



“Scientific and
factual?”

A review of breastmilk
substitute advertising to
healthcare professionals



'Scientific and factual'? A review of breastmilk substitute advertising to healthcare professionals. 2016

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Disclaimer

The opinions given in this resource are those of the authors. We strongly recommend that health professionals review for themselves the evidence provided by manufacturers, and make up their own minds about whether the statements and claims made about the products are scientific and accurate.

This report is provided for information only and individual advice on diet and health should always be sought from appropriate health professionals.

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Photo resources

For information about photo resources for different age groups of children and young people, see the website

www.firststepsnutrition.org

First Steps Nutrition Trust

First Steps Nutrition Trust is a charity which provides evidence-based and independent information and support for good nutrition from pre-conception to five years of age.

First Steps Nutrition Trust

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1 Introduction

International, EU and national regulations allow manufacturers of breastmilk substitutes to advertise their products to healthcare professionals providing the information is 'scientific and factual'. There is, however, no mechanism to challenge whether adverts are in fact 'scientific and factual' in their content and presentation. Manufacturers of breastmilk substitutes advertise their products to healthcare professionals in magazines, through company representatives' information, healthcare professional websites, at study days and via helplines. Many of the claims made by manufacturers are, however, not accepted by scientific bodies, the evidence may be weak or non-existent and it may relate to a product other than that being advertised. We believe that this misleads healthcare professionals.

This resource aims to unpack some of the adverts that have recently been placed in magazines aimed at healthcare professionals, to show why everyone needs to be extremely vigilant before accepting the claims and information provided.

We also think that the editors of journals and magazines should consider whether it is helpful to allow these adverts in publications, which we are sure the editors intend as publications which accurately inform and update their readers.

2 Background

2.1 Regulations relating to advertising of infant formula and follow-on formula to health professionals

The compositional requirements for infant formula and follow-on formula are currently determined by the Infant Formula and Follow-on Formula Regulations (2007) and any amendments to these regulations¹. These follow the EU Directive 2006/141/EU. The EU Directive can be read in full at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006L0141&from=EN>

Below we summarise some of the key points that relate to the advertising of infant formula and follow-on formula in publications for health professionals.

- 1 Advertising is permitted in publications to health professionals, but must be ‘scientific and factual’ in nature. The only claims that can be made are those included in the list of permitted claims in Annex IV of the EU Directive. All other nutrition and health claims are prohibited.
 - ‘Nutrition claim’ means any claim which states, suggests or implies that a food has particular beneficial nutritional properties.
 - ‘Health claim’ means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.
- 2 Annex IV of the EU Directive allows for nutrition claims related to lactose content, added LCP, taurine, fructo-oligosaccharides and galacto-oligosaccharides and nucleotides. However, these components are considered ‘unnecessary’ additions to infant formula and follow-on formula by EFSA (EFSA, 2014). Claims can also be made related to products which are designed for those with an allergy to milk protein. However, there are a number of conditions that must be fulfilled before a health claim can be made. These include providing “*objective and scientifically verified data as proof to the claimed properties*”.
- 3 Claims are regulated wherever they appear on the labelling, on a website or in advertising or presentations. It is not the case that statements constitute claims only when they appear in headings or banners.

¹ http://www.legislation.gov.uk/ukxi/2007/3521/pdfs/ukxi_20073521_en.pdf. Similar regulations are in place in Scotland, Wales and Northern Ireland.

2.2 UK Guidance Notes on the Infant Formula and Follow-on Formula Regulations

In the UK there are Guidance Notes from the Department of Health (relevant to all four health departments of the UK) which explain how the regulations should be interpreted. These Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007 were last published in 2013 and can be accessed at: www.gov.uk/government/uploads/system/uploads/attachment_data/file/204314/Infant_formula_guidance_2013_-_final_6_March.pdf

Restrictions on advertising infant formula (Regulation 21)

Infant formula can be advertised in scientific publications and trade publications.

Advertisements should:

- only contain information of a scientific and factual nature
- not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding.

From: Appendix IV *Guidance on scientific publications and information of a scientific or factual nature*:

Regulation 21 only allows infant formula to be advertised in scientific publications and trade publications and puts in place controls on the content of such advertisements. Below is Department of Health guidance on what constitutes a scientific publication and also guidance on the nature of the information that can be included in advertisements for infant formula.

Scientific publications

“Scientific publications are usually published periodically (at regular or irregular intervals) and aimed at academic and/or professionals in a scientific field, such as GPs, nurses and midwives. They consist of an aggregation of original articles by different authors published under an umbrella title. Articles include those that report new scientific research or review existing scientific research. They may also include editorials, opinion pieces and book or other reviews dealing with a scientific theme.

In addition, they

- are static, rather than dynamic (i.e. the core content is fixed at the time of publication),
- may have been assigned an ISSN.”

Content of infant formula advertisements

“Advertisements for infant formula can only include information that is of a scientific and factual nature (regulation 21(2)). Where that information constitutes a nutrition or health claim, it must be listed in the first column of Annex IV and the product must meet the conditions specified in the second column. All other nutrition and health claims are prohibited. Paragraphs 32-35 provide information on what constitutes a nutrition or health claim.

In the Departments view, to comply with this requirement, it must be possible to support any further information provided, that is not a nutrition or a health claim, with an article from a peer-reviewed scientific journal.”

2.3 Regulations relating to milks marketed for special medical purposes

Whilst infant formula and follow-on formula have legislation regulating the labelling and marketing of products, specialised infant milks which fall under the regulations for foods for special medical purposes currently do not. These milks can be marketed to health professionals without any restrictions, but rules on advertising will be strengthened when the Regulation on Foods for Specific Groups (FSG) (609/2013) comes into force from 2016.

2.4 Why do breastmilk substitute manufacturers advertise?

Companies expect advertising to produce returns in terms of increased product sales, so the best advertisements use images and stories to focus attention on the ‘brand’. The primary mission of any company is to generate profit and increase shareholder value, and infant formula companies use a range of techniques from direct advertising to more subtle approaches via study days, helplines, representative visits and conference marketing to promote their products. Where a product is linked into healthcare systems where advice and recommendations may be made to consumers by healthcare professionals, companies will attempt to impact healthcare professionals’ decision-making and recommendations. Advertisements for company representatives to promote infant formula brands highlight that this role is to “stimulate retail sales through the promotion of infant formulas to gain Healthcare Professionals recommendations²”.

Being able to advertise products directly to health professionals through advertisements in magazines and journals that aim to professionally inform and update gives manufacturers the opportunity both to promote their brand and to make a series of claims that appear evidence-based and believable.

What do we already know about advertising of breastmilk substitutes to health professionals?

A survey on the marketing, advertising and distribution of infant formula and follow-on formula conducted by the Food Safety Authority Ireland (2007) reported that, where adverts for infant formula were found in health professional publications, they were found not to comply with legislation. This was either because they included a picture of an infant, or implied equivalence of their product with breastmilk, or because some of the information provided was not factual. Interestingly in this study, while all advertisements found in non-specialist magazines were fully compliant with the legislation, *all* infant formula advertisements found in Irish health professional publications were found to be in breach of the regulations.

² Quote from an advertisement for a company representative for a formula company seen in 2015.

How do health professionals perceive scientific advertisements?

Health professionals may have the skills to investigate advertisement claims, but are unlikely to have the time and resources to do so for every advert they see. The references provided by manufacturers are often in an extremely small typeface and positioned at the bottom of the advert, the aim being that the statements, pictures, graphs and images 'do the talking'. Studies have examined how those with a heightened awareness of science (such as health professionals) perceive advertising claims which purport to be based on science (Dodds et al, 2008). It was found that advertisements that tapped into current advice and thinking were largely believed uncritically. Science or health-based claims for food products that were clear and that did not contradict prior knowledge and belief were deemed credible. This suggests that many people will take science and health claims at face value. Most health professionals in this study wanted simple, easy-to-understand messages they could relate to their own scientific knowledge. Infant formula manufacturers use this concept to constantly promote the same claims and ideas over time, even when these are not agreed by expert committees. The constant promotion of prebiotics (fructo- and galacto-oligosaccharides) in infant formula as a means of protecting infant health is a good example. Despite the European Food Safety Authority refusing all health claims for infant formula based on the addition of prebiotics, manufacturers continue to make these claims and many people believe this must therefore be based on fact and science.

Health professionals want simplicity in relation to both the visual imagery and the level of detail in advertisements (Dodds et al, 2008) and manufacturers support this by offering adverts for the same product (often in the same publication) – one which is simple and visual, and one which provides apparently much more scientific data. The health professional can then view the simpler advert but be reassured, by a more complex-looking advert, that the information they are being provided with is true.

Using graphs and images to imply scientific credibility

A study by Tal & Wansink (2014) considered how information that has the appearance of being scientific can increase persuasiveness. In a review for a journal on the public understanding of science, they found that even trivial cues can create an appearance of 'a scientific basis'. Simple elements such as graphs or a chemical formula increased belief in a product's efficacy. This appears to be due to the association of such elements with science, rather than this making the information more comprehensible. People who have a belief in science are more likely to be persuaded by information given in graphs, and are more affected by the presence of graphs in information provided to them. The authors concluded that, even when evidence was not scientifically correct or objective, trivial visual elements can increase persuasion of efficacy. Many adverts for breastmilk substitutes use graphs and diagrams to give an impression of scientific validity. Often the scales on the charts are manipulated to make differences look more impressive than they are, and sometimes the data is not referenced at all.

We believe more investigation is needed to consider how health professionals view adverts for breastmilk substitutes, and how this may potentially influence their practice.

References

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3 Adverts reviewed in this resource

The adverts for breastmilk substitutes that we have looked at in this resource were in journals and magazines aimed at health professionals published in 2015/2016. We have considered adverts for the following products:

- Aptamil Profutura Follow On milk
- Cow & Gate Comfort milk
- HiPP Organic Combiotic First Infant Milk
- NANNYcare First Infant Milk
- Nutramigen Hypoallergenic Formula with LGG
- Similac Alimentum
- SMA H.A. Infant Milk
- SMA PRO First Infant Milk.

For each advert we have reviewed the claims and statements made in light of the evidence presented (or not presented) and current expert advice.

NUTRICIA
Early Life Nutrition

INSPIRED BY
**BREASTMILK
RESEARCH**

NEW Aptamil Profutura Follow On milk has a composition and structure closer to that of breastmilk¹⁻⁷

- ✓ Contains our **highest ever levels of Long Chain Polyunsaturated Fatty acids (LCPs)***
- ✓ The first term formulation to include **phospholipid-bound LCPs**.
- ✓ Contains **milk fat**, providing a fatty acid profile closer to that of breastmilk.
- ✓ Contains our unique blend of **Galacto- and Fructo-Oligosaccharides (GOS/FOS)**.

For further information visit: aptamilprofessional.co.uk

OUR MOST ADVANCED FORMULATION YET.



IMPORTANT NOTICE: Breastfeeding is best for babies. Infant formula is suitable from birth when babies are not breastfed. Follow-on milk is only for babies over 6 months, as part of a mixed diet and should not be used as a breastmilk substitute before 6 months. We advise that all formula milks be used on the advice of a doctor, midwife, health visitor, public health nurse, dietitian, pharmacist or other professional responsible for maternal and child care. Foods for special medical purposes should only be used under medical supervision. Suitable for use as the sole source of nutrition for infants from birth, and/or as part of a balanced diet from 6-12 months. Refer to label for details.

References: 1. Ballard & Morrow. *Pediatr Clin North Am* 2013;60(1):49-74. 2. Harzer G et al. *Am J Clin Nutr* 1983;37(4):612-21. 3. Willatts P et al. *Lancet* 1998;352(9129):688-91. 4. Willatts P et al. *Am J Clin Nutr* 2013;98(2):536S-542S. 5. Brenna JT et al. *Prostaglandins Leukot Essent Fatty Acids* 2009;80(2-3):85-91. 6. Brenna JT et al. *Am J Clin Nutr* 2007;85(6):1457-1464. 7. Arslanoglu S et al. *J Biol Reg Homeost Agents* 2012;26S:49-59.8.

*33% more DHA (Omega 3) than in all Aptamil Follow On milks.



Advert for: Aptamil Profutura Follow On milk (Danone Nutricia Early Life Nutrition)

Summary of advert

This advert for a follow-on milk devotes almost 60% of the page to a picture of a mother and baby, with the words “INSPIRED BY BREASTMILK RESEARCH”

positioned centrally. Below the picture are the product details: “NEW Aptamil Profutura Follow On milk has a composition and structure closer to that of breastmilk”. This statement is supported by seven references which are included in very small type at the bottom of the advert. There is also a picture of the product and four specific claims, a link to the website, and the statement “OUR MOST ADVANCED FORMULATION YET.”

Claims made, and evidence given to support them

- 1 “NEW Aptamil Profutura Follow On milk has a composition and structure closer to that of breastmilk¹⁻⁷”

Evidence given to support this claim

Seven references are given to support the ‘closer to breastmilk’ claim. Of these, five scientific articles, published by three research groups between 1983 and 2013, consider lipids only.

The Harzer et al (1983) reference looks at changing patterns of human milk lipids in the course of lactation. This paper clearly makes the point that milk composition changes are found as lactation progresses and in mothers in different areas and 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 was funded by Milupa (a company that merged with Nutricia), but does not in any way support a feed of consistent composition, or this milk, as being ‘closer to breastmilk’.

The two papers by Willatts et al (whose work was also sponsored by Milupa) consider long chain fatty acid supplementation in term infants through formula supplementation and impact on IQ. The studies conclude that there was no impact on IQ of children at 6 years fed a supplemented formula, but small differences were noted in 2 out of 6 parameters of just one of the tests conducted on information processing. The authors’ conclusion that there may be some benefit of

supplementation with long chain polyunsaturated fatty acids is, however, not 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.”

The Brenna et al (2007) reference reports on the DHA and ARA content of human breastmilk worldwide, and Mead Johnson and Martek Biosciences (who provide fatty acid components for infant formula) were involved in this work. The authors provide a comprehensive list of studies where breastmilk fat content has been analysed and indicates significant variations in DHA content suggesting a high degree of variability in DHA in individual samples. It is not clear how this paper relates to Aptamil Profutura being ‘closer to breastmilk’.

The Brenna et al (2009) reference was used by EFSA to provide data on the upper range of DHA found in breastmilk as part of their new recommendation that DHA becomes a mandatory ingredient in infant formula. Most infant formula already contain DHA, and Aptamil First infant milk currently contains 0.01g DHA/100ml, compared to the 0.011g/100ml in Profutura, a minimal change that is likely to be insignificant once variations and degradations within infant milk products are considered. These amounts are within the range that all milks will have to contain when new regulations come into force in 2016.

An additional reference given to a paper by Arslanoglu et al (2012) refers to a study on prebiotic supplementation (reviewed below). A reference to an overview of human milk composition by Ballard and Morrow (2013) is also included, but it is not clear how this supports any of the claims made, since it simply outlines the unique nutrients and bioactive factors in breastmilk.

The statement in this advertisement that this new milk is ‘closer to breastmilk’ is therefore not supported by any evidence provided. EFSA has made it clear that infant formula cannot imitate breastmilk in composition (EFSA, 2014). The UK Department of Health Guidance Notes (Department of Health, 2013), which explain the current infant formula and follow-on formula regulations, 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).”

However, a claim can be made in scientific and factual

advertising to health professionals if evidence is provided in the form of peer-reviewed articles. If this advert were to appear in the public domain, we could challenge the claims made through the Advertising Standards Authority, but this is not the case for adverts to health professionals.

2 “The first term formulation to include phospholipid-bound LCPs”

Evidence given to support this claim

No explanation of benefit, or evidence, is provided for this claim. The EFSA *Scientific opinion on the essential composition of infant formula and follow-on formulae* (EFSA, 2014) stated that, whilst there are phospholipids naturally present in breastmilk: “*there is no convincing evidence for a beneficial effect of using LCPUFA supplied as phospholipids in infant formula.*”

The manufacturers do not explain that the source of the phospholipid is egg, and that this is the first infant formula or follow-on formula on the UK market to include egg lipid.

3 “Contains milk fat, providing a fatty acid profile closer to that of breastmilk.”

Evidence given to support this claim

No evidence is provided to support that claim. The fatty acid profile of all infant formula and follow-on formula must be within the recommendations made in the EU Directive. EFSA, in their review of the fat composition of infant formula and follow-on formula, say that milk fat and vegetable oils can be used as long as the minimum and maximum content of fat, and an adequate range of fatty acids, are achieved (EFSA, 2014).

4 “Contains our unique, patented blend of Galacto- and Fructo-oligosaccharides (GOS/FOS).”

Evidence given to support this claim

The reference given which we assume supports this claim (although it is not specified), Arslanoglu et al (2012), is a paper which extends a previous (flawed) study, published in 2007, considering the impact of oligosaccharides in infant formula on atopic dermatitis and allergy symptoms in the first two years of life. This study follows the same 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 earlier reviews of efficacy of benefit from oligosaccharide addition to infant formula. It is remarkable that this claim is still being made when EFSA have repeatedly denied permission to make a claim based on the use of prebiotics in infant formula and follow-on formula. EFSA clearly state, in their 2014 opinion, that there is no evidence for health benefits

from the addition of prebiotic oligosaccharides (GOS/FOS) to infant or follow-on formula.

Prebiotics are considered ‘unnecessary ingredients’ in infant and follow-on formula by EFSA.

It should be noted that the advert uses the phrase ‘term formulation.’ Although this is an advert for follow-on formula, the use of an image of a baby who could be 3-4 months of age (the baby is lying on its mum’s chest and is not sitting independently), suggesting this is relevant for babies in the first 6 months of life, is a key method used by manufacturers to ensure cross-promotion with their first infant milk.

What does current accepted policy/science say?

There is no clear evidence for the claims being made for this product, and the claims are not supported by recent evidence reviews by expert bodies. The claim that this product has the highest ever levels of LCPs when the increase from previous products as claimed is 1µg/100ml (1/1000th g) is meaningless when normal product variation is considered. The inclusion of phospholipid-bound LCPs in the product is not attached to a claim, but EFSA (2014) states that, whilst there are phospholipids naturally present in breastmilk: “*there is no convincing evidence for a beneficial effect of LCPUFAs supplied as PLs [phospholipids] ... in IF or FOF.*”

The claim that the addition of cows’ milk fat provides a fatty acid profile closer to breastmilk is not substantiated with any evidence, and no independent reviews have suggested that milk fat enhances formula composition. The 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 non-digestible oligosaccharides that have been tested to date in RCTs when added to IF or FOF.*”

Our conclusion

This advert suggests that Danone Nutricia Early Life Nutrition have been inspired by breastmilk research to create a new formula closer to breastmilk, but in fact there is nothing new in this formula other than the unexplained use of egg phospholipid. The advert fails to offer any coherent explanation for the claims made. The use of an emotive picture of an infant, the obvious brand cross-promotion to first infant milk, the claims which are not accompanied by specific references, and the random selection of evidence presented are typical of how health professionals can be misled by adverts purporting to be ‘scientific and factual’.

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Advert for: Cow & Gate Comfort milk (Danone Nutricia Early Life Nutrition)

Advert seen in: *Journal of Health Visiting*, March 2016



It's not just
BABIES
who need relief
from **COLIC**

95% of Paediatricians' reported an improvement in common infant feeding problems with a formula like Cow & Gate Comfort¹



Evidence shows these partially-hydrolysed formula milks containing oligosaccharides (GOS/FOS) improve the symptoms of colic in bottle-fed babies.^{1,2} So if a bottle-fed baby's colic is more than mum can manage with practical tips alone, put digestive care first with Cow & Gate Comfort.

Learn more about the evidence-based management of colic at in-practice.co.uk

*Out of 96 paediatricians

References: 1. Savino F *et al. Acta Paediatr Suppl* 2003; **441**: 86–90.

2. Savino F *et al. Eur J Clin Nutr* 2006; **60**: 1304–1310.



Comfort for babies, relief for mums



Advert for: Cow & Gate Comfort milk (Danone Nutricia Early Life Nutrition)

Summary of advert

This advert uses three-quarters of the page to provide an emotive image of a tired mother. It suggests there is a cure for her baby's colic, which will provide her with more

sleep. One main claim is given (see below). The advert gives a website which, it suggests, can offer "evidence-based management of colic".

Claims made, and evidence given to support them

1 "95% of Paediatricians reported an improvement in common infant feeding problems with a formula like Cow & Gate comfort. [Our italics]

Evidence shows these partially-hydrolysed formula milks containing oligosaccharides (GOS/FOS) improve the symptoms of colic in bottle-fed babies.^{1,2} So if a bottle-fed baby's colic is more than mum can manage with practical tips alone, put digestive care first with Cow & Gate Comfort.

Learn more about the evidence-based management of colic at in-practice.co.uk"

1 Savino et al, 2003. 2 Savino et al, 2006.

Evidence given to support the claims

Savino et al, 2003

This was an observational study carried out in Italy in 2001. In the study, formula-fed babies aged between 1 and 2.5 months with minor GI symptoms were seen by 96 family paediatricians (which, in the UK, would be equivalent to seeing a GP), and 214 presented with colic. Over 14 days they were all given a 'new formula', and symptoms improved in 79% over the period of the study. There was no control group and no information was provided on the age of those children who saw symptoms reduced. Paediatricians were asked to rate improvement of symptoms after treatment with the new formula on a scale of 1 to 10. The study was funded by Numico (Danone).

Savino et al, 2006

This study was conducted in 2002-03 among 199 infants of about 2 months of age. Infants diagnosed with colic were divided into two groups: one group

was given the 'new formula', and the other was given conventional formula plus simethicone. (Simethicone is an anti-foaming agent used to help the transit of gas from the stomach, but used in this study as a placebo.) Self-reported crying incidences were recorded at 1, 7 and 14 days. At days 7 and 14, incidences of crying were significantly reduced in both groups, but more so in the 'new formula' group. There was no reference group. The study was funded by Numico (Danone).

Was the milk used in these trials the same as Cow & Gate Comfort?

Cow & Gate Comfort has similarities to the test formula – for example, it is partially hydrolysed, has lower lactose, starch added and prebiotics. However, it has a lower energy, protein and carbohydrate content, different mineral content and B-palmitate content, and lower osmolality than the test formula. The claims cannot therefore be made about this formula, even if they were scientifically robust.

The text also claims that it is the addition of oligosaccharides GOS/FOS in the formula that provides relief from colic. There is no evidence that the use of prebiotics in infant formula is of any benefit to infants.

What does current accepted policy/science say?

NHS Choices says there is no evidence for any treatment that is beneficial for colic – which resolves itself (NHS Choices, 2016).

The NICE Clinical Knowledge Summary says there is no treatment for colic, and provides practical strategies for families (NICE, 2014). It specifically advises against low-lactose formula.

EFSA, in their *Scientific opinion on the essential composition of infant formula and follow-on formulae*, clearly states that "there is insufficient evidence for beneficial effects on infant health of the non-digestible oligosaccharides that have been tested to date in RCTs when added to IF or FOF."

Our conclusion

This advert misleads health professionals into believing that there is a cure for colic, that a particular infant milk can provide relief, and that this is agreed by medical professionals. The company provides no suitable evidence to support these claims.

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Advert for: HiPP Organic Combiotic First Infant Milk

Advert seen in: *Journal of Family Health*, volume 25, number 4, 2015

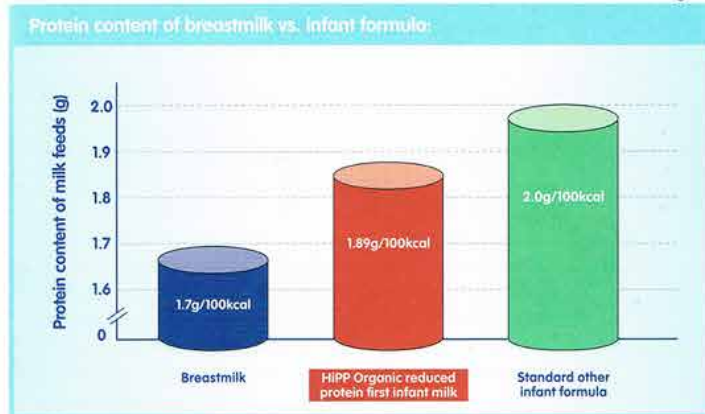
BREASTFEEDING IS BEST FOR BABIES

Less is more: the UK's first reduced protein infant milk, now with alpha-lactalbumin



High protein intake in the first two years of life has been linked with an increased long term risk of being overweight or obese! Our new infant milk with 1.89g protein/100kcal, and added alpha-lactalbumin, is the first formula in the UK to contain less than 2g protein/100kcal (Figure 1).

Figure 1



The BeMIM (Belgrade-Munich Infant Milk) study²

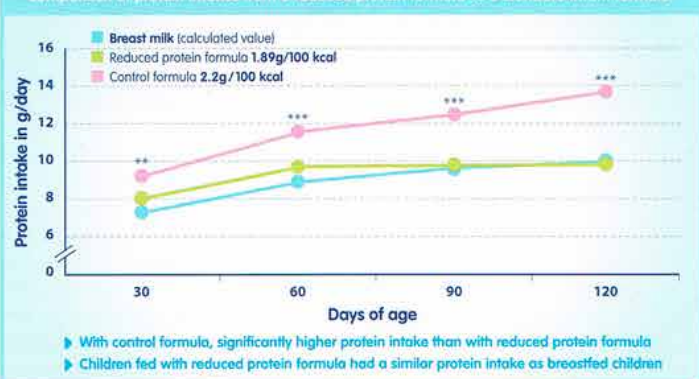
Aim: to prove the safety and suitability of the reduced protein formula for healthy term babies aged 0-4 months and non-inferiority compared to a standard formula.

Figure 2

Results

- **Adequate growth:** no significant difference in weight gain between formula groups
- **Good tolerance and acceptance:** both formulas were well accepted and tolerated. No differences in stool consistency and colour, colic, flatulence, regurgitation or vomiting
- **Protein intakes closer to that of breastfed babies** for those on the reduced protein formula (Figure 2)
- **Positive influence on satiety:** no compensatory increases in formula intake for babies on the reduced protein formula. In fact, these babies consumed significantly less energy at 90 days and 120 days of age compared to the control-fed group. This was explained by lower meal frequency, which might indicate higher satiety
- **Improved energetic efficiency:** Weight gain per 100kcal and length gain per 100kcal were significantly higher in the 4th month for the intervention group compared with the control group. This could be due to the improved protein quality of the intervention formula.

Comparison of protein intakes from a reduced protein formula vs a standard infant formula



The protein intake of the reference group was calculated based on the amount drunk by the intervention and control groups, and adjusted according to the protein content of breastmilk: 1.2g/100ml corresponding to 1.7g/100kcal.¹ Differences between reduced protein and control formula are significant: ** P< 0.01; *** P< 0.001

Study design

- Intervention group with reduced protein infant formula, n=82;
- Control group with standard infant formula, n=82;
- Reference group with breastfed infants, n=92.

All infants examined and anthropometrically measured after 30, 60, 90 and 120 days of age.

The study met ICH guidelines for good clinical practice and SCF recommendations for the study design (2003).

Study registered at ClinicalTrials.gov (NCT01094080)

To find out more, visit hipp4hcps.co.uk

References: 1. Koletzko B et al. *Am J Clin Nutr* 2009; 89 (suppl): 15-75. 2. Fleddermann, M et al. *Clinical Nutrition* 2014, 33, Issue 4, p.588-595 3. Nommsen LA et al. *Am J Clin Nutr* 1991; 53: 457-465.
Important Notice: Breastfeeding is best for babies. Breastmilk provides babies with the best source of nourishment. Infant formula milks and follow on milks are intended to be used when babies cannot be breastfed. The decision to discontinue breastfeeding may be difficult to reverse and the introduction of partial bottle feeding may reduce breastmilk supply. The financial benefits of breastfeeding should be considered before bottle feeding is initiated. Failure to follow preparation instructions carefully may be harmful to a baby's health. Infant formula and follow on milks should be used only on the advice of a healthcare professional.



Advert for: HiPP Organic Combiotic First Infant Milk

Summary of advert

This advert for HiPP Organic Combiotic First Infant Milk provides a chart and graph to emphasise that the information it is providing is scientific and factual and, in a bold subheading,

highlights the name of the study that the data is mainly taken from. The main claim is that this is “the UK’s first reduced protein infant milk, now with alpha-lactalbumin”. A series of highlighted benefits are made (in the Results box), and three scientific references are provided at the bottom of the page to substantiate statements or claims made.

Claims made, and evidence given to support them

- 1 “High protein intake in the first two years of life has been linked with an increased long term risk of being overweight or obese.”

1 Koletzko B et al. *Am J Clin Nutr* 2009; 89 (suppl) 15-7S.

Evidence given to support this claim

Koletzko et al, 2009

This statement is true, but it does not relate to the formulae in this advert but to a global assessment of protein intakes and links to obesity in young children.

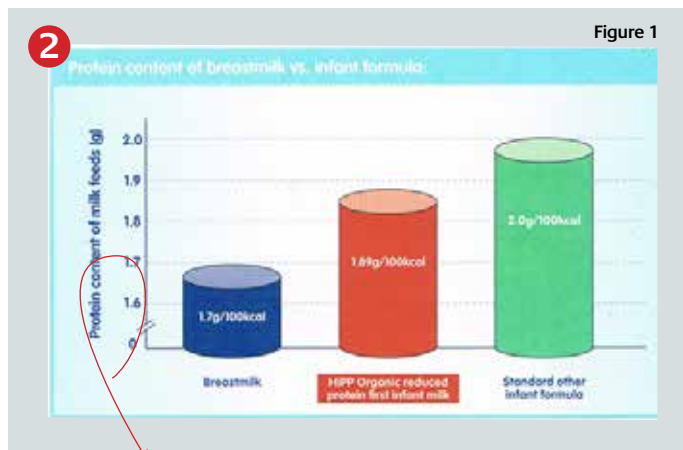


Figure 1 provides a chart showing different amounts of protein in breastmilk, HiPP reduced protein formula and standard other infant formula. The scale used makes it look as if there are large differences between the products, but in fact the differences are minimal. As we normally round protein values to one decimal place, 1.89g/100kcal and 2g/100kcal are in fact both equivalent to 1.3g protein/100ml of formula milk (where formula has 66-67kcal/100ml).

The Results box includes a number of claims based on the findings of the BeMIM study (Fleddermann et al, 2014). This study was funded by HiPP. It compared intakes of two formula: one with a protein content of 1.3g/100ml, and one with a protein content of 1.5g/100ml. There is currently no first infant formula on the UK market that contains 1.5g protein/100ml and therefore this cannot be used to compare HiPP formula in the UK with their competitors as they do. All the ‘hungry baby milks’ marketed in the UK have a protein content of 1.6g protein/100ml, including HiPP Organic Combiotic Hungry Infant Milk, suggesting that that the company’s belief in the benefit of a lower protein content is not strong enough to lead them to alter the composition of all HiPP Organic milks sold for infants in the first 6 months of life. The claims made include the following.

- 3 “Adequate growth ...”

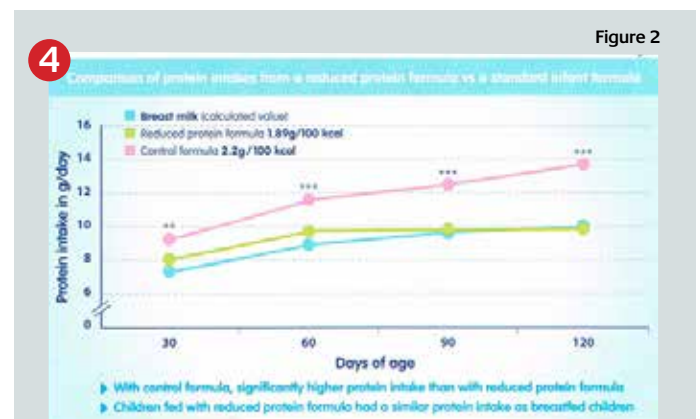
This is to be expected as the milk meets current compositional recommendations.

- 3 “Good tolerance and acceptance ...”

This is also to be expected as the composition was similar to other formula.

- 3 “Protein intakes closer to that of breastfed babies ...” (with reference to Figure 2)

This graph again uses a scale which accentuates small differences. The fact that protein intakes may be similar in breastfed and formula-fed infants does not mean there is any clinical advantage.



“The protein intake of the reference group was calculated based on the amount drunk by the intervention and control groups, and adjusted according to the protein content of breastmilk: 1.2g/100ml corresponding to 1.7g/100kcal.”

3 Nommsen LA et al. *Am J Clin Nutr* 1991; 53, 457-465.

Evidence given to support this claim

Nommsen et al, 1991

The reference group they refer to here is breastfed babies, and they based the calculated protein intake of breastfed babies on breastmilk composition data from a 1991 US study. This study showed that there was significant variation in breastmilk composition related to a number of maternal factors, and it is important to remember that breastmilk changes composition during and between feeds and over time. They used the amounts of formula consumed by infants in this study to estimate the amount of breastmilk consumed, so this graph is simply an estimate of relative intakes. The current estimate of protein content in breastmilk used in the UK is 1.3g/100ml.

5 “Positive influence on satiety ...”

The claims that energy intakes were lower in the intervention formula at 90 days and 120 days are made in comparison to a first infant formula which is not available in the UK and which was also higher in carbohydrate than those currently on the market.

6 “Improved energetic efficiency ...”

The authors of the BeMIM Study paper conclude that, as growth was similar but protein intake was lower, the energetic efficiency was improved by the addition of alpha-lactalbumin as a protein fraction. However, this remains a theoretical, rather than an agreed, claim.

What does current accepted policy/science say?

Having a protein intake in formula-fed babies the same as in breastfed babies is not in itself meaningful. EFSA (2014) says “*Infant milk cannot imitate breastmilk with respect to its energy and protein content*” (EFSA, 2014).

The basis for all the claims made here is that the HiPP formula are significantly different to other milks on the UK market. However, this is not the case.

There is currently no recommendation for the use of alpha-lactalbumin as a protein source in infant formula, and compositional requirements are based on an adequate amino-acid content.



Our conclusion

HiPP suggest in this advertisement that their Organic Combiotic First Infant Milk is significantly different in composition from other first formula on the UK market, which is not true. The data they use to support their claims are from a study which included a first formula milk not available in the UK, and they show a graph and a chart with scales adjusted to over-emphasise small differences. The assertion that a formula has a protein content more similar to breastmilk does not in itself mean that this provides any clinical advantage.

References

- EFSA (2014). *Scientific opinion on the essential composition of infant formula and follow-on formulae*. Parma, Italy: European Food Safety Authority. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/3760>
- Fleddermann M, Demmelmair H, Grote V et al (2014). Infant formula composition affects energetic efficiency for growth: The BeMIM study, a randomized controlled trial. *Clinical Nutrition*; 33: 588-95.
- Koletzko B, von Kreis R, Closa R et al, for the European Childhood Obesity Trial Study Group (2009). Lower protein in infant formula is associated with lower weight up to age 2y: a randomized clinical trial. *The American Journal of Clinical Nutrition*; 89: 1836-45.
- Nommsen LA, Lovelady CA, Heinig MJ et al (1991). Determinants of energy, protein, lipid and lactose concentrations in human milk during the first 12 mo of lactation: the DARLING Study. *The American Journal of Clinical Nutrition*; 53: 457-65.

BREASTFEEDING IS BEST FOR BABIES



Why consider a whole goat milk formula?

Cow's milk is commonly used to manufacture infant formula, generally because it is the most widely available source.



NANNYcare is made from whole goat milk which is now fully regulated and approved for use in infant formula



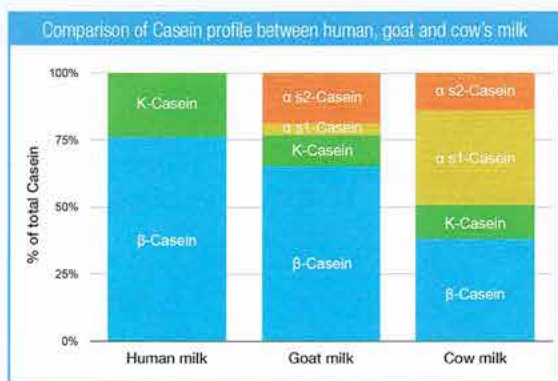
Better digestibility

The immaturity of a new-born infant's digestive tract requires the proteins in formula to be readily digestible. Goat milk proteins are digested more completely than cow's milk proteins¹.

NANNYcare First infant milk:

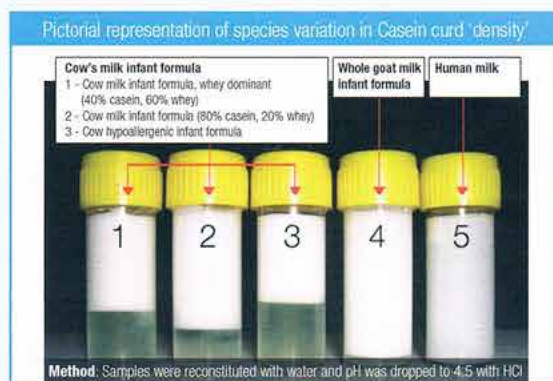
- Behaves more like breast milk in the infant stomach forming looser, softer and more porous curds than cow's milk formula
- This aids digestion by allowing easier access by stomach enzymes
- Nearly 3-fold more beta-lactoglobulin is digested in goat milk compared with cow's milk²

Casein profile



Goat milk has a smaller proportion of α s1-casein than cow's milk and a greater proportion of β-casein, similar to the casein profile of human milk.

For more info visit nannycare.co.uk or email us: enquiry@nannycare.co.uk or call our helpline UK: 0800 328 5826



These factors contribute to the better digestion of goat milk and suggest why a goat milk formula may be beneficial and may simply suit some babies better than cow's milk formulas.

REFERENCES: 1. PINTADO, M. E. & MALCATA, F. X. (2000). Hydrolysis of ovine, caprine and bovine whey proteins by trypsin and pepsin. *Bioprocess Engineering*, 23, 275-282. 2. ALMAAS, H et al (2006). In vitro digestion of bovine and caprine milk by human gastric and duodenal enzymes. *International Dairy Journal*, 16, 961-968

IMPORTANT NOTICE: Breastfeeding is best for babies. Breast milk provides babies with the best source of nourishment. Infant formula milk and follow on milks are intended to be used when babies cannot be breast-fed. The decision to discontinue breast feeding may be difficult to reverse and the introduction of partial bottle-feeding may reduce breast milk supply. The financial benefits of breast feeding should be considered before bottle feeding is initiated. Failure to follow preparation instructions carefully may be harmful to a babies health. Infant formula and follow up milks should be used only on the advice of a healthcare professional. **Goat milk formula is not suitable for a cow milk protein allergy except under the supervision of a suitably qualified health care professional.**



Summary of advert

This advert is for the brand of goats' milk formula NANNYcare, but highlights the First Infant Milk within the advert. The top half of the advert suggests that goats' milk has better

digestibility, behaves more like breastmilk in the infant stomach, and contains more beta-lactoglobulin. (We think they mean beta-lactoglobulin.) The second half of the advert contains a chart of the casein profile of human, goats' and cows' milk, and a chart which shows some test tubes of milk comparing a number of formula types. The claims are supported by two references.

Claims made, and evidence given to support them

1 "Goat milk proteins are digested more completely than cow's milk proteins¹"

1 PINTADO ME, MALCATA FX (2000). *Hydrolysis of ovine, caprine and bovine whey proteins by trypsin and pepsin. Bioprocess Engineering*; 23: 275-82.

Evidence given to support this claim

Pintado and Malcata, 2000

This paper refers to a study of enzymatic hydrolysis of whey proteins only, and was carried out to consider the properties of whey proteins as food ingredients. The study concluded that similar results were observed for wheys from the milk of both cows and goats. It is not clear why this paper is used to suggest more complete digestion of goat milk protein, since it does not consider whole protein digestion, is not based on in vitro digestion and concludes that both bovine and caprine whey hydrolysates contain peptides similar in both quality and quantity. Goats' milk protein has an 80:20 casein to whey ratio, and therefore using a study of whey digestion to make claims about protein digestion per se is misleading. In fact, a more recent study comparing digestion of caseins and whey proteins in bovine and caprine milks using human gastrointestinal enzymes (Inglingstad et al, 2010) showed that bovine and caprine milk behave very similarly during digestion. The European Food Safety Authority (EFSA) have stated that there are no differences in digestibility between goats' milk and cows' milk protein (EFSA, 2012).

2 "NANNYcare First infant milk ... Behaves more like breast milk in the infant stomach forming looser, softer and more porous curds than cow's milk formula"

"This aids digestion by allowing easier access by stomach enzymes"

Evidence given to support the claims

No evidence is given to support these claims in the print advertisement.

NANNYcare provided us with further evidence on request, and it appears that they only have data from an undergraduate student project in New Zealand to support these claims in relation to infant formula. Claims made in advertising to health professionals which claim to be scientific and factual should, by law, be supported by evidence from peer-reviewed journals in the UK (Department of Health, 2013).

3 "Nearly 3-fold more beta-lactoglobulin is digested in goat milk compared with cow's milk²"

2 ALMAAS H, et al (2006). *In vitro digestion of bovine and caprine milk by human gastric and duodenal enzymes. International Dairy Journal*; 16: 961-68

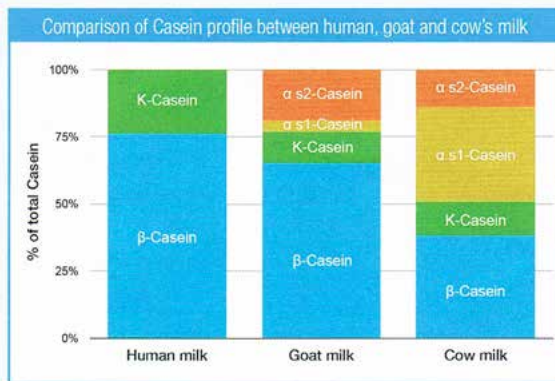
Evidence given to support this claim

Almaas et al (2006)

We think they mean beta-lactoglobulin here. The reference given considered the in vitro digestion of specific varieties of cows' and goats' milk protein by human enzymes. They reported that three times more beta-lactoglobulin was digested in the raw goat milk used in this experiment, compared to a raw cows' milk. However, when milks were pasteurised and heat-treated, the degradation process was significantly different. Whilst it is acknowledged that there are differences in the protein composition between cows' and goats' milk, it is also known that the composition of proteins varies widely depending on breed, stage of lactation, feeding, climate, parity and season, and the number of genetic variants for protein fractions in goats' milk is particularly high (EFSA, 2012). Beta-lactoglobulin is the major whey protein in cows' and goats' milk, but not human milk, and of course the whey content of goats' milk is low. Whether faster digestion of one component of whey protein has any clinical significance to human infants is not presented. It is well established that the resistance of some proteins

to digestion in human milk is one of the unique ways in which human milk provides a defence against pathogenic bacteria and viruses (Lönnerdal, 2013). The advert suggests that this is one of the factors that contributes to better digestion of goat milk and that this explains why “a goat milk formula may be beneficial and may simply suit some babies better than cow’s milk formulas.” However, they provide no evidence that there is any benefit, or that some babies do better on goats’ milk based formula.

Casein profile



- 4** “Goat milk has a smaller proportion of alpha s1-casein than cow’s milk and a greater proportion of beta-casein, similar to the casein profile of human milk.”

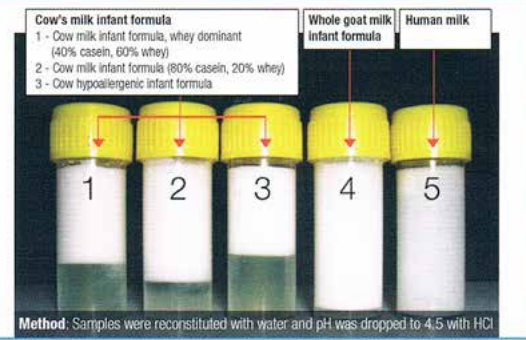
Evidence given to support the claims

No evidence is presented. No reference is given for the data presented on casein fractions in different milk types.

Goats’ milk and cows’ milk have much higher amounts of casein than human milk, and therefore to present a chart of casein profile only is misleading. Human milk contains only 10-20% casein in the early weeks and approximately 60% in mature milk, and it is generally agreed that formula milks should have a low casein level, particularly for the newborn (Lönnerdal, 2013). The k-casein in breastmilk is unique and is known to have antimicrobial activity (Strömqvist et al, 1995).

Allergy to cows’ milk has frequently been attributed to the alpha s1 casein fraction of animal milk. Alpha S1-caseins do differ between species. However, almost all commercially farmed animals produce antigenically similar milk, which is why EFSA clearly state that there is no difference in allergenicity between goats’ and cows’ milk proteins (EFSA, 2012). It is not clear what the advert is implying with the statements made, but simply showing similarity between some of the very many complex protein fractions in human milk and another milk has no clinical significance.

Pictorial representation of species variation in Casein curd 'density'



- 5** Method: Samples were reconstituted with water and pH was dropped to 4.5 with HCl.

This picture shows what happens when acid is added to a range of formula milks, human milk and whole goat milk based infant formula. No reference is given for this evidence. NANNYcare provided an explanation of what this picture depicts, claiming that in lower acid conditions human milk and goats’ milk formula remain more liquid than cows’ milk based formula. The evidence they gave us for this is, however, from studies of yoghurt making, and no published evidence was provided to support this behaviour in a goats’ milk based infant formula.

What does current accepted policy/science say?

EFSA in their scientific opinion on the composition of infant formula and follow-on formulae state that “*Infant milk cannot imitate breastmilk with respect to its energy and protein content*” (EFSA, 2014).

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.

It is not disputed that protein 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 highlight that, if goat milk protein is used in infant formula, particular attention has to be given to the amino acid content by adding appropriate free amino acids to ensure that the profile is adequate.

Our conclusion

There are currently no agreed scientific reviews or consensus statements that suggest formula made from goats' milk protein is superior to that made from cows' milk protein. There is high variability in the protein composition of animal milks, and whilst there are differences in the protein fractions, these differences are of no agreed clinical benefit in infant formula. NANNYcare imply benefits of goats' milk formula over cows' milk protein based formula and suggest that this formula "behaves more like breast milk", but present no data to support this claim. The use of graphs and charts which are not supported by any evidence is a common ploy to suggest scientific validity in adverts. It is a legal requirement that, when a statement about a formula, which is not an agreed health claim, is made in an advertisement to health professionals which purports to be 'scientific and factual', evidence from a peer-reviewed journal should be presented. We believe this advert is not in line with current regulations.

References

- Almaas H, Cases, AL, Devold TG et al (2006). *In vitro* digestion of bovine and caprine milk by human gastric and duodenal enzymes. *International Dairy Journal*; 16: 961-68.
- EFSA (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>
- EFSA (2014). *Scientific opinion on the essential composition of infant formula and follow-on formulae*. Parma, Italy: European Food Safety Authority. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/3760>
- Inglingstad RA, Devold TG, Eriksen EK et al (2010). Comparison of the digestion of caseins and whey proteins in equine, bovine, caprine and human milks by human gastrointestinal enzymes. *Dairy Science Technology*; 90: 549-63.
- Lönnerdal B (2013). Bioactive proteins in breastmilk. *Journal of Clinical Paediatrics and Child Health*; 49 (Suppl 1): 1-7.
- Pintado ME, Malcata FX (2000). Hydrolysis of ovine, caprine and bovine whey proteins by trypsin and pepsin. *Bioprocess Engineering*; 23: 275-82.
- Strömqvist M, Falk P, Lennart Hansson SB et al (1995). Human milk k-casein and inhibition of *Helicobacter pylori* adhesion to human gastric mucosa. *Journal of Pediatric Gastroenterology and Nutrition*; 21: 288-96.



The express route to the end of cow's milk allergy

All the existing benefits of Nutramigen LIPIL with the addition of a probiotic branded LGG®, for no extra cost.

First stop – symptom resolution

- ✓ Proven to have an average efficacy of 99%¹
- ✓ Faster resolution of CMA symptoms vs previous formulation^{2,3}

Final destination – oral tolerance to leave CMA behind

- ✓ The only eHF clinically proven to accelerate time to tolerance⁴
- ✓ 8 out of 10 infants are tolerant to cow's milk after 12 months of use⁴



The world's leading CMA formula⁵



MeadJohnsonTM
Nutrition

A solution for all your CMA needs

Nutramigen with LGG® is not recommended for premature and immunocompromised infants unless directed and supervised by a healthcare professional. www.nutramigen.co.uk

¹ Studied before the addition of LGG®. Calculated using data on allergic reactions after oral food challenge with an eHF from table 3 of Dupont C et al. 2012, as judged by the Committee on Nutrition of the French Society of Paediatrics. ² is an eHF based on casein, rice hydrolysate, soy and amino acid formulas. CMA, cow's milk allergy; eHF, extensively hydrolysed formula; LGG®, *Lactobacillus rhamnosus*:GG. **References:** 1. Dupont C et al. *Br J Nutr* 2012;107:325-338. 2. Nemes M et al. *Clin Exp Allergy* 2010;41:370-77. 3. Saldañarri ME et al. *J Pediatr* 2010;156:397-401. 4. Canani RB et al. *J Pediatr* 2013;163:771-777. 5. Data on file 2014.

IMPORTANT NOTICE: Breastfeeding provides the best nutrition for babies. *Trademark of Mead Johnson & Company, LLC. © 2015 Mead Johnson & Company, LLC. All rights reserved. LGG® is a registered trademark of Valio Ltd, Finland. **This material is for healthcare professionals only.** EU15.572/09-15.

Advert for: Nutramigen Hypoallergenic Formula with LGG (Mead Johnson Nutrition)



Summary of advert

This is an advert for Nutramigen Hypoallergenic Formula with LGG, which was launched on the UK market in 2015 to replace Nutramigen 1 LIPIL. It is an extensively hydrolysed milk for infants with cows' milk protein allergy (CMPA). It contains a probiotic strain *Lactobacillus rhamnosus* (LGG).

The advert claims that Nutramigen Hypoallergenic Formula with LGG provides: "All the existing benefits of Nutramigen LIPIL with the addition of a probiotic branded LGG, for no extra cost."

In the top left-hand corner is a banner with "NEW PREPARATION INSTRUCTIONS" highlighted. No information is given to explain this further in the advertisement. These new instructions require the milk to be made up with water at room temperature to preserve the probiotics present. A discussion on the safety of infant milk preparation and the importance of using water hot enough to kill harmful bacteria that may be present in powdered infant formula can be found at www.firststepsnutrition.org.

At the bottom of the advert in small type is the statement "Nutramigen with LGG is not recommended for premature and immunocompromised infants unless directed and supervised by a healthcare professional." As this is a milk for special medical purposes, it should not be used for any infant without medical supervision. The advert also shows other Mead Johnson Nutrition brands, and a link to their website.

Claims made, and evidence given to support them

1 "Proven to have an average efficacy of 99%"

Evidence given to support this claim

Dupont et al, 2012

A footnote to the statement above says this research is not related to this milk, but to the previous version of it.

The Dupont et al 2012 reference is a review article which says that, for a child with CMPA, the first line of defence is breastfeeding but that, if the child is not breastfed, a number of products are equally good.

2 "Faster resolution of CMA symptoms vs previous formulation"

Evidence given to support this claim

Nermes et al, 2010; Baldassarre et al, 2010

The Nermes et al 2010 reference is a study of 39 children with atopic dermatitis, not CMPA. The Baldassarre et al 2010 reference relates to a small, under-powered study of children with blood in their stools. We do not consider this to be sufficient evidence for the claim.

3 "The only eHF clinically proven to accelerate time to tolerance"

"8 out of 10 infants are tolerant to cow's milk after 12 months of use"

Evidence given to support the claims

Canani et al, 2013. (The same reference is used for both the above claims.)

This Canani study compared outcomes from a non-randomised study of infants given either casein-based eHF with or without LGG, rice hydrolysate, soy or amino-acid formula. However, in the study, infants were divided into groups depending on *formula already given* and this was not a randomized control trial. Breastfeeding time was not explained beyond the percentage breastfed up to the age of at least 2 months, groups were on multiple formula types, and small numbers were involved. Time to tolerance related to whether CMPA was IgE mediated, and whether any eHF was used.

What does current accepted policy/science say?

The World Allergy Organization (WAO) concluded that "No single probiotic supplement or class of supplements has been demonstrated to efficiently influence the course of any allergic manifestation or long-term disease or to be sufficient to do so." (Fiocchi et al, 2012)

The recent EFSA (2014) *Scientific opinion on the essential composition of infant and follow-on formulae* notes that the evidence for any benefit of probiotics on infant health comes from single studies and studies with methodological limitations, and concludes that there is no evidence for beneficial effects and that these are not necessary additions to infant and follow-on formula.

The NICE Clinical Knowledge Summary on managing cows' milk protein allergy makes no mention of probiotics in its treatment recommendations (NICE, 2015). For further information about this product, see www.firststepsnutrition.org.

Our conclusion

We do not believe that the evidence provided here by Mead Johnson to support the claims made in this advertisement is sufficiently robust. One small non-randomised trial is insufficient evidence on which to make a claim for accelerating time to tolerance of CMPA. Some of the claims made relate to a different product, and evidence is provided for other conditions such as atopic dermatitis.

References

- Baldassarre ME, Laforgia N, Fanelli M et al (2010). Lactobacillus GG improves recovery in infants with blood in the stools and presumptive allergic colitis compared with extensively hydrolyzed formula alone. *The Journal of Pediatrics*; 156: 397-401.
- Canani RB, Nocerino R, Terrin G et al (2013). Formula selection for management of children with cow's milk allergy influences the rate of acquisition of tolerance: A prospective multicenter study. *The Journal of Pediatrics*; 163: 771-77.
- Dupont C, Chouraqui JP, de Boisseau D et al (2012). Dietary treatment of cows' milk protein allergy in childhood: a commentary by the Committee on Nutrition of the French Society of Paediatrics. *British Journal of Nutrition*; 107: 325-38.
- EFSA (2014). *Scientific opinion on the essential composition of infant formula and follow-on formulae*. Parma, Italy: European Food Safety Authority. Available at <http://www.efsa.europa.eu/en/efsajournal/pub/3760>
- Fiocchi A, Burks W, Bahna SL et al, on behalf of the WAO Special Committee on Food Allergy and Nutrition (2012). Clinical use of probiotics in pediatric allergy (CUPPA): a World Allergy Organization position paper. *World Allergy Organization Journal*; 5: 148-67.

Advert for: Similac Alimentum (Abbott Nutrition)

Advert seen in: *Complete Nutrition*, March 2016



REFERENCES: 1. Sampson HA *et al.* *J Pediatr* 1991;118(4):520-525. 2. Data on file. Abbott Laboratories Ltd., 2013 (Similac Alimentum case studies). 3. Borschel MW and Baggs GE. *T O Nutr J* 2015;9:1-4. 4. Koo WWK *et al.* *J Am Coll Nutr* 2006;25(2):117-122.

IMPORTANT NOTICE: Breastfeeding is best for babies, and is recommended for as long as possible during infancy. Similac Alimentum is a Food for Special Medical Purposes and should be used under the supervision of a healthcare professional.

Date of preparation: July 2015
RXAN150117

THIS IS HUGE

After months of coping with the sleepless worry and heartbreaking cries of her cow's milk allergy, suddenly, a little moment like this doesn't seem so little after all.



- Proven efficacy – hypoallergenic and has been shown to relieve symptoms^{1,2}
- Proven to be well tolerated – 96% of infants tolerated Similac Alimentum³
- Palm oil and palm olein oil free – supports calcium absorption and bone mineralisation⁴

SIMILAC ALIMENTUM. FOR BIG LITTLE MOMENTS.

Appetite for life

 **Abbott**



Advert for: Similac Alimentum (Abbott Nutrition)

Summary of advert

In this double-page spread advert, the focus is on an attractive young mum with her baby, both sleeping in a sunlit room. The main heading on the second page is “THIS IS HUGE”, with the text below saying “After months of coping with the sleepless worry and heartbreaking cries of her cow’s milk allergy, suddenly, a little moment like this doesn’t seem so little after all.” There is a picture of the tin and three claims, followed by a brand name reminder. The four references given to support the claims are given in very small type on a brown background in the bottom left-hand side of the advert. Below the references there is an ‘Important Notice’ stating that “Breastfeeding is best for babies and is recommended for as long as possible during infancy. Similac Alimentum is a Food for Special Medical Purposes and should be used under the supervision of a healthcare professional.”

Claims made, and evidence given to support them

- 1** “Proven efficacy – hypoallergenic and has been shown to relieve symptoms^{1,2}”

1 Sampson HA et al (1991)

2 Data on file. Abbott Laboratories Ltd, 2013 (Similac Alimentum Case Studies)

Evidence given to support this claim

Sampson et al, 1991

This paper was a simple study which showed that, if infants had been diagnosed with cows’ milk protein allergy, an extensively hydrolysed casein based formula would not stimulate an allergic reaction. This is to be expected and any extensively hydrolysed formula would have this effect. The safety of use of a casein hydrolysate does not qualify as a study of efficacy of outcome.

Data on file. Abbott Laboratories Ltd, 2013

It is quite common for the data that is being used to support claims made in an advertisement to be kept ‘on

file’ by the company. We have asked for access to this particular data and were told by Abbott (15 February 2016) that “The data on file we have is raw data, which is something we are unable to share with you.”

- 2** “Proven to be well tolerated – 96% of infants tolerated Similac Alimentum³”

3 Borschel MW and Baggs GE (2015)

Evidence given to support this claim

Borschel and Baggs, 2015

The reference given here to support this claim was of a small methodologically challenged study funded and authored by Abbott. It was a small non-randomised observational study of 25 infants with varying symptoms such as allergic colitis, persistent formula intolerance, or blood in stools. Some data is provided in the paper: mean age of entry to the study was 12 weeks of age (range 0-180d); seven of the sample were > 4 months old; but no summary table of the baseline characteristics of the sample is provided. The infants were put on a 15-day trial of Similac Alimentum, with parent-reported outcomes and measurements taken at a first visit and exit visit two weeks later. The figure they quote of 96% of infants tolerating this formula is not explained in this short paper and the way that the simple five-point questionnaire categories were analysed (without any statistical analysis) was also biased to positive responses. However, it appears from the data in this paper that, although there were some positive perceived changes over the two-week period, there was a 62% increase in parents reporting watery stools, no change in the amount of vomiting reported, and little change in bad stool odour. This study does not provide sufficient evidence that this milk is proven to be well tolerated.

- 3** “Palm oil and palm olein oil free – supports calcium absorption and bone mineralisation⁴”

4 Koo WWK et al, 2006

Evidence given to support this claim

Koo et al, 2006

Similac Alimentum has maltodextrin as the main ingredient, followed by vegetable oils: high oleic safflower oil, medium chain triglycerides (MCT) oil and soy oil. The paper by Koo et al (2006) is a systematic review of nine studies of infants – including premature infants and those up to around 6 months of age – and suggests that there

are clear links with reduced bone mineralisation when palm olein containing formula are fed. Professor Koo has strong links with Abbott Nutrition. Data from an Abbott funded study by Koo et al (2003) which was influential in this review has been criticised since there was no breastfed reference group and it is known that there is a large variation in normal bone mineral content and density in both human milk fed and formula-fed infants. Whilst there might be significant differences between bone densities in infants in the first months of life by formula type, if these are in the normative range it may not be meaningful. It is well known that the bone density of breastfed babies is often lower than in those fed formula in infancy, without adverse long-term outcomes (Butte et al, 2000). Just because bone mineral accretion levels in infants fed one formula over another is greater, does not in itself have any clinical significance.

What does current accepted policy/science say?

It is known that all extensively hydrolysed formula have efficacy in treating cows' milk protein allergy, but all expert recommendations focus on breastfeeding and maternal diet exclusion as the first line of treatment (NICE, 2015).

The fat and fatty acid content of infant formula (and foods for special medical purposes) is specified by recommendations in the appropriate EU Directive and subsequent regulations. Currently a range of vegetable oils and animal fat are permitted providing that the overall fat profile meets required compositional regulations.

Our conclusion

There is no doubt that an infant diagnosed with cows' milk protein allergy who is not being breastfed requires an extensively hydrolysed formula. However, this advert claims brand superiority through making claims around tolerance, efficacy and better bone mineralisation, all of which are supported by very weak evidence. The aim of the advert is not to support health professionals in their choice of formula through scientific and factual information, but to gain brand awareness and ensure that the brand is associated with warm and emotive images.

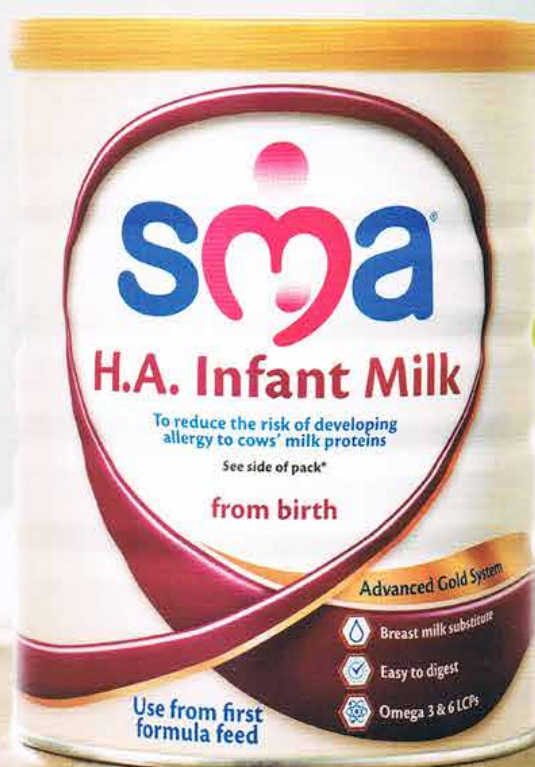
References

- Borschel MW, Baggs GE (2015). A new hydrolysed formula is well tolerated in infants with suspected food protein allergy or intolerance. *The Open Nutrition Journal*; 9: 1-4.
- Butte NF, Wong WW, Hopkinson JM et al (2000). Infant feeding mode affects early growth and body composition. *Pediatrics*; 106: 1355-66.
- Koo WWK, Hockman EM, Dow M (2006). Palm olein in the fat blend of infant formulas: effect on the intestinal absorption of calcium and fat, and bone mineralization. *Journal of the American College of Nutrition*; 25: 117-22.
- Koo W, Hammami M, Margeson DP et al (2003). Reduced bone mineralisation in infants fed palm olein containing formula: a randomised double-blinded prospective trial. *Pediatrics*: 111: 1017-23.
- NICE (2015). Cows' milk protein allergy in children. Available at: <http://cks.nice.org.uk/cows-milk-protein-allergy-in-children>.
- Sampson HA, Bernhisel-Broadbent J, Yang E, Scanlon SM (1991). Safety of casein hydrolysate formula in children with cow milk allergy. *Journal of Pediatrics*; 118: 520-25.

FOR HEALTHCARE PROFESSIONALS ONLY

Especially for Oliver

- ✓ Reduces the risk of developing allergy to cows' milk proteins
- ✓ Easy to digest
- ✓ Omega 3 and 6 LCPs



Oliver has a family history of allergy.

SMA H.A.[®] Infant Milk is a nutritionally complete formula that has been designed to reduce his chances of developing an allergy to cows' milk proteins.

Available to buy at Boots or to order via pharmacies using the following PIP code

Supporting you to support mums



www.smahcp.co.uk
SMA Careline: 0800 0 81 81 80



378-5912
individual tin 800g

Important: SMA H.A.[®] Infant Milk should NOT be used if a baby has already been diagnosed with allergy to cows' milk proteins or is suspected of already having an allergy to cows' milk protein.

IMPORTANT NOTICE: Breast milk is best for babies and breastfeeding should continue for as long as possible. Infant milks should only be used on the advice of a doctor, midwife, health visitor, public health nurse, dietitian or pharmacist, or other professionals responsible for maternal and child care.

[®]Registered trademark

ZTC451d/03/15

Advert for: SMA H.A. Infant Milk (Nestlé)



Summary of advert

This advert has a simple top line sentence: “Especially for Oliver”. Under the main picture is a sentence in smaller type that says “*Oliver has a family history of allergy*”

and “*SMA H.A. Infant Milk is a nutritionally complete formula that has been designed to reduce his chances of developing an allergy to cows’ milk proteins.*”

The main body of the advert also includes a picture of the formula tin, which highlights that this product must be used “*from first formula feed*” and claims to have an “*Advanced Gold System*” although this is not explained. There are also three claims – that the product reduces the risk of developing allergy to cows’ milk proteins, that it is easy to digest and that it contains omega 3 and 6 LCs. No references are given to support these statements and claims. The advert also highlights the SMA careline and websites and where the product can be bought. There is also an important notice in a coloured band at the bottom of the page that states:

“*SMA H.A Infant Milk should NOT be used if a baby has already been diagnosed with allergy to cows’ milk protein or is suspected of already having an allergy to cows’ milk protein.*”

Claims made, and evidence given to support them

1 “Reduces the risk of developing allergy to cows’ milk proteins”

No evidence is presented to support this claim. It is a requirement that adverts to health professionals should be scientific and factual and that, if a claim is made about reduction of risk to allergy, objective and scientifically verified data must be available as proof of the claimed properties.

2 “Easy to digest”

No evidence is given to support this claim.

3 “Contains Omega 3 and 6 LCs”

No additional information is provided to support this statement.

What does current accepted policy/science say?

In the UK, current policy from the last published review undertaken by NICE reported that:

“*There is insufficient evidence that infant formulas based on partially or extensively hydrolysed cows’ milk protein can prevent allergies.*” (NICE, 2008)

In 2013, a ‘review of systematic reviews’ looking at evidence in prevention and aetiology of food allergy considered 14 systematic reviews in this area (Lodge et al, 2013) and concluded that:

“*There is insufficient evidence to conclude that the use of hydrolysed formulas may reduce food allergy/ sensitization when compared with standard formula in high atopy risk children.*”

The EFSA *Scientific opinion on the essential composition of infant and follow-on formulae* in 2014 stated that reducing the size of protein molecules cannot reduce the risk of allergy in infants from at-risk families:

“*The characterisation of protein hydrolysates by molecular weight of the protein cannot predict their potential to reduce the risk of developing allergic manifestations in genetically predisposed infants.*”

In 2016 a systematic review and meta-analysis published in the *British Medical Journal* (Boyle et al, 2016) concluded that “*Overall there was no consistent evidence that partially or extensively hydrolysed formulas reduce risk of allergic or autoimmune outcomes in infants at high pre-existing risk of these outcomes.*”

Our conclusion

The manufacturers provide no evidence to support their claims in this advert and therefore we believe it is not in line with current regulations. This advert has large type at the top of the page suggesting that this product reduces the risk of developing allergy to cows' milk protein, and much smaller type at the bottom making it clear this product should not be used when cow's milk protein allergy is diagnosed or suspected. We believe this is highly confusing, and a potential risk.

The claims made for this product are reviewed in more detail in the report *Infant Milks in the UK*, available at www.firststepsnutrition.org

References

Boyle RJ, Ierodiakonou D, Khan T et al (2016). Hydrolysed formula and risk of allergic or autoimmune disease: systematic review and meta-analysis. *British Medical Journal*; 352: i974 <http://dx.doi.org/10.1136/bmj.i974>

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

Lodge CJ, Allen KJ, Lowe AJ, Dharmage SC (2013). Overview of evidence in prevention and aetiology of food allergy: a review of systematic reviews. *International Journal of Environmental Research and Public Health*; 10: 5781-806.

National Institute for Health and Clinical Excellence (2008). *Maternal and Child Nutrition. Public Health Guideline*. Available at: www.nice.org.uk

Advert for: SMA PRO First Infant Milk – short advert (Nestlé)




Advert seen in: *Dietetics Today*, March 2016

FOR HEALTHCARE PROFESSIONALS ONLY
BREASTFEEDING IS BEST FOR BABIES

Three good reasons to choose our new SMA[®] PRO First Infant Milk*



Available from January 2016.

-  Clinically proven¹
-  Made with SMA[®] Nutrition's exclusive protein process
-  Contains Omega 3 & 6 LCPS and GOS/FOS**

Learn more about SMA[®] PRO range at

www.smahcp.co.uk
www.smahcp.ie

SMA Careline UK: 0800 0 81 81 80
ROI: 1800 931 832



Supporting you
to support parents

IMPORTANT NOTICE: Breast milk is best for babies and breastfeeding should continue for as long as possible. Infant milks should only be used on the advice of a doctor, midwife, health visitor, public health nurse, dietitian or pharmacist, or other professionals responsible for maternal and child care.

*When bottle feeding is considered.

**In powder formulation only; GOS/FOS = Galacto-oligosaccharides/Fructo-oligosaccharides.

Reference: 1. Grathwohl DJ *et al.* Abstract at EAPS congress, 2010.

*Registered trademark

SMA[®] Nutrition UK and Ireland

ZTC1184/11/15

Advert for: SMA PRO First Infant Milk – short advert (Nestlé)



Summary of advert

This advert has a simple heading: “Three good reasons to choose our new SMA® PRO First Infant Milk”. Next to a picture of the tin, there are three claims: that the milk is clinically

proven; that it is made with SMA Nutrition’s exclusive protein process; and that it contains Omega 3 & 6 LCs and GOS/FOS. There is one reference given to support the first of the claims, and asterisks are used to highlight that the third highlighted claim refers only to the powder formulation. The advert also gives details of the SMA Carelines and websites.

Claims made, and evidence given to support them

1 “Clinically proven”

Grathwohl DJ et al. Abstract at EAPS congress. 2010.

This claim is supported by one reference to a poster presentation by Grathwohl et al (2010). This is not a peer-reviewed publication. This poster reported a meta-analysis of four studies looking at the growth of infants fed with Nan milk (another milk produced by Nestlé), and claims that there is good agreement with the WHO growth standard. This data does not appear to have been subsequently published in a peer-reviewed journal, which is not a surprise as it is unlikely that a formula-fed group of infants grew in the same way as breastfed infants. There is no detail about which Nan formula this is, but it was one used in Australia, France and Italy at that time. It is unclear whether the milk advertised here is the same milk as that used in the previous studies and therefore it is impossible to know how they can claim that it is ‘clinically proven’. There is no detail on what it is clinically proven to do.

It is a requirement that adverts that make statements that are not permissible as health claims provide evidence from peer reviewed journals to support this.

2 “Made with SMA® Nutrition’s exclusive protein process”

No evidence is given to explain what this is, and what if any benefits it provides.

3 “Contains Omega 3 & 6 LCs and GOS/FOS**”

** In powder formulation only. GOS/FOS = Galacto-oligosaccharides/Fructo-oligosaccharides

No claims are made for any benefit associated with these components. It is only the powdered formula that contains GOS/FOS, not the ready-to-feed formula, suggesting that the company itself is not convinced of the benefit of adding these components.

It is a regulatory requirement that infant formula provides a specific fatty acid profile, and it is not clear whether the fatty acids in this milk simply ensure that it meets current compositional regulations.

What does current accepted policy/science say?

This advert is so vague that it is hard to know what claims it is making. The claim that it is clinically proven is not supported by evidence. There is no evidence that GOS/FOS offer any benefit when added to infant formula (EFSA, 2014) and no claim is made here and the fatty acids added may simply ensure the formula meets compositional regulations.

Our conclusion

This simplistic advert is used to create brand awareness, with a large picture of the formula tin and some general unsubstantiated claims. It is positioned in magazines on the page before a longer advert which appears to show a much more scientific explanation as to the benefits of this product. This technique is often used in marketing to give health professionals a ‘brand boost’ followed by ‘technical assurance’ of claims made. We review the second advert in this current series on the next page. In other magazines, additional brand confidence is being encouraged by placing this product-specific advert in the same magazine as an advertisement campaign for the brand SMA which promotes breastfeeding and the first 1,000 days. SMA’s aim is to position itself as the ‘breastfeeding-friendly’ brand, while ensuring that the formula brand itself remains centre stage. The halo of goodness from promotion of breastfeeding aims to provide credibility to the brand.

There is no evidence presented here to provide any clarity about this product. The one reference provided is not from a peer-reviewed journal and may not relate to the formula being advertised here.

References

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

Grathwohl D, Macé K, Fichot MC, et al (2010). Evaluation of breastfed infants with respect to WHO growth standard: a meta-analysis. Poster presentation at EAPS Congress. *Pediatric Research*; 68: 602.

Which First Infant Milk is most in line with expert opinion on growth?

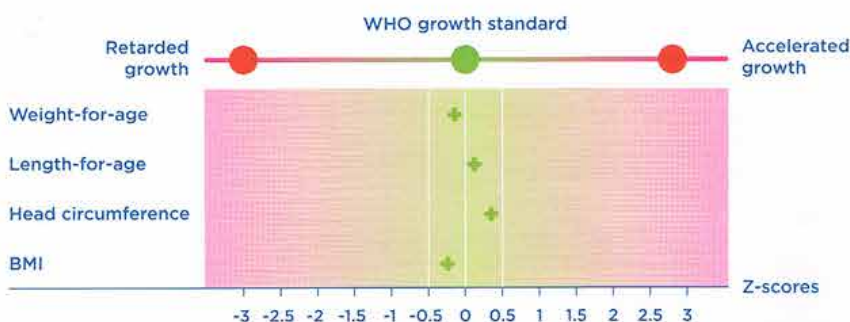
The Department of Health recommends exclusive breastfeeding for the first six months of life.¹

Protein and the importance of slower growth rates

Because the protein in breast milk is adapted to a baby's needs,² a breastfed baby tends to grow more slowly than a formula fed baby.³ This slower growth rate has shown to have significant long-term health benefits, including a lower risk of obesity, cardiovascular disease and diabetes.⁴

SMA PRO First Infant Milk is the only first infant milk clinically proven to achieve a growth rate comparable with a breastfed baby as defined by WHO growth standards¹⁰

SMA PRO First Infant Milk versus WHO growth standard z-scores at 4 months



Green dots represent average growth measurements in infants fed SMA PRO First Infant Milk compared to WHO growth standards. Growth within +/- 0.5 standard deviation of WHO growth standards is desirable.

We've responded to expert opinion about proteins in SMA[®] PRO First Infant Milk

"Protein intakes of infants are generally well above the requirements, so protein content of Infant Formula and Follow-on Formula could be reduced"

European Food Safety Authority 2014¹



SMA PRO First Infant Milk is the lowest protein formula available at 1.25 g*/100 ml (1.87 g*/100 kcal)⁶

*Powder only, liquids will vary

"The breast milk content of amino acids is the best estimate of infant amino acid requirements"

WHO/FAO/UNU 2014¹



SMA PRO First Infant Milk has an essential amino acid profile similar to that of breast milk⁷

Of the essential amino acids, four have been shown, when supplied in excess, to be associated with increased release of insulin. This may trigger a cascade of reactions in the body which may result in faster growth.⁸

European Childhood Obesity Trial Study Group 2015⁹



SMA PRO First Infant Milk has lower levels of insulinogenic amino acids compared with other first infant milks⁸



Visit us: smahcp.co.uk or smahcp.ie

sma
nutrition

Supporting you to support parents

Getting the right quantity and quality of protein in infant and toddler diets has lifelong health benefits.

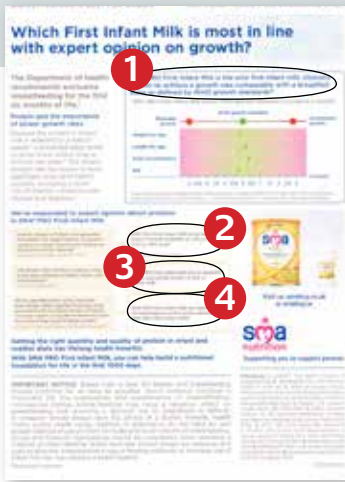
With SMA PRO First Infant Milk, you can help build a nutritional foundation for life in the first 1000 days.

IMPORTANT NOTICE: Breast milk is best for babies and breastfeeding should continue for as long as possible. Good maternal nutrition is important for the preparation and maintenance of breastfeeding. Introducing partial bottle-feeding may have a negative effect on breastfeeding and reversing a decision not to breastfeed is difficult. A caregiver should always seek the advice of a doctor, midwife, health visitor, public health nurse, dietitian or pharmacist on the need for and proper method of use of infant formulae and on all matters of infant feeding. Social and financial implications should be considered when selecting a method of infant feeding. Infant formulae should always be prepared and used as directed. Inappropriate foods or feeding methods, or improper use of infant formula, may present a health hazard.

[®]Registered trademark

References: 1. UNICEF. The Health benefits of breastfeeding. 2. Lönnerdal B. *Am J Clin Nutrition* 2003; 77: 1537-43. 3. WHO UK Growth Charts. <http://www.rcpch.ac.uk/improving-child-health/public-health/uk-who-growth-charts/faqs/uk-who-growth-chart-faqs>. 4. Singhal A & Lucas A. *Lancet* 2004; 363: 1642-1645. 5. EFSA. Scientific Opinion on the essential composition of infant and follow-on formulae. *EFSA Journal* 2014; 12(7): 3760. 6. SMA[®] PRO First Infant Milk Datacard. 7. Protein and Amino Acid Requirements in Human Nutrition, Report of a Joint WHO/FAO/UNU Expert Consensus 2007. 8. Nestlé data on file, 2014. 9. Kirchberg FF *et al.* *J Clin Endocrinol Metab* 2015; 100(1): 149-58. 10. Grathwohl DJ *et al.* Abstract at EAPS Congress, 2010.

ZTC1238/12/15



Summary of advert

This advert for SMA PRO is used in health professional publications, but with a more complex and scientific-appearing messaging than the advert shown on page 33.

The top line “Which First Infant Milk is most in line with expert opinion on growth?” is repeated in the sentence above a graphical image, with a reference to a poster presentation.

The advert uses information about breastmilk to suggest similarity with this product, but the direct claim “SMA PRO has an essential amino acid profile similar to that of breast milk” is supported only by Nestlé data kept on file. The remainder of the claims and references relate to breastmilk.

The advert also states that “We’ve responded to expert opinion about proteins in SMA PRO First Infant Milk”, but all the expert opinion cited relates to breastmilk, not infant formula.

Claims made, and evidence given to support them

1 “SMA PRO First Infant Milk is the only first infant milk clinically proven to achieve a growth rate comparable with a breastfed baby as defined by WHO growth standards.”



Evidence given to support this claim

The chart shows data that does not appear to have been published, and which the manufacturers claim shows that infants fed SMA PRO (although the milk in the studies they allude to may not have been the same milk) have growth within +/- 0.5 standard deviations of WHO growth standards for three anthropometric criteria.

The data presented here is referenced to a 1-page poster presentation by Grathwohl et al (2010), given at a conference. This is not a peer-reviewed publication, the authors are Nestlé employees, and no data is presented. The poster reported a meta-analysis of four studies looking at the growth of infants fed with Nan milk (another milk produced by Nestlé), and claims that there is good agreement with the WHO growth standard. This data does not appear to have been published subsequently, and it is unlikely that a formula-fed group of infants grew in the same way as breastfed infants. It is well established that breastfed babies have different growth rates to formula-fed babies. There is no detail about which Nan formula was given in these studies, but it was one used in Australia, France and Italy when the studies were conducted. It is unclear whether the milk advertised here is the same milk, and therefore it is impossible to know how the manufacturers can claim that it is ‘clinically proven’ or what it is clinically proven to do.

It is a requirement of ‘scientific and factual’ adverts presented in specialist magazines that claims made are supported with evidence from a peer-reviewed journal.

2 “SMA PRO First Infant Milk is the lowest protein formula available at 1.25g/100ml (1.87g/100kcal)¹”
 1 Powder only liquids will vary.

Data given to support this claim is the SMA PRO First Infant Milk datacard.

3 “SMA PRO First Infant Milk has an essential amino acid profile similar to that of breast milk.”

The reference given for this is the SMA PRO First Infant Milk datacard. This provides no evidence of similarity with breastmilk.

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

The reference given for this is Nestlé data on file, 2014. We have requested this data, but it has not been made available.

What does current accepted policy/science say?

There are no recommendations related to the manipulation of proteins which have been shown to offer any benefit to infant growth or health outcome.

All infant formula must meet specified requirements for protein and amino-acid composition.

EFSA (EFSA, 2014) are clear that “*infant formula cannot mimic breastmilk in relation to its energy and protein content*”.

Our conclusion

There is no evidence presented to provide support for the claims made about this product. The reference provided for the main claim of growth comparable to breastfed babies is inadequate as it is a poster presentation by Nestlé staff, and it is not even clear what milk it relates to. Other claims are supported by data that is not published and not available on request. The majority of references presented relate to breastmilk and not to infant formula, and the manufacturers are making a clear link between their product and breastmilk. This advert is put alongside the simple SMA PRO advert discussed on page 33 to provide ‘scientific evidence’ to support the claims made. By using a chart from data that does not appear to have been published, and providing references which are not necessarily related to their product, they attempt to suggest that they have a scientific basis for their claims.

It is a requirement of scientific and factual advertisements presented in healthcare magazines that they support any claims with data from peer-reviewed publications.

References

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>

Grathwohl D, Macé K, Fichot MC et al (2010). Evaluation of breastfed infants with respect to WHO growth standard: a meta-analysis. Poster presentation EAPS Congress. *Pediatric Research*; 68: 602.



FIRST STEPS NUTRITION TRUST

