



White paper

## Human Milk Components – Is This Real Substitute for Breastfeeding?

A mother's milk contains all the essential nutrients such as carbohydrates, protein, fat, vitamins, minerals, digestive enzymes and hormones and is a rich source of immune cells, stem cells and some bioactive component.

In this paper, we discuss the bioactive components present in human milk, market trend of the infant food industry and regulatory requirements for infant foods.

## Introduction

Breast milk, also termed as human milk, is the optimal nutritional source for at least the initial six months for infants. It ensures optimal growth & development of the baby and provides them with innate immunity.

World Health Organization (WHO) recommends that infants should be exclusively breastfed during the first six months of life. The reason being, human milk is a complex matrix of various proteins, lipids, carbohydrates and bioactive components. Its bioactive components supply incomparable benefits such as immunological protection, gut microbiota health, brain development and so on.

Interestingly, the contents of human milk change

dramatically with respect to infant age and requirements. Other factors that influence the changes in milk composition are stage of feeding, maternal diet, race, and geographical factors. This is a natural process.

“There is no doubt that promotion of breastfeeding in preterm and newborn infant contributes to optimal growth and quality health during infancy and childhood, and also determines short- and long-term health outcomes”

Ferdinand Haschke

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## What are the Current Market Demands?

WHO in collaboration with physicians and infant nutrition companies have been conducting breastfeeding awareness campaigns. Physicians unanimously recommend breastfeeding. However, in some cases, a mother's milk may not always be available or suitable for pre-term infants. In other cases, the nutritional composition of preterm milk cannot sufficiently meet the requirements for a healthy infant growth.

According to a WHO report published in 2017, only 40% of infants globally are exclusively breastfed due to reasons such as infectious diseases, lesser awareness and busy lifestyle of mothers.

These factors have resulted in an increase in demand for infant formulas to meet the nutritional requirements of preterm and term infants.

- According to WHO report (2017), only 40% of infants globally are exclusively breastfed.
- Malnutrition among infants and children is common as mothers may face challenges in order to maintain adequate supply of milk with essential nutrients.
- This leads to the need of infant formula similar to human milk.

## What is the Industry Approach to Meet the Market Demands?

Infant nutrition companies such as Nestlé, Danone-Nutricia, Abbott, Mead Johnson, Royal Friesland Campina, etc. have been conducting extensive researches to identify various bioactive components present in human milk. These players are using advanced technologies to identify these various components, its complexities and variations.

These components basically include indigestible oligosaccharides (Human milk oligosaccharides {HMO's}), complex proteins (lactoferrin, osteopontin) and lipid components such as milk fat globule membrane.

What these players compete for is to develop products with the greatest similarities with

respect to ingredients and functionality to human milk? This will benefit the infants to receive formulas that are closer to human milk. However, the biggest challenge that persists in the domain is – How can the industry players commercially extract and market these components? This question requires subsequent attention. Components of human milk cannot be synthesized directly through human milk due to the insufficient availability of milk donors.

A few market players are conducting researches in this space and developing chemical, biosynthesis and fermentation techniques to extract similar components from cow milk and make them structurally identical to those from human milk.

## What are the Components of Breast Milk?

Advancements in technologies have given the opportunity for researchers to have a close-up assess of human milk. The industry players are also making efforts to understand the effect of the bioactive components on infant growth, metabolism, cognition, and immunity development.

The composition of human milk is variable and modifies according to the infant's requirements with his age, growth, lactation stage, maternal diet and health. Mother's milk holds all the essential nutrients such as carbohydrates, protein, fat, vitamins, minerals, digestive enzymes and hormones and is a rich source of immune cells, stem cells and some bioactive components.

Amongst these bioactive molecules, complex sugars, such as human milk oligosaccharides-2'-fucosyllactose, 3'-fucosyllactose, Sialylated oligosaccharide and N-acetylated oligosaccharides are the most studied components in HMR. The studies have

established that they play a pivotal role in developing a diverse and balanced microbiota in infant gut and show anti-infective properties by inhibiting the binding of pathogens to intestinal surface.

"It is now recognized that there are other factors in milk that may be important for infant health, including small molecule metabolites"

Carolyn Slusky

Multi-functional proteins in HM including  $\alpha$ -lactalbumin, sIgA, lactoferrin, osteopontin, and milk fat globule membrane proteins are anti-infective agents and strengthen infant health.

Lipids are the largest energy source present in human milk, and they exist in the form of triglycerides, diglycerides monoacylglycerides, free fatty acids, phospholipids and cholesterol. The fat components in milk fat globule membrane such as phospholipids and sphingomyelin are essential for central nervous system development and enhance cognitive development in pre-term infants.

## Which is the Most Researched Human Milk Component?

HMO's are the most researched segment in the field of human milk. They stand unique due to their prebiotic benefits essential for gut microbiome, immunity and cognitive development. The markets of HMOs include Fucosyllactose-, sialyllactose- and LnNT-based products. Nestlé, Abbott, Danone and Mead Johnson are internationally dominant players in this sector. Other key players include Royal Friesland Campina, Fonterra, Arla, etc.

human milk research focuses on identifying and analyzing the components of human milk and replicating them into commercial products for a much developed infant health.

Despite the fact that research in this sector is progressively growing, it is crucial to understand that infant formulae are no substitute to natural breastfeeding. Bringing awareness among consumers in this regard is vitally important.

Correlating the benefits of human milk components with human health motivates ongoing research in this space. The recent

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## What is the motivation behind the research on human milk (HMR)?

Mothers' milk is a Gold standard for infant nutrition. However, mothers may encounter various challenges in maintaining an adequate supply of breast milk. These challenges include –

- Infection
- Insufficient supply of preterm milk
- Reduction in milk supply
- Lifestyle / busy schedule

Thus, it becomes imperative to provide infant formulae for healthy growth and development of babies.

To meet up with the human milk nutrition, infant formulas need to be compositionally complete and provide sufficient nutrition for overall infant

growth. Moreover, in cases of pre-term infants, even the mothers' milk is not suitable for the catch-up growth of pre-term or low birth weight baby.

Thus, the industry players' drive towards the conducting of researches in this domain is to identify the most important human milk components. This enables them to introduce products that are capable of fortifying breast milk with essential proteins, vitamins and other bioactive elements. Further, the players are competing to introduce infant formulae, which is the closest to human milk in both composition and functionality.

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## Who are the Key Players?

Extensive research and clinical trials have revealed health benefits of human milk components on infant gut, immune, and cognitive health. Infant nutritionist players have started to introduce human milk components in their products and promote HMR.

Companies like DANONE, Prolacta Bioscience, Abbott, Nestlé, and Mead Johnson dominate HMR. Products with human milk components include Similac by Abbott, Enfamil by Mead Johnson, NaN Pro by Nestlé, and so on. Ingredient players such as DuPont offers HMOs, NZMP offers Lactoferrin, DHA offers DSM, etc.

**Figure 1 Key Players in Human Milk Industry**

| Key Players         | HM-based Products | HM Ingredients | HMR |
|---------------------|-------------------|----------------|-----|
| Abbott              | Yes               |                | Yes |
| Arla                |                   |                | Yes |
| Danone              | Yes               |                | Yes |
| DuPont              |                   | Yes            |     |
| Fonterra            |                   | Yes            |     |
| Mead Johnson        | Yes               |                | Yes |
| Nestlé              | Yes               |                | Yes |
| NZMP                |                   | Yes            |     |
| Prolacta Bioscience |                   |                | Yes |
| Royal DSM           |                   | Yes            |     |

## What are the Regulatory Requirements in this Domain?

Infant formula is the most regulated food in the world. International scientific and paediatric community are in accord on the regulation that the formulation of infant products must be safe for consumption and also have scientific evidence and infant formula.

It is mandatory that infant formulae conform to regulatory norms regionally and internationally. According to WHO and FDA, direct infant food promotion or advertisement to parents/consumers for infants below two years is prohibited.

Below are a few restrictions on infant formulae composition and advertisements:

- Any communication on formulae for infants below two years should be through a healthcare practitioner.
- First stage formulae cannot be advertised in the U.S., Europe, or China.
- HMOs yet to be approved in China and India.
- The law abides that market claims and phrases defining components or ingredients in products should be explicit.

- Breast milk is the most significant natural source of nutrition for infants
- WHO, healthcare practitioners, infant nutrition players, and other regulatory bodies recommended exclusive breastfeeding for first six months of infants
- Under few circumstances where mothers are unable to provide breast milk, at that time infant formula should come into picture
- However, formulae for infants below two years, should not be advertised directly to parents and should only come into play when recommended by healthcare practitioners

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