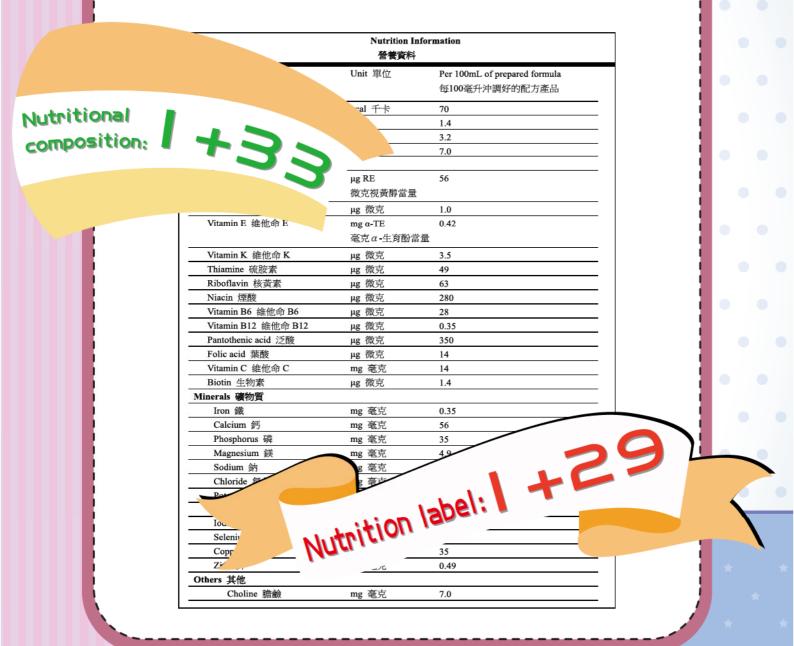
Nutritional Composition and Nutrition Labelling of Infant Formula

Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014







Nutritional Composition and Nutrition Labelling of Infant Formula

Food and Drugs (Composition and Labelling) (Amendment) (No. 2) Regulation 2014

Breastfeeding is unquestionably the best choice of diet for infants, in which breastmilk contains natural antibodies that enhances babies' immunity and offers comprehensive nutrients that foster growth. During the first few months of life, breastmilk alone provides adequate nutrition to meet the requirement of babies. Babies approaching 6 months old start going through a developmental transition from a milk-only diet to an adult diet with varieties. Various nutritious complementary foods are introduced to their diet, while breastfeeding can be continued until the child is 2 years old or older. However, breastfeeding may not be feasible in some cases and caregivers need to take the second choice, i.e. infant formula. Being the sole food source or a substitute for breastmilk for infants during the first few months of life, the safety and nutritional adequacy of infant formula are of paramount importance. Starting from 13 December 2015, infant formula must fulfill a set of nutritional composition requirements, mainly "Energy+33 nutrients" ("1+33"), and provide a nutrition label showing the contents of "Energy+29 nutrients" ("1+29").

Composition of Infant Formula

While the nutritional composition of infant formula mimics that of breastmilk, certain nutrients in breastmilk are more easily absorbed than those of formula. Furthermore, the nutritional content of breastmilk changes as the baby grows. Yet, the composition of infant formula shall provide the nutrients that are essential for growth and development of infants. With regard to the nutritional composition requirements of infant formulae, the government has specified the contents of energy and the 33 essential nutrients (i.e. "1+33") it provides with reference to the standards of the Codex Alimentarius Commission (Codex).

Energy and Essential Components of Infant Formula

Energy

- Fuel for infants.
- It comes from carbohydrates, fat and protein, with carbohydrates being the primary source of energy.

Protein

- Protein is required for maintaining and repairing body tissues as well as producing hormones, antibodies and enzymes.
- It may be sourced from cows milk protein or soy protein.

Fat

- It provides essential fatty acids for normal brain and eye development and absorption of the fat-soluble vitamins.
- Fat stored in the body also reduces body heat loss and protects body organs.

Carbohydrates

 Getting sufficient carbohydrate intake enables normal and efficient use of dietary fat and protein in the body for other essential functions such as building new tissues.

Vitamins and Minerals (e.g. vitamin A, calcium, iron)

- Micronutrients are needed in small amounts but are essential for growth, development and normal body function.
- During infancy and early childhood, the requirement for micronutrients is high.

Other substances

• Choline, Myo-inositol, and L-Carnitine.

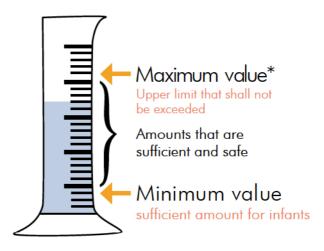
Labels Parents See

Items on the nutrition label	"1+29" label
Energy	✓
Protein	✓
Total fat	✓
Total carbohydrates	✓
Minerals	12 types
Vitamins	13 types
Other substances	✓ (Choline)

The nutrition labelling requirements (i.e. "1+29") are established in accordance with international practices. Infant formula has the contents of energy and nutrients labelled, where it is the sole source of diet for infant when breastfeeding is not feasible.

More is Better?

The standards for the energy and nutrients in infant formula of the Codex are specified with minimum values or ranges; the minimum amounts are levels that considered sufficient to fulfill the nutritional requirements of infants. For some nutrients, maximum values are established and it is important to note that the maximum values are not target values to be achieved by manufacturers of formula products. For nutrients with a documented risk of adverse health effects, maximum values are set on the basis of scientific assessment or, if such data are not available, on the basis of an established history of apparently safe use.



*Specified for some nutrients

There is no need to choose infant formula products with the highest amount of nutrients, provided that the nutrient contents are above the minimum values. The body will excrete nutrients that are not utilised or stored. Taking excess nutrients

may actually put a burden on the infant's metabolism. In addition, too much of some nutrients in formula products is as harmful as not enough. For example, excessive sodium intake may lead to dehydration as a result of high blood sodium levels, a tendency to prefer salty food and elevated blood pressure in the long run. Hence, read the nutrition label to make a better choice.

Taurine, Nucleotides, DHA... What else?

On top of essential compositions, manufacturers often add other substances to formula products, claiming that they bring additional nutritional benefit on various aspects. In fact, these are not essential nutrients in the infant formula and products with or without these ingredients are both acceptable. (See below) Yet, it should be noted that taurine and docosahexaenoic acid (DHA), if added to infant formula, are required to follow the relevant requirements in terms of maximum value and proportion respectively.

Taurine

Taurine is a major constituent of bile salts and is abundant in foetal and neonatal human brain. It plays an important role in the absorption of fat and fat soluble vitamins and maintenance of normal liver functions. Although taurine is commonly added to formula products because of the anticipated benefits on visual, auditory and intestinal development of infants, relevant evidence from human studies is lacking. The Codex considers mandatory addition of taurine is not necessary in formula products. Taurine is available from human breastmilk, and also in seafood and meat.

Nucleotides

Nucleotides are core structural units of DNA and RNA. They are involved in protein synthesis and metabolic regulatory processes. Nucleotides are added to formula products to mimic breastmilk with the anticipated benefits of enhancing immune functions and promoting growth of infants. However, evidences of beneficial effects from nucleotide supplementation of infant formulae are not conclusive. The Codex does not require the addition of nucleotides in formula products. In fact, nucleotides could be produced in the human body and are widely available in foods.

Docosahexaenoic acid (DHA)

DHA is a long-chain polyunsaturated fatty acid which has a critical role in normal retinal and brain development of foetus in the first two years of life. DHA presents in varying amounts in human breastmilk, fish oils, and marine algae. Apart from its dietary sources, the body can produce DHA from α -linolenic acid, which is found in plant oils as well as breastmilk and infant formula.

Some formula manufacturers add DHA-containing ingredients in their formula products. This is mainly to mimic the composition of breastmilk (mean DHA content ranges from 0.2-1.0% of fatty acids), and to take into consideration the typically higher blood level of DHA in breastfed infants than that in infants fed with formulae not containing DHA. However, when coming to the question about the actual benefit of adding DHA to formula products, the issue is still controversial.

In fact, there are concerns that for nutrients added to formula products, including DHA, their structures and functions may not be the same as those present in breastmilk as they are extracted from cows milk or other ingredients (such as marine oils in the case of DHA). Therefore, taking into account that DHA could be synthesised in the body from α -linolenic acid, the Codex does not consider DHA to be an essential composition of infant formula and follow-up formula products. In view of the possible benefits to certain babies, addition of DHA is generally acceptable.

Should I Give My Baby Products With Added "Nutritive" Substances?

There is no international consensus that formula products with additional "nutritive" substances provide added benefits to infants. In fact, normal infants below six months old could usually obtain adequate nutrients from breastmilk or infant formulae meeting the Codex basic compositional requirements.

Exemption for Some Infant Formula Products

Formula for special medical purposes for infants and young children marked or labelled with required information is exempted from the requirements of nutritional composition and nutritional labelling as formulation of these products is varied to fit different medical purposes arising from diseases, disorders or medical conditions.

In addition, infant formula packed in a container which has a total surface area of less than 250cm² is exempted from the nutrition labelling requirements.

Nutritional composition and nutrition labelling requirements of infant formula in a glance

	Nutritional composition		
Energy/ Nutrient	Unit in kcal	Unit in kJ	Nutrition labelling
Energy	60 - 70 kcal/100ml	250 - 295 kJ/100ml	✓
Protein	1.8 - 3.0 g/100kcal (based on cows milk protein) 2.25 - 3.0 g/100kcal (based on soy protein isolate)	0.45 - 0.7 g/100kJ (based on cows milk protein) 0.5 - 0.7 g/100kJ (based on soy protein isolate)	~
Total fat	4.4 - 6.0 g/100kcal	1.05 - 1.4 g/100kJ	✓
Linoleic acid	300 - NS mg/100kcal	70 - NS mg/100kJ	
α -Linolenic acid	50 - NS mg/100kcal	12 - NS mg/100kJ	
Total carbohydrates	9.0 - 14.0 g/100kcal	2.2 - 3.3 g/100kJ	✓
Vitamins			
Vitamin A	60 - 180 μg RE /100kcal	14 - 43 μg RE /100kJ	✓
Vitamin D3	1 - 2.5 μg/100kcal	0.25 - 0.6 μg/100kJ	✓
Vitamin E	0.5 - NS mg α-TE/100kcal	0.12 - NS mg $lpha$ -TE/ 100kJ	✓
Vitamin K	4 - NS μg/100kcal	1 - NS μg/100kJ	✓
Thiamine / Vitamin B1	60 - NS μg/100kcal	14 - NS μg/100kJ	✓
Riboflavin / Vitamin B2	80 - NS μg/100kcal	19 - NS μg/100kJ	✓
Niacin / Vitamin B3	300 - NS μg/100kcal	70 - NS μg/100kJ	✓
Vitamin B6	35 - NS μg/100kcal	8.5 - NS μg/100kJ	✓
Cobalamin / Vitamin B12	0.1 - NS μg/100kcal	0.025 - NS μg/100kJ	✓
Pantothenic acid / Vitamin B5	400 - NS μg/100kcal	96 - NS μg/100kJ	✓
Folic acid / Vitamin B9	10 - NS μg/100kcal	2.5 - NS μg/100kJ	✓
Vitamin C	10 - NS mg/100kcal	2.5 - NS mg/100kJ	✓
Biotin	1.5 - NS μ g/100kcal	0.4 - NS μg/100kJ	✓
Minerals			
Iron	0.45 - NS mg/100kcal	0.1 - NS mg/100kJ	✓
Calcium	50 - NS mg/100kcal	12 - NS mg/100kJ	✓
Phosphorus	25 - NS mg/100kcal	6 - NS mg/100kJ	✓
Magnesium	5 - NS mg/100kcal	1.2 - NS mg/100kJ	✓
Sodium	20 - 60 mg/100kcal	5 - 14 mg/100kJ	✓
Chloride	50 - 160 mg/100kcal	12 - 38 mg/100kJ	✓
Potassium	60 - 180 mg/100kcal	14 - 43 mg/100kJ	✓
Manganese	1 - NS μg/100kcal	0.25 - NS μg/100kJ	✓
lodine / lodide	10 - NS μg/100kcal	2.5 - NS μg/100kJ	✓
Selenium	1 - NS μg/100kcal	0.24 - NS μg/100kJ	✓
Copper	35 - NS μg/100kcal	8.5 - NS μg/100kJ	✓
Zinc	0.5 - NS mg/100kcal	0.12 - NS mg/100kJ	✓
Others			
Choline	7 - NS mg/100kcal	1.7 - NS mg/100kJ	✓
Myo-Inositol	4 - NS mg/100kcal	1 - NS mg/100kJ	
L-Carnitine	1.2 - NS mg/100kcal	0.3 - NS mg/100kJ	

Remarks:

NS = not specified / RE = Retinol Equivalent / TE = Tocopherol Equivalent