

The safety and nutrition of freeze-dried breast milk: an evidence-based review for providers

Updated May 2023

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

KEY POINTS

- Freeze-drying is an effective way of preserving macronutrients, micronutrients, and other unique bioactive components of breast milk
- The safety of freeze-dried breast milk is entirely dependent on the process used, and must include temperature controls and process controls designed to prevent both the introduction of contamination from equipment and cross-contamination between milk from different clients
- Freeze-dried breast milk is not suggested as an exclusive method of feeding, but rather as a supplement to already established feeding methods.

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 to gradually remove water from breast milk while it is still frozen (the temperature used is dependent on the service provider). 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-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).

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 to 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)
3. 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).
4. García-Lara NR et al. Effect of freezing time on macronutrients and energy content of breastmilk. *Breastfeeding Medicine*. 2012;7(4):295-301.
5. Raouf NA, Adamkin DH, Radmacher PG, et al. Comparison of lactoferrin activity in fresh and stored human milk. *J Perinatol* 2016;36:207–209.
6. Rollo DE, Radmacher PG, Turcu RM, et al. Stability of lactoferrin in stored human milk. *J Perinatol* 2014;34: 284–286
7. La Leche League. Milk Donation and Sharing (2020) Accessed at: <https://www.llli.org/breastfeeding-info/milk-donation/>

SAFETY OF FREEZE-DRIED BREAST MILK

The safety of freeze-dried breast milk is entirely dependent on the process used, and must include temperature controls and process controls designed 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. Parents and care teams should perform careful diligence before choosing a company to freeze-dry breast milk.

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 water balance of the milk. As the water content of the milk can vary bag-to-bag, consumers are advised against using services which pool the milk for processing, and/or do not provide data-backed rehydration ratios.

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

Facility design

The Milkify facility is the only cGMP-certified processing facility in the U.S. built for exclusively freeze-drying breast milk. Milkify is located at 2501 Central Parkway B-18, Houston, Texas 77092, and all operations are performed in-house. The Milkify facility includes laboratory-grade equipment (ISO5 cleanroom workstations) for all processing operations and a full suite of quality control testing equipment. Milkify's process controls and facility have been inspected and audited 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. These 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. 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. Milkify also 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 and is also regularly inspected by Food Safety International to ensure compliance with state regulations regarding safe food handling practices. 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

Milkify operates in a “closed-loop system” with customers 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.

- **Specialized freeze-drying pouches**

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). Each bag of frozen milk provided to Milkify is processed individually inside a specially-designed freeze-drying pouch (SafeDry™). Our patent-pending freeze-drying pouches allow water vapor to escape while protecting the milk from contamination. Milkify does not pool milk on trays for processing and each frozen lactation bag sent to Milkify becomes its own pouch of powder. This means that the milk remains labeled with the client's name and tracking numbers even while in the freeze-dryer. The SafeDry pouches that protect the breast milk during processing and packaging at Milkify are specially manufactured and the patent-pending process has not been licensed out to any other companies.

- **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. The very low heat used in the freeze-drying process (less than body temperature) is unlikely to cause nutrient degradation or protein denaturation.

- **Shelf life testing**

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 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 and each lactation bag provided to Milkify becomes its own pouch of powder.

- **Custom and accurate rehydration ratio is printed on every individual bag**

The freeze-dried breast milk powder is packaged in food-safe, high-barrier packaging. Each pouch of powder has a custom label that indicates how much water to add back to rehydrate the milk to its original consistency. This water ratio is calculated using the original frozen weight of each bag, and the resulting moisture content of the freeze-dried powder.

- **Sterile handling**

Trained technicians use 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, and every bag is packaged individually (no powder dispensers). The Milkify processing team has over 40 combined years of sterile handling expertise and 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 your milk is handled safely from start to finish.

NUTRITION OF FREEZE DRIED BREAST MILK

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. 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	Measured value (g/100mL)	Reference value (1) (g/100mL)**
Fat	3.2 +/- 0.9	3.2 +/- 1
Carbohydrates	7.6 +/- 0.6	7.8 +/- 0.9
Crude protein	1.0 +/- 0.3	1.2 +/- .5
	Measured value (kCal/100mL)	Reference value (kCal/100mL)
Calories	63.9 +/- 7.4	65 +/- 9

*Average +/- SD. N=45 samples of powdered breast milk rehydrated according to package instructions.

Samples were analyzed at Milkify using a Miris Human Milk Analyzer.

**Reference values are reported as average +/- SD from donor milk samples

(1) K. Wojcik, D. Rechtman, M. Lee, A. Montoya, and E. Medo. "Macronutrient analysis of a nationwide sample of donor breast milk". *J. Am Diet Assoc.* vol 109, pp 137-140, 2009.

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

1. Cavazos-Garduño, A. , Serrano-Niño, J. , Solís-Pacheco, J., Gutierrez-Padilla, J., González-Reynoso, O. , García, H. , & Aguilar-Uscanga, B. (2016). Effect of Pasteurization, Freeze-drying and Spray Drying on the Fat Globule and Lipid Profile of Human Milk. *Journal of Food and Nutrition Research*, 4(5), 296-302.
2. Manin, L.P., Rydlewski, A.A., Galuch M.B., Pizzo, J.S., Zappiolo, C.D., Senes, C.E.R., Santos, O.O., Visentainer, J.V. (2019) Evaluation of the Lipid Quality of Lyophilized Pasteurized Human Milk for Six Months by GC-FID and ESI-MS. *Journal of the Brazilian Chemical Society*. 30 (8)
3. Cortez, Mariela Valentina and Soria, Elio Andrés.(2016). The Effect of Freeze-Drying on the Nutrient, Polyphenol, and Oxidant Levels of Breast Milk. *Breastfeeding Medicine*. 11(10). 551-554.
4. Hahn, W., Kim, J., Song, S., Park S., and Kang, N.M. (2019). The human milk oligosaccharides are not affected by pasteurization and freeze-drying. *The Journal of Maternal-Fetal & Neonatal Medicine*. 32:6, 985-991.
5. Martysiak-Żurowska D, Puta M, Rodzik A, Malinowska-Panczyk E. (2017). The effect of lyophilization on selected biologically active components (Vitamin C, Catalase, Lysozyme), total antioxidant capacity, and lipid oxidation in human milk. *Food Sci Technol Qual*. 24, 3 (112), 121 – 128.
6. Jarzynka S, Strom K, Barbarska O, Pawlikowska E, Minkiewicz-Zochniak A , Rosiak E, Oledzka G and Wesolowska A. (2021). Combination of High-Pressure Processing and Freeze-Drying as the Most Effective Techniques in Maintaining Biological Values and Microbiological Safety of Donor Milk. *International Journal of Environmental Research and Public Health*, 18, 2147.
7. Hahn, W.-H., Bae, S.-P., Lee, H., Park, J.-M., Park, S., Lee, J., & Kang, N. M. (2020). The impact of freeze-drying on the glycoproteomic profiles of human milk. *Analytical Science and Technology*, 33(4), 177–185.
8. Castro-Albarrán, J., Aguilar-Uscanga, B.R., Calon, F., St-Amour, I., Solís-Pacheco, J., Saucier, L., and Ratti, C. (2016). Spray and Freeze Drying of Human Milk on the Retention of Immunoglobulins (IgA, IgG, IgM). *Drying Technology*. 34.

SHELF LIFE OF FREEZE DRIED BREAST MILK

Just like any other food that you find in your pantry, freeze-dried breast milk does have an expiration date. Why is this important? 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.

Since breast milk powder is very hydrophilic (it attracts moisture from the environment very quickly), it's important that it is packaged in single-use pouches. Once opened, these pouches should be used within 3 days. Packaging breast milk powder in large containers that are meant to be opened and closed multiple times (like a formula canister or large bag) greatly reduces its shelf life. Companies shipping breast milk powder in large containers are doing so to save money on packaging and sell "convenience", but in reality are putting the safety of infants at risk by not warning about the reduced shelf life. Additionally, the use of oxygen/moisture absorber packets is not a substitute for an actual shelf life analysis, which must be done by an outside laboratory.

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. No oxygen/moisture absorbers are used in packaging by Milkify and each lactation bag provided to Milkify becomes its own pouch of powder.

IS THIS COVERED BY INSURANCE/HSA/EMPLOYEE BENEFIT?

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.

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

For preterm or low birthweight infants requiring nutritional fortification, freeze-dried breast milk may present an alternative to bovine-based fortifiers. In this scenario, referred to as *autologous fortification*, a mother's freeze-dried breast milk may be added to liquid breast milk to increase the caloric content of feedings. This novel method of fortification offers the opportunity to provide an increased caloric and protein density sourced from the mother's own milk and without the use of bovine or plant based derivatives. Autologous fortification 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 determination of the caloric density and protein amount in each sample of breast milk and can serve as a mechanism to target each individual infant's nutritional goals. The amount of fortification can be adjusted based 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. Fortification 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 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.