

Freeze-dried Human Milk

Developed by Registered Dietitians

Key Messages

- Due to the lack of available evidence on the osmolar, microbial, and nutritional safety of freeze-dried human milk, Nutrition Services does not recommend its use. This includes use in reconstituted form or as a fortifier in any setting.
- Before the use of freeze-dried human milk can be recommended, more research is needed to assess osmolar, microbial, and nutritional safety and whether there are benefits.
- Research of any type at a clinical or practice level is absent. Adequate safety and efficacy need to be established and policies developed to protect infants. Clinical trials are required that include rigorous human milk analysis.
- Human milk provided at the breast or expressed and fed to the infant, human milk provided by a Human Milk Banking Association of North America (HMBANA) approved milk bank, and formula approved for use in Canada are safe and nutritionally sound ways to feed infants in the first year of life.
- For further questions about this topic please contact your local public health or clinical dietitian.

What is freeze-dried human milk?

Freeze-drying, also known as lyophilization, is a process that diminishes water content at freezing temperatures¹ and under vacuum.² Freeze-drying results in a powdered product that needs to be reconstituted prior to consumption. Freeze-drying human milk has been experimented as an alternative to freezer storage at human milk banks; the appeal is to theoretically allow for a longer shelf life,³ easier transport,⁴ and a lower cost of storage.³

Why might you be asked about freeze-dried human milk?

Freeze-dried human milk is currently available in Alberta and online through private companies offering a paid service to individual clients. The product is promoted on the internet and various social media platforms with testimonials and how-to videos.

Does evidence exist to support freeze-dried human milk use?

No. Published research is limited to studies conducted in laboratory settings (in vitro research) with samples of expressed human milk from a small number of women or samples of pooled milk from milk banks. The studies followed different processes. As far as we are aware, no

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standard processes have been established to allow for objective comparison of results or to determine best practice or to support safe use of this product.

Research on freeze-dried human milk that explores the safety of this product in home and/or clinical settings, from microbiological, osmolality and nutritional perspectives, is absent. The available published research is limited and to date have investigated the impact of the freeze-drying process on pathogen growth^{1,3} and/or specific nutrients⁴⁻¹² and bioactive factors^{1,2,5,7,8} in human milk.

What evidence is there for the microbial safety of freeze-dried human milk?

Freeze-drying does **not** remove bacteria or viruses present in human milk.^{1,3} Only a few studies explored microbiological changes; results indicated freeze-drying may prevent growth of potentially harmful bacteria,^{1,3} although in one study, the growth of some harmful bacteria, but not all, was reduced.¹ Contamination during handling remains a potential concern.

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

Limited evidence explored the effects of freeze-drying on various nutritional properties of human milk such as: concentrations of carbohydrates,^{5,6} proteins,^{4,5} lipids and fatty acids,^{5,7,9-11} antioxidants,^{7,8} immunoglobulins,² and bioactive factors.^{1,2,5,7,8} Study design varied among the available research and employed different conditions prior to freeze-drying, including non-pasteurized, pasteurized, homogenized, pooled, and pre-frozen. Examples of other methodological variations included temperature and length of storage prior to analysis, with 6 months being the longest length of storage time studied.

Freeze-drying did not affect carbohydrate^{5,6} or protein^{4,5} content or composition when stored for up to 6 months. Conservation of carbohydrate and protein levels beyond 6 months is unclear.⁴⁻⁶ Various fat/lipid characteristics of freeze-dried human milk were analyzed.^{5,8-11} While fat content,^{9,10} triglycerides,⁵ triacylglycerol profile,⁹ and fatty acid content^{8,11} were not significantly affected, other lipid characteristics including fat globule size and polydispersity¹⁰ were altered. Variations in storage time, storage temperature, and specific lipid characteristics analyzed added further complexity to study results. Studies exploring the effect of freeze-drying on antioxidant content found total antioxidant capacity,⁷ vitamin C,^{8,11} and vitamin E¹¹ decreased after freeze-drying, with antioxidants further lowered by storage temperatures above 4°C.^{8,11} Bioactive factors studied were largely unaffected; study components were specific hormones (adiponectin,¹ insulin,¹ lactoferrin,⁸ leptin¹), hepatocyte growth factors,¹ and some enzymes.^{1,5,7,8}

While the preliminary research may appear promising, product claims of nutritional superiority of freeze-dried human milk, when compared with fresh or frozen human milk, are inaccurate and unfounded. Changes were observed after freeze-drying for some nutrient properties, most notably lipid and antioxidant composition. The significance of these changes to infant health is uncertain. Nutrient retention at various storage conditions and storage lengths beyond 6

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months is unknown. Clinical trials are needed to assess safety and efficacy, including a process with rigorous human milk analysis.

Are there concerns about the use of freeze-dried human milk in a home or hospital setting?

Yes. To date, limited research has been conducted. Within this limited research, none have studied the expression, transportation, freeze-drying, reconstitution, or storage and use of the product in a home or hospital setting. Critical questions remain about the appropriate use of freeze-dried human milk in both home and hospital settings. Moreover, no evidence was found to suggest the superiority of freeze-dried human milk over fresh or frozen human milk to support normal infant growth. Clinical trials have not been conducted to support claims that adding freeze-dried human milk to food or beverages is safe or has immunological or nutritional advantages for the infant.

Can freeze-dried human milk be used as a fortifier?

No. Research on the use of freeze-dried human milk as a powdered fortifier to add to expressed human milk at a practice level is absent. Clinical trials have not been conducted on the use of freeze-dried human milk as a fortification strategy in a home or clinical setting for preterm, medically fragile, or term infants. It is not known how the use of freeze-dried human milk as a concentrate will influence key outcomes, such as infant growth, length of hospital stay, and necrotizing enterocolitis. Studies conducted are limited to a few in vitro studies that analyzed macronutrient and micronutrient composition of human milk samples to which a freeze-dried human milk concentrate was added.^{13–15}

What approvals exist for the freeze-drying service available in Alberta?

Alberta Health Services approval has been limited to a food handling permit for the freeze-dried human milk process. A food handling permit ensures the business' compliance with infrastructure, sanitation, and food processing standards; however, it does not validate the microbiological safety, or nutritional quality of the product (freeze-dried human milk).

Freeze-dried human milk will not be used in Alberta Health Services neonatal intensive care units (NICUs) to fortify human milk unless it is used under a Conjoint Ethics Board approved research study. Investigation of freeze-dried human milk in a research setting to examine safety and nutritional benefits would provide additional evidence-informed guidance for healthcare providers.

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References

1. Jarzynka S, Strom K, Barbarska O, Pawlikowska E, Minkiewicz-Zochniak A, Rosiak E, et al. Combination of high-pressure processing and freeze-drying as the most effective techniques in maintaining biological values and microbiological safety of donor milk. *Int J Environ Res Public Health*. 2021;18(4):1–16.
2. Castro-Albarrán J, Aguilar-Uscanga BR, Calon F, St-Amour I, Solís-Pacheco J, Saucier L, et al. Spray and freeze drying of human milk on the retention of immunoglobulins (IgA, IgG, IgM). *Dry Technol*. 2016;34(15):1801–9.
3. Salcedo J, Gormaz M, López-Mendoza MC, Nogarotto E, Silvestre D. Human milk bactericidal properties: Effect of lyophilization and relation to maternal factors and milk components. *J Pediatr Gastroenterol Nutr*. 2015;60(4):527–32.
4. Hahn WH, Bae SP, Song S, Park S, Lee J, Seo JB, et al. The freeze-drying does not influence the proteomic profiles of human milk. *J Matern Neonatal Med*. 2020;33(12):2069–74.
5. Cortez MV, Soria EA. The Effect of Freeze-Drying on the Nutrient, Polyphenol, and Oxidant Levels of Breast Milk. *Breastfeed Med*. 2016;11(10):551–4.
6. Hahn W ho, Kim J, Song S, Park S, Kang NM. The human milk oligosaccharides are not affected by pasteurization and freeze-drying. *J Matern Neonatal Med*. 2019;32(6):985–91.
7. Martysiak-Żurowska D, Puta M, Rodzik A, Malinowska-Pańczyk E. The effect of lyophilization on selected biologically active components (vitamin C, catalase, lysozyme), total antioxidant capacity and lipid oxidation in human milk. *Zywn Nauk Technol Jakosc/Food Sci Technol Qual*. 2017;24(3):121–8.
8. Martysiak-Żurowska, Dorota, Rozek P, Puta M. The effect of freeze-drying and storage on lysosyme activity, lactoferrin content, superoxide dismutase activity, total antioxidant capacity and fatty acid profile of freeze-dried human milk. *Dry Technol*. 2020;
9. Manin LP, Rydlewski AA, Galuch MB, Pizzo JS, Zappiello CD, Senes CER, et al. Evaluation of the lipid quality of lyophilized pasteurized human milk for six months by GC-FID and ESI-MS. *J Braz Chem Soc*. 2019;30(8):1579–86.
10. Cavazos-Garduño A, Serrano-Niño JC, Solís-Pacheco JR, Gutierrez-Padilla JA, González-Reynoso O, García HS, et al. Effect of Pasteurization, Freeze-drying and Spray Drying on the Fat Globule and Lipid Profile of Human Milk. *J Food Nutr Res*. 2016;4(5):296–302.
11. Lozano B, Castellote AI, Montes R, López-Sabater MC. Vitamins, fatty acids, and antioxidant capacity stability during storage of freeze-dried human milk. *Int J Food Sci Nutr*. 2014;65(6):703–7.
12. Hahn WH, Bae SP, Lee H, Park JM, Park S, Lee J, et al. The impact of freeze-drying on the glycoproteomic profiles of human milk. *Anal Sci Technol*. 2020;33(4):177–85.
13. Oliveira MM, Aragon DC, Bomfim VS, Trevilato TMB, Alves LG, Heck AR, et al. Development of a human milk concentrate with human milk lyophilizate for feeding very low birth weight preterm infants: A preclinical experimental study. *PLoS One*. 2019;14(2):1–16.
14. Bomfim VS, Jordão AA, Alves LG, Martinez FE, Camelo JS. Human milk enriched with human milk lyophilisate for feeding very low birth weight preterm infants: A preclinical experimental study focusing on fatty acid profile. *PLoS One*. 2018;13(9):1–17.
15. Oliveira MM, Trevilato TMB, Segura-Muñoz SI, Aragon DC, Alves LG, Nadal M, et al. Essential and toxic elements in human milk concentrate with human milk lyophilizate: A preclinical study. *Environ Res*. 2020;188(May):109733.