

Infant formula – An overview

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Dr Helen Crawley and Susan Westland

DISCLAIMER

The opinions given in this resource are those of the authors. We have reviewed the claims made by manufacturers on their websites over a period of time and considered the evidence given to support them. We have summarised how these claims match current expert opinion from respected scientific bodies. We strongly recommend that health professionals review the evidence for themselves and make their own minds up about whether the statements and claims made by companies about their products are scientific and factual.

This report is provided for information only and individual advice on diet and health should always be sought from appropriate health professionals. The information on products is the best available to us at the date of this report, but health professionals should check any critical compositional information with manufacturers.

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First Steps Nutrition Trust

The Food Exchange
New Covent Garden Market
London SW8 5EL

www.firststepsnutrition.org

E: Helen@firststepsnutrition.org

Registered charity number: 1146408

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Introduction

What information is in this resource?

This resource provides information about **infant formula**. These are breastmilk substitutes which have to meet the current UK Infant Formula Regulations¹, and which can be used from birth as the sole source of nutrition. In the UK we recommend infant formula is used throughout the first year of life as the main milk drink if infants are not breastfed or receiving breastmilk, or if they are partially breastfed.

What is the aim of this resource?

Despite regulations which state that all infant formula marketed in the UK must be of an agreed nutritional composition, and be appropriately labelled, products within the market may appear to be quite different. Manufacturers market their product by making claims about scientific innovation and superiority of ingredients. Company representatives, mailings, websites and conference exhibitors can provide confusing information for health professionals, and the evidence the manufacturers present may appear convincing, although this may sometimes contradict public health guidance.

As health professionals may be asked about how infant formula differ, this resource provides an independent assessment of the products currently available in the UK.

This resource does not provide information about follow-on formula (which are not needed) or specialist formula. Information about all infant milks marketed in the UK, current regulations and an assessment of infant formula composition can be found in the report *Infant Milks in the UK* at www.firststepsnutrition.org.

A brief summary of current regulations and expert views on composition

The compositional requirements are currently determined by the Infant Formula and Follow-on Formula Regulations (2007) and any amendments to those regulations. New regulations in the EU as part of delegated acts to the Foods for Special Groups Directive (EC 609/2013) have been published, but manufacturers have until 2020 to bring products in line with the new requirements and we will report on how this might affect products in future reports. The current compositional requirements which infant formula have been based on since 2007 are shown in Table 1. These have been recalculated to show them per 100ml of formula.

¹ <http://www.legislation.gov.uk/uksi/2007/3521/contents/made>

TABLE 1

Macro and micronutrient requirements for infant formula and follow-on formula

Regulations for infant formula (re-calculated by volume)		
MACRONUTRIENTS	Min/100ml	Max/100ml
Energy kJ	250	295
kcal	60	70
Protein g	1.2	2.0
Carbohydrate g	6.0	9.4
of which lactose g	3.0	N/S
Fat g	2.9	4.0
Linoleic acid mg	200	800
Linolenic acid mg	33.5	N/S
VITAMINS		
Vitamin A µg-RE	40	121
Vitamin C mg	10	20.1
Vitamin E mg	0.34*	3.35
Vitamin D µg	0.67	1.68
Vitamin K µg	2.68	16.75
Thiamin (B₁) µg	40.2	201
Riboflavin (B₂) µg	53.6	268
Niacin µg	201	1005
Vitamin B₆ µg	23.45	117.25
Vitamin B₁₂ µg	0.07	0.34
Folic acid µg	6.7	33.5
Biotin µg	1.01	5.03
Pantothenic acid µg	268	1340
MINERALS		
Calcium mg	34	94
Chloride mg	33.5	107.2
Copper µg	23.45	67
Fluoride µg	N/S	67
Iodine µg	6.7	33.5
Iron** mg	0.2	0.87
Magnesium mg	3.35	10
Manganese µg	0.67	67
Phosphorus** mg	16.8	60.3
Potassium mg	40.2	107.2
Selenium µg	0.67	6.0
Sodium mg	13.4	40.2
Zinc mg	0.34	1.0
OTHER		
Choline mg	4.7	33.5
Taurine mg	N/S	8.0
Nucleotides mg	N/S	3.35
Inositol mg	2.68	26.8
L-carnitine mg	0.8***	N/S

See the notes on next page.

Note: Where regulations do not state a minimum amount, they are not considered a requirement. In these cases, the average stated for currently available first infant milks does not include those milks where the ingredient is not present.

N/S = not stated

- * Vitamin E: 0.5mg/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds but in no case less than 0.5mg/100kcal, maximum 5.0mg/100kcal.
- ** For products manufactured from soya protein isolates or in a mixture with cows' milk, minimum and maximum values for iron for infant formula are 0.45mg and 2.0mg respectively, and for follow-on formula 0.9mg and 2.5mg respectively. For phosphorus, minimum and maximum values for both infant and follow-on formula are 30mg and 100mg respectively.
- *** The L-carnitine concentration is only specified for formula containing protein hydrolysates or soya protein isolates.

Expert opinion on infant formula composition

In 2014 the European Food Safety Authority (EFSA) reviewed the essential composition of infant formula and follow-on formula (EFSA, 2014²). EFSA independently analysed all the evidence available to determine the necessary, and unnecessary, components of infant formula, and considered other key issues related to ensuring products are safe and appropriate. Table 2 summarises some of the key points that EFSA made about infant formula (EFSA, 2014).

TABLE 2
Key points made by EFSA about infant formula

Nutrient/component	EFSA (2014) opinion/comment
Can formula milk be 'close' to breastmilk?	<p>Breastmilk is the preferred food for all healthy infants. Whereas the composition of infant formula remains stable over time, breastmilk composition changes continuously and therefore infant formula cannot imitate breastmilk.</p> <p>Human milk composition can provide guidance on the composition of formula, but compositional similarity to human milk is not the only determinant or indicator of safety and nutritional suitability of formula.</p> <p>The mere presence of a substance in human milk does not necessarily indicate a specific benefit of this substance for the infant, nor do the concentrations of nutrients in human milk necessarily reflect infants' dietary requirements because they may mirror maternal intakes rather than infants' needs, or because absorption efficiency of certain nutrients differ between breastmilk and formula.</p> <p>Infant formula cannot imitate breastmilk with respect to its energy and protein content.</p>

Nutrient/component	EFSA (2014) opinion/comment
<p>Can formula milk be 'close' to breastmilk?</p>	<p>The structure of about 200 human milk oligosaccharides has been identified. The production of oligosaccharides is genetically determined and the individual pattern of oligosaccharides differs between women. The oligosaccharides of human milk are considered to be one of the principal growth factors, for example, for <i>Bifidobacteria</i> in the infant gut and are responsible for the composition of the gut microbiota found in breast-fed infants.</p> <p>There is no evidence for health benefits from the addition of prebiotic oligosaccharides (GOS/FOS) to infant or follow-on formula.</p>
<p>Is it safe to add ingredients that are not needed, or in amounts higher than necessary?</p>	<p>Nutrients and substances should be added to formulae for infants <i>only</i> in amounts that serve a nutritional or other benefit. The addition in amounts higher than those serving a nutritional or other benefit or the inclusion of unnecessary substances in formulae may put a burden on the infant's metabolism or on other physiological functions, as substances which are not used or stored have to be excreted.</p>
<p>Are there risks when nutrients are added at maximum amounts?</p>	<p>There is a lack of studies designed to investigate the short- or long-term health consequences of consumption of formulae containing the currently permitted maximum amounts of nutrients in infant formula.</p>
<p>Ingredients added to infant formula which are <u>unnecessary</u></p>	<ul style="list-style-type: none"> • Arachidonic acid (ARA) • Eicosapentaenoic acid (EPA) • Non-digestible oligosaccharides (prebiotics. GOS/FOS mixtures) • Probiotics • Synbiotics (a mix of prebiotics and probiotics) • Chromium • Fluoride • Taurine • Nucleotides • Phospholipids as a source of long-chain polyunsaturated fatty acids instead of triacylglycerols • Triacylglycerols with palmitic acid predominantly esterified in the <i>sn</i>-2 position

² EFSA (2014). *Scientific opinion on the essential composition of infant and follow-on formulae*. Parma, Italy: European Food Safety Authority. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/3760>

Which infant formula are discussed in this resource?

TABLE 3
Infant formula discussed in this resource

Category of infant formula	Names of infant formula included in this category
Infant formula suitable from birth (cows' milk based)	Aptamil 1 First Milk Aptamil Profutura 1 First Infant Milk Aptamil Sensavia 1 First Infant Milk Arla Baby & Me First Infant Milk Castlemil First Infant Milk Cow & Gate 1 First Infant Milk Hipp Organic Combiotic First Infant Milk Holle Organic Infant Formula 1 Kendamil 1 First Infant Milk Kendamil Mehadrin First Infant Milk Kendamil Organic First Infant Milk Mamia First Infant Milk Sainsbury's Little Ones First Infant Milk SMA Advanced First Infant Milk SMA Little Steps First Infant Milk SMA Organic First Infant Milk SMA Pro First Infant Milk SMA Wysoy (for use under medical supervision)
Infant formula suitable from birth (goats' milk based)	Holle Organic Infant Goat Milk Formula 1 Kabrita Gold 1 NANNYcare First Infant Milk
Infant formula marketed for hungrier babies, suitable from birth (cows' milk based)	Aptamil Hungry Milk Cow & Gate Infant Milk for Hungrier Babies Hipp Organic Combiotic Hungry Infant Milk SMA Extra Hungry
<i>These milks are not recommended.</i>	

For each milk we summarise the key features of the milk, claims that have been made for it recently by the manufacturer, and its cost relative to other products. For a full nutritional breakdown of all products in this resource see the report *Infant Milks in the UK* available at www.firststepsnutrition.org. A summary of the costs of milks highlighted in this report can be found in the Appendix. A full summary of the costs of all infant milks on the UK market as of April 2019 can also be found on the website www.firststepsnutrition.org.

Aptamil 1 First Milk

Aptamil 1 First Milk is sold in 800g packets of powder, 700g cans of powder (Lidl only) and as 70ml, 200ml and 1 litre RTF (ready-to-feed) bottles. Information for health professionals about Aptamil and Cow & Gate brand products can be found at www.eln.nutricia.co.uk. The claims made on the website and in print literature change over time, but are often recycled, and we present some of those currently on the website or that have been made recently.

Key components of this product

TABLE 4
Key components of Aptamil 1 First Milk

Aptamil 1 First Milk		
	Powdered infant milk	RTF (ready-to-feed) 1 litre bottle
Composition	Meets current regulations for infant formula composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Prebiotics, *postbiotics, nucleotides, taurine, arachidonic acid	Prebiotics, nucleotides, taurine, arachidonic acid
Allergens	Cows' milk, soya, fish	Cows' milk, soya, fish
Protein source	Cows' milk	Cows' milk
Whey:casein ratio	50:50	60:40
Fats used	Palm, rapeseed, coconut, high oleic sunflower and sunflower oils Fish and algal oils (single cell oils)	Palm, rapeseed, coconut and sunflower oils Fish and algal oils (single cell oils)
Suitability	Not suitable for vegetarians Halal approved 800g Not halal approved 700g tin purchased in Lidl.	Not suitable for vegetarians Not halal approved
Cost per 100ml	18p	37p
For comparison: Cheapest first infant milk currently available that meets all infant nutritional requirements/100ml (based on powdered formulation)	10p	10p

* Postbiotics are the metabolic by-products of fermentation by probiotic bacteria, they are unnecessary ingredients. Please see our report Infant Milks in the UK for more information about postbiotics .
www.firststepsnutrition.org.

Claims made about Aptamil 1 First Milk

Contains our unique blend of ingredients

Danone add a number of ingredients to Aptamil brand formula milks that includes galacto- and fructo-oligosaccharides (GOS/FOS), long chain polyunsaturated fatty acids, and nucleotides. This blend was patented as Pronutra+ but a recent product change has resulted in the Pronutra+ name being dropped from the pack and website branding.

... with our blend of prebiotic galacto- and fructo-oligosaccharides, shown to reduce the risk of allergies up to 5 years

The reference given to support this claim, Arslanoglu et al (2012), is a follow-up study from a previous Arslanoglu et al, 2007 study. The authors followed up some of the original cohort to 5 years, but only 42 children remained in the intervention group from the 102 original completers. The original study was reviewed and discounted as evidence by EFSA reviews of efficacy of benefit from oligosaccharide addition to infant formula.

...contains GOS/FOS, non-digestible carbohydrates that occur naturally in breastmilk. They decrease the presence of pathogens in the gut flora increasing the growth of friendly bacteria such as bifidobacteria and lactobacilli. These friendly bacteria are an integral part of a baby's natural immune system.

The references given to support this statement are from clinical trials conducted by Knol et al, 2005, Moro et al, 2002 and Costalos et al, 2008. Knol et al (2005) looked at whether or not standard infant formula supplemented with GOS/FOS was able to establish a bifido-dominant microflora, not only in numbers, but also with respect to the metabolic activity in the colon. After 6 weeks, the mean proportion of *Bifidobacteria* was significantly higher in the group given formula with GOS/FOS and the authors concluded that the addition of the prebiotic GOS/FOS mixture to an infant formula had a stimulating effect on the growth of *Bifidobacteria* and on the metabolic activity of the total intestinal flora. This study was included in the review commissioned by EFSA (2014) but was not accepted as evidence of benefit from the addition of GOS/FOS to infant formula.

The study by Moro et al (2002), was undertaken at the Numico (Danone) Research Centre and included 90 healthy term infants who were allocated to receive formula milk supplemented with oligosaccharides at a concentration of 0.4g/100ml or 0.8g/100ml or placebo, over a period of 28 days. The infant formula used in this study was different to Aptamil 1 First Milk as it had higher protein and fat contents and a different range of added ingredients. The infants receiving the formula milk supplemented with oligosaccharides showed a dose-dependent increase in the amount of *Bifidobacteria* in stools. However, this does not mean that there is any clinical benefit to the addition of oligosaccharides.

A further study by Costalos et al, 2008, using a test formula milk with a concentration of oligosaccharides different to the currently marketed product, reported a lower percentage of faecal *Clostridia* and a higher percentage of faecal *Bifidobacteria* in the group receiving the test formula with added oligosaccharides. This study was also included in the review by EFSA (2014) but was not accepted as evidence of benefit from the addition of GOS/FOS to infant formula.

Babies fed a formula containing GOS/FOS have been shown to have a lower incidence of recurrent upper respiratory tract infections, diarrhoea, infections requiring antibiotics and atopic dermatitis than those fed a formula without GOS/FOS.

References are given to studies sponsored by the manufacturer (Numico, now Danone) to support these claims. Those by Arslanoglu et al (2007) and Moro et al (2006) consider the impact of oligosaccharides in infant formula on infections and atopic dermatitis in the first 6 months of life within the same cohort of infants at risk of atopy. Both studies reported reduced incidence of their outcome measures within the test groups compared to the control groups. The milk used in both the test and control groups was a formula containing extensively hydrolysed proteins supplemented with oligosaccharides, but Aptamil 1 First Milk does not contain hydrolysed proteins.

Another reference given to support the claims above is a study by Bruzzese et al (2009), also sponsored by Numico, which looked at the impact of infant formula milk supplemented with GOS/FOS at 0.4mg/100ml on the incidence of intestinal and respiratory infections in a cohort of healthy term infants. This study reported a lower incidence of gastroenteritis and fewer children receiving multiple courses of antibiotics within a year for the group receiving supplemented formula. The study was reviewed by EFSA (2014) as part of the evidence that led to their conclusion that there was insufficient evidence to support claims made about prebiotics in infant formula. This statement is no longer made for Aptamil first milk on the manufacturers website.

Bottlefed babies given a formula containing GOS/FOS also have softer stools than those fed a formula without GOS/FOS.

Evidence is suggested to come from the study by Moro et al (2002), undertaken at the Numico (Danone) Research Centre and described above. This statement is no longer made for Aptamil first milk on the manufacturers website.

It is disappointing that claims are still being made for prebiotics when EFSA has repeatedly denied permission for a health claim based on the use of prebiotics in infant formula and follow on formula.

EFSA (2014) states that:

“ ... there is no evidence for health benefits from the addition of prebiotic oligosaccharides (GOS/FOS) to infant or follow-on formula.”

In July 2018, Danone introduced new versions of their Aptamil first, follow-on, growing up milk 3 and growing up milk 4. The new milks contain postbiotics derived from fermented milk. The term ‘postbiotics’ refers to soluble products or metabolic byproducts secreted by live bacteria (probiotics), or released after bacterial break down, such as enzymes, peptides, polysaccharides, cell surface proteins, and organic acids.

Now, Aptamil powder formulations undergo Nutricia's unique process, producing postbiotics.

Danone have marketed the change as being related mainly to the introduction of a new processing method rather than to a reformulation of the product itself. There is little information about the new process on the website, however it involves the fermentation of milk with the lactic acid producing bacterial strains *Bifidobacterium breve* and *Streptococcus thermophiles*. Approximately a quarter of the milk powder used in the new versions of the milks is derived from milk fermented in this way. A number of claims are being made by Danone about the use of postbiotics in combination with their prebiotic GOS:FOS mix in the new Aptamil products

This combination of prebiotics and postbiotics have been shown to support a healthy gut in infants, important for immune system development and functioning

Now combined with our unique process to produce postbiotics, which have been shown to support gut and immune markers closer to breastfed infants.

Danone support these claims by reference to 2 clinical trials and a review article. The review article written by Wopereis et al, 2014, from the Nutricia research centre is used to support the use of prebiotics combined with postbiotics, however this article does not refer to postbiotics or to the combination of prebiotics and postbiotics in infant formula milks.

The first clinical trial by Rodriguez-Herrera et al 2018, examined the faecal microbiota of infants consuming a test formula with prebiotics and fermented milk or a control formula without prebiotics or fermented milk. This trial reported that in contrast to the infants consuming the control product the infants consuming the test formula showed a saccharolytic fermentation profile (lower pH, higher level of acetic acid, higher level of sIgA). The authors also reported that the levels of some bacterial groups changed consistently between the test and control formula and levels in the test arm appeared to be more in line with levels detected in the breastfed reference group. Metabolomic data showed differences in faecal metabolites between the study groups (*Rodriguez-Herrera et al 2018*).

A further clinical trial by Tims et al, 2018, investigated the effect of partly fermented formula using 3 different ratios of fermented formula on base powder, 15%, 30% and 50% along with prebiotics (GOS/FOS 9:1) on the composition of the infant gut microbiota. These test formulae were compared to 3 control products, formula with prebiotic only, formula with fermented addition only and a formula without either. A breastfed reference group was included. The authors reported that the faeces of infants consuming one of the experimental products showed similar saccharolytic fermentation profile to infants consuming the control formula with prebiotics and the breastfed infants (lower pH, higher level of acetic acid, higher level of sIgA) compared to those consuming formula without prebiotic. There was no dose response effect noted for the fermented formulae and no clinical benefits were reported (Tims, et al, 2018).

These trials were reported as either abstract or oral presentation at the ESPGHAN conference in May 2018 and not as peer reviewed papers from scientific journals. Neither of the trials reported any benefit for GOS:FOS combined with a proportion of fermented milk compared to formula with GOS:FOS 9:1 only. It is therefore difficult to establish any scientific rationale for the addition of fermented milk to a formula milk containing GOS/FOS. No data is given to support the claims made and it is not clear if the products used in the trials are the same as the currently marketed product.

enriched with LCPs, including DHA (Omega 3), at levels that are scientifically recognised by the European Food Safety Authority (EFSA) to support normal visual development and have a ratio of AA:DHA that meets consensus recommendations.

The references given to support this statement are Koletzko et al (2008), and an EFSA opinion paper (EFSA, 2009).

The review article by Koletzko et al (2008) summarises the evidence for the role of DHA and AA in maternal and term infant nutrition as well as infant development, and makes recommendations concerning their inclusion in the infant diet. The review concluded that the fetus and neonate should receive LC-PUFA in amounts sufficient to support optimal visual and cognitive development. It recommended breastfeeding as the best way to achieve this and that if breastfeeding were not possible, formula supplemented with DHA and AA should be used. DHA supplementation should be at levels between 0.2 and 0.5 weight percent of total fat, with the minimum amount of AA equivalent to the contents of DHA.

In 2009, EFSA approved the claim that “*DHA contributes to the visual development of infants*” (EFSA, 2009). However, the validity of this claim is still debated, as it is argued that visual acuity develops slowly during the early years of life and early observations of visual measurements in infants are not predictive of later visual functions. Studies would have to follow children for seven years or longer to see if small clinical changes observed in early life had any real impact (Chambers et al, 2013).

The EFSA *Scientific opinion on the essential composition of infant and follow-on formulae* (EFSA, 2014) presents a useful summary of all the evidence relating to fatty acids in human and artificial milks, but concludes that, whilst they still believe that DHA should be added to infant and follow-on formulae in similar amounts as are present in breastmilk as a ‘prudent measure’:

“The panel notes there is no convincing evidence that the addition of LCPUFA to IF or FoF has any benefits beyond infancy on any functional outcomes.”

Aptamil 1 First Milk currently contains 0.01g DHA/100ml (0.32% fatty acids). This amount of DHA is within the range that all milks will have to contain by law when new regulations are brought in from July 2016. (Manufacturers are given a period of grace of several years from a change in regulation to update their products in line with any new recommendations.)

... contains nucleotides, which form the building blocks of every cell in the body, including those of the immune system.

Whilst no direct claims are made for the addition of nucleotides, Aptamil support their addition by reference to Pickering et al (1998) and Yau et al (2003).

Both of these clinical trials looked at the immune response of infants fed formula milk supplemented with nucleotides at 7.2mg/100ml. The trials had conflicting results. Yau et al (2003) reported that, at 8-28 weeks, infants fed the supplemented formula were shown to have a 25.4% lower risk of diarrhoea and higher concentrations of serum IgA throughout the study than infants fed the control formula. Both groups had a similar antibody response to hepatitis B immunisation and similar incidence of lower respiratory tract infections, whilst the

risk of upper respiratory tract infections was 1.13 times higher in the group fed supplemented formula. Pickering et al (1998) reported that, compared to the control group, at 7 months of age the supplemented group had significantly higher H influenzae type b and diphtheria humoral antibody responses. The antibody responses to tetanus and polio virus were not enhanced by nucleotide fortification.

The fact that the formulas used in the trials were different to Aptamil 1 First Milk (which contains 3.2mg nucleotides/100ml), as well as the differences between outcomes in trials makes it difficult to see how this evidence might support the use of nucleotides in this infant formula. Both trials used milks supplemented with nucleotides at 7.2mg/100ml.. These studies were reviewed by EFSA (2014) and not accepted as evidence that nucleotides are beneficial.

EFSA (2014) state that:

“there is no necessity to add nucleotides to infant or follow-on formula.”

Our conclusion

Aptamil 1 First Milk meets the required compositional criteria for infant formula.

This formula contains postbiotics as well as a similar range of unnecessary ingredients as may be found in other brands on the market. However, in our opinion, there is no convincing evidence presented for the claims being made for these unnecessary ingredients, and claims are not supported by recent evidence reviews by expert bodies.

In our opinion the differences between this formula and Aptamil Profutura 1 First Infant Milk do not warrant the price differential between the products.

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Aptamil Profutura 1 First Infant Milk

Aptamil Profutura is available in 800g packs of powder, and 70ml and 200ml RTF bottles. Table 5 gives the data for the powder and 200ml RTF formula. Claims highlighted are those made currently or recently on the website www.eln.nutricia.co.uk.

Key components of this product

TABLE 5
Key components of Aptamil Profutura 1 First Infant Milk

Aptamil Profutura 1 First Infant Milk		
	Powdered infant milk	RTF (ready-to-feed) 200ml bottle
Composition	Meets current regulations for infant formula composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Prebiotics, nucleotides, taurine, phospholipids, arachidonic acid	Prebiotics, nucleotides, taurine, phospholipids, arachidonic acid
Allergens	Cows' milk, soya, egg, fish	Cows' milk, soya, egg, fish
Protein source	Cows' milk	Cows' milk
Whey:casein ratio	60:40	60:40
Fats used	Egg phospholipid Anhydrous milk fat, rapeseed oil, sunflower oil, coconut oil Fish oil and algal oil (single cell oils)	Egg phospholipid Anhydrous milk fat, rapeseed, corn, coconut and sunflower oil Fish oil and algal oil (single cell oils)
Suitability	Not suitable for vegetarians Not halal approved	Not suitable for vegetarians Halal approved
Cost per 100ml	23p	50p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p	10p

What claims are made for this infant formula?

Egg lipid has been added.

This is the first infant formula for healthy infants in the UK that contains egg lipid and which must therefore include egg as an allergen on the label (to add to the other allergens present: cows' milk, fish, milk and soya).

Danone, the manufacturer of this milk, have said in a letter to First Steps Nutrition Trust that:

“The egg phospholipid in Aptamil Profutura milk RTF is sourced from egg yolk. We are confident that the egg phospholipid does not pose a risk of causing an allergic reaction and our supplier guarantees that the level of egg protein in the egg phospholipid is <0.001ppm per mg.”

Apparently of the 11mg/100ml docosahexaenoic acid (DHA) present in the milk, 2.2mg comes from egg phospholipid. The remainder is provided by the fish oil and algal oils used.

Is there any benefit to adding phospholipids to infant formula?

“Contains phospholipid-bound LCs inspired by the complex structure of fats within breastmilk”.

The EFSA 2014 opinion on the essential composition of infant formula stated that, whilst there are phospholipids naturally present in breastmilk:

“There is no convincing evidence for a beneficial effect of using LCPUsFA supplied as phospholipids in infant formula.”

The manufacturer currently makes no claims specifically about the egg lipid as a source of LCPUsFA in this formula, simply stating it is present, so it is not clear why they are using this as a partial source of DHA.

Contains our highest level of LCs (long chain polyunsaturated fatty acids).

The manufacturers claim that Aptamil Profutura 1 First Infant Milk has increased levels of LCs. Aptamil 1 First Milk currently contains 0.01g DHA/100ml, and Aptamil Profutura 1 First Infant Milk contains 0.011g/100ml (1/1000th g more per 100ml). This is a minimal change that is likely to be insignificant once compositional differences and compositional degradations within infant milk products are considered. These amounts are within the range that all milks will have to contain by law when new regulations come into force from July 2016. (Manufacturers are given a period of grace of three years from a change in regulation to update their products in line with any new recommendations.)

The manufacturers claim on the website that Aptamil Profutura 1 First Infant Milk:

“Contains our highest levels of DHA to support normal visual development”.

They support this claim with papers by Koletzko et al (2008), Willatts et al (1998), and an EFSA paper from 2009. All this data was reviewed by EFSA (2014) and they concluded that:

“The panel notes there is no convincing evidence that the addition of LCPUsFA to IF or FoF has any benefits beyond infancy on any functional outcomes.”

Furthermore, the claims do not make it clear that an increased amount of LCs will not be of any greater benefit than the amount already used.

The product uses anhydrous milk fat / contains milk fat

Contains milk fat to provide a fatty acid profile closer to that of breast milk

The website also claims:

“In breastmilk, when palmitic acid is in the beta position it has certain benefits for babies, including better fat absorption, easy digestion, softer stools and reduced constipation.”

Anhydrous milk fat is simply milk fat (butter fat) that has had all water removed. The references given to support this type of fat having properties which may aid fat and calcium absorption come from Jensen et al (1978), Carnielli et al (1996) and Kennedy et al (1999). The Jensen et al (1978) study reports on the variable composition of human milk in relation to maternal diet, and highlights the lack of reliable data at that time on milk composition. This paper offers no support for the statements made.

The studies by Carnielli et al (1996) and Kennedy et al (1999) have previously been used to support claims that use of synthetic triglycerides with a higher proportion of palmitate in the *sn-2* position improves fat and calcium absorption. They are now being used to support the same claims for the use of anhydrous milk fat, which has a greater proportion of palmitate in the *sn-2* position than the vegetable oils commonly used in infant formula milks. Both of these studies examined the impact on fat and calcium absorption when infants were fed formula containing higher proportions of palmitic acid in the *sn-2* position than are present in Aptamil Profutura 1 First Infant Milk as a result of the use of anhydrous milk fat. The Kennedy et al study also reported that a number of parents reported concern about runny stools after feeding formula containing high *sn-2* palmitate.

The recent EFSA *Scientific opinion on the essential composition of infant and follow-on formulae* (2014) concluded that there was no convincing evidence for a beneficial effect of the use of palmitic acid predominantly esterified in the *sn-2* position in infant or follow-on formula.

Other claims made about Aptamil Profutura 1 First Infant Milk

The following claims have also been made about Aptamil Profutura 1 First Infant Milk on the website or in print media.

“Nutritionally closer to breastmilk in fat composition and structure than any other brand”

It is important to note that EFSA (2014) clearly state in their opinion that:

“Infant formula cannot imitate breast-milk with respect to its energy and protein content.”

Aptamil Profutura support this claim with a chart comparing their milk with others, and base the claim on the added phospholipid and the fat composition which we have already reviewed above. They claim that:

LCPs in breastmilk come in two different forms: phospholipid-bound and triglyceride-bound.

The reference given to support this, Harzer et al (1983), looks at changing patterns of human milk lipids in the course of lactation, and clearly makes the point that milk composition changes as lactation progresses, and in mothers in different areas. It concludes that, because there are strong intra-individual differences in the composition of breastmilk, care should be taken when taking samples of breastmilk for analysis. This study does not in any way support a feed of consistent composition, or this milk, as being 'close to breastmilk'. Just because manufacturers manipulate fat composition to mimic breastmilk components does not make it 'closer to breastmilk' in function.

The statement that this new milk is 'closer to breastmilk' is therefore not supported by any evidence provided in these references, nor in any of those references given to support fatty acid profiles of milks reviewed earlier. The UK Guidance Notes (Department of Health, 2013) which explain the current regulations on infant formula, state that:

*“Non-mandatory text or pictures on infant formula and follow-on formula labelling must not make reference to ‘breastmilk’, ‘breastfeeding’, ‘moving on from breastfeeding’ or ‘**closer to/inspired by breastmilk**’. Use of such terms would not comply with Regulation 17 (2) or 18(2).”*

In our opinion, infant formula companies should not make claims that any infant formula is 'closer to breastmilk' on websites or in marketing materials, as this is not allowed on labels.

The website also makes the following claim about Aptamil Profutura First Infant Milk:

Our innovative formulation also contains nucleotides, these form the building blocks of every cell in the body, including those of the immune system.

Two references are given to support this: Pickering et al (1998) and Yau et al (2003). Both of these clinical trials looked at the immune response of infants fed formula milk supplemented with nucleotides at 7.2mg/100ml. Aptamil Profutura 1 First Infant Milk contains 3.2mg nucleotides/100ml so these studies do not directly relate to this formula. The trials had conflicting results.

Yau et al (2003) reported that, at 8-28 weeks, infants fed the supplemented formula were shown to have a 25.4% lower risk of diarrhoea and higher concentrations of serum IgA throughout the study than infants fed the control formula. Both groups had a similar antibody response to hepatitis B immunisation and similar incidence of lower respiratory tract infections, whilst the risk of upper respiratory tract infections was 1.13 times higher in the group fed supplemented formula. Pickering et al (1998) reported that, compared to the control group, at 7 months of age, the supplemented group had significantly higher H influenzae type b and diphtheria humoral antibody responses. The antibody responses to tetanus and polio virus were not enhanced by nucleotide fortification. The fact that the formulas used in the trials were different to Aptamil Profutura 1 First Infant Milk, and the differences between outcomes in trials makes it difficult to interpret how this evidence might support the use of nucleotides in infant formula.

EFSA (2014) has stated that:

“Taking into account the lack of convincing evidence for a benefit of the addition of nucleotides to IF and/or FOF, the Panel considers that there is no necessity to add nucleotides to IF or FOF.”

Contains our patented blend of GOS/FOS (9:1) bringing the intestinal microflora closer to that of a breastfed infant

The manufacturers provide a reference from Moro et al (2002) to support this statement. In this study, 90 healthy term infants were randomly allocated to receive formula milk supplemented with oligosaccharides at a concentration of 0.4g/100ml, or 0.8g/100ml, or placebo, over a period of 28 days. The formulas used in this study have a different composition to Aptamil Profutura 1 First Infant Milk as they were higher in protein, lower in fat, had a different range of added ingredients and lower osmolality. The infants receiving the formula milk supplemented with oligosaccharides in this study showed a dose-dependent increase in the amount of *Bifidobacteria* in stools, but this alone does not provide evidence of clinical impact.

It is disappointing that this claim is still being made for prebiotics when EFSA has repeatedly denied permission to make a claim based on the use of prebiotics in infant formula and follow-on formula.

EFSA (2014) states that:

“... there is no evidence for health benefits from the addition of prebiotic oligosaccharides (GOS/FOS) to infant or follow-on formula.”

Our conclusion

Aptamil Profutura 1 First Infant Milk meets the required compositional criteria for infant formula.

In our opinion, this formula offers no advantage over any other first infant formula. The very high cost of this milk, the increased range of potential allergens included, and the high number of unnecessary ingredients could be seen as making this a less good choice.

EFSA (2014) clearly state: *“Nutrients and other substances should be added to formulae for infants only in amounts that serve a nutritional or other benefit. The addition in amounts higher than those serving a benefit, or the inclusion of unnecessary substances in formulae puts a burden on the infant’s metabolism and/or physiological functions as substances which are not used or stored have to be excreted.”*

Using 70ml RTF bottles of Aptamil Profutura 1 First Infant Milk to feed an infant in the first week of life would cost over £100. (For a list of the cost of various types of infant milks, see Appendix 1)

In our opinion the differences between this formula and Aptamil 1 First Milk do not warrant the price differential between the products.

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Aptamil Sensavia 1 First Infant Milk

Aptamil Sensavia 1 First Infant Milk is available in 800g packs of powder, and 70ml RTF starter packs. Table 6 gives the data for the powder and 200ml RTF formula. Claims highlighted are those made currently or recently on the website www.eln.nutricia.co.uk.

Key components of this product

TABLE 6
Key components of Aptamil Sensavia 1 First Infant Milk

Aptamil Profutura 1 First Infant Milk		
	Powdered infant milk	RTF (ready-to-feed) 70ml starter pack
Composition	Meets current regulations for infant formula composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Prebiotics, nucleotides, taurine, arachidonic acid	Prebiotics, nucleotides, taurine, , arachidonic acid
Allergens	Cows' milk, soya, fish	Cows' milk, soya, fish
Protein source	Cows' milk	Cows' milk
Whey:casein ratio	100:0	100:0
Fats used	Palm, rapeseed, coconut and sunflower oils	Palm, rapeseed, coconut and sunflower oils
	Fish oil and algal oil (single cell oils)	Fish oil and algal oil (single cell oils)
Suitability	Not suitable for vegetarians Not halal approved	Not suitable for vegetarians Halal approved
Cost per 100ml	22p	£2.62 (available as starter packs only)
For comparison: Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p	10p

What claims are made for this infant formula?

On the website it states the following:

Aptamil Sensavia First Infant Milk is based on partially hydrolysed milk protein, where the milk protein has been broken into smaller pieces, is suitable from birth for combination or bottle-fed infants.

- With partially hydrolysed milk protein, where the milk protein has been broken into smaller pieces
- Contains Aptamil's blend of Galacto- and Fructo-oligosaccharides (scGOS/lcFOS) (0.8g per 100ml)
- Contains Omega-3 LCs
- Contains nucleotides (3.2g per 100ml)

Currently no claims are made on the website about the benefits related to the composition of this product or the additional nutrients stated. There is no evidence that partially hydrolysed infant formula are of any benefit to infants and GOS/FOS and nucleotides are considered as unnecessary ingredients.

Arla Baby & Me Organic First Infant Milk

This organic cows' milk based infant formula manufactured by Arla Foods is currently available on-line only, directly from the manufacturer. It is available as 800g tins.

Key components of this product

TABLE 7

Key components of Arla Baby & Me Organic First Infant Milk

Arla baby & Me Organic First Infant Milk	
	Powdered infant milk (800g tin)
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Arachidonic acid, prebiotics
Allergens	Cows' milk, soya
Protein source	Cows' milk
Whey:casein ratio	65:35
Fats used	Palm, rapeseed, soya and coconut and single cell oils
Suitability	Suitable for vegetarians Not Halal approved.
Cost per 100ml	19p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p

Claims made

No claims are currently made for this milk on the Arla Foods website except to say that it is EU certified organic.

Castlemil First Infant Milk

This cows' milk based infant formula milks is currently only available on-line from a limited number of retailers. The products are available as powder formulation in 800g tins.

Key components of this product

Table 8: Key components of Castlemil First Infant Milk

Castlemil First Infant Milk	
Powdered infant milk	
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Arachidonic acid, prebiotics, taurine, nucleotides
Allergens	Cows' milk, soya, fish
Protein source	Cows' milk
Whey:casein ratio	60:40
Fats used	Sunflower, rapeseed, palm, coconut, fish and algal oils (single cell oils) milk fat
Suitability	Not suitable for vegetarians Not Halal approved
Cost per 100ml¹	We cannot currently find any on-line retailers stocking this product.
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on powdered formulation)	10p

Claims made

The Castlemil website claims that:

'Whole milk contains high levels of calcium, which is great for your Baby's developing teeth and bones. It is also an abundant source of natural fatty acids and because of this, less manufactured vegetable oil needs to be added to our formulas to reach the required fat content'.

All infant formula contain similar amounts of calcium and the calcium content of cows' milk is not determined by the amount of fat the milk contains, so this is a false claim.

Cow & Gate 1 First Infant Milk

Cow & Gate 1 First Infant Milk is sold in 800g packets of powder, 700g cans of powder (Lidl only) and as 70ml, 200ml and 1 litre RTF (ready-to-feed) bottles.

Key components of this product

TABLE 9
Key components of Cow & Gate 1 First Infant Milk

Cow & Gate 1 First Infant Milk		
	Powdered infant milk	RTF (ready-to-feed) 1 litre bottle
Composition	Meets current regulations for infant formula composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Prebiotics, nucleotides, taurine, arachidonic acid	Prebiotics, nucleotides, taurine, arachidonic acid
Allergens	Cows' milk, soya, fish	Cows' milk, soya, fish
Protein source	Cows' milk	Cows' milk
Whey:casein ratio	60:40	60:40
Fats used	Palm, rapeseed, coconut and sunflower oils Fish and algal oils (single cell oils)	Palm, rapeseed, coconut and sunflower oils Fish and algal oils (single cell oils)
Suitability	Not suitable for vegetarians Halal approved 800g Not halal approved 700g tin purchased in Lidl.	Not suitable for vegetarians Not halal approved
Cost per 100ml	13p	32p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p	10p

Claims made about Cow & Gate 1 First Infant Milk

Cow & Gate do not make specific claims for their First Infant Milk on the product pages of the eln.nutricia website. They simply state some of the ingredients used and make a general claim that these help support healthy growth and development:

Cow & Gate first infant milk contains prebiotic oligosaccharides (OS), nucleotides and a fat blend that includes long chain polyunsaturated fatty acids (LCPs). It also contains calcium: phosphorus in a ratio that aids calcium absorption, and added vitamins and minerals, to help support normal healthy growth and development.

No claims are made for any specific benefit associated with any of these components, and the entire statement is supported by nine references.

Cow & Gate Infant Milk contains nucleotides.

The two papers we think are being used to support the addition of nucleotides are Pickering et al (1998) and Maldonado Lozano et al (2001). Pickering et al studied two groups of healthy term infants that were fed either formula milk supplemented with nucleotides at 7.2mg/100ml or formula that was not supplemented. They reported no differences between the groups at 6 months of age, but at 7 months of age, the supplemented group had significantly higher H influenzae type b and diphtheria humoral antibody responses. The antibody responses to tetanus and polio virus were not enhanced by nucleotide fortification. Maldonado Lozano et al (2001) reviewed the literature on the impact of adding nucleotides to cows' milk based infant formula and concluded that their addition seems to produce a favourable effect on the immune function. Cow & Gate 1 First Infant formula contains 3.2mg nucleotides/100ml and is therefore not equivalent to the milk used in this study.

EFSA (2014) however, reviewing all the evidence in this area have concluded that:

“Taking into account the lack of convincing evidence for a benefit of the addition of nucleotides to IF and/or FOF, the Panel considers that there is no necessity to add nucleotides to IF or FOF.”

Cow & Gate Infant Milk contains LCPs.

The three papers we believe are used to support the addition of LCPs are Willatts et al (1998), Birch et al (1998), and Birch et al (2000).

The Willatts et al (1998) study, funded by Milupa (Danone), considers long chain fatty acid supplementation in term infants through formula supplementation and impact on IQ. Cognitive behaviour was tested at 10 months by a three-step solution to uncovering and retrieving a hidden toy. The authors conclude that there may be some benefit of supplementation with long chain polyunsaturated fatty acids, but whether it is possible to measure cognitive behaviour at this age is debateable.

Birch et al (1998) reported that the supplementation of term infant formula with DHA or with DHA and AA during the first 4 months of life yields better sweep visual evoked potential acuity at 6, 17 and 57 weeks of age but not at 26 weeks when acuity development reaches a plateau.

Birch et al (2000) reported a statistically significant developmental age advantage for DHA and DHA+AA supplemented groups in the cognitive and motor subscales of the Bayley Scales of Infant Development compared to the unsupplemented group, but no such increase was observed for the language, psychomotor development index or behaviour rating scale. On the basis of their results, the authors suggest that early dietary supply of DHA was a dietary determinant of improved performance on the mental development index.

None of these conclusions are supported by EFSA (2014), who conclude that:

“The panel notes there is no convincing evidence that the addition of LCPUFA to IF or FoF has any benefits beyond infancy on any functional outcomes.”

Cow & Gate Infant Milk contains prebiotic oligosaccharides.

The three papers we believe are referenced to support the addition of prebiotics were all sponsored by Numico (Danone).

Arslanoglu et al (2008) extends a previous study (also sponsored by Danone) in which healthy term infants at risk of atopy were fed either a hypoallergenic (hydrolysed) formula supplemented with GOS/FOS or the same formula with placebo of maltodextrins. The aim of this study was to evaluate whether or not protective effects against allergic manifestations and infections observed in an initial 6-month trial and attributed by the authors to GOS/FOS, extended as far as 2 years of life. The authors reported that at 2 years the cumulative incidences of atopic dermatitis, recurrent wheezing and allergic urticaria (itching) were lower in the group that received GOS/FOS compared to the placebo group, but it is difficult to attribute this solely to early formula use.

Bruzzese et al (2009) looked at the impact of standard infant formula supplemented with GOS/FOS on the incidence of intestinal and respiratory infections in a cohort of healthy, term infants. This study reported a lower incidence of gastroenteritis, and fewer children receiving multiple courses of antibiotics within a year for the group receiving supplemented formula.

Knol et al (2005) looked at whether or not standard infant formula supplemented with GOS/FOS was able to establish a bifido-dominant microflora, not only in numbers, but also with respect to the metabolic activity in the colon. After 6 weeks, the mean proportion of *Bifidobacteria* was significantly higher in the group given formula with GOS/FOS and the authors concluded that the addition of the prebiotic GOS/FOS mixture to an infant formula had a stimulating effect on the growth of *Bifidobacteria* and on the metabolic activity of the total intestinal flora.

All of these studies were included in the review by EFSA (2014) but were not accepted as evidence of benefit from the addition of GOS/FOS to infant formula.

Whilst no direct claims are made for Cow & Gate First Infant Milk on the product pages of the eln.nutricia website, the different sections of the feeding problems and allergy pages place great emphasis on prebiotics, the following claims are made on the page for constipation:

"Q6 How can healthcare professionals advise parents who switch between formula milks?

...Choosing one which contains prebiotic oligosaccharides has been shown to increase the growth of friendly bacteria (including bifidobacteria and lactobacilli) - an integral part of an infant's immune system. Prebiotic oligosaccharides have also been shown to decrease the numbers of potentially pathogenic bacteria and help soften stools..."

These statements are supported by reference to clinical trials conducted by Numico (Danone) Research in which 90 healthy term infants were randomly allocated to receive formula milk supplemented with oligosaccharides over a period of 28 days (Moro et al, 2002). The authors reported that after 28 days there was a dose-dependent increase in the number of *Bifidobacteria* in the stools of both groups receiving GOS/FOS, but this alone

does not provide evidence of clinical benefit. The particular blend of oligosaccharides used in Cow & Gate Infant Milks was subject to a wide range of clinical trials carried out by, or sponsored by, the then parent company Numico (now Danone).

The study by Knol et al (2005) which is used again to support the claim that the specific blend of prebiotics used discourages the growth of harmful pathogens. However, this study looked at whether or not standard infant formula supplemented with GOS/FOS is able to establish a bifido-dominant microflora. It does not therefore directly support the claim concerning harmful pathogens.

The study by Moro et al (2002) is used to support claims related to increased stool softness, despite this being generally a subjective measure. Moro et al (2002) reported that stool softness was only increased in the group receiving formula supplemented at 0.8g/dL and not in those receiving 0.4g/100ml GOS/FOS. Cow & Gate 1 First Infant Milk is currently supplemented at a rate of 0.6g/100ml, but this infant formula is different to the one used in the studies as it has a lower protein and fat content, a different range of added ingredients and a higher osmolality.

Nutricia have previously made claims for the use of their blend of GOS/FOS on the allergy pages of the website:

...our unique GOS/FOS blend is clinically proven to reduce the risk of developing allergic manifestations and severity of symptoms for up to five years

Two papers by Arslanoglu et al, one published in 2008 and the other in 2012, and a paper by Pampura et al (2014) are used in support of the claims made concerning allergic manifestations and their severity. The two studies by Arslanoglu et al are from a series of studies which follow the same cohort of children at risk of atopy from the first 6 months of life to 5 years. The original study by Arslanoglu et al (2007) reports on the impact of supplementation of hypoallergenic, hydrolysed whey-based formula milk with either 0.8g/100ml GOS/FOS or 0.8g/100ml maltodextrin as placebo on atopic dermatitis and allergy symptoms in the first 6 months of life. The two Arslanoglu et al (2008) and Arslanoglu et al (2012) studies cited extend the previous (flawed) study published in 2007 to 2 years and 5 years respectively. At 5 years only 42 children remained in the intervention group from the 102 original completers.

The original study (Arslanoglu et al, 2007) was reviewed and discounted as evidence by earlier reviews of efficacy of benefit from oligosaccharide addition to infant formula and was also reviewed by EFSA (2014).

The study by Pampura et al (2014) was a small Russian multicentre study of 51 infants of about 6 months of age with symptoms of atopic dermatitis. The infants were fed hydrolysed Nutrilon containing Nutricias' patented blend of GOS/FOS. The study reports a reduction in symptoms of atopic dermatitis after 4 weeks of feeding with the test formula. As the test formula was based on hydrolysed whey protein, it is not possible to establish links between the inclusion of GOS/FOS and the amelioration of the symptoms of atopic dermatitis.

Whilst this claim no longer appears on the Cow & Gate First Infant Milk pages of the website, a similar claim is still being made for another Danone product, Aptamil First Milk.

Claims for the addition of GOS/FOS have been made for many years, despite a clear statement from EFSA (2014) that:

“There is insufficient evidence for beneficial effects on infant health of the oligosaccharides that have been tested to date in RCTs when added to infant or follow-on formula.”

Our conclusion

Cow & Gate 1 First Infant Milk meets the required compositional criteria for infant formula.

This milk contains a similar range of unnecessary added ingredients as other brands on the market. It offers no evidence-based advantage over any other first infant milk.

The GOS/FOS blend used by Cow & Gate has been emphasised on the website, creating the impression that this is superior to those used by other manufacturers, but the evidence used to support the inclusion of any type or blend of prebiotic has been clearly refuted by EFSA.

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Hipp Organic Combiotic First Infant Milk

This milk is available as a powdered formulation in 800g powder packs and as 200ml and 90ml RTF (ready-to-feed). Table 8 gives details for the powder and 200ml RTF.

Key components of this product

TABLE 10
Key components of Hipp Organic Combiotic First Infant Milk

Hipp Organic Combiotic First Infant Milk		
	Powder	RTF (ready-to-feed) 200ml carton
Composition	Meets current regulations for infant formula composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Prebiotics, arachidonic acid	Prebiotics, arachidonic acid,
Allergens	Cows' milk, fish	Cows' milk, soya
Protein source	Cows' milk	Cows' milk
Whey:casein ratio	60:40	60:40
Fats used	Rapeseed, palm and sunflower oils Fish and algal oils (single cell oils)	Rapeseed, palm, coconut and sunflower oils Fungal and algal oils (single cell oils)
Suitability	Not suitable for vegetarians Not halal approved	Not suitable for vegetarians Not halal approved
Cost per 100ml	15p	38p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p	10p

Claims made for this product

Hipp are no longer making the claims for product composition and efficacy previously seen on the website and in print literature and now have a simple statement on their website that says:

'HiPP gentle organic formula is specially formulated using only the finest organic milk and contains Omega 3 & 6 LCPs (DHA & AA) and PRÆBIOTIK® oligosaccharides (GOS), as well as all the important vitamins, minerals and other nutrients (required by law) that babies need to grow strong and healthy'

No direct health claims are now made for health benefits of either fatty acids or oligosaccharides in Hipp Organic Combiotic First Infant Milk and no evidence is provided to explain why these are added.

Hipp do however make claims for the benefits of their organic formula milks over milks produced using conventional farming methods:

All infant and follow on milks are required to meet strict regulations to make sure they are nutritionally adequate for baby - but our Combiotic® range has the added benefits that come from using organic ingredients

Some of the benefits claimed for the Combiotic range include:

'making sure there are no pesticides used on the farms where the cows graze: babies are known to be more susceptible to the effects of pesticide residues so choosing an organic diet for babies is very important'

Whilst the organic status of Hipp Organic Combiotic First Infant Milk distinguishes it from most other infant milks on the UK market, it is important to note that there are limits on the level of any individual pesticide residue that may be present in infant formula and follow-on formula and specific upper limits for toxic pesticides.

'Our milks are tested for purity at every stage of production'

There is however no indication of what the product is tested for or how this compares to the testing of products from other manufacturers that might suggest that their organic product is more beneficial.

Hipp Organic previously claimed on their website that research shows that:

'..babies consuming organic dairy products are less likely to suffer from atopic eczema'

The authors of the report referenced to support this statement speculate that the protective effect reported may be due to a high intake of n-3 fatty acids and/or conjugated linoleic acid from organic dairy products (Kummeling et al, 2008). It is important to point out that this research does not support the use of organic infant milk as protective against eczema as no information other than whether or not the infant received breastmilk was collected for the first year of life, during which time maternal diet was used as a proxy for infant diet. The authors

concluded that it was uncertain whether their finding represented a true association and that it should be interpreted with caution (Kummeling et al, 2008).

Whilst this claim no longer appears on the website, the referenced study remains despite not supporting any of the other claims made.

It is important to note that whilst these claims are made for the Combiotic range, Hipp Combiotic Growing-up Milk 4 and Hipp Combiotic Comfort Milk are not certified organic.

Our conclusion

Hipp Organic Combiotic First Infant Milk meets all the required compositional criteria for infant formula.

In our opinion it offers no clinical advantage over any other first infant milk, but it has fewer unnecessary ingredients added than some other types of milk and is organically certified.

References

Kummeling I, Thijs C, Huber M et al. (2008) Consumption of organic foods and risk of atopic disease during the first 2 years of life in the Netherlands. *British Journal of Nutrition* 99 ,598-605

Holle Organic Infant Formula 1

This organic cows' milk based infant formula is available in specialist health food shops in powdered form in the UK. It is imported from Switzerland.

Key components of this product

TABLE 11: Key components of Holle Organic Infant Formula 1

Holle Organic Infant Formula 1	
Powdered infant milk (400g box)	
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	None
Allergens	Cows' milk
Protein source	Cows' milk
Whey:casein ratio	57:43
Fats used	Palm, rapeseed and sunflower oils
Suitability	Not suitable for vegetarians Not halal approved
Cost per 100ml	28p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p
Preparation instructions	The instructions recommend that the formula is made up with water at 50°C which is not in line with UK recommendations. We recommend that the formula is made up following UK guidance.

Claims made

No specific claims are made for this milk except that the milk used to prepare this infant formula is 'biodynamic.' Biodynamic farming shares many principles with organic farming but also has a spiritual-ethical dimension. Information about biodynamic farming can be found at www.biodynamics.com.

Holle Organic Infant Goat Milk Formula 1

This organic goats' milk based infant formula is available in specialist health food shops in powdered form in the UK. It is imported from Switzerland.

Key components of this product

TABLE 12: Key components of Holle Organic Infant Goat Milk Formula 1

Holle Organic Infant Goat Milk Formula 1	
Powdered infant milk (400g box)	
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	None
Allergens	Goats' milk
Protein source	Goats' milk
Whey:casein ratio	17:83
Fats used	Palm, rapeseed and sunflower oils
Suitability	Suitable for vegetarians* Not halal approved
Cost per 100ml	53p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p
Preparation instructions	The instructions recommend that the formula is made up with water at 50°C, which is not in line with UK recommendations. We recommend that the formula is made up following UK guidance.

*Awaiting reconfirmation from manufacturer

Claims made

No specific claims are made for this milk, except that the milk used to prepare this infant formula is organic.

Kabrita Gold 1

This goats' milk based formula is available in 800g tins in specialist food shops.

Key components of this product

TABLE 13: Key components of Kabrita Gold 1

Kabrita Gold 1	
	Powdered infant milk
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Prebiotics, taurine arachidonic acid
Allergens	Goats' milk, fish, soya
Protein source	Goats' milk
Whey:casein ratio	64:36
Fats used	Soybean, sunflower and palm kernel oil; with high sn-2 palmitic acid oil
Suitability	Not suitable for vegetarians Not halal approved
Cost per 100ml	33p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p

Claims made

Is naturally easy to digest (due to a unique fat and protein composition).

It is naturally rich in important nutrients such as Ca and vitamin A, and has a high bio-availability of iron.

It has a deliciously mild taste.

Kabrita contains our special DigestX OPO-fat blend (also known as beta-palmitate). Breast milk is known to contain a high amount of beta-palmitate and contributes to the typical breast-fed stools and calcium absorption.

Kabrita also contains prebiotic fibers: GOS / FOS. These fibers have a positive effect on the bacterial composition in the gut by stimulating growth of beneficial bacteria (Bifido- and lactobacilli).

No evidence is given on the website to support any claim, but many of the claims made are similar to those made elsewhere for infant formula that we do not believe are supported by evidence. This milk meets current compositional requirements, and is more modified than other goats' milk based formula.

Note: The website for this brand of infant formula is based in Europe and the instructions for making up the milk on this website are not in line with current UK recommendations. However, the product sold in the UK does have appropriate labelling for making the product up safely, and these are the instructions that should be followed.

Kendamil 1 First Infant Milk

This cows' milk based infant formula manufactured by Kendal Nutricare is currently available in the North West of England and in selected Morrisons and Asda supermarkets nationwide. The product is available in the UK as powder formulation only in 150g bag in box, 400g and 900g tins.

Key components of this product

TABLE 14: Key components of Kendamil 1 First Infant Milk

Kendamil 1 First Infant Milk	
Powdered infant milk (900g tin)	
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Arachidonic acid, prebiotics, taurine, nucleotides
Allergens	Cows' milk
Protein source	Cows' milk
Whey:casein ratio	60:40
Fats used	Sunflower, coconut, canola and algal oils (single cell oils), whole milk fat
Suitability	Suitable for vegetarians Halal approved
Cost per 100ml	13p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p

Claims made

Kendal Nutricare make the following claims for their Kendamil milks on the company website:

'Milder and more natural taste than formulas made from skimmed milk'

'Retains all the natural goodness and benefits of full cream nutrients'

'Better suited for sensitive babies digestive systems than skimmed milk products'

'Formulated to include the essential nutrients your baby needs to complement a balanced weaning diet'

These claims are not substantiated by reference to either scientific or anecdotal evidence. It is important to ensure families do not believe that whole animal 'full-cream' milk is a breastmilk alternative. Claims suggesting that full cream milk is full of natural goodness and more wholesome for infants could be misleading.

The company website states that the product is made using whole milk. Whilst whole milk is used in the product manufacture, after drying, it only accounts for about 16% of the dry weight of the powder, the majority being composed of whey powder, vegetable oils and lactose.

Kendamil Mehadrin First Infant Milk

This cows' milk based infant formula manufactured by Kendal Nutricare has been specifically formulated and manufactured to comply with the beliefs and practices of Orthodox Jewish parents and carers. It is currently distributed via Global Kosher and is available only in stores they supply in London, Manchester and Gateshead. The infant milk is marketed as suitable for infants from birth to 12 months and is available in the UK as powder formulation only in 150g bag in box and in 800g tins.

Key components of this product

TABLE 15: Key components of Kendamil Mehadrin First Infant Milk

Kendamil Mehadrin First Infant Milk	
	Powdered infant milk (800g tin)
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Arachidonic acid, taurine, nucleotides
Allergens	Cows' milk
Protein source	Cows' milk
Whey:casein ratio	60:40
Fats used	Rapeseed, coconut, sunflower and algal oils (single cell oils) milk fat
Suitability	Suitable for vegetarians Suitable for those following a Kosher diet.
Cost per 100ml	20p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p

Claims made

No specific health claims are made for this milk on the company website, however it does state that the product is made using whole milk.

Whilst whole milk is used in the product, after drying, it only accounts for about 11% of the dry weight of the powder, the majority being composed of lactose, vegetable oils and skimmed milk powder.

Kendamil Organic First Infant Milk

This organic cows' milk based infant formula manufactured by Kendal Nutricare is currently available in the UK as powder formulation only in 800g tins. It is currently only available at Sainsbury's stores.

Key components of this product

TABLE 16. Key components of Kendamil Organic First Infant Milk

Kendamil Organic First Infant Milk	
	Powdered infant milk (800g tin)
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	None
Allergens	Cows' milk
Protein source	Cows' milk
Whey:casein ratio	60:40
Fats used	Sunflower, coconut and rapeseed oils and milk fat
Suitability	Halal approved.
Cost per 100ml	19p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p

Claims made

Kendal Nutricare make the following claims for their Kendamil organic milks on the company website:

'Milder and more natural taste than formulas made from skimmed milk'

'Retains all the benefits of full cream nutrients'

'Formulated to include the essential nutrients your baby needs'

These claims are not substantiated by reference to either scientific or anecdotal evidence. It is important to ensure families do not believe that whole animal 'full-cream' milk is a breastmilk alternative. Claims suggesting that full cream milk is full of natural goodness and more wholesome for infants could be misleading.

Mamia First Infant Milk

Mamia milk is marketed in ALDI stores and is sold as powder only in 900g tins.

Key components of this product

TABLE 17: Key components of Mamia First Infant Milk

Mamia First Infant Milk	
Powdered infant milk 900g tin	
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Arachidonic acid, prebiotics, taurine, nucleotides
Allergens	Cows' milk, soya, fish
Protein source	Cows' milk
Whey:casein ratio	60:40
Fats used	Palm, palm kernel, sunflower, rapeseed, fish and soya oils
Suitability	Not suitable for vegetarians Halal approved
Cost per 100ml¹	10p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on powdered formulation)	10p

There is currently no marketing information in the UK for this product but we will update this section if this becomes available.

The milk meets the compositional criteria required for infant milks.

For information about protein in infant milks see the report *Infant Milks in the UK* at www.firststepsnutrition.org.

NANNYcare First Infant Milk

NANNYcare First Infant Milk is a goats' milk formula. It is available in powder form in 400g and 900g tins at some supermarkets and in specialist food shops.

Key components of this product

TABLE 18: Key components of NANNYcare First Infant Milk

NANNYcare First Infant Milk	
	Powdered infant milk
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Taurine
Allergens	Goats' milk
Protein source	Goats' milk
Whey:casein ratio	20:80
Fats used	High oleic sunflower, rapeseed and sunflower oils
Suitability	Not suitable for vegetarians Halal approved
Cost per 100ml	29p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p

Claims made

The only goat milk formula supported by clinical trials

On the manufacturer's website, reference is made to a trial by Zhou et al (2014) which was used as evidence to EFSA (2012) when they reviewed the safety of goats' milk protein as a source of protein in infant formula. NANNYcare First Infant Milk was the formula used in that study. The EFSA recommendation was that milk from goats' milk or cows' milk can be a suitable protein source for infant formula provided the final product complies with the composition criteria laid down in the relevant EU Directive. The EFSA panel highlights that, if goat milk protein is used in infant formula, particular attention has to be given to the amino acid content by adding in appropriate free amino acids to ensure that the profile is adequate.

The following claims are also made:

Goat milk:

Is an excellent source of high quality, readily digestible proteins.

Forms looser, softer and more porous curds in the baby's stomach. (This is particularly helpful to the baby's delicate developing digestive system.)

Has a casein profile which is closer to human milk (than cow's milk).

Has high levels of medium-chain fatty acids.

Has high levels of nucleotides.

No evidence is provided on the website to support these claims.

In their evaluation of the suitability of goats' milk protein as the protein source in infant formula, EFSA clearly state that, while they note the differences in the composition of the caseins between goat and cow milk, no difference in digestibility has been observed (EFSA, 2012). In addition they state that there is no convincing evidence to support a lower incidence of allergic reactions in infants fed formula based on goats' milk protein compared with those fed cows' milk protein based formula.

The relevance of high levels of medium-chain fatty acids or nucleotides is not explained, but as stated previously, whether an infant formula is made from cows' or goats' milk protein, the composition has to meet current regulations.

References

European Food Safety Authority (2012). *Scientific opinion on the suitability of goat milk protein as a source of protein in infant formulae and in follow-on formulae*. Parma, Italy: European Food Safety Authority. Available at: <http://www.efsa.europa.eu/en/efsajournal/pub/2603.htm>

Zhou SJ, Sullivan T, Gibson RA et al (2014). Nutritional adequacy of goat milk infant formula for term infants: a double blind randomised controlled trial. *British Journal of Nutrition* 111: 1641-51.

Sainsbury's Little Ones First Infant Milk

This cows' milk based infant formula is marketed as suitable for infants from birth to 12 months and is available in the UK as powder formulation in 900g cartons.

Key components of this product

TABLE 19: Key components of Sainsbury's Little Ones First Infant Milk

Sainsbury's Little Ones First Infant Milk	
Powdered infant milk (900g carton)	
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Arachidonic acid, prebiotics, taurine, nucleotides
Allergens	Cows' milk
Protein source	Cows' milk
Whey:casein ratio	60:40
Fats used	Sunflower, coconut and canola oils, milk fat
Suitability	Suitable for vegetarians Not halal approved.
Cost per 100ml	10p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p

Claims made

No specific health claims are made for this milk on Sainsbury's website, however it does state that the product is made using whole milk.

Whilst whole milk is used in the product, after drying, it only accounts for about 16% (our estimate based on other products using a similar quantity of whole milk) of the dry weight of the powder, the majority being composed of lactose, vegetable oils and skimmed milk powder.

SMA Advanced First Infant Milk

This cows' milk based infant formula is marketed as suitable for infants from birth to 12 months and is available in the UK as powder formulation in 800g tins.

Key components of this product

TABLE 20: Key components of SMA Advanced

SMA Advanced First Infant Milk	
	Powdered infant milk (800g tin)
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Structurally identical human milk oligosaccharides 2'FL LNnT, arachidonic acid, taurine, nucleotides
Allergens	Cows' milk, fish oil
Protein source	Cows' milk
Whey:casein ratio	100:0
Fats used	Sunflower oil, coconut and rapeseed oils
Suitability	Not suitable for vegetarians Not halal approved.
Cost per 100ml	24p
<i>For comparison:</i>	10p
Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	

Claims made

On the website www.smahcp.co.uk it is stated that

This formula contains structurally identical Human Milk Oligosaccharides (HMOs)* which is the latest breakthrough in infant nutrition.

****HMOs: structurally identical Human Milk Oligosaccharides, not sourced from breast milk.***

The structurally identical human-milk oligosaccharides (HMO) added are 2'-Fucosyllactose (2'FL) and Lacto-N-neotetraose (LNnT). Additional information can be downloaded about the product in a 'leave piece' and this provides 7 pages of information and claims about the benefits of adding structurally identical HMOs to infant formula. On page 4 of this document a series of claims are made based on evidence from 1 clinical trial.

- **70% lower risk of parent-reported bronchitis**
- **55% lower risk of parent-reported lower respiratory tract infections**
- **More than 50% lower use of antipyretics and antibiotics.**

The claims are based on a single trial conducted by Puccio et al (2017), which enrolled fully formula fed infants at 14 days or younger, randomised to either a test or control infant formula for 6 months. The study was sponsored by Nestlé and five of the study authors were employed in Nestlé funded centres. Nestlé also funded editorial assistance for paper preparation.

The test and control formula used in the trial were identical apart from the addition of the two artificial oligosaccharides (1.0g of 2'FL and 0.5g LNnT per litre, replacing lactose). The authors provided limited information about the formula saying that it has 67kcal/100ml, contained long-chain polyunsaturated fatty acids, 1.8g protein/100kcal (equivalent to 1.2g/100ml) and a whey casein ratio of 70:30. It should be noted that the Nestlé Advanced range of milks for which claims based on this paper are being made are 100% whey based and therefore not the same as this test formula. The authors acknowledged they did not measure the osmolality of the two products. Families were given the test and control formula for 6 months and then both groups were given the same un-supplemented follow on formula from 6 months, with complementary foods allowed from 4 months.

The study was conducted between 2012-2015 in Italy and Belgium. There was no breastfed reference group recruited for this study. The primary outcome measure was weight gain between enrolment and 4 months of age, and the sample size was powered for this outcome. A series of secondary outcomes were included drawing on diary data collected by the parents on stooling, and from structured questions and grids on which parents recorded a range of other variables from colic, flatulence, being irritable and waking in the night to illnesses and medication use. 175 infants were enrolled in the study, but 44 infants (20 in control, 24 in the test group, i.e. 25% overall) withdrew before the 4 month primary outcome measurement. The primary outcome was similar weight gain in both groups, which was to be expected when the test and control formula were identical in nutrient composition. Intake of formula was similar in both groups.

As well as reporting on the primary outcome (weight gain between enrolment and 4 months) the authors reported on a range of secondary outcomes which form the basis of the positive health benefits suggested. However, it is important to remember that the study was not powered to have these as primary outcomes; the study sample was relatively small, which limited its statistical power, created a greater chance of discovering differences which didn't really exist and meant that any differences detected were likely larger than the reality; some outcomes were only reported for small sub-groups or at specific time points; the outcomes were reported by parents, so are not as objective as those assessed by a clinician and there was no reference group of breastfed babies to compare optimal outcomes with these outcomes of fully formula fed babies.

Secondary outcomes reported:

GI symptoms (flatulence, spitting up and vomiting) showed no significant difference between the two groups. Stool softness showed no significant difference between the two groups at any visit, except a small (but apparently significant) difference reported at two months. The authors reported that a sub-group of infants delivered by caesarean section (about a 1/3 of the sample) were reported to have colic (based on simplistic categorical parental report) less frequently at four months and simple categorical reporting of child waking was suggested by the authors to show a small but significant difference between test and control formula groups in the first two months only. As described above, this fishing for outcomes at different ages and in sub-groups has highly questionable validity.

When assessing morbidity, there were no statistically significant differences between the two groups in reports of 'adverse events' across all the categories investigated, with the authors reporting that the group of 'infections and infestations' were '*approaching statistical significance*' difference between the two groups. Within the 'infections and infestations' category the authors claimed statistically significant differences in the parentally reported outcomes of bronchitis, lower respiratory tract infection, antibiotic and antipyretic use, but some of these differences were at certain time points only. No significantly different outcomes were reported for other infections.

The trial findings do not prove health benefits from the addition of the two artificial HMOs to the test formula, and the authors (Puccio et al, 2017) accept that all these findings need to be properly considered in further studies. A paper published in 2018 by Vandenplas et al (2018) - with an authorship with considerable conflict of interest, including Nestlé Nutrition Institute staff - acknowledged that there are no established benefits for the addition of HMOs to infant formula.

Our conclusion

SMA Advanced First Infant Milk meets the required compositional criteria for infant formula.

This infant formula offers no evidence-based advantage over any other first infant milk. The claims made for the addition of 2 structurally identical human milk oligosaccharides are supported by one clinical trial, that in our opinion, does not provide suitable and robust evidence for the claims made. For more information on claims related to this infant milk see www.firststepsnutrition.org/statements.

References

Puccio G, Alliet P, Cajozzo C, Janssens E, Corsello G et al (2017). Effects of infant formula with human milk oligosaccharides on growth and morbidity: a randomized multicentre trial. *Journal of Pediatric Gastroenterology and Nutrition*, **64**, 624-631.

Vandenplas Y, Berger B, Carnielli VP, Ksiazek J et al (2018). Human milk oligosaccharides: 2'-Fucosyllactose (2'FL) and Lacto-N-Neotetrose (LNnT) in infant formula. *Nutrients*, **10**, 1161-1173.

SMA Little Steps First Infant Milk

This cows' milk based infant formula is marketed as suitable for infants from birth to 12 months and is available in the UK as powder formulation in 800g tins.

Key components of this product

TABLE 21: Key components of SMA Little Steps First Infant Milks

SMA Little Steps First Infant Milk	
Powdered infant milk (800g tin)	
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Taurine
Allergens	Cows' milk, fish oil, soya lecithin
Protein source	Cows' milk
Whey:casein ratio	60:40
Fats used	Sunflower, coconut and rapeseed oils
Suitability	Not suitable for vegetarians Halal approved.
Cost per 100ml	12p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p

Claims made

No specific health claims are made for this milk on SMA or the SMA health professional website. On the health professional website it suggests there is a 'leave piece' for information about this formula but the link is not active and it currently says next to this that *'more information is coming soon on our new website.'*

SMA Organic First Infant Milk

SMA Organic First Infant Milk is available as powdered infant formula only. It is available in Tesco, Asda, Morrisons, Boots, Sainsburys, Ocado and Amazon.

Key components of this product

TABLE 22: Key components of SMA Organic First Infant Milk

SMA Organic First Infant Milk	
	Powdered infant milk (900g carton)
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Arachidonic acid
Allergens	Cows' milk
Protein source	Cows' milk
Whey:casein ratio	70:30
Fats used	Sunflower, rapeseed
Suitability	Not suitable for vegetarians Halal approved
Cost per 100ml	22p
<i>For comparison:</i>	10p
Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	

What claims are made for this infant formula?

SMA Organic First Infant Milk has a low protein content of 1.27 g/100 ml (1.89 g/100 kcal), and is whey-dominant making it easy to digest

This is supported by reference to the NHS Choices website which states that whey-based formula milks are suitable for newborns as they are thought to be easier to digest than casein-based formula milks (NHS Choices, 2014). This is not unique to SMA Pro as all first infant formula based on cows' milk available in the UK are based on whey protein.

A lower protein content formula has been shown to provide growth rates more like a breastfed baby.

This claim is supported by reference to a meta-analysis of eleven Nestlé sponsored studies looking at the growth of infants fed with Nan milk with a protein content of 1.8g/100kcal (Alexander et al., 2016). It is not surprising that this study showed that for the breastfed group and both formula fed groups, the pooled group analysis for BMI, weight for age, length

for age and head circumference for each of the groups was within 0.5 standard deviations of the WHO Growth Standard, as the protein levels were within the EU regulations for infant formula milks.

What the study also showed, however, were significant differences in both growth and rate of growth between the breastfed and formula fed groups. Formula fed infants in both formula groups had significantly greater BMI and weight for age at 4 months than the breastfed group. When rates of growth were categorised as slow, gradual and fast there were no significant differences between groups for the proportion of the group in the gradual growth group but significantly more infants from the formula fed groups were in the fast group and less in the slow group compared to the breastfed group. This does not support the claim that this milk has been shown to provide growth rates comparable with a breastfed baby. It is established internationally that infant formula-fed infants grow at a different pace to breastfed infants (Garza and de Onis, 2004). SMA Organic First Infant Milk does not appear to be the same as the one used in the studies which they say support this claim.

This slower growth rate has been linked to long-term health benefits, including a lower risk of obesity, cardiovascular disease and diabetes.

This statement is referenced with a review article by Singhal et al, 2004 on the association between early nutrition and later risk for cardiovascular disease, obesity and diabetes. Since this time there has been a significant reduction in the protein content of most infant formula milks on the UK market.

SMA are linking the 2 claims above to suggest that their lower protein formula leads to slower growth rates than formula milks with a higher protein content, which in turn may reduce later risk for obesity, cardiovascular disease and diabetes, however, the role of protein in increased growth rate and higher BMI in childhood is still a matter of debate and requires more research (EFSA, 2014). SMA Organic currently has a stated protein content of 1.25g/100ml, which is similar to other infant formula on the UK market, most of which are at the lower end of the minimum-maximum protein range of the EU Regulations providing a protein content of 1.2g - 1.3g/100ml. It is worth noting that at 1.6g/100ml, Aldi Mamia infant milk provides the highest level of protein of all of the cows' milk based infant formula on the UK market.

SMA Organic First Infant Milk contains Omega 3 and 6 LCPs for brain and eye development.

This statement is supported by reference to a review article by Koletzko et al (2008) which summarises the evidence for the role of DHA and AA in maternal and term infant nutrition as well as infant development, and makes recommendations concerning their inclusion in the infant diet. The review concluded that the foetus and neonate should receive LC-PUFA in amounts sufficient to support optimal visual and cognitive development. It recommended breastfeeding as the best way to achieve this and that if breastfeeding were not possible, formula supplemented with DHA and AA should be used. DHA supplementation should be at levels between 0.2 and 0.5 weight percent of total fat, with the minimum amount of AA equivalent to the contents of DHA.

In 2009, EFSA approved the claim that “DHA contributes to the visual development of infants” (EFSA, 2009). However, the validity of this claim is still debated, as it is argued that

visual acuity develops slowly during the early years of life and early observations of visual measurements in infants are not predictive of later visual functions. Studies would have to follow children for seven years or longer to see if small clinical changes observed in early life had any real impact (Chambers et al, 2013).

The EFSA *Scientific opinion on the essential composition of infant and follow-on formulae* (EFSA, 2014) presents a useful summary of all the evidence relating to fatty acids in human and artificial milks, but concludes that, whilst they still believe that DHA should be added to infant and follow-on formulae in similar amounts as are present in breastmilk as a 'prudent measure':

"The panel notes there is no convincing evidence that the addition of LCPUFA to IF or FoF has any benefits beyond infancy on any functional outcomes."

Our conclusion

SMA Organic First Infant Milk meets the required compositional criteria for infant formula.

This infant formula offers no evidence-based advantage over any other first infant milk. The reduced protein emphasised on the website is similar to other infant formula milks on the UK market.

This milk is significantly more expensive than other brands of organic first infant milk which may offer better value for money.

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SMA Pro First Infant Milk

SMA Pro First Infant Milk is available as powdered infant formula, a 70ml RTF (ready-to-feed) formulation and in 200ml and 1 litre RTF cartons.

Key components of this product

TABLE 23: Key components of SMA Pro First Infant Milk

SMA Pro First Infant Milk		
	Powder formulation	RTF (Ready to feed) 1 litre carton
Composition	Meets current regulations for infant formula composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Prebiotics, taurine, arachidonic acid	Taurine, arachidonic acid, nucleotides
Allergens	Cows' milk, soya, fish	Cows' milk, soya, fish
Protein source Whey:casein ratio	Cows' milk 70:30	Cows' milk 65:35
Fats used	Palm, rapeseed, coconut and sunflower oils Fish and algal oils (single cell oils)	Palm, rapeseed, coconut and sunflower oils Fish and algal oils (single cell oils)
Suitability	Not suitable for vegetarians Halal approved	Not suitable for vegetarians Halal approved
Cost per 100ml	16p	35p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p	10p

What claims are made for SMA Pro?

The quantity of protein has been reduced.

SMA Nutrition claim to have used a “*new exclusive protein process*” to produce the protein component of their infant milk. No information is given on the website to explain what this process is, but in an email to First Steps Nutrition Trust, Nestlé Nutrition said that:

“This patented process allows SMA Nutrition to reduce the total protein content in SMA PRO First Infant Milk to 1.25g/100ml (1.87g/100kcal) in line with scientific opinion while maintaining a desirable amino acid profile.”

This infant milk claims to have the lowest protein content of any infant milk on the market. However, the difference is not sufficiently significant to differentiate it from all other brands; the difference in protein content between it and the brand with the next lowest protein content is 0.02g/100kcal (0.01g/100ml).

It has been suggested that a higher protein content in infant formula is associated with higher weight in the first two years of life (Koletzko et al, 2009). This association is thought to be a result of higher levels of circulating branched chain amino-acids in formula-fed infants compared to breastfed infants. Concentrations of these amino-acids are linked to insulin release, which in turn is linked to metabolic alterations which might be mechanisms for weight gain (Trabulsi et al, 2011). These two factors are being linked to suggest that lower protein milks may reduce weight gain in formula-fed infants, but whether protein plays a role in increased growth rate and higher BMI in childhood is still a matter of debate and requires considerably more research (EFSA, 2014).

Currently the four most commonly purchased infant formulas on the UK market all have around 1.3g protein/100ml. All infant formula must contain amino-acids in amounts specified in the regulations.

The SMA professional website claims that SMA Pro First Infant Milk is a:

Nutritionally complete infant milk with a unique protein profile that is closer to breastmilk

SMA PRO First Infant Milk has lower levels of insulinogenic amino acids compared with other first infant milks.

Insulinogenic amino acids are shown to contribute to obesity later in life.

There are, however, no articles from peer-reviewed journals to support these claims, and all of the claims above are referenced only as “*on file at Nestlé*”. We have asked for this data but it has not been provided.

Further claims made on the SMA Professional website include that SMA Pro First Infant Milk:

Is the only First Infant Milk clinically proven to achieve a growth rate comparable with a breastfed baby.

This claim is supported by reference to a meta-analysis of eleven Nestlé sponsored studies looking at the growth of infants fed with Nan milk with a protein content of 1.8g/100kcal (Alexander et al., 2016). It is not surprising that this study showed that for the breastfed group and both formula fed groups, the pooled group analysis for BMI, weight for age, length for age and head circumference for each of the groups was within 0.5 standard deviations of the WHO Growth Standard, as the protein levels were within the EU regulations for infant formula milks.

What the study also showed, however, were significant differences in both growth and rate of growth between the breastfed and formula fed groups. Formula fed infants in both formula groups had significantly greater BMI and weight for age at 4 months than the breastfed group. When rates of growth were categorised as slow, gradual and fast there were no significant differences between groups for the proportion of the group in the gradual growth group but significantly more infants from the formula fed groups were in the fast group and less in the slow group compared to the breastfed group. This does not support the claim that this milk is clinically proven to achieve a growth rate comparable with a breastfed baby.

It is established internationally that infant formula-fed infants grow at a different pace to breastfed infants (Garza and de Onis, 2004). It is unclear whether SMA Pro First Infant Milk is the same milk as the one used in the studies which they say support this claim, currently SMA Pro First Infant Milk has a protein content 1.87g/100kcal.

The website also claims that SMA Pro First Infant Milk is:

Easy to digest

This is supported by reference to the NHS Choices website which states that whey-based formula milks are suitable for newborns as they are thought to be easier to digest than casein-based formula milks (NHS, 2014). This is not unique to SMA Pro as all first infant formula based on cows' milk available in the UK are based on whey protein.

Contains GOS/FOS for increased gastrointestinal comfort and softer stools similar to that of a breastfed infant.

They provide references from two clinical trials to support this statement, one from Moro et al (2002) and the other from Vivatvakin et al (2010). In the study by Moro et al (2002), 90 healthy term infants were randomly allocated to receive formula milk supplemented with oligosaccharides at a concentration of 0.4g/100ml or 0.8g/100ml or placebo, over a period of 28 days. The infants receiving the formula milk supplemented with oligosaccharides showed a dose-dependent increase in the amount of *Bifidobacteria* in stools, but this may have no clinical significance. Stool softness was increased in the group receiving formula supplemented at 0.8g/100ml. The concentration of oligosaccharides which were used in the formula that resulted in greater stool softness was double that currently used in SMA Pro First Infant Milk.

Vivatvakin et al (2010) reported that infants fed a whey-based infant formula supplemented with oligosaccharides and long-chain polyunsaturated fatty acids had fewer hard stools and more soft stools than infants fed a casein-based formula with no additional ingredients. Infants fed the whey-based formula also had a microbiota composition and gastric and intestinal transit times closer to those of breastfed infants. The authors concluded that, based on parental reports of regurgitation, vomiting, crying and colic, whey-based formula supplemented with oligosaccharides and LCPs provides superior gastrointestinal comfort than casein-based formula that does not contain these added ingredients.

This trial was sponsored by Nestlé and does little to support the use of oligosaccharides in infant formula because the parental reported effects could not be attributed solely to the presence of GOS/FOS, as one of the trial formula milks was whey-based and the other

casein-based. Current recommendations in the UK are that a first infant formula should be whey-based as whey is thought to be easier to digest than casein.

It is worth noting that only SMA Pro powdered formula contains GOS/FOS, not the ready-to-feed formula, suggesting that the company itself may not be convinced of the benefit of adding prebiotic: if it was, GOS/FOS would be added to all formula.

EFSA (2014) state that:

“there is no evidence for health benefits from the addition of prebiotic oligosaccharides (GOS/FOS) to infant or follow-on formula.”

Although LCPs can be made in the body, infants have a high demand for these nutrients. SMA PRO First Infant Milk contains Omega 3 and 6 LCPs.

It is a regulatory requirement that infant formula provides a specific fatty acid profile, and it is not clear how the claim being made here about fatty acids in the milk relate to mandatory versus optional ingredients.

Our conclusion

SMA Pro First Infant Milk meets the required compositional criteria for infant formula.

This infant formula offers no evidence-based advantage over any other first infant milk. The reduced protein emphasised on the website is only marginally lower than that found in other infant milks, and no evidence has been given to explain the new protein process which they say makes this formula ‘closer to breastmilk’.

The addition of prebiotics to the powdered version of SMA Pro means that this product is now more similar to other infant milks available on the market than the previous formulation, but the composition of these milks now vary by format (powder or RTF), which makes claims made for this product confusing.

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SMA Wysoy

Soya protein based infant formula are permitted within the Infant Formula regulations, but in the UK the use of soya formula for infants under 6 months is not recommended without medical advice. There are a number of concerns about potential risks of soya formula use: soya proteins are potential allergens; the phyto-oestrogens present may have an impact on the future reproductive health of infants; the carbohydrate source is glucose syrup which is a greater risk for tooth decay; soya protein based formula have higher aluminium contents.

Only one brand of soya based formula is available in the UK. The product is not suitable for vegans as the vitamin D is sourced from sheep's wool lanolin. It is available in powdered form only in 860g tins.

Key components of this product

TABLE 24: Key components of SMA Wysoy

SMA Wysoy	
	Powdered Infant Milk 860g
Composition	Meets current regulations for infant formula composition
Unnecessary added ingredients	Taurine, arachidonic acid, nucleotides
Allergens	Soya
Protein source	Soya
Fats used	Palm, soya, coconut and sunflower oils Algal oils (single cell oils)
Carbohydrates used	Glucose syrup
Suitability	Suitable for vegetarians Halal approved
Cost per 100ml	20p
<i>For comparison:</i> Cheapest first infant milk currently available that meets all infant requirements/100ml (based on a powdered formulation)	10p

No specific claims are made for Wysoy beyond the fact that it is lactose free and contains long chain fatty acids as required by the regulations.

‘Hungry baby’ milks

There are four brands of so called hungry baby milks on the market: Aptamil Hungry Milk, Cow & Gate Infant Milk for Hungrier Babies, Hipp Organic Combiotic Hungry Infant Milk and SMA Extra Hungry. We have grouped these together as they are not recommended for use, and are all very similar. We do not believe that this name is appropriate for these milks since the term ‘hungry baby’ suggests a claim that this milk has proven efficacy.

Interestingly, as brands have altered their first infant milks, the hungry baby milks have not been changed, so either the companies do not consider these milks important enough in terms of the market share to make the same changes to as they have to their first infant milks, or they are not completely convinced by the evidence that they give for their own first milks. For example, despite SMA Pro and Hipp Organic Combiotic first milks making claims about the importance of lower protein in infant formula, they have not made changes to their hungry baby milks which both have 1.6g protein/100ml, an amount they claim is linked to higher weight gain. All hungry baby milks have a protein content considerably higher than the majority of first infant milks.

These hungry baby milks are casein-based and the manufacturers suggest that a whey:casein ratio of approximately 20:80 (which is similar to that in cows’ milk) can result in slower gastric emptying, resulting in greater satiety. Evidence used to support this suggestion has, however, been from small studies of infants with reflux difficulties (Billeaud et al, 1990; Tolia et al, 1992) and these findings are not accepted as evidence of efficacy.

The manufacturers also suggest that the use of these milks may help delay weaning, but there is no scientific evidence to support this.

The nutritional composition of casein-dominant formulas is slightly different to that of whey-dominant infant formulas. However, the reported nutrient composition for hungry baby milks here is within recommended levels. A whey-based infant formula is recommended for use throughout the first year of life and therefore none of these milks should be recommended.

TABLE 25

Summary of composition of hungry baby milks (powdered formulations only)

Nutrients per 100ml	Aptamil Hungry Milk	Cow & Gate Infant Milk for Hungrier Babies	Hipp Organic Combiotic Hungry Infant Milk	SMA Extra Hungry
Energy kcal	66	66	67	67
Protein g	1.6	1.6	1.6	1.6
Whey:casein ratio	20:80	20:80	20:80	20:80
Carbohydrate g	7.7	7.7	7.3	7.0
– of which lactose g	7.4	7.4	7.1	7.0
Source of added carbohydrate	Lactose, oligo-saccharides	Lactose, oligo-saccharides	Lactose, oligo-saccharides	Lactose
Fat g	3.1	3.1	3.5	3.6
Fat source	Palm, rapeseed, coconut and sunflower oils	Palm, rapeseed, coconut and sunflower oils	Palm, rapeseed and sunflower oils	Palm, coconut, sunflower and soya oils
Added LCPUFAs				
ARA	✓	✓	✓	✓
DHA	✓	✓	✓	✓
LCPUFA source	Fish and single cell oils	Fish and single cell oils	Fish and single cell oils	Single cell oils
Amounts of vitamins and minerals meet regulations	✓	✓	✓	✓
Prebiotics	✓	✓	✓	✗
Probiotics	✗	✗	✗	✗
Nucleotides	✓	✓	✗	✓
Taurine	✓	✓	✗	✓
L-carnitine	✓	✓	✗	✗
Contains soya	✓	✓	✗	✓
Contains fish oil	✓	✓	✓	✗
Suitable for vegetarians	✗	✗	✗	✓
Halal approved	✓	✓	✗	✓
Cost per 100ml	19p	14p	14p	16p

Note: Check the packaging of RTF milks as these milks may vary in composition and suitability from the equivalent powder format.

References

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Appendix

Cost of infant formula in the UK – April 2019

Costs of powdered infant formula have been calculated based on scoop weight and cost per 100ml prepared formula. For full information on how these have been costed see the report 'Costs of Infant milk in the UK' at <https://www.firststepsnutrition.org/composition-claims-and-costs>.

TABLE 26. Cost of starter packs of infant formula in the UK – June 2019

Milk name	Volume	Cost (April2019)	Where costed	Cost per 100ml	Cost per day birth – 2 weeks (8 bottles per day)
Aptamil Profutura 1 First Milk RTF	6 x70 ml starter pack	£10.99	Boots	£2.62	£14.65
Aptamil Sensavia 1 First Milk RTF	6 x70 ml starter pack	£10.99	Boots	£2.62	£14.65
Aptamil 1 First Infant Milk	6 x 70ml starter pack	£8.00	Boots	£1.90	£10.67
Hipp Organic Combiotic First Infant Milk	6 x 90ml starter pack	£8.00	Boots	£1.48	£10.67
SMA Pro First Infant Milk RTF	6 x 70ml Starter pack	£7.00	Boots	£1.67	£9.33
Cow & Gate 1 First Infant Milk RTF	6 x 70ml starter pack	£6.50	Boots	£1.55	£8.67

* We have calculated the cost per day based on guidance that approximately 8 feeds are given in 24hours in the first week of life, therefore this calculation is based on 8 bottles and not on volume. As these milks are provided with integral teats any milk remaining in the bottle should be discarded after a feed in line with guidance on the safe use of infant formula. This is likely to lead to significant waste.

TABLE 27: Cost of infant formula: RTF formulations

Milk name	Volume	Cost (June 2019)	Where costed	Cost per 100ml	Cost per day (920ml/day)	Cost per week (6440ml/week)
Aptamil Profutura 1 First Infant Milk RTF	200ml	£1.00	Boots	50p	£4.60	£32.20
Aptamil 1 First Infant Milk RTF	200ml	85p	Boots	43p	£3.96	£27.69
Aptamil Hungry Milk RTF	200ml	85p	Boots	43p	£3.96	£27.69
SMA Pro First Infant Milk RTF	200ml	80p	Boots	40p	£3.68	£25.76
SMA Extra Hungry RTF	200ml	80p	Boots	40p	£3.68	£25.76
Cow & Gate 1 First Infant Milk RTF	200ml	75p	Boots	38p	£3.50	£24.47
Cow & Gate Infant Milk for hungrier babies RTF	200ml	75p	Boots	38p	£3.50	£24.47
Hipp Organic Combiotic First Infant Milk RTF	200ml	75p	Boots	38p	£3.50	£24.47
Aptamil Hungry Milk RTF	1000ml	£3.70	Boots	37p	£3.40	£23.83
Aptamil 1 First Infant Milk RTF	1000ml	£3.70	Boots	37p	£3.40	£23.83
SMA Pro First Infant Milk RTF	1000ml	£3.50	Boots	35p	£3.22	£22.54
Cow & Gate Infant Milk for hungrier babies RTF	1000ml	£3.19	Boots	32p	£2.94	£20.61
Cow & Gate 1 First Infant Milk RTF	1000ml	£3.19	Boots	32p	£2.94	£20.61

TABLE 28: Cost of infant formula: powdered formulations (PIF)

Milk name	Weight	Cost (June 2019)	Where costed	Cost per 100ml made up milk	Cost per day (920ml/day)	Cost per week (6440ml/week)
Holle Organic Infant Goat Milk Formula 1	400g	£16.57	Organic supplier	53p	£4.88	£34.13
Kabrita Gold 1 (goats' milk based)	800g	£19.95	Boots	33p	£3.04	£21.25
NANNYCare First Infant Milk (goats' milk based)	900g	£21.00	Boots	29p	£2.67	£18.68
Holle Organic Infant Formula 1	400g	£8.69	Organic supplier	28p	£2.58	£18.03
SMA Advanced First Infant Milk	800g	£16.00	Tesco	24p	£2.21	£15.46
Aptamil Profutura 1 First Infant Milk	800g	£14.00	Boots	23p	£2.12	£14.81
Aptamil Sensavia 1 First Infant Milk	800g	£13.99	Boots	22p	£2.02	£14.17
SMA Organic First Infant Milk	800g	£13.99	Boots	22p	£2.02	£14.17
Kendamil Mehadrin First Infant Milk	800g	£12.99	Manufacturer	20p	£1.84	£12.88
SMA Wysoy	800g	£12.95	Boots	20p	£1.84	£12.88
Aptamil Hungry Milk	800g	£10.99	Boots	19p	£1.75	£12.24
Arla Baby & Me Organic Infant Milk	800g	£12.00	Arla Foods	19p	£1.75	£12.24
Kendamil Organic First Infant Milk	800g	£12.00	Manufacturers online shop	19p	£1.75	£12.24
Aptamil 1 First Milk	800g	£10.99	Boots	18p	£1.66	£11.59
Aptamil 1 First Milk @Lidl	700g	£9.49	Lidl	18p	£1.66	£11.59
SMA Extra Hungry	800g	£10.00	Boots	16p	£1.47	£10.30
SMA Pro First Infant Milk	800g	£10.00	Boots	16p	£1.47	£10.30
HiPP Organic Combiotic First Infant Milk	800g	£9.50	Boots	15p	£1.38	£9.66

Milk name	Weight	Cost	Where costed	Cost per 100ml made up milk	Cost per day (920ml/day)	Cost per week (6440ml/week)
Cow & Gate Infant Milk for hungrier babies	800g	£7.99	Boots	14p	£1.29	£9.02
HiPP Organic Combiotic Hungry Infant Milk	800g	£8.50	Boots	14p	£1.29	£9.02
Cow & Gate 1 First Infant Milk	800g	£7.99	Boots	13p	£1.20	£8.37
Cow & Gate 1 First Infant Milk @ Lidl	700g	£6.99	Lidl	13p	£1.20	£8.37
Kendamil 1 First Milk	900g	£9.00	Manufacturers online shop	13p	£1.20	£8.37
SMA Little Steps First Infant Milk	800g	£7.50	Tesco	12p	£1.10	£7.73
Mamia First Infant Milk	900g	£6.99	ALDI (only available at ALDI)	10p	92p	£6.44
Sainsbury's Little Ones First Infant Milk	900g	£7.00	Sainsbury's (only available at Sainsbury's)	10p	92p	£6.44

