DRAFT REVISED STANDARD R7 - INFANT FORMULAS

1. The Food Standards Code is amended by inserting

"STANDARD 2.9.1 - Infant formula products"

PURPOSE

This Standard provides for the compositional, microbiological and labelling requirements of foods intended or represented for use as a substitute for human 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.

Additionally, recommended guidelines regarding vitamins and minerals are contained at the end of this Standard.

Drafting Note:

This draft Standard will be reformatted to be consistent with the structure of the revised Code.

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PART 1 - GENERAL PROVISIONS

Division 1 - Interpretation

Definitions

1. (1) In this Standard -

'follow-on formula' means infant formula product represented as being suitable as the principal source of food for infants aged over six months.

'infant' means a child under the age of 12 months.

'infant formula' means an infant formula product that is represented as being suitable as the principal source of food for infants.

Editorial Note: A reference to infant formula product may include a reference to infant formula but the converse does not apply.

an **'infant formula product'** is a product based on milk or other edible food constituents of animal or plant origin and which is intended to be, and is suitable for use as, the principal source of nourishment for infants.

Editorial Note: The intent of this definition is to limit the addition of ingredients to infant formula product to ingredients which would be considered as foods. The addition of an ingredient that is not considered to be a food is prohibited unless specifically permitted elsewhere in this Standard.

'lactose free formula' and **'low lactose formula'** mean infant formula products represented as being the principal source of food for lactose intolerant infants.

'medium chain triglycerides' in this Standard means triacylglycerols which contain predominantly the saturated fatty acids 8:0 and 10:0.

'pre-term formula' means infant formula product represented as being suitable as the principal source of food for infants of less than 37 weeks gestation.

'protein equivalent' means the amount of nitrogen from hydrolysates and/or L-amino acids expressed as protein.

'protein substitute' means L-amino acids and/or the hydrolysate of one or more of the proteins on which infant formula product is normally based.

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

Interpretation

2. In the compositional requirements of this Standard a reference to any '**infant formula product'** 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.

Division 2 – Calculations

Calculation of energy

3. 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.

Calculation of protein

4. The protein content of infant formula product, must be calculated as follows:

(a) For milk proteins and their partial protein hydrolysates:

Protein content = nitrogen content x 6.38; or

(b) In any other case:

Protein content = nitrogen content x 6.25.

Calculation of Potential Renal Solute Load

5. The potential renal solute load must be calculated as follows:

Potential renal solute load in mOsm/100 kJ

= [Na (mg/100 kJ) /23] + [Cl (mg/100 kJ) /35] + [K (mg/100 kJ) /39] + [P(mg/100 kJ)/31] + [protein (mg/100 kJ)/175].

Calculation of amino acid score

6. 'amino acid score' means the lowest of the ratios between the quantity in the infant formula product of the L-amino acid listed in column 1 of the Table to this clause and the quantity of the corresponding L-amino acid listed in column 2 of the Table to this clause.

TABLE TO CLAUSE 6

Column 1	**Column 2**
L-Amino Acid	**per 100 g of protein**
Histidine	2.60 g
Isoleucine	4.60 g
Leucine	9.30 g
Lysine	6.60 g
Cystine	2.45 g
Methionine	1.27 g
Phenylalanine	4.19 g
Tyrosine	4.75 g
Threonine	4.30 g
Tryptophan	1.70 g
Valine	5.50 g

Division 3 - General Compositional Requirements

Restrictions and prohibitions

7. (1) A vitamin, mineral, food additive or nutritional substance must not be added to infant formula product unless:

(a) expressly permitted by this Standard; or

(b) it is included in the infant formula as naturally present in an ingredient of the infant formula product.

(2) Infant formula product must not contain any detectable gluten.

Editorial Note: Infant formula product must not contain novel foods or novel food ingredients which are not permitted under Standard 1.5.1.

Permitted optional nutritional substances

8. (1) Any nutritional substance listed in column 1 of the Table to this clause may be added to infant formula product provided that:

(a) the nutritional substance is in one or more of the forms specified in column 2 of the Table to this clause in relation to that substance; and

(b) the total amount of the nutritional substance in the infant formula product is not more than the amount specified in column 4 of the Table to this clause.

(2) Infant formula product must not be labelled with words indicating, or any other indication, that the product contains an ingredient specified in column 1 or in column 2 of the Table to this clause unless the total amount of the nutrient in the food is not less than the amount specified in column 3 of the Table to this clause.

Editorial Note: The Australia New Zealand Food Authority has issued a guideline on the use and format of nutrient information tables.

TABLE TO CLAUSE 8

Column 1	**Column 2**	**Column 3**	**Column 4**
Nutritional Substance	**Permitted Forms**	**Minimum Amount for Claim per 100 kJ**	**Maximum Permitted Amount per 100 kJ**
Choline	Choline chloride Choline bitartrate	1.7 mg	5.4 mg
Inositol	Inositol	1.0 mg	5.4 mg
Taurine	Taurine	0.8 mg	3 mg
L-carnitine	L-carnitine	0.21 mg	0.42 mg
Cytidine 5′-monophosphate	Cytidine 5′-monophosphate Cytidine 5′-monophosphate sodium salt	0.22 mg	0.6 mg
Uridine 5′-monophosphate	Uridine 5′-monophosphate Uridine 5′-monophosphate sodium salt	0.13 mg	0.42 mg
Adenosine 5′-monophosphate	Adenosine 5′-monophosphate Adenosine 5′-monophosphate sodium salt	0.14 mg	0.38 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

Limit on nucleotide 5′-monophosphates

9. Infant formula product must not contain more than a total amount of 1.2 mg of nucleotide 5′-monophosphates per 100 kJ.

Editorial Note: Refer to Standard 1.3.4 Identification and Purity for specifications for nucleotides

Lactic acid cultures

10. L(+) producing lactic acid cultures may be added to infant formula product subject to subclause 27(b).

Food Additives

11. (1) Infant formula product may contain food additives specified in column 1 of the Table to this clause provided that the total amount of the food additive is not more than the amount specified in column 2 of the Table.

Editorial Note: The total amount of the food additive includes food additive that is present or naturally occurring in any ingredient in the infant formula product.

TABLE TO CLAUSE 11

Column 1	**Column 2**
Food additive	**Maximum amount per 100 mL**
Thickening agents	
Guar gum	0.1 g
Locust bean gum	0.1 g
Emulsifiers	
Lecithin	0.5 g
Mono- and diglycerides	0.4 g
pH-Adjusting agents	
Sodium hydroxide, Sodium hydrogen carbonate, Sodium carbonate	
Potassium hydroxide, Potassium hydrogen carbonate, Potassium carbonate	
Calcium hydroxide	
Sodium citrate	
Potassium citrate	
L(+) Lactic acid	
Citric acid	
Antioxidants	
Mixed tocopherols concentrate	1 mg
L-Ascorbyl palmitate	1 mg

Editorial Note: With the exception of L(+) lactic acid and citric acid, where no maximum is set for a substance in this Table, note that the quantity of this substance permitted in an infant formula product is limited by the maximums specified in the Table to Clause 31 in the case of infant formula and follow-on formula, and in the Table to Clause 35 in the case of pre-term formula. The maximum levels of L(+) lactic acid and citric acid should be determined by good manufacturing practice.

(2) Soy-based infant formula product must not contain:

(a) more than 0.5 g of distarch phosphate per 100 mL;

(b) more than 0.5 g, either singly or in combination, acetyl distarch phosphate, phosphated distarch phosphate or hydroxypropyl starch per 100 mL.

(3) Liquid infant formula product must not contain more than 0.03 g carrageenan per 100 mL.

Carry-over of food additives

12. Other than by direct addition, a food additive may be present in infant formula product as a result of carry-over from an ingredient, provided that:

(a) (i) it is a nutrient as specified in the Tables to clauses 31 and 35; or

(ii) it is a food additive specified in the Table to clause 11; and

(iii) the amount of the nutrient or food additive is not more than the maximum level stipulated in the relevant table; and

(b) the level of the food additive in the final food is not more than would be introduced by the use of the food additive under proper technological conditions and good manufacturing practice.

Limit on aluminium

13. (1) Infant formula product, other than a soy-based formula product or pre-term formula, must not contain more than 0.05 mg of aluminium per 100 mL.

(2) Pre-term formula must not contain more than 0.02 mg of aluminium per 100 mL.

(3) Soy-based formula must not contain more than 0.1 mg of aluminium per
100 mL.

Limit on lead

14. Infant formula product must not contain more than 2 μg of lead per 100 mL.

Composition of lactose free and low lactose formulas

15. (1) A lactose free or low lactose variety of infant formula product 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 not contain any detectable lactose.

(3) Low lactose formula must not contain more than 0.24 g per 100mL of lactose.

Division 4 - General Labelling and Packaging Requirements

Representations of food as infant formula product

16. A food must not be represented as being suitable as a sole or principal source of nutrition for infants unless it complies with this Standard.

Names

17. The names by which infant formula products are defined in this Standard are not prescribed names except for 'Infant Formula' and 'Follow-on Formula'.

Requirement for a measuring scoop

18. A package, other than a single serve sachet, containing infant formula product in a powdered form, must contain a scoop which facilitates the use of the infant formula product in accordance with the directions contained in the label on the package.

Required statements

19. (1) The label on an infant formula product must contain the following statements:

(a) in the case of powdered infant formula product
'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on

medical advice. Inappropriate use or preparation can make your baby very ill';

(b) in the case of concentrate infant formula product 'Warning – follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of concentrate except on medical advice. Inappropriate use or preparation can make your baby very ill';

(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 concentrate this ready to drink formula except on medical advice. Inappropriate use or preparation can make your baby very ill'.

(2) The label on an infant formula product must contain directions for the preparation and use of the infant formula product which include words and pictures that instruct:

(a) that each bottle should be prepared individually;

(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;

(c) that potable, previously boiled water should be used;

(d) where a package contains a measuring scoop, that only the enclosed scoop should be used;

(e) that formula left in the bottle after a feed must be discarded.

(3) Subject to subclause (4) the label on an infant formula product must contain statements indicating that:

(a) breast feeding is superior to the use of infant formula product in the feeding of infants;

(b) the infant formula product should only be used on the advice of a medical practitioner or health worker as to the need for its use and the proper method of its use;

(c) the infant formula product may be used from birth, in the case of infant formula;

(d) the infant formula product should not be used for infants aged under 6 months in the case of follow-on formula;

(e) except in the case of packages of pre-term formula, infants over the age of 6 months should receive foods in addition to the infant formula product.

(4) The statements required by subclause (3) must occur under a heading that reads 'Important Notice' or any word or words having the same or similar effect.

Print and package size

20. (1) Where infant formula product is in a package having a net weight of more than 1 kg, the statements required by clauses 19(1) and 36(1) must be in size of type of not less than 3 mm.

(2) Where infant formula product is in a package having a net weight of less than 1 kg, the statements required by clauses 19(1) and 36(1) must be in size of type of not less than 1.5 mm.

Declaration of nutrition information

21. The label on an infant formula product must include a statement, which may be in the form of a table, that contains the following information:

(1) (a) the average energy content expressed in kJ per 100 mL in the case of ready to drink formula;

(b) in the case of powdered or concentrated infant formula product:

(i) the average energy content expressed in kJ per 100 mL of infant formula product that has been reconstituted according to directions; and

(ii) the average energy content expressed in kJ per 100 g of the infant formula product prior to reconstitution in the case of powdered infant formula product or kJ per 100 mL prior to reconstitution in the case of liquid concentrated infant formula product.

(2) (a) the average amount of each of protein, fat and carbohydrate expressed in g per 100 mL in the case of ready to drink formula;

(b) in the case of powdered or concentrated infant formula product:

(i) the average amount of each of protein, fat and carbohydrate expressed in g per 100 mL of infant formula product that has been reconstituted according to directions; and

(ii) the amount of each of protein, fat and carbohydrate expressed in g per 100 g of infant formula product prior to reconstitution in the case of powdered infant formula product or g per 100 mL prior to reconstitution in the case of liquid concentrated infant formula product.

(3) (a) the average amount for each vitamin, mineral and any other nutritional substance permitted by this standard expressed in weight per 100 mL in the case of ready to drink formula;

(b) in the case of powdered or concentrated infant formula product:

(i) the average amount for each vitamin, mineral and any other nutritional substance permitted by this Standard expressed in weight per 100 mL of infant formula product that has been reconstituted according to directions; and

(ii) the average amount for each vitamin, mineral and any other nutritional substance permitted by this Standard expressed in weight per 100 g prior to reconstitution in the case of powdered infant formula product or weight per 100 mL prior to reconstitution in the case of liquid concentrated infant formula product.

Date marking and storage instructions

22. (1) Notwithstanding the provisions in subclause 2(1) of Standard 1.2.5, the label on an infant formula product must include a statement of the best before date.

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

Editorial Note: The appropriate storage instructions should be valid for the full range of climatic conditions that exist in Australia and New Zealand.

Statement of protein source

23. The label on an infant formula product must contain a statement of the source 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 23 of this Standard applies only to the name as labelled on the product in accordance with the requirement in Standard 1.2.2.

Statement on dental fluorosis

24. (1) An infant formula product that:

(a) contains more than 17 μg of fluoride per 100 kJ prior to reconstitution, in the case of powdered or concentrated infant formula product; or

(b) contains more than 0.15 mg of fluoride per 100 mL, in the case of ready to drink formula;

must comply with subclause (2) of this clause.

(2) The label on an 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.

Labelling of lactose free and low lactose formulas

25. (1) The words ‘lactose free' must appear as part of the appropriate designation of lactose free formula.

(2) The words ‘low lactose' must appear as part of the appropriate designation of low lactose formula.

(3) The label on a package containing a lactose free formula or a low lactose formula must include the following statements:

(a) The amount of lactose expressed in g per 100 mL; and

(b) The amount of galactose expressed in g per 100 mL.

Prohibited representations

26. The label on a package containing infant formula product must not contain:

(a) a picture of an infant;

(b) a picture that idealises the use of infant formula product;

(c) the word 'humanised' or 'maternalised' or any word or words having the same or similar effect;

(d) words claiming that the formula is suitable for all infants;-

(e) information relating to the nutritional content of human milk;

(f) subject to subclause 38(2) a reference to the presence of any nutrient or nutritional substance, except for a reference to a nutrient or nutritional substance in:
  (i) the name of a lactose free formula or a low lactose formula
  (ii) a statement of ingredients or
  (iii) a nutrition information statement;

(g) subject to Part 3, Division 2 representation that the food is suitable for a particular condition, disease or disorder.

Editorial Note: Part 3, Division 2 relates to infant formula product formulated for metabolic or immunological conditions. Clause 38 permits labelling which varies from this clause.

Division 5 - General Microbiological Requirements

Microbiological standards

27. Infant formula product:

(a) in powdered form, must:

  (i) have a standard plate count of not more than 1000 micro-organisms per g;
  (ii) be free from coliforms in 1 g;
  (iii) be free from coagulase-positive staphylococci in 0.1g;
  (iv) be free from *Salmonella* in 25 g;
  (v) have a *Bacillus cereus* count of not more than 100 micro-organisms per g;

(b) in powdered form with added L($^+$) producing lactic acid cultures, must:

  (i) be free from coliforms in 1 g;
  (ii) be free from coagulase-positive staphylococci in 0.1g;
  (iii) be free from *Salmonella* in 25 g;
  (iv) have a *Bacillus cereus* count of not more than 100 micro-organisms per g;

(v) have prior to the addition of L(+) producing lactic acid cultures a standard plate count of not more than 1000 micro-organisms per g;

(c) in liquid concentrate form or ready to drink form must not exhibit any detectable microbial growth.

PART 2 - INFANT FORMULA AND FOLLOW-ON FORMULA

Composition

28. (1) Infant formula and follow-on formula must:

(a) have an energy content of not less than 2500 kJ/L and not more than 3150 kJ/L in the case of infant formula, and not less than 2500 kJ/L and not more than 3550 kJ/L in the case of follow-on formula;

(b) must contain an amount of each nutrient specified in column 1 of the Table to this clause which is not less than the amount specified in column 2 of the Table and not more than the amount specified in column 3 of the Table.

TABLE TO CLAUSE 28

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 not more than 8 mOsm/100 kJ.

Protein

29. (1) The protein in infant formula and follow-on formula must have an amino acid score of not less than 0.8.

(2) L-amino acids may be added solely for the purpose of achieving the amino acid score specified in subclause (1).

Fat

30. 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 a natural constituent of a milk-based ingredient of that particular infant formula or follow-on formula;

(b) have a ratio of linoleic acid to α–linolenic acid of not less than 5 to 1 and not more than 15 to 1;

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

(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) of 2 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-formula, the eicosapentanoic acid (20:5 n-3) content of not more than the docosahexanoic acid (22:6 n-3) content.

TABLE TO CLAUSE 30

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)	1.75	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

Vitamins and minerals

31. (1) Infant formula and follow-on formula must contain the vitamins and minerals specified in column 1 of the Table to this clause provided that, in relation to each vitamin or mineral:

(a) the added vitamin or mineral is in a form specified in the Schedule;

(b) the infant formula or follow-on formula contains not less than the quantity specified in column 2 of the Table; and

(c) the infant formula or follow-on formula contains not more than the quantity specified in column 3 of the Table, if any.

TABLE TO CLAUSE 31

Column 1 Nutrient	Column 2 Minimum per 100 kJ	Column 3 Maximum 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	2.0 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	1.0 µg	
Minerals		
Sodium	5 mg	15 mg
Potassium	20 mg	50 mg
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	0.36 µg	0.9 µg

(2) Infant formula and follow-on formula must contain not 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 not less than 1.2 to 1 and not more than 2 to 1.

(4) The ratio of zinc to copper in infant formula and follow-on formula must not be more than 12 to 1.

Editorial Note: While there are no maximum levels specified in relation to a number of the vitamins and minerals in this table the Australia New Zealand Food Authority has recommended guidelines for levels of vitamins and minerals that as a matter of good practice should not be exceeded.

PART 3 - INFANT FORMULAS FOR SPECIAL DIETARY USE

Division 1 - Pre-term formula

Composition

32. Pre-term formula must:

(a) have an energy content of not less than 2720 kJ/L and not more than 3556 kJ/L;

(b) contain an amount of each nutrient specified in column 1 of the Table to this clause which is not less than the amount specified in column 2 of the Table and not more than the amount specified in column 3 of the Table.

TABLE TO CLAUSE 32

Column 1 Nutrient	Column 2 Minimum amount per 100 kJ	Column 3 Maximum amount per 100 kJ
Protein	0.6 g	0.76 g
Fat	1.05 g	1.5 g

Protein

33. (1) The protein in pre-term infant formula must have an amino acid score not less than 0.8.

(2) L-amino acids may be added solely for the purpose of achieving the amino acid score specified in subclause (1).

Fat

34. The fats in pre-term infant formula must comply with the provisions of clause 30 as if pre-term formula were infant formula or follow-on formula.

Vitamins and minerals

35. (1) Pre-term formula must contain the vitamins and minerals specified in column 1 of the Table to this clause provided that, in relation to each vitamin or mineral:

(a) the added vitamin or mineral is in a form specified in the Schedule;

(b) the formula contains not less than the amount specified in column 2 of the Table to this clause; and

(c) the formula contains not more than the amount specified in column 3 of the Table to this clause.

TABLE TO CLAUSE 35

Column 1	**Column 2**	**Column 3**
Nutrient	**Minimum per 100 kJ**	**Maximum per 100 kJ**
Vitamins		
Vitamin A	20 µg	36 µg
Vitamin D	0.75 µg	2.0 µg
Vitamin C	3.5 mg	9.6 mg
Preformed Thiamin	10 µg	48 µg
Riboflavin	14 µg	86 µg
Preformed Niacin	0.18 mg	0.89 mg
Vitamin B_6	9.0 µg	42 µg
Folate	5.0 µg	10 µg
Pantothenic acid	0.24 mg	0.36 mg
Vitamin B_{12}	0.04- µg	0.13 µg
Vitamin K	1.0 µg	3.6 µg
Biotin	0.36 µg	2.7 µg
Vitamin E	0.18 mg	1.6 mg
Minerals		
Sodium	9.0 mg	14 mg
Potassium	20 mg	36 mg
Chloride	14 mg	22 mg
Calcium	17 mg	34 mg
Phosphorus	12 mg	22 mg
Magnesium	1.5 mg	3.6 mg
Iron	0.01 mg	0.4 mg
Iodine	2.4 µg	10 µg
Copper	23 µg	30 µg
Zinc	0.12 mg	0.36 mg
Manganese	1.2 µg	1.8 µg
Selenium	0.50 µg	0.9 µg

(2) A pre-term infant formula must contain not less than 0.9 mg of Vitamin E per g of polyunsaturated fatty acid.

(3) The ratio of calcium to phosphorus in pre-term formula must be not less than 1.4 to 1 and not more than 2.0 to 1.

(4) The ratio of zinc to copper in pre-term formula must be not more than 12 to 1.

Labelling

36. (1) The label on a package containing pre-term formula must include the statement:

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

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

Division 2 - Infant formula products formulated for metabolic and immunological conditions

Composition

37. Infant formula product may be specifically formulated to satisfy particular metabolic or immunological conditions and must comply with:

(a) this Division; and

(b) with all the other requirements of this Standard that are not inconsistent with this Division.

Additional Labelling

38. (1) The label on a package containing an infant formula product formulated for metabolic or immunological conditions must include a statement indicating that the product is not suitable for general use and should be used under medical supervision.

(2) The appropriate designation of a food standardised in this Division must include a statement indicating:

(a) the condition, disease or disorder for which the food has been specially formulated; and

(b) the nutritional modifications which have been made to the infant formula product.

Subdivision 1 - Infant formula products for specific dietary use based upon protein substitutes

Composition

39. (1) An infant formula product for specific dietary use based upon protein substitutes must:

(a) have an energy content of not less than 2500 kJ/L and not more than 3150 kJ/L in the case of infant formula, and not less than 2500 kJ/L and not more than 3550 kJ/L in the case of follow-on formula;

(b) have a potential renal solute load of not more than 8 mOsm per 100 kJ; and

(c) must contain an amount of each nutrient specified in column 1 of the Table to this clause which is not less than the amount specified in column 2 of the Table and not more than the amount specified in column 3 of the Table.

TABLE TO CLAUSE 39

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

Protein

40. (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 protein in an infant formula product based upon protein substitutes must have an amino acid score of not less than 0.8.

Vitamins and minerals

41. An infant formula product for specific dietary use based upon protein substitutes must:

(a) contain chromium in an amount of not less than 0.35 μg per 100 kJ and not more than 2.0 μg per 100 kJ; and

(a) contain molybdenum in an amount of not less than 0.36 μg per 100 kJ and not more than 3.0 μg per 100 kJ.

Editorial Note: The provisions of clause 31 of this standard also applies in respect of the vitamins and minerals permitted in an infant formula product for specific dietary use based upon protein substitutes.

Additional permitted additions

42. An infant formula product based upon protein substitutes for specific dietary use may contain:

(a) added medium chain triglycerides;

(b) food additives specified in column 1 of the Table to this clause provided that the total amount of the food additive, including food additive that is present or naturally occurring in any food in the infant formula product, is not more than the amount specified in column 2.

TABLE TO CLAUSE 42

Column 1	**Column 2**
Food additive	**Maximum amount per 100 mL**
Thickening agents	
Distarch phosphate	2.5 g
Acetylated distarch phosphate Phosphated distarch phosphate Hydroxypropyl starch	2.5 g singly or in combination
Carrageenan	0.1 g
Mono- and diglycerides	0.5g
Diacetyl tartaric acid esters of mono and diglycerides (DATEM)	0.4g

SCHEDULE 1

PERMITTED FORMS OF VITAMINS AND MINERALS IN INFANT FORMULA PRODUCTS

Column 1	**Column 2**
Substance	
Vitamins	**Permitted Forms**
Vitamin A	Retinol Forms
	vitamin A (retinol)
	vitamin A acetate (retinyl acetate)
	vitamin A palmitate (retinyl palmitate)
	Carotenoid Forms
	beta-carotene
Vitamin D	vitamin D_2 (ergocalciferol)
	vitamin D_3 (cholecalciferol)
Vitamin C	ascorbic acid
	ascorbyl palmitate
	calcium ascorbate
	potassium ascorbate
	sodium ascorbate
Thiamin	thiamin hydrochloride
	thiamin mononitrate
Riboflavin	riboflavin
	riboflavin-5'-phosphate, sodium
Niacin	niacinamide (nicotinamide)
Vitamin B_6	pyridoxine hydrochloride
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

Column 1	**Column 2**
Minerals	**Permitted Forms**
Vitamin K	vitamin K_1, as phylloquinone (phytonadione)
Sodium	sodium bicarbonate
	sodium carbonate
	sodium chloride
	sodium citrate
	sodium gluconate
	sodium hydroxide
	sodium iodide
	sodium lactate
	sodium phosphate, dibasic
	sodium phosphate, monobasic
	sodium phosphate, tribasic
	sodium sulphate
	sodium tartrate
Potassium	potassium bicarbonate
	potassium carbonate
	potassium chloride
	potassium citrate
	potassium glycerophosphate
	potassium gluconate
	potassium hydroxide
	potassium phosphate, dibasic
	potassium phosphate, monobasic
	potassium phosphate, tribasic
Chloride	calcium chloride
	magnesium chloride
	potassium chloride
	sodium chloride
Calcium	calcium carbonate
	calcium chloride
	calcium citrate
	calcium gluconate
	calcium glycerophosphate
	calcium hydroxide
	calcium lactate
	calcium oxide
	calcium phosphate, dibasic
	calcium phosphate, monobasic

Column 1	**Column 2**
Minerals	**Permitted Forms**
	calcium phosphate, tribasic
	calcium sulphate
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
Magnesium	magnesium carbonate
	magnesium chloride
	magnesium gluconate
	magnesium oxide
	magnesium phosphate, dibasic
	magnesium phosphate, tribasic
	magnesium sulphate
Iron	ferric ammonium citrate
	ferric pyrophosphate
	ferrous citrate
	ferrous fumarate
	ferrous gluconate
	ferrous lactate
	ferrous succinate
	ferrous sulphate
Iodine	potassium iodate
	potassium iodide
	sodium iodide
Copper	copper gluconate
	cupric sulphate
Zinc	zinc acetate
	zinc chloride
	zinc gluconate

Column 1 Minerals	Column 2 Permitted Forms
	zinc oxide
	zinc sulphate
Manganese	manganese chloride
	manganese gluconate
	manganese sulphate
Selenium	sodium selenite
	seleno methionine
Chromium	chromium sulphate
Molybdenum	sodium molybdateVI dehydrate

2. Standard 1.3.4 is amended by inserting:

"SPECIFICATIONS FOR NUCLEOTIDES DESCRIPTION/ PHYSICAL CONSTRAINTS"

Inosine - 5' monophosphate disodium salt (IMP)

1. Chemical nomenclature: C_{10} H_{11} N_4 Na_2 O_8 P· 7.5H_2 O
   In addition the compound must be of the 5 species, eg the disodium monophosphate structure is attached to the fifth carbon in the central structure.

2. Molecular weight: 527.25

3. Structure/ Physical character: Occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic taste.

4. Solubility: 24 g is soluble in 100 g of water at 20°C; is stable in acid liquids under the identical conditions

Uridine - 5' monophosphate disodium salt (UMP)

1. Chemical nomenclature: C_9 $H_{11}N_2$ O_9 PNa_2
   In addition the compound must be of the 5 species, eg the disodium monophosphate structure is attached to the fifth carbon in the central structure.

2. Molecular weight: 368.15

3. Structure/ Physical character: Occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic taste.

4. Solubility: Freely soluble in water; very slightly soluble in alcohol.

Adenosine- 5' monophosphate (AMP)

1. Chemical nomenclature: C_{10} $H_{14}N_5$ O_7 P
   In addition the compound must be of the 5 species, eg the monophosphate structure is attached to the fifth carbon in the central structure.

2. Molecular weight: 347.22

3. Structure/ Physical character: Occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic acidic taste.

4. Solubility: Very slightly soluble in water; practically insoluble in alcohol.

Cytidine - 5' monophosphate

1. Chemical nomenclature: C_9 $H_{14}N_3$ O_8 P
   In addition the compound must be of the 5 species, eg the monophosphate structure is attached to the fifth carbon in the central structure.

2. Molecular weight: 323.20

3. Structure/Physical character: Occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic slightly acidic taste.

4. Solubility: Very slightly soluble in water; practically insoluble in alcohol.

Guanosine - 5' monophosphate disodium salt

1. Chemical nomenclature: C_{10} $H_{12}N_5$ Na_2 O_8 P· 7.OH_2O
   In addition the compound must be of the 5 species, eg the disodiummonophosphate structure is attached to the fifth carbon in the central structure.

2. Molecular weight: 533.26

3. Structure/ Physical character: Occurs as a colourless or white crystal or as a white crystalline powder. It is odourless and has a characteristic taste.

4. Solubility: 20 g is soluble in 100g of water at 20°C; becomes gelatinous in acid liquids under the identical conditions

TESTING REQUIREMENTS FOR NUCLEOTIDES

1. Physical inspection: white crystals or crystalline powder

2. Identification:

   a) Ultraviolet absorbance: A1 in 12,500 solution of the powder in 0.01N hydrochloric acid exhibits an absorbance maximum at:

Absorbance	**Nucleotide**
250+- 2nm	Inosine - 5' monophosphate disodium salt
260+- 2nm	Uridine - 5' monophosphate disodium salt
257+- 2nm	Adenosine- 5' monophosphate
280+- 2nm	Cytidine - 5' monophosphate
256+- 2nm	Guanosine - 5' monophosphate disodium salt

   b) IMP, UMP and GMP must test positive for sodium phosphate

   c) IMP,UMP,AMP, CMP and GMP must test positive for organic phosphate

3. Assay (HPLC):
   Optimum - not less than 96% (corrected for moisture content).

4. IMP and GMP have a pH of a 1 in 20 solution: between 7.0 and 8.5

5. Clarity and colour of solution:

   500mg/10mL H_2O for IMP: is colourless and shows only a trace of turbidity
   100mg/10mL H_2O for GMP: is colourless and shows only a trace of turbidity

6. Moisture

Nucleotide	**Moisture**
Inosine - 5' monophosphate disodium salt	Not more than 28.5%: Karl Fischer
Uridine - 5' monophosphate disodium salt	Not more than 26.0%: Karl Fischer
Guanosine - 5' monophosphate disodium salt	Loss in drying - not more than 25% (4 hrs @ 120°C
Cytidine - 5' monophosphate	Not more than 6.0%: Loss in drying (4 hrs @ 120°C
Adenosine- 5' monophosphate	Not more than 6.0%: Loss in drying (4 hrs @ 120°C

7. Impurities - all nucleotides

Impurity	Nucleotide
amino acids: negative	IMP, GMP
ammonium salts: negative	IMP, GMP
arsenic: not more than 2ppm	IMP, UMP, AMP, CMP, GMP
heavy metals: not more than 10ppm	IMP, UMP, AMP, CMP, GMP

8. Related foreign substances:

For IMP: only 5' - inosinic acid is detected by thin layer chromatography
For GMP: only 5' - guanylic acid is detected by thin layer chromatography

9. Bacteriological profile

a) SPC: not more than 1000/g, test per current FDA/BAM procedures

b) Coliforms: Negative by test; test per current FDA/BAM procedures

c) Yeast and mold: not more than 300/g, test per current FDA/BAM procedures

d) Salmonella: negative, test per current FDA/BAM procedures."

RECOMMENDED GUIDELINES

Guideline for maximum levels 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 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 Special purpose formulas (Part 3 Div 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 on the label of an infant formula product to the effect that no further consumption of vitamin or mineral preparations are necessary.

Nutrition information table

The nutrition information contained on the label on a package containing 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 as bought (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
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 nutritional substance 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 bought in ready to drink form