STANDARD 2.9.1

INFANT FORMULA PRODUCTS

Purpose

This Standard provides for the compositional, and labelling requirements for foods intended or represented for use as a substitute for breast milk, herein referred to as 'infant formula products'. This Standard applies to all infant formula products whether in powder, liquid concentrate or 'ready to drink' forms.

This Standard also provides for infant formula products intended for infants with special nutritional requirements.

There are *Guidelines for Infant Formula Products* at the end of this Standard. These *Guidelines* do not form part of the legally binding Standard.

Standard 1.3.1 contains provisions relating to the food additives permitted in infant formula products. Standard 1.6.1 contains the microbiological limits in relation to infant formula products. Standard 1.3.4 contains specifications for permitted nucleotides and added nutrients. Standard 1.1.1 defines nutritive substances for the purposes of this Code.

See Standard 1.5.1 – Novel Foods for requirements for novel food and novel food ingredients.

Table of Provisions

Clauses

Division 1
Subdivision 1 – Interpretation

1 Definitions

(1) The definitions in clauses 1 and 2 of Standard 1.2.8 apply to this Standard.

(2) In this Code –

infant means a person under the age of 12 months.

infant formula product means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.

infant formula means an infant formula product represented as a breast milk substitute for infants and which satisfies the nutritional requirements of infants aged up to four to six months.

follow-on formula means an infant formula product represented as either a breast-milk substitute or replacement for infant formula and which constitutes the principal liquid source of nourishment in a progressively diversified diet for infants aged from six months.

lactose free formula and **low lactose formula** means infant formula products which satisfy the needs of lactose intolerant infants.

pre-term formula means an infant formula product specifically formulated to satisfy particular needs of infants born prematurely or of low birthweight.

soy-based formula means an infant formula product in which soy protein isolate is the sole source of protein.

medium chain triglycerides means triacylglycerols which contain predominantly the saturated fatty acids designated by 8:0 and 10:0.

protein substitute means –

(a) L-amino acids; or
(b) the hydrolysate of one or more of the proteins on which infant formula product is normally based; or
(c) a combination of L-amino acids and the hydrolysate of one or more of the proteins on which infant formula product is normally based.

Editorial note:

Subclause 1(2) is structured to indicate that the definitions of specific infant formula products are within the more general 'infant formula product' definition. Therefore the usual practice of listing definitions in alphabetical order has not been applied in this subclause.

2 Interpretation

A reference to any infant formula product in the compositional provisions of this Standard is a reference to –

(a) a powdered or concentrated form of infant formula product which has been reconstituted with water according to directions; or
(b) an infant formula product in 'ready to drink' form.

Subdivision 2 – Calculations

3 Calculation of energy

The energy content of infant formula product, expressed in kilojoules (kJ), must be calculated using –

(a) only the energy value contributions of the fat, protein and carbohydrate ingredients of the infant formula product; and
(b) the relevant energy factors set out in Standard 1.2.8.

4 Calculation of protein

The prescribed formula for the calculation of the protein content of infant formula product for the purposes of this Standard is –

Formula

For milk proteins and their partial protein hydrolysates –

Protein content = nitrogen content x 6.38; or

In any other case –

Protein content = nitrogen content x 6.25.

5 Calculation of potential renal solute load

The prescribed formula for the calculation of the potential renal solute load for the purposes of this Standard is –

Formula

Potential renal solute load in mOsm/100 kJ = [Na (mg/100 kJ) /23] + [Cl (mg/100 kJ) /35] + [K (mg/100 kJ) /39] + [P_{avail} (mg/100 kJ)/ 31] + [N (mg/100 kJ) /28)].

In this formula P_{avail} = P of milk-based formula + 2/3 of P of soy-based formulas.

Subdivision 3 – General compositional requirements

6 Restrictions and prohibitions

(1) A vitamin, mineral, food additive or nutritive substance must not be added to infant formula product unless –

(a) expressly permitted by this Code; or
(b) it is naturally present in an ingredient of the infant formula product.

(2) Infant formula product must contain no detectable gluten.

7 Permitted nutritive substances

(1) Any nutritive substance listed in column 1 of the Table to this clause may be added to infant formula product provided that –

(a) the nutritive substance is in one or more of the forms specified in column 2 of the Table in relation to that substance; and
(b) the total amount of the nutritive substance in the infant formula product is no more than the added and any naturally occurring amount specified in column 4 of the Table.

(2) The label on a package of infant formula product must not include any words indicating, or any other indication, that the product contains a nutritive substance specified in column 1 or in column 2 of the Table to this clause unless the total amount of the added and any naturally occurring nutritive substance in the food is no less than the amount specified in column 3 of the Table.

Table to clause 7

Column 1	Column 2	Column 3	Column 4
Nutritive substance	**Permitted forms**	**Minimum amount per 100 kJ**	**Maximum amount per 100 kJ**
Adenosine 5′-monophosphate	Adenosine 5′-monophosphate	0.14 mg	0.38 mg
L-carnitine	L-carnitine	0.21 mg	0.8 mg
Choline	Choline chloride Choline bitartrate	1.7 mg	7.1 mg
Cytidine 5′-monophosphate	Cytidine 5′-monophosphate	0.22 mg	0.6 mg
Guanosine 5’-monophosphate	Guanosine 5′-monophosphate Guanosine 5′-monophosphate sodium salt	0.04 mg	0.12 mg
Inosine 5′-monophosphate	Inosine 5′-monophosphate Inosine 5′-monophosphate sodium salt	0.08 mg	0.24 mg
Lutein	Lutein from *Tagetes erecta L.*	1.5 µg	5 µg
Inositol	Inositol	1.0 mg	9.5 mg
Taurine	Taurine	0.8 mg	3 mg
Uridine 5′-monophosphate	Uridine 5′-monophosphate sodium salt	0.13 mg	0.42 mg

8 Limit on nucleotide 5′-monophosphates

Infant formula product must contain no more than 3.8 mg/100 kJ of nucleotide 5′-monophosphates.

Editorial note:

Standard 1.3.4 contains specifications for nucleotides.

9 Lactic acid cultures

L(+) producing lactic acid cultures may be added to infant formula product.

9A Permitted inulin-type fructans and galacto-oligosaccharides

(1) Infant formula product may contain no more than –

(a) 110 mg per 100 kJ of inulin-type fructans; or
(b) 290 mg per 100 kJ of galacto-oligosaccharides; or
(c) 290 mg per 100 kJ of combined inulin-type fructans and galacto-oligosaccharides, where the inulin-type fructans is no more than 110 mg per 100 kJ.

(2) For subclause (1) the maximum permitted amount only applies when the substances are added. In that case the maximum permitted amount then applies to the sum of the naturally occurring and the added substances.

10 Limit on aluminium

(1) Infant formula product, other than a pre-term formula or soy-based formula product, must contain no more than 0.05 mg of aluminium per 100 mL.

(2) Pre-term formula must contain no more than 0.02 mg of aluminium per 100 mL.

(3) Soy-based formula must contain no more than 0.1 mg of aluminium per 100 mL.

Editorial note:

Standard 1.4.1 contains the maximum level (ML) of lead contaminant in infant formula products.

Subdivision 4 – General labelling and packaging requirements

11 Representations of food as infant formula product

A food must not be represented as an infant formula product unless it complies with this Standard.

12 Prescribed names

'Infant Formula' and 'Follow-on Formula' are prescribed names.

13 Requirement for a measuring scoop

(1) A package of infant formula product in a powdered form must contain a scoop to enable the use of the infant formula product in accordance with the directions contained in the label on the package.

(2) Subclause (1) does not apply to single serve sachets, or packages containing single serve sachets of an infant formula product in a powdered form.

14 Required warnings, directions and statements

(1) The label on a package of infant formula product must include the following warning statement –

(a) in the case of infant formula product in powdered form –

'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill'; and

(b) in the case of concentrated infant formula product –

'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of concentrate except on medical advice. Incorrect preparation can make your baby very ill'; and

(c) in the case of 'ready to drink' infant formula product –

'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not dilute or add anything to this 'ready to drink' formula except on medical advice. Incorrect preparation can make your baby very ill'.

(2) The label on a package of infant formula product must include directions for the preparation and use of the infant formula product which include words and pictures instructing –

(a) that each bottle should be prepared individually; and
(b) that if a bottle of made up formula is to be stored prior to use, it must be refrigerated and used within 24 hours; and
(c) that potable, previously boiled water should be used; and
(d) where a package contains a measuring scoop, that only the enclosed scoop should be used; and
(e) that formula left in the bottle after a feed must be discarded.

(3) Subject to subclause (4), the label on a package of infant formula product must contain the following warning statement –

'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.';

under a heading that states –

'Important Notice' or any word or words having the same or similar effect.

(4) Subclause (3) does not apply to infant formula products for metabolic, immunological, renal, hepatic or malabsorptive conditions.

(5) The label on a package of an infant formula product must contain statements indicating that –

(a) the infant formula product may be used from birth, in the case of infant formula; and
(b) the infant formula product should not be used for infants aged under 6 months in the case of follow-on formula; and
(c) except in the case of packages of pre-term formula, it is recommended that infants over the age of 6 months should be offered foods in addition to the infant formula product.

15 Print and package size

(1) Where an infant formula product is in a package having a net weight of more than 500 g, the statements required by subclauses 14(1), (3) and 26(1) must be in size of type of no less than 3 mm.

(2) Where an infant formula product is in a package having a net weight of 500 g or less the statements required by subclauses 14(1), (3) and 26(1) must be in size of type of no less than 1.5 mm.

16 Declaration of nutrition information

(1) The label on a 'ready to drink' infant formula product must include a statement, which may be in the form of a table, that contains the following information –

(a) the average energy content expressed in kJ per 100 mL; and
(b) the average amount of protein, fat and carbohydrate expressed in g per 100 mL; and
(c) the average amount of each vitamin, mineral and any other nutritive substance permitted by this Standard expressed in weight per 100 mL; and
(d) when added, the average amount of –

(i) a combination of inulin-type fructans and galacto-oligosaccharides; or
(ii) inulin-type fructans; or
(iii) galacto-oligosaccharides

expressed in weight per 100 mL.

(2) The label on a powdered or concentrated form of infant formula product must include a statement, which may be in the form of a table that contains the following information –

(a) the average energy content expressed in kJ per 100 mL of infant formula product that has been reconstituted according to directions; and
(b) the average amount of protein, fat and carbohydrate expressed in g per 100 mL of infant formula product that has been reconstituted according to directions; and
(c) the average amount of each vitamin, mineral and any other nutritive substance permitted by this Standard expressed in weight per 100 mL of infant formula product that has been reconstituted according to directions; and
(d) a declaration –

(i) of the weight of one scoop in the case of powdered infant formula; and
(ii) of the proportion of powder or concentrate required to reconstitute the formula according to directions; and

(e) when added, the average amount of –

(i) a combination of inulin-type fructans and galacto-oligosaccharides; or
(ii) inulin-type fructans; or
(iii) galacto-oligosaccharides

expressed in weight per 100 mL when the product is reconstituted in accordance with directions.

Editorial note:

As a guide to how nutrition information may be presented, see the *Guidelines for Infant Formula Products* at the end of this Standard. These *Guidelines* do not form part of the legally binding Standard.

17 Date marking and storage instructions

(1) Paragraphs 2(1)(c) and (d) of Standard 1.2.5 do not apply to this Standard.

(2) A label on a package of infant formula product must contain storage instructions covering the period after it is opened.

Editorial note:

The full range of climatic conditions that exist in Australia and New Zealand may need to be considered when determining valid and appropriate storage instructions.

18 Statement of protein source

The label on a package of infant formula product must contain a statement of the specific source, or sources, of protein in the infant formula product immediately adjacent to the name of the infant formula product.

Editorial note:

Standard 1.2.2 requires that all food be labelled with its name. The requirement in clause 18 of this Standard applies only to the name on the label on the product in accordance with the requirement in Standard 1.2.2.

19 Statement on dental fluorosis

(1) An infant formula product must comply with subclause (2) where it contains –

(a) more than 17 µg of fluoride per 100 kJ prior to reconstitution, in the case of powdered or concentrated infant formula product; or
(b) more than 0.15 mg of fluoride per 100 mL, in the case of 'ready to drink' formula.

(2) The label on a package of infant formula product referred to in subclause (1) must contain statements –

(a) indicating that consumption of the formula has the potential to cause dental fluorosis; and
(b) recommending that the risk of dental fluorosis should be discussed with a medical practitioner or other health professional.

20 Prohibited representations

(1) The label on a package of infant formula product must not contain –

(a) a picture of an infant; or
(b) a picture that idealises the use of infant formula product; or
(c) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect; or
(d) words claiming that the formula is suitable for all infants; or
(e) information relating to the nutritional content of human milk; or
(f) subject to clause 28, a reference to the presence of any nutrient or nutritive substance, except for a reference to a nutrient or nutritive substance in –

(i) accordance with clause 30 – Claims relating to lactose free formula or low lactose formulas; or
(ii) the statement of ingredients in accordance with Standard 1.2.4 – Labelling of Ingredients; or
(iii) the nutrition information statement in accordance with clause 16 of this Standard – Declaration of nutrition information; or

(g) subject to Division 3, a representation that the food is suitable for a particular condition, disease or disorder.

(2) Subject to clause 28, the label on a package of infant formula product must not contain a reference to inulin-type fructans or galacto-oligosaccharides except for a reference to either substances in –

(a) the statement of ingredients in accordance with Standard 1.2.4 – Labelling of Ingredients; or
(b) the nutrition information statement in accordance with clause 16 of this Standard – Declaration of nutrition information.

Editorial Note:

Division 3 relates to Infant Formula Products for Special Dietary Use. Clause 28 permits labelling which varies from this clause.

Division 2 – Infant Formula and Follow-on Formula

21 Composition

(1) Infant formula and follow-on formula must –

(a) have an energy content of no less than 2500 kJ/L and no more than 3150 kJ/L in the case of infant formula, and no less than 2500 kJ/L and no more than 3550 kJ/L in the case of follow-on formula; and

(b) contain an amount of each nutrient specified in column 1 of the Table to this clause which is no less than the amount specified in column 2 of the Table and no more than the amount specified in column 3 of the Table.

Table to clause 21

Column 1	Column 2	Column 3
Nutrient	**Minimum amount per 100 kJ**	**Maximum amount per 100 kJ**
Protein	0.45 g	0.7 g for infant formula 1.3 g for follow-on formula
Fat	1.05 g	1.5 g

(2) Follow-on formula must have a potential renal solute load value of no more than 8 mOsm/100 kJ.

22 Protein

(1) The L-amino acids listed in column 1 of the Table to this clause must be present in infant formula and follow-on formula at the minimum level specified in column 2 of the Table, subject to subclause 2 and 3.

Table to clause 22

Column 1	Column 2
L-Amino Acid	**Minimum amount per 100 kJ**
Histidine	10 mg
Isoleucine	21 mg
Leucine	42 mg
Lysine	30 mg
Cysteine, cystine and methionine	19 mg
Phenylalanine & Tyrosine	32 mg
Threonine	19 mg
Tryptophan	7 mg
Valine	25 mg

(2) Infant formula or follow-on formula must provide no less than –

(a) 6 mg of cysteine, cystine or combined cysteine and cystine per 100 kJ; and

(b) 17 mg phenylalanine per 100 kJ.

(3) L-amino acids listed in the Table to this clause must be added to infant formula or follow-on formula only in an amount necessary to improve protein quality.

23 Fat

The fats in infant formula and follow-on formula must –

(a) not contain medium chain triglycerides except where a medium chain triglyceride is present in a particular infant formula or follow-on formula as the result of being –

(i) a natural constituent of a milk-based ingredient of that particular infant formula or follow-on formula or;

(ii) a processing aid used in preparations of permitted fat soluble vitamins of that particular infant formula or follow-on formula where the fat soluble vitamins have been specified in Schedule 1 to this Standard; and

(b) have a ratio of linoleic acid to α-linolenic acid of no less than 5 to 1 and no more than 15 to 1; and

(c) if specified in column 1 of the Table to this clause, comply with the limits, if any, specified in columns 2 and 3 of the Table; and

(d) have a ratio of total long chain omega 6 series fatty acids (C>= 20) to total long chain omega 3 series fatty acids (C>= 20) that is not less than 1 in an infant formula or follow-on formula which contains those fatty acids; and

(e) where long chain polyunsaturated fatty acids are present in an infant formula or follow-on formula, an eicosapentaenoic acid (20:5 n-3) content of no more than the docosahexaenoic acid (22:6 n-3) content.

Table to clause 23

Column 1	Column 2	Column 3
Fatty acids	**Minimum % total fatty acids**	**Maximum % total fatty acids**
Essential fatty acids		
Linoleic acid (18:2)	9	26
α-Linolenic acid (18:3)	1.1	4
Long chain polyunsaturated fatty acids		
Long chain omega 6 series fatty acids (C>= 20)		2
Arachidonic acid (20:4)		1
Long chain omega 3 series fatty acids (C>= 20)		1
Total *trans* fatty acids		4
Erucic acid (22:1)		1

Editorial note:

Standard 1.3.4 contains specifications for dried marine microalgae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA), oil derived from marine microalgae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA), oil derived from the algae *Crypthecodinium cohnii* rich in docosahexaenoic acid (DHA), oil derived from the fungus *Mortierella alpina* rich in arachidonic acid (ARA), and oil derived from marine microalgae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA).

24 Vitamins, minerals and electrolytes

(1) Infant formula and follow-on formula must contain the vitamins, minerals and electrolytes specified in column 1 of the Table to this subclause provided that, in relation to each vitamin, mineral or electrolyte –

(a) the added vitamin, mineral or electrolyte is in a permitted form as listed in Schedule 1; and

(b) the infant formula or follow-on formula contains no less than the amount specified in column 2 of the Table; and

(c) the infant formula or follow-on formula contains no more than the amount specified in column 3 of the Table, if any.

Table to subclause 24(1)

Column 1	Column 2	Column 3
Nutrient	**Minimum amount per 100 kJ**	**Maximum amount per 100 kJ**
Vitamins		
Vitamin A	14 µg	43 µg
Vitamin D	0.25 µg	0.63 µg
Vitamin C	1.7 mg	
Thiamin	10 µg	
Riboflavin	14 µg	
Preformed Niacin	130 µg	
Vitamin B_6	9 µg	36 µg
Folate	2 µg	
Pantothenic acid	70 µg	
Vitamin B_{12}	0.025 µg	
Biotin	0.36 µg	
Vitamin E	0.11 mg	1.1 mg
Vitamin K	1 µg	
Minerals		
Chloride	12 mg	35 mg
Calcium	12 mg	
Phosphorus	6 mg	25 mg
Magnesium	1.2 mg	4.0 mg
Iron	0.2 mg	0.5 mg
Iodine	1.2 µg	10 µg
Copper	14 µg	43 µg
Zinc	0.12 mg	0.43 mg
Manganese	0.24 µg	24.0 µg
Selenium	0.25 µµg	1.19 µg
Electrolytes		
Sodium	5 mg	15 mg
Potassium	20 mg	50 mg

(2) Infant formula and follow-on formula must contain no less than 0.5 mg of Vitamin E per g of polyunsaturated fatty acids.

(3) The ratio of calcium to phosphorus in infant formula and follow-on formula must be no less than 1.2 to 1 and no more than 2 to 1.

(4) The ratio of zinc to copper –

(a) in infant formula must be no more than 15 to 1; and
(b) in follow-on formula must be no more than 20 to 1.

Editorial note:

This Standard contains guidelines setting out the recommended levels of vitamins, minerals and electrolytes that as a matter of good practice should not be exceeded.

Division 3 – Infant Formula Products for Special Dietary Use

Subdivision 1 – Infant formula products formulated for premature or low birthweight infants

25 Composition and labelling

Infant formula products may be specifically formulated for premature or low birthweight infants provided that in all other respects they comply with this Standard.

26 Additional labelling

(1) The label on a package of pre-term formula must include the warning statement –

'Suitable only for pre-term infants under specialist medical supervision'.

(2) The words 'pre-term' must appear as part of the name of a food standardised in this subdivision.

Subdivision 2 – Infant formula products for metabolic, immunological, renal, hepatic and malabsorptive conditions

27 Composition

Infant formula products may be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions provided that in all other respects the products comply with this Division.

28 Required statements for products under this Subdivision

The label on an infant formula product that is specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions must contain a statement that indicates –

(a) that the product is not suitable for general use and should be used under medical supervision; and
(b) the condition, disease or disorder for which the food has been specially formulated; and
(c) the nutritional modifications, if any, which have been made to the infant formula product.

29 Composition of lactose free and low lactose formulas

(1) A lactose free formula or low lactose formula must, except for the lactose content, comply with the compositional and labelling requirements which apply to the infant formula product of which they are a variety.

(2) Lactose free formula must contain no detectable lactose.

(3) Low lactose formula must contain no more than 0.3 g lactose per 100 mL of infant formula product.

30 Claims relating to lactose free and low lactose formulas

Where a label contains a claim that the infant formula product is lactose free, low lactose or words of similar import, the label on a package of lactose free or a low lactose formula product must include –

(a) the words 'lactose free' as part of the name of lactose free formula; and
(b) the words 'low lactose' as part of the name of low lactose formula; and
(c) the following statements –

(i) the amount of lactose expressed in g per 100 mL; and
(ii) the amount of galactose expressed in g per 100 mL.

Subdivision 3 – Infant formula products for specific dietary use based upon protein substitutes

31 Composition

An infant formula product for specific dietary use based upon protein substitutes must –

(a) have an energy content of no less than 2500 kJ/L and no more than 3150 kJ/L in the case of infant formula, and no less than 2500 kJ/L and no more than 3550 kJ/L in the case of follow-on formula; and
(b) have a potential renal solute load of no more than 8 mOsm per 100 kJ; and
(c) contain an amount of each nutrient specified in column 1 of the Table to this clause which is no less than the amount specified in column 2 of the Table and no more than the amount specified in column 3 of the Table.

Table to clause 31

Column 1	Column 2	Column 3
Nutrient	**Minimum amount per 100 kJ**	**Maximum amount per 100 kJ**
Protein	0.45 g	1.4 g
Fat	0.93 g	1.5 g

32 Protein

(1) The protein content of an infant formula product for specific dietary use based upon protein substitutes may be in the form of protein substitute.
(2) The L-amino acids listed in column 1 of the Table to this clause must be present in infant formula product for special dietary use at the minimum level specified in column 2 of the Table, subject to subclause 3 and 4.

Table to clause 32

Column 1	Column 2
L-Amino Acid	**Min amount per 100 kJ**
Histidine	10 mg
Isoleucine	21 mg
Leucine	42 mg
Lysine	30 mg
Cysteine, cystine and methionine	19 mg
Phenylalanine & Tyrosine	32 mg
Threonine	19 mg
Tryptophan	7 mg
Valine	25 mg

(3) Infant formula product for specific dietary use based upon protein substitutes must provide no less than –

(a) 6 mg of cysteine, cystine or combined cysteine and cystine per 100 kJ; and
(b) 17 mg phenylalanine per 100 kJ.

(4) L-amino acids listed in the Table to this clause must be added to infant formula product for specific dietary use based upon protein substitutes only in an amount necessary to improve protein quality.

33 Vitamins and minerals

An infant formula product for specific dietary use based upon protein substitutes must contain –

(a) chromium in an amount of no less than 0.35 µg per 100 kJ and no more than 2.0 µg per 100 kJ; and
(b) molybdenum in an amount of no less than 0.36 µg per 100 kJ and no more than 3.0 µg per 100 kJ.

Editorial note:

The provisions of clause 24 of this Standard also apply in respect of the vitamins, minerals and electrolytes permitted in an infant formula product for specific dietary use based upon protein substitutes.

34 Additional permitted triglycerides

An infant formula product for specific dietary use based upon protein substitutes may contain added medium chain triglycerides.

SCHEDULE 1

PERMITTED FORMS OF VITAMINS, MINERALS AND ELECTROLYTES IN INFANT FORMULA PRODUCTS

Column 1	Column 2
Vitamins, Minerals and Electrolytes	**Permitted Forms**
Vitamin A	Retinol Forms vitamin A (retinol) vitamin A acetate (retinyl acetate) vitamin A palmitate (retinyl palmitate) retinyl propionate Carotenoid Forms beta-carotene
Vitamin C	L-ascorbic acid L-ascorbyl palmitate calcium ascorbate potassium ascorbate sodium ascorbate
Vitamin D	vitamin D_2 (ergocalciferol) vitamin D_3 (cholecalciferol) vitamin D (cholecalciferol-cholesterol)
Thiamin	thiamin hydrochloride thiamin mononitrate
Riboflavin	riboflavin riboflavin-5′-phosphate, sodium
Niacin	niacinamide (nicotinamide)
Vitamin B_6	pyridoxine hydrochloride pyridoxine-5′-phosphate
Folate	folic acid
Pantothenic acid	calcium pantothenate dexpanthenol
Vitamin B_{12}	cyanocobalamin hydroxocobalamin
Biotin	d-Biotin
Vitamin E	dl-α-tocopherol d-α-tocopherol concentrate tocopherols concentrate, mixed d-α-tocopheryl acetate dl-α-tocopheryl acetate d-α-tocopheryl acid succinate dl-α-tocopheryl succinate
Vitamin K	vitamin K_1, as phylloquinone (phytonadione) phytylmenoquinone
Calcium	calcium carbonate calcium chloride calcium citrate calcium gluconate calcium glycerophosphate calcium hydroxide calcium lactate calcium oxide calcium phosphate, dibasic calcium phosphate, monobasic

SCHEDULE 1

PERMITTED FORMS OF VITAMINS, MINERALS AND ELECTROLYTES IN INFANT FORMULA PRODUCTS (CONTINUED)

	calcium phosphate, tribasic calcium sulphate
Chloride	calcium chloride magnesium chloride potassium chloride sodium chloride
Chromium	chromium sulphate
Copper	copper gluconate cupric sulphate cupric citrate
Iodine	potassium iodate potassium iodide sodium iodide
Iron	ferric ammonium citrate ferric pyrophosphate ferrous citrate ferrous fumarate ferrous gluconate ferrous lactate ferrous succinate ferrous sulphate
Magnesium	magnesium carbonate magnesium chloride magnesium gluconate magnesium oxide magnesium phosphate, dibasic magnesium phosphate, tribasic magnesium sulphate
Manganese	manganese chloride manganese gluconate manganese sulphate manganese carbonate manganese citrate
Molybdenum	sodium molybdate VI
Phosphorus	calcium glycerophosphate calcium phosphate, dibasic calcium phosphate, monobasic calcium phosphate, tribasic magnesium phosphate, dibasic potassium phosphate, dibasic potassium phosphate, monobasic potassium phosphate, tribasic sodium phosphate, dibasic sodium phosphate, monobasic sodium phosphate, tribasic
Potassium	potassium bicarbonate potassium carbonate potassium chloride potassium citrate potassium glycerophosphate potassium gluconate potassium hydroxide potassium phosphate, dibasic

SCHEDULE 1

PERMITTED FORMS OF VITAMINS, MINERALS AND ELECTROLYTES IN INFANT FORMULA PRODUCTS (CONTINUED)

	potassium phosphate, monobasic potassium phosphate, tribasic
Selenium	seleno methionine sodium selenate sodium selenite
Sodium	sodium bicarbonate sodium carbonate sodium chloride sodium chloride iodised sodium citrate sodium gluconate sodium hydroxide sodium iodide sodium lactate sodium phosphate, dibasic sodium phosphate, monobasic sodium phosphate, tribasic sodium sulphate sodium tartrate
Zinc	zinc acetate zinc chloride zinc gluconate zinc oxide zinc sulphate

GUIDELINES FOR INFANT FORMULA PRODUCTS
(These guidelines are not part of the legally binding Standard)

Guideline for maximum amount of vitamins and minerals in infant formula products

It is recommended that the quantities specified in the table below be observed as the maximum levels of vitamins and minerals in infant formula product.

Nutrient	Recommended maximum amount per 100 kJ
Vitamins	
Vitamin C	5.4 mg
Thiamin	48 µg
Riboflavin	86 µg
Preformed Niacin	480 µg
Folate	8.0 µg
Pantothenic acid	360 µg
Vitamin B_{12}	0.17 µg
Vitamin K	5.0 µg
Biotin	2.7 µg
Minerals	
Calcium	33 mg
Phosphorus	22 mg
Manganese	7.2 µg for infant formula products regulated by Division 3, Subdivision 2 only
Chromium	2.0 µg
Molybdenum	3 µg

Guideline on advice regarding additional vitamin and mineral supplementation

Manufacturers are recommended to provide an advice in the label on a package of infant formula product to the effect that consumption of vitamin or mineral preparations are not necessary.

Nutrition information table

The nutrition information contained in the label on a package of infant formula product is recommended in the following format –

NUTRITION INFORMATION

	Average amount per 100 mL made up formula *1	Average amount per 100 g of powder (or per 100 mL for liquid concentrate) *2
Energy	kJ	kJ
Protein	g	g
Fat	g	g
Carbohydrate	g	g
Vitamin A	µg	µg
Vitamin B_6	µg	µg
Vitamin B_{12}	µg	µg
Vitamin C	mg	mg
Vitamin D	µg	µg
Vitamin E	µg	µg
Vitamin K	µg	µg
Biotin	µg	µg

NUTRITION INFORMATION (CONTINUED)

	Average amount per 100 mL made up formula *1	**Average amount per 100 g of powder (or per 100 mL for liquid concentrate) *2**
Niacin	mg	mg
Folate	µg	µg
Pantothenic acid	µg	µg
Riboflavin	µg	µg
Thiamin	µg	µg
Calcium	mg	mg
Copper	µg	µg
Iodine	µg	µg
Iron	mg	mg
Magnesium	mg	mg
Manganese	µg	µg
Phosphorus	mg	mg
Selenium	µg	µg
Zinc	mg	mg
Chloride	mg	mg
Potassium	mg	mg
Sodium	mg	mg
(insert any other nutritive substance or inulin-type fructans and galacto-oligosaccharides to be declared)	g, mg, µg	g, mg, µg

***1** – Delete the words 'made up formula' in the case of formulas sold in 'ready to drink' form.
***2** – Delete this column in the case of formulas sold in 'ready to drink' form.

Amendment History

The Amendment History provides information about each amendment to the Standard. The information includes commencement or cessation information for relevant amendments.

These amendments are made under section 92 of the *Food Standards Australia New Zealand Act 1991* unless otherwise indicated. Amendments do not have a specific date for cessation unless indicated as such.

About this compilation

This is a compilation of Standard 2.9.1 as in force on **30 October 2014** (up to Amendment No. 150). It includes any commenced amendment affecting the compilation to that date.

Prepared by Food Standards Australia New Zealand on **30 October 2014**.

Uncommenced amendments or provisions ceasing to have effect

To assist stakeholders, the effect of any uncommenced amendments or provisions which will cease to have effect, may be reflected in the Standard as shaded boxed text with the relevant commencement or cessation date. These amendments will be reflected in a compilation registered on the Federal Register of Legislative Instruments including or omitting those amendments and provided in the Amendment History once the date is passed.

The following abbreviations may be used in the table below:

ad = added or inserted
am = amended
exp = expired or ceased to have effect
rep = repealed
rs = repealed and substituted

Standard 2.9.1 was published in the Commonwealth of Australia Gazette No. P 30 on 20 June 2002 as part of Amendment No. No. 60 (F2008B00798 – 19 December 2008) and has been amended as follows:

Clause affected	A'ment No.	FRLI registration Gazette	Commencement (Cessation)	How affected	Description of amendment
Purpose	103	F2008L03741 9 Oct 2008 FSC45 9 Oct 2008	9 Oct 2008	am	Purpose relating to infant formula products.
Table of Provs	78	F2005L01246 26 May 2005 FSC20 26 May 2005	26 May 2005	rs	New heading for clause 24.
Table of Provs	138	F2013L00050 14 Jan 2013 FSC80 18 Jan 2013	18 Jan 2013	am	Amendment relating to the heading of clause 28.
Table of Provs	150	F2014L01427 28 Oct 2014 FSC92 30 Oct 2014	30 Oct 2014	ad	Reference to clause 9A to reflect previous amendment.
1	124	F2011L01450 8 July 2011 FSC66 11July 2011	11 July 2011	am	Definition of 'protein substitute'.
1(2)	101	F2008L03058 14 Aug 2008 FSC43 14 Aug 2008	14 Aug 2008	rep	Editorial notes in the definitions.

Clause affected	A'ment No.	FRLI registration Gazette	Commencement (Cessation)	How affected	Description of amendment
1(2)	101	F2008L03058 14 Aug 2008 FSC43 14 Aug 2008	14 Aug 2008	ad	Editorial note relating to infant formula product definitions after the subclause.
1(2)	103	F2008L03741 9 Oct 2008 FSC45 9 Oct 2008	9 Oct 2008	rs	Subclause.
7	101	F2008L03058 14 Aug 2008 FSC43 14 Aug 2008	14 Aug 2008	rep	Editorial note before the Table to clause 7..
7(1)(b)	103	F2008L03741 9 Oct 2008 FSC45 9 Oct 2008	9 Oct 2008	ad	After 'the total amount of the' inserting 'added and any naturally occurring'.
7(2)	103	F2008L03741 9 Oct 2008 FSC45 9 Oct 2008	9 Oct 2008	ad	After 'the total amount of the' inserting 'added and any naturally occurring'.
Table to clause 7	108	F2009L02066 28 May 2009 FSC50 28 May 2009	28 May 2009	am	Column headings.
Table to clause 7	108	F2009L02066 28 May 2009 FSC50 28 May 2009	28 May 2009	ad	Entry for lutein.
Table to clause 7	124	F2011L01450 8 July 2011 FSC66 11July 2011	11 July 2011	rs	Entries for adenosine 5′-monophosphate, cytidine 5′-monophosphate and uridine 5′-monophosphate.
9A	105	F2009L00076 15 Jan 2009 FSC47 15 Jan 2009	15 Jan 2009	ad	New clause related to inulin-derived substances and galacto-oligosaccharides.
9A	142	F2013L01465 30 July 2013 FSC84 1 Aug 2013	1 Aug 2013	rs	'Inulin-derived substances' replaced with 'inulin-type fructans' and consequential amendment to the Table of Provisions.
16	101	F2008L03058 14 Aug 2008 FSC43 14 Aug 2008	14 Aug 2008	ad	Editorial note after the clause relating to the Guideline at the end of this Standard.
16	142	F2013L01465 30 July 2013 FSC84 1 Aug 2013	1 Aug 2013	rs	'Inulin-derived substances' replaced with 'inulin-type fructans'.
16(1)	105	F2009L00076 15 Jan 2009 FSC47 15 Jan 2009	15 Jan 2009	rs	Consequential amendments related to inulin-derived substances and galacto-oligosaccharides.
16(2)(e)	124	F2011L01450 8 July 2011 FSC66 11July 2011	11 July 2011	rs	Clarification of the intent of the paragraph.
17	101	F2008L03058 14 Aug 2008 FSC43 14 Aug 2008	14 Aug 2008	am	Editorial note after the clause.
20	105	F2009L00076 15 Jan 2009 FSC47 15 Jan 2009	15 Jan 2009	rs	Consequential amendments related to inulin-derived substances and galacto-oligosaccharides.

Clause affected	A'ment No.	FRLI registration Gazette	Commencement (Cessation)	How affected	Description of amendment
20(1)(f)	124	F2011L01450 8 July 2011 FSC66 11July 2011	11 July 2011	rs	Clarification of the intent of the paragraph.
20(2)	124	F2011L01450 8 July 2011 FSC66 11July 2011	11 July 2011	rs	Clarification of the intent of the subparagraphs.
20(2)	142	F2013L01465 30 July 2013 FSC84 1 Aug 2013	1 Aug 2013	rs	'Inulin-derived substances' replaced with 'inulin-type fructans' and consequential amendment to the Table of Provisions.
22	72	F2008B00819 24 Dec 2008 FSC14 20 May 2004	20 May 2004	rs	References for 'cysteine' amended to 'cyst(e)ine'.
22(2)(a	103	F2008L03741 9 Oct 2008 FSC45 9 Oct 2008	9 Oct 2008	rs	'Cyst(e)ine & methionine' replaced with 'cysteine, cystine and methionine' and related consequential amendments.
Table to clause 22	101	F2008L03058 14 Aug 2008 FSC43 14 Aug 2008	14 Aug 2008	rep	Editorial note after the Table.
Table to clause 22	103	F2008L03741 9 Oct 2008 FSC45 9 Oct 2008	9 Oct 2008	rs	'Cyst(e)ine & methionine' replaces with 'cysteine, cystine and methionine' and related consequential amendments.
Table to clause 22	141	F2013L00811 21 May 2013 FSC83 23 May 2013	23 May 2013	rs	Entry for histidine.
23(a)	88	F2006L03270 5 Oct 2006 FSC30 5 Oct 2006	5 Oct 2006	am	Reference to medium chain triglycerides.
23(d)	95	F2007L04700 13 Dec 2007 FSC37 13 Dec 2007	13 Dec 2007	am	Long chain omega 3 and 6 series fatty acid ratio.
Table to clause 23	101	F2008L03058 14 Aug 2008 FSC43 14 Aug 2008	14 Aug 2008	rep	Editorial notes.
Table to clause 23	124	F2011L01450 8 July 2011 FSC66 11July 2011	11 July 2011	rs	Editorial note after the Table arising from amendments to specifications in Standard 1.3.4.
24	78	F2005L01246 26 May 2005 FSC20 26 May 2005	26 May 2005	rs	Heading of clause to include reference to electrolytes.
24(1), Table to s'clause 24(1)	78	F2005L01246 26 May 2005 FSC20 26 May 2005	26 May 2005	rs	Amend subclause and Editorial note after the clause to treat potassium and sodium as electrolytes, rather than minerals.
27	99	F2008L02297 26 June 2008 FSC41 26 June 2008	26 June 2008	rs	To clarify operation of the clause.
28	138	F2013L00050 14 Jan 2013 FSC80 18 Jan 2013	18 Jan 2013	am	Consequential amendment relating to Standard 1.2.7.

Clause affected	A'ment No.	FRLI registration Gazette	Commencement (Cessation)	How affected	Description of amendment
32	72	F2008B00819 24 Dec 2008 FSC14 20 May 2004	20 May 2004	rs	References for 'cysteine' amended to 'cyst(e)ine'.
32(3)(a)	103	F2008L03741 9 Oct 2008 FSC45 9 Oct 2008	9 Oct 2008	rs	'Cyst(e)ine & methionine' replaced with 'cysteine, cystine and methionine' and related consequential amendments.
32(4)	67	F2008B00814 24 Dec 2008 FSC9 31 July 2003	31 July 2003	am	Typographical error.
Table to, clause 32	103	F2008L03741 9 Oct 2008 FSC45 9 Oct 2008	9 Oct 2008	rs, am	'Cyst(e)ine & methionine' replaced with 'cysteine, cystine and methionine' and related consequential amendments.
Table to clause 32	141	F2013L00811 21 May 2013 FSC83 23 May 2013	23 May 2013	rs	Entry for histidine.
Sch 1	72	F2008B00819 24 Dec 2008 FSC14 20 May 2004	20 May 2004	ad	Reference to sodium selenate.
Sch 1	88	F2006L03270 5 Oct 2006 FSC30 5 Oct 2006	5 Oct 2006	rep	'dehydrate' from the listing for the permitted form of molybdenum.
Infant Formula Prods G'lines	105	F2009L00076 15 Jan 2009 FSC47 15 Jan 2009	15 Jan 2009	rs	Guidelines
Infant Formula Prods G'lines	105	F2009L00076 15 Jan 2009 FSC47 15 Jan 2009	15 Jan 2009	rep	Editorial note after the Guidelines after the table.
Infant Formula Prods G'lines	142	F2013L01465 30 July 2013 FSC84 1 Aug 2013	1 Aug 2013	rs	'Inulin-derived substances' replaced with 'inulin-type fructans' and consequential amendment to the Table of Provisions.