What's in formula milk?

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Key learning points

1. Breast milk is the optimal food for infants; however, some mothers may choose not to breastfeed or have difficulties initiating or maintaining breastfeeding for a variety of reasons. All parents having difficulties should be offered support
2. If unable to breastfeed, infant formula is a complete substitute for breast milk that meets the full nutritional needs of infants
3. Strict EU regulations ensure all formula milk sold in the UK follow a clear set of compositional guidelines to ensure all are safe to feed an infant
4. Infant formula is based on cow's milk, goat's milk or soya beans and contains protein, carbohydrates, fats, and micronutrients
5. Infant formulas are often divided by age groups, typically with first formulas suitable from birth, follow-on formulas suitable from six months of age and toddler milks suitable from 12 months of age
6. Formula milk has changed over the past 50 years, with innovations aiming to replicate some of the benefits of breast milk. Inclusion of components such as nucleotides, prebiotic fibres, specific fatty acids and lipids have shown promising benefits to infant health, akin to those provided by breast milk
7. Formula milk composition varies, with some different formula milks marketed to support the management of conditions such as reflux, colic, lactose intolerance and cow's milk protein allergy
8. No formula milk is close to replicating human milk, which includes benefits that extend beyond nutritional composition. However, innovation remains important within formula milk manufacturing to help optimise the health of formula-fed infants

Breast milk is the ideal

Breast milk is the ideal food for infants, providing energy and essential nutrients alongside a range of other physiological benefits that support the short- and long-term health of infants **Factsheet 5.2**

The World Health Organisation and UNICEF recommend that infants are breastfed exclusively for the first six months of life, and breastfeeding is continued alongside introduction of solids (complementary feeding) beyond that for up to two years of age or beyond[1,2].

Although some mothers find it hard to breastfeed and others cannot do so for medical reasons (such as significant illness, history of breast surgery—e.g. mastectomy), with suitable support most healthy term infants are able to breastfeed. However, despite well-established public health guidance over the past 30 years, the UK's breastfeeding rates remain significantly below this ideal. While 72% of mothers are reported to breastfeed within the first 48 hours of life, rates of exclusive breastfeeding at six months drop to 1% [3,4]. This figure reflects introduction of formula milk and/or solids by six months of age.

Given the significant proportion of infants currently fed formula milk within their first six months of life, it is important to recognise that infant formula is an essential source of nutrition for many infants. Infant formula is a complete breast milk substitute for babies who are not breastfed or who are mixed or combination fed.

Key facts relating to formula feeding

(From last Infant Feeding Survey – 2010)[4]

of parents had given their baby milk other than breast milk by 6 weeks of age

this increased to 88% by six months of age

The composition of formula milk

Infant formulas are the only suitable alternative to breast milk for healthy infants during the first year of life. Infant formulas are based on modified cow's milk, goat's milk or soya protein (the only permitted protein sources) with added nutrients to ensure they are suitable for babies.

Infant formula comes in several different presentations or forms. Usually it consists of a dry powder that is made up with water or a ready-to-feed liquid formula, but occasionally formula milk can also be in the form of pre-measured compact tablets. For advice on how to make up formula milk appropriately, please refer to https://www.nhs.uk/conditions/baby/breastfeeding-and-bottle-feeding/bottle-feeding/making-up-baby-formula/.

Key ingredients in infant formula milk

There are a wide variety of formula milks available for infants. While there are some differences in nutritional composition, it is important to note that the composition of infant formula milk is strictly regulated in the UK by EU Regulations on manufacturing and marketing. These regulations ensure that formula milks are as close as possible to the composition of breast milk. If scientific studies have identified that an ingredient is beneficial for infants, then it should be included within formula milk[5]. The price of a formula milk should not be regarded as an indication of its nutritional content.

As a simple guide, all formula milks include proteins, carbohydrates, fats and micronutrients, the primary building blocks that infants need to grow and develop.

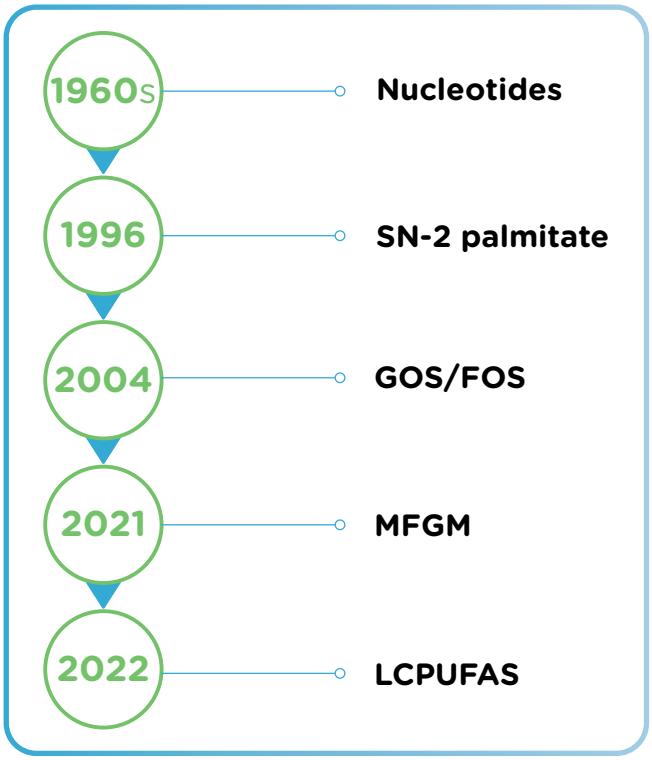
- **Protein** – from cow's milk, goat's milk or soya bean
- **Carbohydrates** – such as maltodextrin, starch, lactose, and occasionally glucose
- **Fats** – multiple sources (predominantly vegetable oils) in an attempt to replicate a fatty acid profile similar to breast milk. Essential fatty acids like docosahexaenoic acid (DHA), in the form of fish oils, are also added
- **Micronutrients** – including vitamins, minerals and trace elements

The evolution of infant formula

It is impossible to replicate the hundreds of components that are contained within breast milk. Over the past 50 years however, a range of specific ingredients have been added or altered within infant formula to try and narrow the gap between breast milk and formula milk composition. Key changes to macronutrient composition have also been made. For instance, the protein content of formula milk has been reduced to better match breast milk. The significance of this has been demonstrated in studies showing slower infant weight gain (closer to that of a breastfed baby) and reduction in obesity risk in later life[6].

Timeline

The timeline below provides the dates that specific ingredients were first added to infant formula.



Nucleotides

Nucleotides within breast milk have an essential role in infant growth, forming the basis of DNA and RNA. Their cellular and metabolic functions are associated with key benefits, including the support of intestinal flora development and immune system functioning[7,8] **Factsheet 5.2**. Artificially derived nucleotides have been added to formula milk since the 1960s. However, evidence of their beneficial impact on immune functioning and gut and intestinal flora development has been inconclusive[9]. As such, it is unclear whether the benefits incurred from nucleotides present in breast milk can be replicated.

SN-2 palmitate

Fatty acids are a key component of breast milk, with palmitic acid being the most abundant. Unique to breast milk is the presence of a specific structure of palmitic acid, known as SN-2. This fatty acid formulation helps optimise bone density, the intestinal flora and stool consistency. SN-2 palmitate has been added to formula milk since the 1996, and a recent meta-analysis has identified benefits including improved growth, improved bone mineralisation, reduced faecal calcium soaps (which can contribute to hard stools) and a healthier gut microbiome[10].

GOS and FOS (Galactooligosaccharides and Fructooligosaccharides)

GOS and FOS are forms of prebiotic fibres added to formula milk from 2004 onwards. These are designed to mimic the benefits of human milk oligosaccharides (HMOs), which are found in human breast milk **Factsheet 5.2** but not in cow's or goat's milk. While it is impossible to replicate the variety of breast milk HMOs, GOS and FOS prebiotic fibres reach the infant gut undigested and may support the growth of beneficial bacteria and microorganisms in a similar way to HMOs. This may offer benefits to bowel functioning and an infant's immune function[11].

Milk fat globule membrane (MFGM)

The MFGM in breast milk has a distinctive and complex structure — including proteins, cholesterol and phospholipids — that is believed to benefit infant brain development and immune functioning[12]. MFGM in cow's milk is destroyed through the pasteurisation process but can now be included in infant formula due to advances in manufacturing. Early research suggests this addition may be linked to long-term cognitive benefits in children at six years of age[13].

Long chain polyunsaturated fatty acids (LCPUFAS)

LCPUFAs, including arachidonic acid (AA) and docosahexaenoic acid (DHA) are essential fatty acids present in high amounts within breast milk. These lipids have a fundamental role in the composition of cell membranes and have a functional role in growth. DHA and AA specifically are also widely acknowledged to have a critical role in brain and visual development in babies[14]. Given the evidence base behind the critical role of these fatty acids in breast milk, mandatory supplementation of formula milk with DHA and AA came into place in 2022[15].

Other research areas

Research in formula development continues, with ongoing advances and exploration in the use of synthetic HMOs, complex sugars and differing protein blends.

Different types of infant formula

Cow's milk based infant formula

Infant formula that is suitable from birth is sometimes called 'first milk' or 'stage 1 milk'. This milk is often described as suitable for babies from birth up to six months of age; however it is suitable to continue past six months of age.

There are two main types **(see Chart 1)**:

1. Whey dominant, based on intact protein – The protein in these milks is 60% whey and 40% casein, which is similar to the whey to casein ratio in breast milk. The majority of infant formulas suitable from birth are whey dominant.
2. Casein dominant, based on intact protein – The protein in these milks is 20% whey and 80% casein, which is the same as cows' milk. They form a firmer curd in the stomach, which delays gastric emptying. This type of milk is often marketed as a 'hungry baby' formula, although there is no evidence to support the use of these.

Soya-based infant formula

Suitable from six months of age, these formulas contain protein from soya beans rather than cow's milk, and glucose rather than lactose. Soya formulas are designed for use in infants unable to tolerate cow's milk protein or lactose, or they may be chosen by families for personal or cultural reasons. They are available over the counter and on prescription.

Current advice from the Chief Medical Officer for England is that they should not be used as the feed of first choice in infants[16] because concerns have been raised regarding the naturally occurring phytoestrogens within soya. Whilst these plant-derived oestrogens are recognised to be different to the female hormone oestrogen, concerns have been raised about the potential for phytoestrogens to mimic the effects of female hormones, the consequences of which remain uncertain, particularly with infants under six months of age.

Soya formula may be recommended to families following a vegan diet, and who wish to use a plant-based infant formula for their infant. At present there are no completely vegan soya based infant formulas available in the UK, as the Vitamin D with the formula milk continues to be derived from an animal source.

Goat's milk based infant formula

Goat's milk formula, suitable from birth, has been allowed in the UK since 2014. Goat's milk formula follows the same nutrition standards as all other infant formulas that are suitable from birth. There are some naturally occurring differences in the protein composition, which are often suggested to have digestive benefits. Currently robust evidence for these claims does not exist. Goat's milk formula is not suitable for children with cow's milk protein allergy, as goat's milk proteins share a high percentage of similarity with cow's milk, thus presenting a high risk of cross reaction for these infants.[17,18]

Follow-on formulas

Suitable from six months of age, follow-on formulas differ from infant formulas suitable from birth in having higher amounts of some added vitamins and minerals – iron, zinc and vitamin D in particular. They are suitable from six months onwards and can be used in place of cow's milk after 12 months of age. The protein ratio of all current follow-on formulas in the UK is 80 per cent casein and 20 per cent whey. In the UK, it is not essential to change to a follow-on formula when an infant is over six months, and the World Health Organisation (2013) declared follow-on formula as "unnecessary". In practice, these milks are not a necessity, and infants can remain on a 'first' milk past six months of age. In some specific circumstances, the addition of extra nutrients in follow on milk may be useful for infants and young toddlers who have an inadequate nutrient intake from solid foods.

Infant formulas with specific claims or ingredient variability

There are a range of infant formulas in the UK marketed with additional nutritional composition differences, with proclaimed benefit to infants who may be presenting with common functional gastrointestinal disorders, e.g. colic, constipation, reflux **(see table 1)**. Typically, these are suitable from birth but recommended to be used under medical supervision.

Infant formulas used for specialised medical reasons

A range of infant formula milks exist to support the management of specific medical conditions **(see table 2)**. They have formulation or composition differences that adapt the milk to be suitable for infants with specific medical diagnoses. These formula milks should always be used under medical supervision.

Growing up (Toddler) milks

Growing up milks are designed specifically for toddlers from 12 months of age and are more nutrient-dense alternatives to cow's milk (Full fat cow's milk can be given from 12 months). They are not considered a nutritional necessity for infants over 12 months of age who are managing an age-appropriate balanced diet. They can be useful if there is concern that a toddler's diet is inadequate.

Factsheet 1.6,4.4,4.7

Chart 1: Comparison between whey and casein dominant infant milks, breastmilk and cow's milk

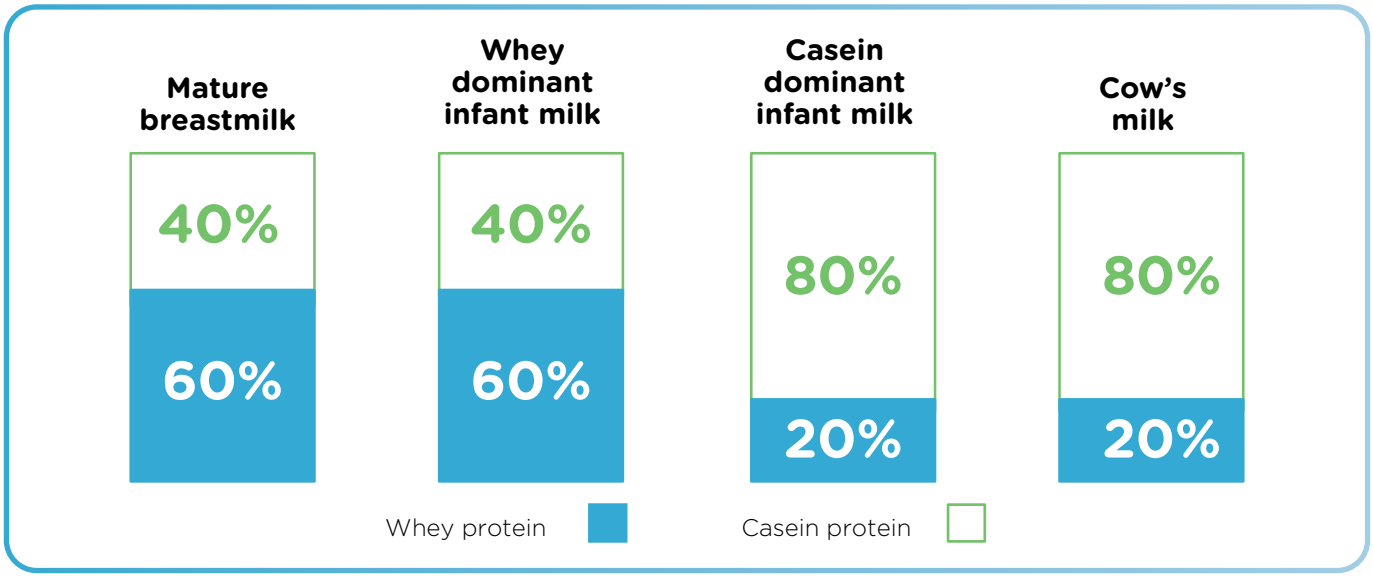


Table 1: Infant formulas with specific claims or ingredient variability

Formula 'type'	Composition differences	Marketed to support with?	Evidence base
Anti-reflux (stay down)	Contain a thickener – to increase feed viscosity May also be lower in lactose	Infant reflux or regurgitation	Limited evidence base to support their efficacy
Comfort	May be: – Lower in lactose – Contain partially hydrolysed (broken down) proteins	Gastrointestinal disorders including colic and constipation	No robust evidence base

Table 2: Infant formulas used for specialised medical reasons

Formula 'type'	Formulation or composition differences	Used in the management of	Comments
Lactose free	Lactose (the naturally occurring sugar in milk) is removed	Lactose intolerance e.g. transient lactose intolerance under medical supervision	This formula is not suitable for use in the management of Cow's Milk Protein Allergy (CMPA)
Extensively hydrolysed	The proteins in these formula milks have been extensively hydrolysed (broken down). Some contain lactose, whilst others do not	Cow's milk protein allergy (CMPA) – these formulas are typically used for first line management of mild or moderate CMPA * Not all are suitable for management of lactose intolerance	These formulas should always be used under medical supervision. Only available on prescription
Amino acid	The proteins within these formula milks have been fully broken apart to amino acids	Cow's milk protein allergy (CMPA) These formulas are used for children with severe CMPA, or those who continue to react with use of an extensively hydrolysed formula	Amino acid formula is more expensive than extensively hydrolysed formula. These formulas should always be used under medical supervision. Only available on prescription.

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Understanding what's in formula milk

GUIDANCE & TIPS FOR PARENTS

Infant formula is a complete breast milk substitute for babies who are not breast fed or who are combination fed.

All infant formula milks in the UK have to follow strict guidelines in terms of their ingredients and the nutrition they provide your baby. The nutritional recommendations are designed to bring formula milk as close as possible to the nutritional composition of breast milk.

Infant formula milks include proteins, carbohydrates, fats and micronutrients, the primary building blocks that your baby needs to grow and develop.

There are some ingredients included in all or some infant formula milks that are added to support the health of babies. Some of these components include:

- **Nucleotides** – these are found in breast milk and are small molecules that help to form the building blocks of DNA in cells. They have other roles in preventing infections and keep babies tummies healthy. Nucleotides have been added to infant formula since the 1960s, however at present there is not enough evidence to suggest they have the same benefits as nucleotides found in breast milk.
- **SN-2 palmitate** – this is a type of fat found in breast milk that manufacturers have tried to replicate in formula milk since the 1990s. Recent research suggests that adding this into formula milk can support a baby's growth and bones and help promote softer stools.
- **GOS/FOS** – these are types of dietary fibre called prebiotics that help the growth of good bacteria in a baby's gut. These prebiotics have been added to formula milk since 2004 and are considered important because breast milk contains its own type of prebiotic called Human Milk Oligosaccharides (HMOs).

No formula milk is close to replicating breast milk, which has benefits that extend far past the nutrition it provides for babies. Manufacturers are however continuing to explore ways to mirror the health benefits of breast milk through the addition of ingredients in formula milk that may be able to mimic the benefits of specific components in breast milk.

If you live in England, Wales or Northern Ireland and receive Healthy Start Vouchers, these can be used towards the purchase of infant formula suitable from birth. More information about this can be found via your GP, Health Visitor or via the Healthy Start website **https://www.healthystart.nhs.uk/**.

If you live in Scotland, you can get help from Best Start Foods, which is a prepaid card that can be used towards the purchase of infant formula **https://www.mygov.scot/best-start-grant-best-start-foods**.

There are a range of infant formulas available in the UK.

Type of formula	Comments
Based on cow's milk	Suitable from birth
Based on goat's milk	Suitable from birth
Based on soya	Not recommended before six months
Follow-on milk	Contains some small differences in amounts of certain vitamins and minerals but is not a necessity for babies. You can continue an infant formula suitable from birth past six months of age.
Formulas for specific needs	Some infant formulas sold in the UK may advise that they have been formulated to meet the needs of babies with specific conditions e.g. colic, constipation or reflux. There is currently limited evidence to suggest these formulas are necessary or beneficial for babies with these specific conditions. It is also advisable that if used, that this is under medical supervision.
Formulas for specialised medical conditions	If your baby has a cow's milk protein allergy, they should be prescribed a specialist infant formula by a suitable health care professional. Although based on cow's milk, the proteins in these formulas have been broken down so that they don't cause allergic symptoms. Goat's milk formula is not suitable for babies with an allergy to cow's milk.
Growing up (toddler) formulas	Designed for children over 12 months of age. These contain more nutrients e.g., vitamins and minerals than full fat cow's milk, so may be helpful for children with a limited diet but are not necessary for all children over 12 months of age. Most children will transition to full fat cow's milk alongside a balanced diet.

The optimal food for babies during the first six months of life is breast milk. If you are faced with difficulties initiating or continuing breastfeeding, you can find support from your health professional e.g., Health Visitor and/or breastfeeding support organisations.

Infant& Toddler Forum
The healthiest start in life from pregnancy to preschool

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