processed and packaged by Milkify is 3 years from the date of freeze-drying. Milkify's shelf-life testing was performed by Addium (formerly Meter Group). Milkify uses laboratory grade testing equipment (the Aqualab3 water activity meter) to test every batch of freeze-dried breast milk before packaging, to ensure that the 3 year shelf-life estimate we provide is accurate.

IS THIS COVERED BY INSURANCE/HSA/EMPLOYEE BENEFIT?

Breast milk processing is covered under FSA/HSA plans. Insurance companies may reimburse for the service cost if it is considered medically-necessary. Parents traveling or moving for work are usually able to receive full or partial employer reimbursement for the cost of the service.

CAN FREEZE-DRIED BREAST MILK BE USED FOR CALORIC FORTIFICATION?

For preterm or low birthweight infants requiring nutritional fortification, freeze-dried human milk may present an alternative to bovine-based fortifiers. In this scenario, a mother’s own freeze-dried breast milk may be added to her liquid breast milk to increase the caloric content of feedings in a targeted manner. This novel method of supplementation offers the opportunity to provide an increased caloric and protein density sourced from the mother's own milk, without the use of bovine or plant-based derivatives. **Caloric supplementation with freeze-dried breast milk has not been subject to clinical trials, so determination of suitability should be made by a medical provider prior to use.**

Milkify offers a medical nutritional analysis service, using the FDA-approved Miris Human Milk Analyzer. This allows for precise, quantitative determination of macronutrient concentrations in both “baseline” (frozen) breast milk and freeze-dried breast milk powder. This quantification can

serve as the basis of a “recipe” formulation targeting an individual infant's nutritional goals. The recipe for caloric supplementation can be adjusted based on real-time lab and growth parameters.

This scenario requires breast milk to be sent-out for freeze-drying, which must be in excess of the amount of milk that is required to meet the infant's feeding volume goals. A very small amount, typically less than 3 mL (or 1 gram of powder), is needed for nutritional analysis from each bag or sample of frozen breast milk. Caloric supplementation using freeze-dried breast milk can occur with feeding volumes as small as one ounce.

IS THIS FDA-APPROVED?

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 certified by a third-party agency to be in full compliance with FDA Title 21 regulations relating to current Good Manufacturing Practices for food (21CFR110) and the Milkify facility is registered as a food facility with the FDA (registration number 16969346312).