

Soya protein-based infant formula

Key points

Soya protein-based infant formula use protein from soya beans and contain no animal protein or lactose.

The carbohydrate source in soya protein-based infant formula is maltodextrin rather than lactose, these milks therefore have a greater potential to cause dental caries than animal milk based infant formula.

Concerns have been raised over the potential allergenic effect of soya protein-based infant formula in infants at high risk of atopy and over the effects that the phyto-oestrogens present in soya protein-based formula might have on future reproductive health.

A report by The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) concluded that the high levels of phyto-oestrogens present in soya protein-based milks posed a potential risk to the future reproductive health of infants (COT, 2003)

A more recent statement by COT concluded that the available evidence on risks to reproductive health is too limited to provide strong reassurance of safety and stated that there is no scientific basis for a change in the current government advice (COT 2013).

The UK government advises that soya protein-based infant formula should only ever be used if it has been recommended or prescribed by a health visitor or GP, and then only from 6 months.

Soya protein-based infant formula combine protein from soya beans with water, vegetable oils, maltodextrins, vitamins and minerals. The amino acid profile of soya protein is deficient in sulphur-containing amino acids, and soya protein-based milks must therefore be fortified with the sulphur-containing amino acid L-methionine.

Soya protein based infant formula (supplemented with methionine) support normal growth and development in healthy term infants during the first year of life (Mendez et al, 2002),

The required composition of soya protein based infant formula is different to that of cows' or goats' milk based infant formula for a number of micronutrients including iron and phosphorus due to differences in bioavailability. Soya protein-based infant formula is suitable for vegetarians, but not for vegans, as the Vitamin D is sourced from sheep's wool lanolin.

Maltodextrin is used in place of lactose as the main carbohydrate in soya protein-based infant formula in the UK. Whilst lactose is a non-cariogenic sugar, the relationship between maltodextrin and dental caries is not fully understood due to a scarcity of studies reporting its cariogenic potential and its association with other carbohydrates. It has however, been



reported that maltodextrin has an acidogenic potential lower than sucrose (Rezende and Hashizume, 2018). Parents and carers using soya protein-based infant formula are advised to avoid prolonged contact of milk feeds with their baby's teeth and ensure that they clean their baby's teeth after the last feed at night.

Soya based infant formula has sometimes been used for children who require an alternative to cows' milk based infant formula because they have an allergy or intolerance to cows' milk, or because they have a specific condition such as galactosaemia or galactokinase deficiency, however, its use for children aged under 6 months is controversial. Concerns have been raised over the potential allergenic effect of soya protein-based infant formula in infants at high risk of atopy and the potential role of phyto-oestrogens on infant development.

Soya protein and cows' milk protein allergy

Soya protein-based infant formula has been used as an alternative to cows' milk protein-based infant formula in children with cows' milk protein allergy (CMPA). In a review of trials comparing the effect of prolonged feeding of either soya or cows' milk protein-based infant formula, meta-analysis found no significant difference between feeding groups in the incidence of childhood asthma, eczema or rhinitis. The authors concluded that soya protein-based infant formula cannot be recommended for allergy prevention or food intolerance in infants at high risk of atopy (Osborn and Sinn, 2006).

It is recognised that a proportion of children with CMPA are also allergic to soya protein. The Chief Medical Officer has recommended that soya protein-based infant formula should not be used as the first line of treatment for infants under 6 months of age who have CMPA or cows' milk protein intolerance, as this is the period when they are most likely to become sensitised to soya protein (Chief Medical Officer, 2004). ESPGHAN recommends that soya protein-based infant formula should not be used for infants under 6 months of age and that the use of therapeutic milks based on extensively hydrolysed proteins (or amino acid preparations if hydrolysates are not tolerated) should be preferred to the use of soya protein formula in the treatment of cows' milk protein allergy (Agostoni et al, 2006).

Phyto-oestrogens and reproductive health

Concerns have been raised over the effects that phyto-oestrogens in soya protein-based infant formula might have on future reproductive health which relate mainly to their ability to mimic the female hormone oestrogen. Soya protein-based formula contain much higher levels of phyto-oestrogens than infant formula based on cows' milk or goats' milk protein. The highest potential exposures of infants to isoflavones (a type of phyto-oestrogen) come from exclusive consumption of soya-based infant formula (COT, 2013). It has been estimated that infants aged 1 to 4 months who were fed soya protein-based infant formula would receive 6-12mg/kg of body weight of phyto-oestrogens per day, compared to 0.7-1.4mg/kg body weight per day for adults consuming soya protein-based products (Setchell et al, 1998)



While the small number of available epidemiological studies does not suggest that such consumption leads to adverse health effects in humans, the results of animal studies indicate a possible concern, and there is thus some uncertainty about the safety of soya-based infant formula.

In their most recent statement, the COT conclude that the available studies have produced conflicting results, and while the balance of evidence from these does not suggest important adverse effects of soy infant formula on reproductive development, they are too limited to provide strong reassurance of safety and that there is no scientific basis for changing the current government advice – namely, that there is no substantive medical need for, nor health benefit arising from the use of soya-based infant formula, and that it should be used only in exceptional circumstances to ensure adequate nutrition (COT, 2013).

More recent research has looked at potential links between soya infant formula and seizures in children with autism. Westmark et al, (2014) hypothesised that phyto-oestrogens in soya protein-based infant formula can contribute to lower seizure threshold. Whilst this study reports links using data from retrospective data collection and therefore cannot confirm an association, it reiterates the need for caution in the use of soya protein-based formula in infancy.

The NHS recommend that soya formula should only be used if it has been recommended or prescribed by a health visitor or GP, and then only from 6 months of age.

References

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