



National Standards of People’s Republic of China

GB 10766—xxxx

Formulas for Special Medical Purposes Intended for
Infants

(Draft for Soliciting Opinions)

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Foreword

This standard is modified in relation to CODEX STAN 72-1981 (Revision 2007) (Part B 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.

Formulas for Special Medical Purposes Intended for Infants

1 Scope

This present National Standard specifies the technical requirements, inspection method, labels, and packaging of formulas for special medical purposes intended for infants of 0~12 months old.

This present National Standard applies to production, circulation, supervision and administration of formulas for special medical purposes intended for infant.

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. However, parties to agreements based on this present national standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. As for the references that are not dated, their most recent editions are applicable to this present national standard.

GB 2760 Hygienic Standards for Uses of Food Additives

GB 4789.1 Microbiological Examination of Food Hygiene – General principles

GB 4789.2 Microbiological Examination of Food Hygiene – Detection of Total Colony Count

GB 4789.3 Microbiological Examination of Food Hygiene – Detection of coliform bacteria

GB 4789.4 Microbiological Examination of Food Hygiene – Examination of Salmonella

GB 4789.26 Microbiological examination of food hygiene - Examination of commercial sterilization of canned food

GB 4789.40 Microbiological Examination of Food Hygiene - Examination of Enterobacter Sakazakii

GB 5009.3 Determination of moisture in Foods

GB 5009.4 Determination of ash in Foods

GB 5009.5 Determination of protein in Foods

GB 5009.12 Determination of Lead in Foods

GB 5009.18 Determination of Fluorine in Foods

GB 5009.24 Method for Determination of Aflatoxins M₁ and B₁ in Foods

GB 5009.93 Determination of Selenium in Foods

GB 5009.123 Determination of Chromium in Foods

GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of Fatty Acid

- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of Fat
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of trans Fatty Acid
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of lactose and sucrose
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of Insoluble Dietary Fiber
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamins A, D, and E content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin K₁ content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin B₁ content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin B₂ content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin B₆ content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin B₁₂ content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of niacin and niacinamide
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of folic acid (folate activity)
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of pantothenic acid
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of vitamin C content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of free biotin content
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of choline content
- GB xxxx Milk Powder and Formula Foods for Infants and young children--Determination of calcium, iron, zinc, sodium, potassium, magnesium, copper and manganese
- GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of phosphorus

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GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of iodine content

GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of chlorine

GB xxxx Milk Powder and Formula Foods for Infants and young children – Determination of Inositol

GB xxxx Milk powder and formula foods for infants and young children--Determination of taurine content

GB xxxx Milk powder and formula foods for infants and young children--Determination of solubility

GB xxxx Milk powder and formula foods for infants and young children--Determination of impurity

GB xxxx Milk Powder and Formula Foods for Infants and young children - Determination of Urease

GB xxxx Milk Powder and Formula Foods for Infants and young children - Determination of nitrate and nitrite

GB xxxx Milk Powder and Formula Foods for Infants and young children - Determination of L-carnitine

GB 13432 General standard for the Labeling of Prepackaged Foods for Special Dietary Uses.

GB 14880 Hygienic Standard for the Use of Nutritional Fortification Substances in Foods

3 Terms and Definitions

The following terms and definitions are applicable to this present National Standard.

3.1 Infants: refer to persons of 0 ~ 12 months old.

3.2 Formulas for special medical purposes intended for infants: refer to liquid or powder formulas that are made specially to meet the requirement of nutrition of infants who suffer special disorder or illness, and those under medical condition, which can satisfy the special nutrition requirements of the specific infants.

4 Requirements

Formulas for special medical purpose intended for infants should rely on correct medical and nutritional principle. The safety, abundance of the nutrition and pertinence should comply with the scientific verification. The energy and nutrients should be capable of satisfying the growth and development of infants with special requirements.

4.1 Requirements for Raw Materials

4.1.1 The raw and supplementary materials for formulas for special medical purpose intended for infants should comply with the related national or trade standards or regulations.

Non-desalted whey powders should NOT be used. Ingredients and food additives adopted should NOT contain gluten.

4.1.2 Hydrogenated oil and fat should NOT be used in formulas for special medical purpose intended for infants.

4.1.3 Raw and supplementary materials treated by irradiation should NOT be used in formulas for special medical purpose intended for infants.

4.2 Sensory requirement

The color, flavor, smell, structure, and fast dissolvability of the product should meet the requirement on the quality of related products.

4.3 Essential components

4.3.1 The energy and nutritional components in formulas for special medical purpose intended for infants should be based on the essential components of infant formula, whereas they can be adjusted according to the special requirements of illness or medical condition to satisfy the requirement of nutrition of the infants in special medical conditions.

4.3.2 In general, the energy contained per 100 ml of the instant formula for special medical purpose intended for infants should be within the range of 250 kJ (60 kcal)~ 295 kJ (70 kcal), whereas the energy may be adjusted accordingly according to the special medical condition and nutrition requirement of some infants, which should be clearly indicated.

4.3.4 Individual amino acids can be added to the formulas for special medical purposes intended for infants by reference to the amino acid content in breast milk in Annex A of GB10765 Infant Formula only for the purpose of improving the protein quality or raising the nutritional value of such formulas, whereas it is only allowed to use L type amino acid. Source of the amino acid used should meet the specification of GB14880. For infant formula based on hydrolyzed or partly-hydrolyzed milk protein or individual amino acids, the content of essential and semi-essential amino acids should not be lower than that of amino acids in breast milk described in Annex A of GB10765.

4.3.5 Protein, fat and carbohydrate content in the formulas for special medical purposes intended for infants should meet the specification in Table 1.

Table 1 Indices of Protein, Fat and Carbohydrate

Nutrient	Unit	Per 100 kJ		Per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
Protein ²⁾					
Milk-based infant formula	g	0.45	0.7	1.8	3.0
Soybean-based infant formula	g	0.5	0.7	2.25	3.0
Fat ³⁾	g	1.05	1.4	4.4	6.0
if which: linoleic acid	g	0.07	0.33	0.3	1.4
α - linolenic acid	mg	12	N.S. ¹⁾	50	N.S. ¹⁾
linoleic acid/ α - linolenic acid ratio		5:1	15:1	5:1	15:1

Total carbohydrate	g	2.2	3.3	9.0	14.0
¹ N.S.: No specification ² For infant formulas based on milk protein and its processed products, the content of lactalbumin should be over or equal to 60%; the content of protein should be calculated as nitrogen (N) \times 6.25; for infant formulas based on beans and their processed products, the content of protein should be calculated as nitrogen (N) \times 5.71. ³ In the finished products, the total content of lauric acid and myristic acid (tetradecanoic acid) should not exceed 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. In the calculation of total fatty acid, C4~C24 fatty acids should be involved.					

4.3.6 Vitamin

Indices of vitamin content in formulas for special medical purposes intended for infants should meet the specification in Table 2.

Table 2 Indices of Vitamin

Nutrient	Unit	Per 100 kJ		Per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
Vitamin A	$\mu\text{g RE}^{1)}$	14	43	60	180
Vitamin D ²⁾	μg	0.25	0.6	1	2.5
Vitamin E	$\text{mg } \alpha\text{-TE}^{3)}$	0.12 ⁴⁾	1.2	0.5 ⁴⁾	5
Vitamin K	μg	1	6.5	4	27
Vitamin B ₁	μg	14	72	60	300
Vitamin B ₂	μg	19	119	80	500
Niacin ⁵⁾	μg	70	360	300	1500
Vitamin B ₆	μg	8.5	45	35	175
Vitamin B ₁₂	μg	0.025	0.36	0.1	1.5
Pantothenic acid	μg	96	478	400	2000
Folic acid	μg	2.5	12	10	50
Vitamin C ⁵⁾	mg	2.5	17	10	70
Biotin	μg	0.4	2.4	1.5	10
¹⁾ RE is retinol equivalent. 1 $\mu\text{g RE}$ =3.33 IU A=1 μg All trans retinol (Vitamin A). Ingredients of Vitamin A shall come from preformed retinol. When calculating or claiming activities of Vitamin A, no carotenoid ingredient shall be included. ²⁾ Calciferol, 1 μg Calciferol = 40 IU Vitamin D ³⁾ 1 $\text{mg } \alpha\text{-TE}$ (α -tocopherol equivalent)=1 $\text{mg d-}\alpha$ -tocopherol. ⁴⁾ The content of Vitamin E should be at least 0.5 $\text{mg of } \alpha\text{-TE}$ per gram of polyunsaturated fatty acid. The minimum 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 $\text{mg of } \alpha\text{-TE}$ per gram of linoleic acid (18:2 n-6); 0.75 $\text{mg of } \alpha\text{-TE}$ per gram of α -linolenic acid (18:3 n-3); 1.0 $\text{mg of } \alpha\text{-TE}$ per gram of arachidonic acid (20:4 n-6); 1.25 $\text{mg of } \alpha\text{-TE}$ per gram of Eicosapentaenoic Acid (20:5 n-3); 1.5 $\text{mg of } \alpha\text{-TE}$ per gram of docosahexenoic acid (22:6 n-3).. ⁵⁾ Niacin: excludes precursor form.					

⁶⁾ Expressed as ascorbic acid.

4.3.7 Minerals

The indices of minerals and microelements in formulas for special medical purposes intended for infants should meet the specification of Table 3.

Table 3 Indices of Minerals and Microelements

Nutrient	Unit	Per 100 kJ		Per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
Calcium	mg	12	35	50	140
Phosphorus ¹⁾	mg	6	24 ¹⁾	25	100 ¹⁾
Calcium/phosphorus ratio		1:1	2:1	1:1	2:1
Magnesium	mg	1.2	3.6	5	15 ¹⁾
Sodium	mg	5	14	20	60
Chloride	mg	12	38	50	160
Potassium	mg	14	43	60	180
Iron	mg	0.1	0.36	0.45	1.5
Zinc	mg	0.12	0.36	0.5	1.5
Manganese	μg	1.2	24	4.8	100
Iodine	μg	2.5	14	10	60
Selenium	μg	0.48	1.9	2	8
Copper	μg	8.5	29	35	120
¹⁾ ONLY applicable to formulas based on milk protein and its hydrolysate.					

4.4 Optional components

4.4.1 In addition to the essential components of formulas for special medical purposes intended for infants in 4.4, other beneficial components found in human milk, or those that have been verified to have similar feeding effect to similar components in human milk, can also be added, whereas the scope of applicability and category should comply with related regulations of China.

4.4.2 One or more optional components listed in Table 4 can be selected, whereas the content of such nutrients should meet the specification of Table 4.

Table 4 Indices of Optional Components

Optional Components	Unit	Per 100 kJ		Per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
Chromium	μg	0.4	2.4	1.5	10
Molybdenum	μg	0.4	2.4	1.5	10
Taurine	mg	N.S. ²⁾	3	N.S. ²⁾	12
Choline	mg	1.7	12	7.0	50

Inositol	mg	1.0	9.5	4.0	40
L-Carnitine	mg	0.3	N.S. ²⁾	1.2	N.S. ²⁾
Docosahexaenoic acid	% total fatty acid ³⁾	N.S. ²⁾	0.5	N.S. ²⁾	0.5
Arachidonic acid	% total fatty acid ³⁾	N.S. ²⁾	1	N.S. ²⁾	1
1) 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 content should not exceed that of docosahexaenoic acid. 2) NS: No specification. 3) During calculation of total fatty acid, C4 ~ C24 fatty acid should be involved.					

4.4.3 Other nutrients not shown in Table 4 can also be added to formulas for special medical purposes intended for infants, whereas such nutrients should comply with related national regulations and standards

4.5 Other indices

Other indices of the components in formulas for special medical purposes intended for infants should meet the specification of Table 5.

Table 5 Other Indices

Item	Index
Water content, g% ^① ≤	5.0
Ash, ^①	
Milk based products, % ≤	3.5
Bean based products, milk and bean based products, % ≤	5.0
Impurities	
Powder product, mg/kg ≤	12
Liquid product, g/kg ≤	2
①The above indices are only limited to powder products.	

4.6 Nutrient compounds

Nutrient compounds that can be used in formulas for special medical purposes intended for infants should comply with GB 14880.

4.7 Food Additives

Food additives that can be used in formulas for special medical purposes intended for infants should comply with GB 2760.

4.8 Hygienic requirements

4.8.1 Indices of contaminants

Indices of contaminants in formulas for special medical purposes intended for infants should meet the specification of Table 6. It is not allowed to add fluorine to formulas for special medical purposes intended for infants.

Table 6 Indices of Contaminants (calculated based on dry matter)

Item	Index
Lead, mg/kg ≤	0.15
Nitrate (based on NaNO ₃), mg/kg ≤	100
Nitrite (based on NaNO ₂) ^① , mg/kg ≤	2
Aflatoxin M ₁ or Aflatoxin B ₁ ^② , µg/kg ≤	0.5
<p>① Determination of nitrite is not necessary for bean-based products.</p> <p>② The index of Aflatoxin M₁ is applicable to products of which the main materials are cow's (or other animals') milk and its products; the index of Aflatoxin B₁ is applicable to products of which the main materials are beans and their products; the indices of Aflatoxin M₁ and Aflatoxin B₁ are applicable to products of which the main materials are cow's (or other animals') milk and its products, and beans and their products.</p>	

4.8.2 Indices of Microorganisms

Indices of Microorganism in formulas for special medical purposes intended for infants should meet the specification of Table 7. The liquid formulas for special medical purposes intended for infants should meet the requirement of commercial sterilization.

Table 7 Indices of Microorganisms

Microorganism	Sampling plan ^a and limit (If not specified, it should be expressed in cfu/g)			
	n	c	m	M
Total colony count ^b	5	2	1000	10000
Coliform bacteria	5	2	10	100
Enterobacter sakazakii ^c	3	0	0/100 g	—
Salmonella	5	0	0/25 g	—
<p>a. Comply with 4.2.1 of GB/T 4789.1</p> <p>b. Not applicable to formulas for special medical purposes intended for infants supplemented with probiotic bacteria.</p> <p>c. Only applicable to formulas for special medical purposes intended for infants of 0-6 months old.</p>				

4.8.3 Urease

The activity of urease is ONLY for bean-based product. The result of qualitative detection should be negative, and that of the quantitative detection should be less than 0.02 U/g.

4.8.4 Other hygienic requirements

Residue of active substances of drug in the formulas for special medical purposes intended for infants should meet the related provisions of China.

5. Inspection method

5.1 Energy density

The determined values of protein and fat and the calculated value of carbohydrate multiply the energy factor, 17 kJ/g, 37 kJ/g, and 17 kJ/g respectively, and the sum is the value in kilo Joule per 100 g (kJ/100g); or the determined values of protein and fat and the calculated value of carbohydrate multiply the energy factor, 4 kcal/g, 9 kcal/g, and 4 kcal/g respectively, and the sum is the value in kilo calorie per 100 g (kcal/100g).

5.2 Protein

Determine according to the method specified in GB 5009.5.

5.3 Fat

Determine according to the method specified in GB xxxx.

5.4 Linoleic acid, lauric acid, myristic acid, erucic acid, docosahexaenoic acid, and arachidonic acid

Determine according to the method specified in GB xxxx.

5.5 Trans fatty acid

Determine according to the method specified in GB xxxx.

5.6 Calculation of Carbohydrates

The mass fraction A_1 of carbohydrate is calculated as per formula (1):

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

Where,

A_1 —— Mass fraction of carbohydrate, %;

A_2 ——Mass fraction of Protein, %;

A_3 ——Mass fraction of Fat, %;

A_4 ——Mass fraction of Moisture, %;

A_5 ——Mass fraction of Ash, %;

A_6 ——Mass fraction of insoluble dietary fiber, %.

5.7 Sucrose

Determine according to the method specified in GB xxxx.

5.8 Vitamin A, D, E

Determine according to the method specified in GB xxxx.

5.9 Vitamin K

Determine according to the method specified in GB xxxx.

5.10 Vitamin B₁

Determine according to the method specified in GB xxxx.

5.11 Vitamin B₂

Determine according to the method specified in GB xxxx.

5.12 Vitamin B₆

Determine according to the method specified in GB xxxx.

5.13 Vitamin B₁₂

Determine according to the method specified in GB xxxx.

5.14 Niacin

Determine according to the method specified in GB xxxx.

5.15 Folic acid

Determine according to the method specified in GB xxxx.

5.16 Pantothenic acid

Determine according to the method specified in GB xxxx.

5.17 Vitamin C

Determine according to the method specified in GB xxxx.

5.18 Biotin

Determine according to the method specified in GB xxxx.

5.19 Calcium, iron, zinc, sodium, potassium, magnesium, copper and manganese

Determine according to the method specified in GB xxxx.

5.20 Chlorine

Determine according to the method specified in GB xxxx.

5.21 Phosphorus

Determine according to the method specified in GB/T 5413.22.

5.22 Iodine

Determine according to the method specified in GB xxxx.

5.23 Selenium

Determine according to the method specified in GB xxxx.

5.24 Taurine

Determine according to the method specified in GB xxxx.

5.25 Choline

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Determine according to the method specified in GB xxxx.

5.26 Inositol

Determine according to the method specified in GB xxxx.

5.27 L-Carnitine

Determine according to the method specified in GB 17787.

5.28 Moisture

Determine according to the method specified in GB 5009.3.

5.29 Ash

Determine according to the method specified in GB 5009.4.

5.30 Impurities

Determine according to the method specified in GB xxxx.

5.31 Solubility

Determine according to the method specified in GB xxxx.

5.32 Insoluble dietary fiber

Determine according to the method specified in GB xxxx.

5.33 Lead

Determine according to the method specified in GB 5009.12.

5.36 Chromium

Determine according to the method specified in GB 5009.123.

5.38 Nitrate/ nitrite

Determine according to the method specified in GB xxxx.

5.39 Urease activity

Determine according to the method specified in GB xxxx.

5.40 Aflatoxins M₁ and B₁

Determine according to the method specified in GB/T 5009.24.

5.41 Commercial sterilization

Determine according to the method specified in GB 4789.26.

5.42 Colony count

Determine according to the method specified in GB 4789.2.

5.43 Coliform Bacteria

Determine according to the method specified in GB 4789.3.

5.44 *Enterobacter Sakazakii*

Determine according to the method specified in GB 4789.40.

5.45 *Salmonella*

Determine according to the method specified in GB 4789.4

6. Labeling, packaging, transportation and storage

6.1 Labels

- 6.1.1 Contents indicated on the label should be subject to specifications of GB 13432. In addition, nutrients and optional components should be indicated as “content per 100 kJ or 100 kcal”.
- 6.1.2 The package should be indicated in clear black fonts “Please use the product under the guidance of doctors”.
- 6.1.3 The source of protein in products should be indicated on the label.
- 6.1.4 If the formulas for special medical purpose intended for infants contain modified protein, fat or carbohydrate, the labels should be indicated with the related information about the modified protein, fat or carbohydrate and the composition of amino acids, fatty acids or carbohydrate.
- 6.1.5 Labels should be indicated with product category, target infant population and applicable month age.

6.2 Packaging

- 6.2.1 Under normal conditions, packages used should not break or be contaminated.
 - 6.2.2 The products should be packaged with containers that can ensure hygiene, safety and product quality. Packages should be completely sealed; Carbon dioxide and/or nitrogen may serve as packaging medium.
 - 6.2.3 Containers and packaging materials of the products must be safe, which should satisfy the usage and meet the requirement of the related national standards.
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