



National Standard of the People's Republic of China

GB 10767-201X

National food safety standard

Young children formula

(exposure draft)

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**National Health Commission of the People's Republic of China
State Administration for Market Regulation**

Foreword

This standard replaces the contents of formulas suitable for young children of 13~36 month of age in GB 10767-2010 “National food safety standard Older infants and young children formula”.

Compared with formulas suitable for young children of 13~36 month of age in GB 10767-2010, the major changes of this standard are as follows:

- the scope of the standard has been revised;
- the requirements for lactose ratio have been added;
- the minimum or maximum values of some nutrients haven been adjusted or added;
- the test methods have been updated.

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1 Scope

This standard applies to formulas suitable for young children of 13~36 month of age.

2 Terms and Definitions

2.1 Young children formula

It refers to the product produced by taking milk and milk protein products and/or soybean and soybean protein products as major protein sources with addition of an appropriate amount of vitamins, minerals and/or other raw materials and only through physical methods. It is suitable for young children consumption and the energy and nutritional components therein can meet partial nutritional needs of normal young children.

3 Technical Requirements

3.1 Raw material requirements

3.1.1 The raw materials used in the product shall comply with corresponding safety standards and/or relevant provisions, and shall ensure the safety of young children and meet their nutritional needs. It shall not use substances harming young children's nutrition and health.

3.1.2 The hydrogenated oils and fats shall not be used.

3.1.3 The irradiated raw materials shall not be used.

3.2 Sensory requirements

The color, taste, odor, structural state and reconstituability of young children formula shall comply with the characteristics of corresponding product and shall have no foreign materials visible by normal eyesight.

3.3 Essential components

3.3.1 All essential components contained in the product are necessary for young children's growth and development.

3.3.2 Each 100 mL of the product shall contain 250 kJ (60 kcal)~334 kJ (80 kcal) energy in the ready-to-eat state. The energy shall be calculated by multiplying the contents of proteins, fats and carbohydrates per 100 mL of the product by the energy coefficients 17 kJ/g, 37 kJ/g and 17 kJ/g (8 kJ/g for dietary fiber), respectively, then sum them up to get value which is expressed in kilojoule/100 milliliter (kJ/100 mL), finally the sum value is divided by 4.184 to obtain the value expressed in kilocalorie/100 milliliter (kcal/100 mL).

3.3.3 The amounts of proteins, fats and carbohydrates contained per100 kJ (100 kcal) of the product shall comply with the provisions of Table 1.

Table 1 Protein, fat and carbohydrate indicators

Nutrients	Indicators				Test methods
	/100 kJ		/100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Protein ^a /(g)	0.43	0.96	1.8	4.0	GB 5009.5
Fat ^b /(g)	0.84	1.43	3.5	6.0	GB 5009.6
of which: Linoleic acid/(g)	0.07	0.33	0.3	1.4	GB 5009.168
α -Linolenic acid/(mg)	12	N.S. ^c	50	N.S. ^c	
Ratio of linoleic acid to α -linolenic acid	5:1	15:1	5:1	15:1	-
Carbohydrate ^{d, e} /(g)	1.8	3.6	7.5	15.0	-

^a The protein content shall be calculated by nitrogen (N)×6.25.

^b The content of *trans*-fatty acids shall ≤3% of total fatty acids. The total fatty acids refer to the sum of C4~C24 fatty acids.

^c N.S. refers to not specified.

^d The lactose contained in milk-based young children formulas (excluding lactose-free and low-lactose products) shall account for ≥50% of total carbohydrates. (The lactose content shall be ≤0.5 g/100 g in solid lactose-free formulas and that in solid low-lactose formulas shall be ≤2 g/100 g)

^e The carbohydrate content A_1 shall 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 —the carbohydrate content, g/100 g;

A_2 —the protein content, g/100 g;

A_3 —the fat content, g/100 g;

A_4 —the moisture content, g/100 g;

A_5 —the ash content, g/100 g;

A_6 —the dietary fiber content (as addition amount of oligosaccharide and/or polysaccharide), g/100 g.

3.3.4 Vitamins: it shall comply with the provisions of Table 2.

Table 2 Vitamin indicators

Nutrients	Indicators				Test methods
	/100 kJ		/100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Vitamin A/(μg RE) ^a	18	43	75	180	GB 5009.82
Vitamin D/(μg) ^b	0.48	1.20	2.0	5.0	GB 5009.82
Vitamin E/(mg α-TE) ^c	0.14	1.20	0.6	5.0	GB 5009.82
Vitamin K ₁ /(μg)	0.96	6.45	4.0	27.0	GB 5009.158
Vitamin B ₁ /(μg)	14	72	60	300	GB 5009.84
Vitamin B ₂ /(μg)	19	155	80	650	GB 5009.85
Vitamin B ₆ /(μg)	11.0	41.8	46	175	GB 5009.154
Vitamin B ₁₂ /(μg)	0.041	0.478	0.17	2.00	GB 5413.14
Niacin (nicotinamide) ^d /(μg)	110	359	460	1500	GB 5009.89
Folic acid/(μg)	2.4	12.0	10	50	GB 5009.211
Pantothenic acid/(μg)	96	478	400	2000	GB 5009.210
Vitamin C/(mg)	2.4	16.7	10	70	GB 5413.18
Biotin/(μg)	0.41	2.39	1.7	10.0	GB 5009.259

^a RE refers to retinol equivalent. 1 μg of RE=1 μg of *all-trans*-retinol (vitamin A)=3.33 IU of vitamin A. Vitamin A only includes preformed retinol, and the calculation and claim of vitamin A activity do not include any carotenoid component.

^b Calciferol, 1 μg of vitamin D=40 IU of vitamin D.

^c 1 mg of d-α-tocopherol=1 mg of α-TE (α-tocopherol equivalent); 1 mg of dl-α-tocopherol=0.74 mg of α-TE (α-tocopherol equivalent).

^d Niacin does not include precursor forms.

3.3.5 Minerals: it shall comply with the provisions of Table 3.

Table 3 Mineral indicators

Nutrients	Indicators				Test methods
	/100 kJ		/100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Sodium/(mg)	N.S. ^a	20	N.S. ^a	84	GB 5009.91 GB 5009.268
Potassium/(mg)	18	69	75	290	GB 5009.91 GB 5009.268
Copper/(μg)	6.9	34.9	29	146	GB 5009.13 GB 5009.268
Magnesium/(mg)	1.4	4.3	6.0	18.0	GB 5009.241 GB 5009.268
Iron/(mg)	0.24	0.60	1.0	2.5	GB 5009.90 GB 5009.268
Zinc/(mg)	0.10	0.31	0.40	1.30	GB 5009.14 GB 5009.268
Calcium/(mg)	17	50	71	210	GB 5009.92 GB 5009.268
Phosphorus/(mg)	8	26	35	110	GB 5009.87 GB 5009.268
Calcium-phosphorus ratio	1.2:1	2:1	1.2:1	2:1	-
Iodine/(μg)	1.4	14.1	6	59	GB 5009.267
Chlorine/(mg)	N.S. ^a	52	N.S. ^a	218	GB 5009.44

^a N.S. refers to not specified.

3.4 Optional components

3.4.1 In addition to the essential components in 3.3, if one or more of the components listed in Table 4 are selected to add in product or marked in label, the corresponding contents shall comply with the provisions of Table 4.

3.4.2 If substances other than those in Table 4 are added to the product, they shall comply with relevant national regulations.

Table 4 Optional component indicators

Optional components	Indicators				Test methods
	/100 kJ		/100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Selenium/(μg)	0.48	1.91	2.0	8.0	GB 5009.93 GB 5009.268
Choline/(mg)	4.8	23.9	20	100	GB 5413.20
Manganese/(μg)	0.24	23.90	1.0	100.0	GB 5009.242 GB 5009.268
Inositol/(mg)	1.0	9.6	4	40	GB 5009.270
Taurine/(mg)	0.8	4.0	3.5	16.7	GB 5009.169
L-carnitine/(mg)	0.3	1.5	1.3	6.3	GB 29989
Docosahexaenoic acid (DHA)/(mg)	N.S. ^a	9.6	N.S. ^a	40	GB 5009.168
Arachidonic acid (AA/ARA)/(mg)	N.S. ^a	19.1	N.S. ^a	80	GB 5009.168

^a N.S. refers to not specified.

3.5 Other indicators: it shall comply with the provisions of Table 5.

Table 5 Other indicators

Items	Indicators	Test methods
Moisture/(%) ^a	≤ 5.0	GB 5009.3
Ash		
Solid products/(%)	≤ 5.0	GB 5009.4
Liquid products (as total dry matters)/(%)	≤ 5.3	
Impurity ^b		
Solid products/(mg/kg)	≤ 12	GB 5413.30
Liquid products/(mg/kg)	≤ 2	

^a Only limited to solid products.
^b Not applicable to products added with vegetables and fruits.

3.6 Maximum levels of contaminants: it shall comply with the provisions of GB 2762.

3.7 Maximum levels of mycotoxins: it shall comply with the provisions of GB 2761.

3.8 Microbiological limits: the microbiological indicators of solid products shall comply with the provisions of Table 6. The microbiological indicators of liquid products shall comply with the requirements of commercial sterilization, and shall be tested according to the methods specified in GB 4789.26.

Table 6 Microbiological limit indicators

Items	Sampling plan ^a and limits (expressed in CFU/g or CFU/mL, unless otherwise specified)				Test methods
	n	c	m	M	
Total plate count ^b	5	2	1000	10000	GB 4789.2
Coliforms	5	2	10	100	Plate count method in GB 4789.3
<i>Salmonella</i>	5	0	0/25 g	-	GB 4789.4

^a The analysis and treatment of the samples shall be carried out in accordance with GB 4789.1 and GB 4789.18.
^b Not applicable to the products added with active probiotics [the viable count of each active probiotics added shall be $\geq 10^6$ CFU/g (mL)].

3.9 Food additives and nutritional fortification substances

3.9.1 The use of food additives and nutritional fortification substances shall comply with the provisions of GB 2760 and GB 14880.

3.9.2 The quality of food additives and nutritional fortification substances shall comply with the corresponding standards and/or relevant provisions.

3.10 Urease activity: the urease activity of the products taking soybeans or soybean products as a protein source shall comply with the provisions of Table 7.

Table 7 Urease activity indicators

Items	Indicators	Test methods
Qualitative determination of urease activity	Negative	GB 5413.31 ^a

^a The sampling volume of liquid products shall be converted according to the dry matter content.

4 Others

4.1 Labeling

4.1.1 The product labeling shall comply with GB 13432 and/or relevant provisions, for the marking of essential component and optional component content, the content in “100 kJ” shall be added.

4.1.2 The product category, attributes (e.g. product status) and applicable age shall be indicated on the label.

4.2 Instructions for use

4.2.1 Relevant product usage, preparation instructions and illustrations, storage conditions shall be clearly stated on the label. When the maximum surface area of the package is less than 100 cm² or the product mass is less than 100 g, the illustration may be exempted from marking.

4.2.2 Instruction shall give the warning statements to health hazards that may be resulted from improper preparation and improper use.

4.3 Packaging

The carbon dioxide and/or nitrogen of food grade or with purity $\geq 99.9\%$ can be used as packaging medium.
