

National Standards on Food Safety of P. R. China

GB 10765-2010

National food safety standard

Infant formula

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Foreword

This standard is modified in relation to CODEX STAN 72-1981 (Revision 2007) (Part A of the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants) formulated by Codex Alimentarius Commission and by reference to Chinese Dietary Reference Intakes compiled by Chinese Nutrition Society in 2000.

This Standard will replace GB 10765-1997, *Infant Formula* □, GB 10766-1997, *Infant Formula II, III*, and GB10767-1997, *General Technical Regulations for Infant Blended Milk Powder and Infant Completed Grain Flour* and amendments thereto.

Compared with GB 10765-1997, GB 10766-1997 and GB 10767-1997, the following changes have been made to the Standard:

——Integrate the above three standards to one, titled as “Infants Formula”;

——Provisions therein are modified.

Annex A and Annex B of this present National Standard is informative.

The original editions replaced by this present National Standard include:

——GB 10765-1997;

——GB 10766-1997;

——GB 10767-1997.

National food safety standard

Infant Formula

1. Scope

This Standard applies to infant formulas.

2. Normative References

The following standards contain provisions which, through reference in this text, constitute provisions of this present standard. Note: As for the dated references, all the amendments or revisions after them except the corrigenda are not applicable to this present standard. As for the references that are not dated, their most recent editions are applicable to this present national standard.

3. Terms and Definitions

3.1 Infants:

Refer to persons of 0 ~ 12 months old.

3.2 Infant formula:

3.2.1 Milk-based infant formula: refers to liquid or powder products made only through physical methods, of which the main material is milk and milk protein products, supplemented with a proper amount of vitamin, minerals and other supplementary materials, which are applicable to normal infants, where the energy and nutrition can satisfy the requirements of growth and development of normal infants of 0~6 months old.

3.2.2 Soybean-based infant formula: refers to liquid or powder products made only through physical methods, of which the main material is soybean and soybean protein products, supplemented with a proper amount of vitamin, minerals and other supplementary materials, which are applicable to normal infants, where the energy and nutrition can satisfy the requirements of growth and development of normal infants of 0~6 months old.

4. Technical Requirements

4.1 Requirements for Raw Materials

The raw materials should comply with the related safety standard and/or related regulations, should ensure the infants' safety and meet the nutrition demands, and should not use the substances that may endanger the nutrition and health of infants.

Ingredients and food additives adopted should not contain gluten.

Hydrogenated oil and fat should NOT be used.

Raw and supplementary materials treated by irradiation should NOT be used.

4.2 Sensory requirement: Should comply with the requirements set out in Table 1.

Table 1 Sensory Requirements

Item	Requirements
Color	Should conform to the features of related products.
Taste and odor	Should conform to the features of related products.
Structural state	Should conform to the features of related products.no visible foreign substances should be included in the product.
Dissolvability	Should conform to the features of related products.

4.3 Essential components

4.3.1 All essential components in the product is essential for the growth and development of infants.

4.3.2 The energy in the ready-to-eat infant formulas per 100ml should be within the range of 250 kj (60 kcal)~ 295 kj (70 kcal). The calculation of energy should be the value of the product of the content of protein, fat and carbohydrate per 100 ml product multiplied by the energy coefficient of 17 kj / g, 37 kj / g, 17 kj / g (the energy coefficient of dietary fiber should be based on 50% of carbohydrate energy coefficient) respectively, and the sum (kj/100ml) is divided by 4.184 to kcal / 100 ml.

4.3.3 The protein, fat, carbohydrate content of infant formula per 100kj (100 kcal) should be consistent with the provisions set out in Table 2.

4.3.4 For milk-based infant formula, the preferred carbohydrate should be lactose, or lactose and the polymer of glucose. Only after pre-gelatinization, the starch can be added into the infant formula. Fructose can NOT be used.

Table 2 Indices of Protein, Fat and Carbohydrate

Nutrient	Per 100 kj		Per 100 kcal		Test method
	Minimum	Maximum	Minimum	Maximum	
Protein ^{a)}					
Milk-based infant formula/(g)	0.45	0.70	1.88	2.93	GB 5009.5
Soybean-based infant formula/(g)	0.50	0.70	2.09	2.93	
Fat ^{b)} ? (g)	1.05	1.40	4.39	5.86	GB5413.3
In which: linoleic acid(g)	0.07	0.33	0.29	1.38	GB5413.27
α - linolenic acid(mg)	12	N.S. ^c	50	N.S. ^c	
Linoleic acid/ α - linolenic acid ratio	5:1	15:1	5:1	15:1	-
Total carbohydrate ^{d,a)} /(g)	2.2	3.3	9.2	13.8	-
^{a.} For milk based infant formulas, the content of whey protein should be over or equal to 60%; the content of protein should be calculated as nitrogen (N) \times 6.25 ^{b.} Among the finished products, the amount of lauric acid and myristic acid (tetradecanoic acid) should account for no more than 20% of the total fatty acid; the maximum content of trans fatty acid should not exceed 3% of the total fatty acid; the erucic acid content should not exceed 1% of the total fatty acid. The total fatty acid refers to the sum of C4 ~ C24 fatty acid. ^{c.} N.S.: No specification ^{d.} The content of lactose in total carbohydrate should be over or equal to 90%. For calculation of the proportion of lactose among the total carbohydrates, the added oligosaccharides and polysaccharides should not be included; the requirement of lactose content percentage does not apply to soy-based formula. ^{e.} Carbohydrate content A1 should be calculated according to formula(1):					

$$A_1 = 100 - (A_2 + A_3 + A_4 + A_5 + A_6) \dots\dots\dots (1)$$

Where:

A_1 —carbohydrate content, g/100g;

A_2 —protein content, g/100g;

A_3 —fat content, g/100g;

A_4 —moisture content, g/100g;

A_5 —ash content, g/100g;

A_6 —dietary fiber content, g/100g.

4.3.5 Vitamin: shall comply with the provisions set out in Table 3.

Table 3 Indices of Vitamin

Nutrient	Per 100 kJ		Per 100 kcal		Test Method
	Minimum	Maximum	Minimum	Maximum	
Vitamin A($\mu\text{g re}^a$)	14	43	59	180	GB5413.9
Vitamin D(μg^b)	0.25	0.60	1.05	2.51	
Vitamin E /mg $\alpha\text{-te}^c$	0.12	1.20	0.50	5.02	
Vitamin K1/(μg)	1.0	6.5	4.2	27.2	GB 5413.10
Vitamin B ₁ /(μg)	14	72	59	301	GB 5413.11
Vitamin B ₂ /(μg)	19	119	80	498	GB 5413.12
Vitamin B ₆ /(μg)	8.5	45.0	35.6	188.3	GB 5413.13
Vitamin B ₁₂ /(μg)	0.025	0.360	0.105	1.506	GB 5413.14
Niacin (niacinamide) /(μg^d)	70	360	293	1506	GB 5413.15
Folic acid/(μg)	2.5	12.0	10.5	50.2	GB 5413.16
Pantothenic acid/(μg)	96	478	402	2000	GB 5413.17
Vitamin C /(mg)	2.5	17.0	10.5	71.1	GB 5413.18
Biotin/(μg)	0.4	2.4	1.5	10.0	GB 5413.19

^a. RE is retinol equivalent. 1 $\mu\text{g RE}$ =1 μg All trans retinol (Vitamin A) =3.33 IU A. Ingredients of Vitamin A shall only include preformed retinol. When calculating or claiming activities of Vitamin A, no carotenoids ingredient shall be included.

^b. Calciferol, 1 μg Vitamin D = 40 IU Vitamin D

^c. 1 mg $\alpha\text{-TE}$ ($\alpha\text{-tocopherol}$ equivalent) =1 mg d- $\alpha\text{-tocopherol}$.
The content of Vitamin E should be at least 0.5mg of $\alpha\text{-TE}$ per gram of polyunsaturated fatty acid. The minimum content of Vitamin E content should be regulated according to the number of double bonds in polyunsaturated fatty acids in the formula as follows: 0.5 mg of $\alpha\text{-TE}$ per gram of linoleic acid (18:2 n-6); 0.75 mg of $\alpha\text{-TE}$ per gram of $\alpha\text{-linolenic}$ acid (18:3 n-3); 1.0 mg of $\alpha\text{-TE}$ per gram of arachidonic acid (20:4 n-6); 1.25mg of $\alpha\text{-TE}$ per gram of Eicosapentaenoic Acid (20:5 n-3); 1.5mg of $\alpha\text{-TE}$ per gram of docosahexenoic acid (22:6 n-3).

^d. Niacin: excludes precursor form.

4.3.6 Minerals

The indices of minerals in infant formulas should meet the specification of Table 4.

Table 4 Indices of Minerals

Nutrient	Per 100 kJ		Per 100 kcal		Test Method
	Minimum	Maximum	Minimum	Maximum	
Sodium/(mg)	5	14	21	59	GB5413.21
Potassium/(mg)	14	43	59	180	
Copper/(ug)	8.5	29.0	35.6	121.3	
Magnesium/(mg)	1.2	3.6 ^a	5.0	15.1 ^a	
Iron/(mg)	0.10	0.36	0.42	1.51	
Zinc/(mg)	0.12	0.36	0.50	1.51	
Manganese/(mg)	1.2	24.0	5.0	100.4	
Calcium/(mg)	12	35	50	146	
Phosphorus/(mg)	6	24 ^a	25	100 ^a	GB5413.22
Calcium/phosphorus ratio	1:1	2:1	1:1	2:1	-
Iodine/(ug)	2.5	14.0	10.5	58.6	GB5413.23
Chloride/(mg)	12	38	50	159	GB5413.24
Selenium/(ug)	0.48	1.90	2.01	7.95	GB5009.93

4.4 Optional components

4.4.1 In addition to the essential components in 4.3, if one or more nutrients listed in Table 5 can be selected to add or claimed on label, whereas the content of such nutrients should meet the specification of Table 5.

4.4.2 To improve the protein quality of infant formula or enhance its nutritional value, the monomer L-amino acid may be added by referring to the amino acid content recommended in Annex A. The used L-amino acid monomer sources shall comply with GB14880 or Appendix B requirements.

4.4.3 If other substances are added not covered in Table 5 and Annex B, they shall comply with the relevant state regulations.

Table 5 Indices of Optional Components

Optional Components	Per 100 kJ		Per 100 kcal		Test method
	Minimum	Maximum	Minimum	Maximum	
Choline(mg)	1.7	12.0	7.1	50.2	GB/T5413.20
Inositol(mg)	1.0	9.5	4.2	39.7	GB/T5413.25
Taurine(mg)	N.S. ^a	3	N.S. ^a	13	GB/T5413.26
L-Carnitine(mg)	0.3	N.S. ^a	1.3	N.S. ^a	-
Docosahexaenoic acid(% total fatty acid)	N.S. ^a	0.5	N.S. ^a	0.5	GB/T5413.27
Arachidonic acid(% total fatty acid)	N.S. ^a	1	N.S. ^a	1	GB/T5413.27

^a N.S.: No specification.
^b If docosahexaenoic acid (22:6 n-3) is supplemented to the infant formula, at least the same amount of Arachidonic acid (20:4 n-6) should be supplemented. Eicosapentaenoic acid (20:5 n-3) may exist in long chain unsaturated fatty acids, of which the total content should not exceed that of docosahexaenoic acid.
^c Total fatty acid refers to the sum of C4 ~ C24 fatty acids.

4.5 Other indices

Other indices of the components in infant formulas should meet the specification of Table 6.

Table 6 .Other Indices

Item	Index	
Moisture, % ^a ≤	5.0	GB5009.3
Ash		GB5009.4
Milk –based powder products, % ≤	4.0	
Milk –based liquid products (calculated by dry substance) % ≤	4.2	
Bean based powder products, % ≤	5.0	
Bean based liquid products(calculated by dry substance) % ≤	5.3	
Impurities (for milk based product ONLY)		GB5413.30
Powder product, mg/kg ≤	12	
Liquid product, mg/kg ≤	2	
^a Only for powdered infant formula.		

4.6 Limits of contaminants

The limit of contaminants in infant formulas should meet the specification of Table 7.

Table 7 Indices of Contaminants (calculated based on power product)

Item	Index	Test method
Lead, mg/kg ≤	0.15	GB 5009.12
Nitrate (based on NaNO ₃), mg/kg ≤	100	GB 5009.33
Nitrite (based on NaNO ₂) ^a , mg/kg ≤	2	
^a Only for milk-based infant formulas.		

4.7 Limit of mycotoxin: the limit of mycotoxin should meet the specification of Table 8.

Table 8 limit of mycotoxin (calculated based on power product)

Item	Index	Test Method
Aflatoxin M ₁ or aflatoxin B ₁ ^a / (μg/kg) ≤	0.5	GB 5009.24
A Limit of Aflatoxin M ₁ is for the milk-based infant formulas; and a Limit of aflatoxin B ₁ is for the soybean-based infant formulas.		

4.8 Limit of Microorganisms: Limit of Microorganism in power infant formulas should meet the specification of Table 9; the liquid infant formulas should meet the requirement of commercial sterilization and should be tested in accordance with the methods provided in GB/T 4789.26.

Table 9 Limit microorganisms

Microorganism	Sampling plan ^a and limit (Unless specified otherwise, it should be expressed in cfu/g or cfu/ml)				Test method
	n	c	m	M	
Total plate count ^b	5	2	1000	10000	GB4789.2
Coliform bacteria	5	2	10	100	GB4789.3 plate count method
Staphylococcus aureus	5	2	10	100	GB4789.10 plate count method
Enterobacter sakazakii ^c	3	0	0/100 g	—	GB4789.40 plate count method
Salmonella	5	0	0/25 g	—	GB 4789.4

^a. Sample analysis and handling should comply with GB/T 4789.1 and GB4789.18.
^b. Not applicable to products supplemented with active bacteria(aerobic and anaerobic probiotics)[the number of active bacteria of active probiotics in products should be $\geq 10^6$ CFU / g (ml)].
^c. Only applicable to formulas for infants of 0-6 months old.

4.9 Food additives and nutrition fortifiers

4.9.1 Quality of food additives and nutrition fortifier should be consistent with relevant safety standards and requirements.

4.9.2 The use of food additives and nutrient fortifiers should conform to GB 2760 and GB 14880 requirements.

4.10 Urease activity: the urease activity of products containing soy component should be consistent with the provisions of Table 10.

Table 10 Indices of Urease Activity

Item	Index	Test method
Qualitative determination of urease activity	Negative	GB/T 5413.31 ^a

^a. The sampling quantity of liquid infant formulas should be converted according to the content of dry substances.

5. Others

5.1 Labels

5.1.1 Contents indicated on the label should be subject to specifications of GB 13432. In addition, nutrient or nutritional component content as per 100kJ should be claimed.

5.1.2 On the label, product category and type (such as milk-based or soybean-based product and product form) and applicable infant age should be indicated. Label of the formula applicable to infants over 6 months old should be indicated with "If this product serves infants elder than 6 month, supplementary foods should also be used".

5.1.3 Label of the infant formula should be indicated with "the most ideal food for infants is breast milk for infants of 0-6 months; when breast milk is absent or not enough, this product can be used."

5.1.4 Images of infants or women cannot appear on the labels. It is not allowed to use the expressions such as "like human milk", "like breast milk" or similar terms.

5.2 Directions for use

- 5.2.1 The directions for use, proper preparation and illustration as well as storage condition of the product should be clearly indicated on the label. If maximum surface area of the package is less than 100 cm² or if the quantity of product is less than 100 g, illustration is not necessary.
- 5.2.2 The directions indicated should cover warning on the hazard to health resulting from incorrect preparation or application.

5.3 Packaging

Food-grade carbon dioxide and/or nitrogen with purity $\geq 99.9\%$ may serve as packaging medium.

Annex A

(Informative index)

Recommendation on essential and semi-essential Amino Acids Used in Infant Formula

- A.1 By reference to the representative data that have been published related to essential and semi-essential amino acids and nitrogen content and/or protein content in human milk in China and considering a certain range of variation, the lower limit of essential and semi-essential amino acids in infant formula can be calculated (mg/g N).
- A.2 According to the lower limit level of each kind of amino acid (mg/g N) in breast milk in China, to calculate the amino acid content per 100kcal infant formula when the protein content is lowest (1.88g/100 kcal), the method is the amino acid level (in milligram) per gram of nitrogen in breast milk is divided by the nitrogen conversion factor, 6.25, and then multiplied by 1.88, the results see Table A1. The essential and semi-essential amino acids in infant formula are recommended not less than the recommended level in Table A1.
- A.3 In the calculations, the concentration of tyrosine and phenylalanine can be added; if the proportion of methionine to cysteine is less than 2:1, the content can be added also.

Table A.1.: Content of essential and semi-essential amino acids in recommended infant formula

Amino acid	mg/g N	mg/100kcal
Cystine	80	24.1
Histidine	120	36.1
Isoleucine	300	90.2
Leucine	540	162.4
Lysine	350	105.3
Methionine	65	19.6
Phenylalanine	180	54.1
Threonine	250	75.2
Tryptophan	110	33.1
Tyrosine	200	60.2
Valine	310	93.2

Annex B

(Informative Annex)

Monomer Amino Acid could be used in Infant Formula

B.1 L-phenylalanine

B.1.1 Name and Origin

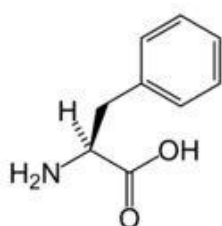
Name: L-phenylalanine L-2-amino -3 - phenyl propionate

Source: non-animal derived materials

Food Grade

B.1.2 Chemical structure, molecular formula and molecular weight

Chemical structure:



Molecular Formula: C₉ H₁₁ NO₂

Molecular Weight: 165.19

B.1.3 Physical and chemical properties: free flow of white crystal or crystalline powder.

B.1.4 Physical and chemical indicators: should be consistent with the provisions of Table B.1.

Table B.1 L-phenylalanine physical and chemical indices

Item	Value
Specific rotation $[\alpha]_D^{20}$	-33.2~-35.2
Content(calculated by dry substance) (%) \geq	98.5
Moisture / (%) \leq	0.2
pH value	5.4~6.0
Ash / (%) \leq	0.1
Lead (calculated as Pb) (mg/kg) \leq	0.3
Arsenic (calculated as As) (mg/kg) \leq	0.2

B.2 L-cystine

B.2.1 Name and source

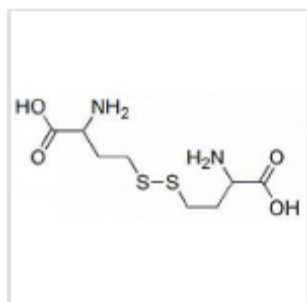
Name: L-cystine L-3, 3'-dithio-bis (2 - alanine)

Source: non-animal derived materials

Food Grade

B.2.2 Chemical structure, molecular formula and molecular weight

Chemical structure:

Molecular Formula: $C_6H_{12}N_2O_4S_2$

Molecular Weight: 240.3

B.2.3 Physical and chemical properties: Colorless to white crystal or crystalline powder, odorless.

B.2.4 Physical and chemical indicators: should be consistent with the provisions of Table B.2.

Table B.2 Physical and chemical indices of L-cystine

Item	Value
Specific rotation $[\alpha]_D^{20}$	-215~-225
Content(calculated by dry substance) (%) \geq	98.5
Moisture / (%) \leq	0.2
pH value	5.0~6.5
Ash / (%) \leq	0.1
Pb (mg/kg) \leq	0.3
As (mg/kg) \leq	0.2

B.3 L-leucine

B.3.1 Name and source

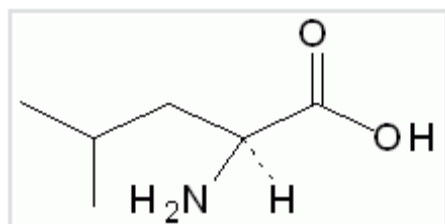
Name: L-Leucine L-2-amino -4 - methyl pentanoic acid

Source: non-animal derived materials

Food Grade

B.3.2 Chemical structure, molecular formula and molecular weight

Chemical structure:

Molecular Formula: $C_6H_{13}NO_2$

Molecular Weight: 131.17

B.3.3 Physical and Chemical Properties: White crystal or crystalline powder; no smell, taste slightly bitter.

B.3.4 Physical and chemical indicators: should be consistent with the provisions of B.3.

Table B.3 Physical and chemical indices of L- leucine

Item	Value
Specific rotation $[\alpha]_D^{20}$	14.5~16.5
Content(calculated by dry substance) (%) \geq	98.5
Moisture / (%) \leq	0.2
pH value	5.5~6.5
Ash / (%) \leq	0.1
Pb (mg/kg) \leq	0.3
As (mg/kg) \leq	0.2

B.4 L-tyrosine

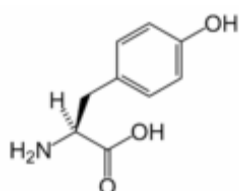
B.4.1 Name and source

Name: L-tyrosine S-amino -3 (4 - hydroxyphenyl) - propionic acid

Source: Separation from the beet wine

B.4.2 Chemical structure, molecular formula and molecular weight

Chemical Structure



Molecular Formula: $C_9H_{11}NO_3$

Molecular Weight: 181.19

B.4.3 Physical and Chemical Properties: This product is a white silk-like crystal or crystalline powder.

B.4.4 Physical and chemical indicators: should be consistent with the provisions of Table B.4.

Table B.4. Physical and chemical indices of L-tyrosine

Item	Value
Specific rotation $[\alpha]_D^{20}$	-11.0~-12.3
Content(calculated by dry substance) (%) \geq	99.0
Moisture / (%) \leq	0.3
pH value ^a	-
Ash / (%) \leq	0.1
Pb (mg/kg) \leq	0.3
As (mg/kg) \leq	0.2
^a pH value is not required for tyrosine.	

B.5 L-Tryptophan

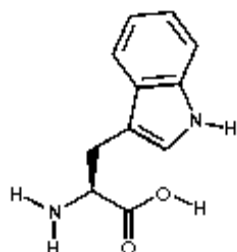
B.5.1 Name and source

Name: L-Tryptophan L-2-amino-3-indolyl-1-propionic acid

Source: derived from decomposition of serine and indole through E.coli fermentation

B.5.2 Chemical structure, molecular formula and molecular weight

Chemical structure:



Molecular Formula: C₁₁H₁₂N₂O₂

Molecular Weight: 204.23

B.5.3 Physical and Chemical Properties: white to yellow white crystal or crystalline powder.

B.5.4 Physical and chemical indicators: should be consistent with the provisions of Table B.5.

Table B.5 Physical and chemical indices of L-tryptophan

Item	Value
Specific rotation [α] _D ²⁰	-30.0~-33.0
Content(calculated by dry substance) (%) \geq	98.5
Moisture / (%) \leq	0.3
pH value	5.5~7.0
Ash / (%) \leq	0.1
Pb (mg/kg) \leq	0.3
As (mg/kg) \leq	0.2

B.6 L-histidine

B.6.1 Name and source

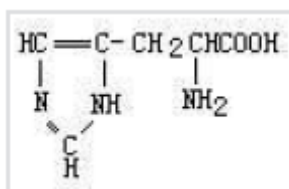
Name: L-histidine α -amino- β -imidazole propionic acid

Source: non-animal derived materials

Food Grade

B.6.2 Chemical structure, molecular formula and molecular weight

Chemical structure:



Molecular Formula: $C_6H_9N_3O_2$

Molecular Weight: 155.15

B.6.3 Physical and chemical properties: free flow of white crystal or crystalline powder.

B.6.4 Physical and chemical indicators: should be consistent with the provisions of Table B.6.

Table B.6 Physical and chemical indices of L-histidine

Item	Value
Specific rotation $[\alpha]_D^{20}$	11.5~13.5
Content(calculated by dry substance) (%) \geq	98.5
Moisture / (%) \leq	0.2
Ph value	7.0~8.5
Ash / (%) \leq	0.2
Pb (mg/kg) \leq	0.3
As (mg/kg) \leq	0.2