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GB 10766-2021

National food safety standard
Older infant formula

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Foreword

This standard replaces the contents of formula suitable for consumption of older infant of 6~12 months in GB 10767-2010 “National food safety standard Older infants and young children formula”.

Compared with the content about formula suitable for older infant of 6~12 months in GB 10767-2010, the major changes of this standard are as follows:

——the scope of the standard has been revised;

——the terms and definitions have been revised;

——the requirements for whey protein and lactose ratio have been added;

——the minimum and maximum values of majority nutrients have been revised and added;

——the requirements for the content of protein, iron, zinc and phosphorus in bean-based older infant formula have been added;

——the manganese, selenium and choline have been revised to essential components from optional components;

——certain requirements for label have been revised;

——the Annex A and Annex B have been added;

——the test methods have been revised.

National food safety standard
Older infant formula

1 Scope

This standard applies to the formulas suitable for consumption of older infant of 6~12 months.

2 Terms and Definitions

2.1 Older infant formula

It refers to the formula that applies to consumption of normal older infants, the energy and nutrients of which can meet partial nutritional needs of older infant of 6~12 months.

2.2 Milk-based older infant formula

It refers to such products that are manufactured and processed only through physical method by taking milk and milk protein products as the main protein source with the addition of an appropriate amount of vitamins, minerals and/or other raw materials.

2.3 Bean-based older infant formula

It refers to such products that are manufactured and processed only through physical method by taking soy and soy protein products as the main protein source with the addition of an appropriate amount of vitamins, minerals and/or other raw materials.

3 Technical Requirements

3.1 Raw material requirements

3.1.1 The raw materials used in the product shall comply with the corresponding safety standards and/or relevant provisions, and shall ensure the safety of older infants and meet their nutritional needs. The substances that are detrimental to the nutrition and health of older infants shall not be used.

3.1.2 The raw materials and food additives used shall not contain gluten.

3.1.3 Hydrogenated oil and fat shall not be used.

3.1.4 Raw materials treated by irradiation shall not be used.

3.2 Sensory requirements

The color, taste, odor, structural state and reconstituability of older infant formula shall comply with the characteristics of the corresponding product, and the products shall not contain foreign matter visible under normal eyesight.

3.3 Essential components

3.3.1 All essential components in the product are necessary for the growth and development of older infants.

3.3.2 The energy contained in each 100 mL of the product under the ready-to-eat state shall fall within the range of 250 kJ (60 kcal)~314 kJ (75 kcal). For calculation of energy, the content of protein, fat and carbohydrate per 100 mL of the product is multiplied by the energy coefficient of 17 kJ/g, 37 kJ/g and 17 kJ/g (8 kJ/g for dietary fiber) respectively, and the obtained sum expressed in kJ/100 mL is divided by 4.184 to obtain a value expressed in kcal/100 mL.

3.3.3 The content of protein, fat and carbohydrate contained per 100 kJ (100 kcal) of the product shall comply with the provisions of Table 1.

3.3.4 For older infant formula, fructose and sucrose shall not be used as the source of carbohydrate, while appropriate amount of glucose polymer may be added (the starch can be added only after pre-gelatinization); for milk-based older infant formula, lactose shall be preferred as the source of carbohydrate (lactose shall account for ≥90% of the carbohydrate).

Table 1 Protein, fat and carbohydrate indicators

Nutrients	Indicators				Test methods
	/100 kJ		/100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Protein [a]					
Milk-based older infant formula/(g)	0.43	0.84	1.8	3.5	GB 5009.5
Bean-based older infant formula/(g)	0.53	0.84	2.2	3.5	
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]	
Linoleic acid: α-linolenic acid	5:1	15:1	5:1	15:1	-
Carbohydrate [d]/(g)	2.2	3.3	9.0	14.0	-

[a] Protein content shall be calculated by nitrogen (N)×6.25. Whey protein content in milk-based older infant formula shall be ≥ 40% (may be calculated according to the amount of raw materials added). In order to improve the protein quality of older infant formula or enhance its nutritional value, the L-type monomeric amino acid may be added with reference to the content of essential and semi-essential amino acids in Annex A, and its source shall comply with the provisions of Annex B.

[b] Total content of lauric acid and myristic acid (tetradecanoic acid) in fat of the final product shall be ≤ 20% of total fatty acids; the content of *trans* fatty acid shall be ≤3% of total fatty acids; the content of erucic acid shall be ≤1% of total fatty acids; total fatty acids refers to the sum of C4~C24 fatty acids.

[c] N.S. refers to not specified.

[d] Carbohydrate content A_1 shall be calculated according to Formula (1):

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

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 (calculated as the addition amount of oligosaccharides and/or polysaccharides), g/100 g.

3.3.5 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	
Vitamin E/(mg α-TE)[c]	0.14	1.20	0.6	5.0	
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	120	80	500	GB 5009.85
Vitamin B_6/(μg)	11.0	41.8	46	175	GB 5009.154
Vitamin B_{12}/(μg)	0.041	0.359	0.17	1.50	GB 5413.14
Niacin (niacinamide)[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
Choline/(mg)	4.8	23.9	20	100	GB 5413.20

[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 does not include any carotenoid components when the activity of Vitamin A is calculated and claimed.

[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.

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

Table 3 Minerals 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
Potassium/(mg)	18	54	75	225	
Copper/(μg)	8.4	28.7	35	120	GB 5009.13
Magnesium/(mg)	1.2	3.6	5.0	15.0	GB 5009.241
Iron/(mg)					GB 5009.90
Milk-based	0.24	0.48	1.0	2.0	
Bean-based	0.36	0.48	1.5	2.0	
Zinc/(mg)					GB 5009.14
Milk-based	0.12	0.36	0.50	1.50	
Bean-based	0.18	0.36	0.75	1.50	
Manganese/(μg)	0.24	23.90	1.0	100.0	GB 5009.242
Calcium/(mg)	17	43	71	180	GB 5009.92
Phosphorus/(mg)					GB 5009.87
Milk-based	8	26	35	110	
Bean-based	10	26	42	110	
Calcium phosphorus ratio	1.2:1	2:1	1.2:1	2:1	-
Iodine/(μg)	3.6	14.1	15	59	GB 5009.267
Chlorine/(mg)	N.S.[a]	52	N.S.[a]	218	GB 5009.44
Selenium/(μg)	0.48	2.06	2.0	8.6	GB 5009.93

[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 content 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	
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	N.S.[b]	1.3	N.S.[b]	GB 29989
Docosahexaenoic acid (DHA) [a]/(mg)	3.6	9.6	15	40	GB 5009.168
Arachidonic acid (AA/ARA)/(mg)	N.S.[b]	19.1	N.S.[b]	80	GB 5009.168

[a] If docosahexaenoic acid (22:6 n-3) is added to the older infant formula, at least the same amount of arachidonic acid (20:4 n-6) shall be added. The amount of eicosapentaenoic acid (20:5 n-3) shall not exceed the amount of docosahexaenoic acid.
[b] 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			GB 5009.4
Milk-based solid products/(%)	≤	4.0	
Milk-based liquid products (as total dry matter)/(%)	≤	4.2	
Bean-based solid products/(%)	≤	5.0	
Bean-based liquid products (as total dry matter)/(%)	≤	5.3	
Impurity (limited to milk-based older infant formula)			GB 5413.30
Solid products/(mg/kg)	≤	12	
Liquid product/(mg/8L)	≤	2	
[a] Only limited to solid products.			

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

3.8.1 The pathogenic bacteria limits of solid products shall comply with the provisions of GB 29921, and the other microbiological indicators shall comply with the provisions of Table 6.

3.8.2 The liquid products shall comply with the requirements of commercial sterilization, and shall be inspected according to the methods specified in GB 4789.26.

Table 6 Microbiological limit indicators

Items	Sampling plan [a] and limits (unless otherwise specified, all expressed in CFU/g or CFU/mL)				Test methods
	n	*c*	*m*	*M*	
Total plate count [b]	5	2	1000	10000	GB 4789.2
Coliforms	5	2	10	100	GB 4789.3 Plate count method
[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 strains (aerobes and facultative anaerobes) [the viable count in product shall be $\geq 10^6$ CFU/g or $\geq 10^6$ CFU/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 regulations.

3.10 Urease activity

The urease activity in the bean-based older infant formula 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 product 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, and for the content identification of essential component and optional component, the content labeling of “per 100 kilojoules (100 kJ)” shall be added.

4.1.2 The category, attributes (e.g. milk-based or bean-based products and product status) and applicable age of product shall be indicated on the label. Meanwhile, the older infant formula shall indicate as follows: “Complementary foods shall be supplemented”.

4.1.3 There must be no image of infants and women on the label, and the expressions such as “like human milk”, “like breast milk” or similar terms shall not be used.

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 cm^2 or the product mass is less than 100 g, the illustration may not be marked.

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 complying with national food safety standard can be used as packaging medium.

Annex A

Recommended values of essential and semi-essential amino acid in older infant formula

A.1 The recommended lower limit value (mg/g N) of essential and semi-essential amino acid in older infant formula is calculated by referring to the published data on content of essential and semi-essential amino acids and on content of nitrogen and/or protein in representative Chinese human milk, and considering the range of variation.

A.2 According to the low limit value (mg/g N) of each kind of amino acid in Chinese human milk, the amino acid content corresponding to per 100 kcal of older infant formula at the lowest protein content of 1.8 g/100 kcal shall be calculated as follows: the milligrams of amino acids per gram of nitrogen in human milk is divided by the nitrogen conversion factor of 6.25 and then multiplied by 1.8. In addition, reference was made to provisions of corresponding standards of Codex Alimentarius Commission. The results are shown in Table A.1. It is recommended that the value of essential and semi-essential amino acids contained in older infant formula shall be not less than the recommended values in Table A.1.

A.3 In the calculation, the concentration of tyrosine and phenylalanine can be summed up; if the ratio of methionine to cysteine is less than 2:1, the two can also be summed up together.

Table A.1 Recommended values of essential and semi-essential amino acid contained in older infant formula

Amino acids	Indicators	
	mg/g N	mg/100 kcal
Cysteine	131	38
Histidine	141	41
Isoleucine	319	92
Leucine	586	169
Lysine	395	114
Methionine	85	24
Phenylalanine	282	81
Threonine	268	77
Tryptophan	114	33
Tyrosine	259	75
Valine	315	90

Annex B

Monomeric amino acids that can be used in older infant formula

Table B.1 Monomeric amino acids [a] that can be used in older infant formula

No.	Amino acid	Source of compound	Chemical name	Molecular formula	Relative molecular mass	Specific optical rotation α (20 °C, D)	pH	Purity (%) ≥	Loss on drying (%) ≤	Residue on ignition (%) ≤	Lead (mg/kg) ≤	Arsenic (mg/kg) ≤
1	Cysteine	L-cysteine	L-α-amino-β-mercaptopropionic acid	$C_3H_7NO_2S$	121.16	+8.3~+9.5	4.5~5.5	98.5	0.5	0.1	0.3	0.2
		L-cysteine hydrochloride monohydrate	L-2-amino-3-mercaptopropionic acid hydrochloride monohydrate	$C_3H_7NO_2S·HCl·H_2O$	175.64	+5.5~+7.0	1.5~2.0	98.5	8.0~12	0.1	0.3	0.2
		L-cysteine hydrochloride	L-2-amino-3-mercaptopropionic acid hydrochloride	$C_3H_7NO_2S·HCl$	157.62	+5.6~+8.9	1.5~2.0	98.5	2.0	0.1	0.3	0.2
		L-cystine	L-3,3'-dithiobis (2-aminopropionic acid)	$C_6H_{12}N_2O_4S_2$	240.3	-215~-230	5.0~6.5	98.5	0.2	0.1	0.3	0.2
2	Histidine	L-histidine	α-amino β-imidazolyl propionic acid	$C_6H_9N_3O_2$	155.15	+12.0~+12.8	7.0~8.5	98.5	0.2	0.2	0.3	0.2
		L-histidine hydrochloride monohydrate	L-2-amino-3-imidazolyl propionic acid hydrochloride	$C_6H_9N_3O_2·HCl·H_2O$	209.63	+8.5~+10.5	3.5~4.5	98.5	0.2	0.1	0.3	0.2
3	Isoleucine	L-isoleucine	L-2-amino-3-methyl pentanoic acid	$C_6H_{13}NO_2$	131.17	+38.9~+41.8	5.5~6.5	98.5	0.2	0.2	0.3	0.2
4	Leucine	L-leucine	L-2-amino-4-methyl pentanoic acid	$C_6H_{13}NO_2$	131.17	+14.9~+16.0	5.5~6.5	98.5	0.2	0.2	0.3	0.2
5	Lysine	L-lysine hydrochloride	L-2,6-diaminocaproic acid hydrochloride	$C_6H_{14}N_2O_2·HCl$	182.65	+20.4~+21.5	5.0~6.0	98.5	0.4	0.1	0.3	0.2
		L-lysine acetate	L-2,6-diaminocaproic acid acetate	$C_6H_{14}N_2O_2·C_2H_4O_2$	206.24	+8.5~+10.0	6.5~7.5	98.5	0.3	0.2	0.3	0.2
6	Methionine	L-methionine	2-amino-4-methylmercaptobutyric acid	$C_5H_{11}NO_2S$	149.21	+21.0~+25.0	5.6~6.1	98.5	0.2	0.2	0.3	0.2
		N-acetyl-L-methionine	*N*-acetyl-2-amino-4-methylmercapto-butyric acid	$C_7H_{13}NO_3S$	191.25	-18.0~-22.0	-	98.5	0.5	0.1	0.3	0.2

No.	Amino acid	Source of compound	Chemical name	Molecular formula	Relative molecular mass	Specific optical rotation α (20 °C, D)	pH	Purity (%) ≥	Loss on drying (%) ≤	Residue on ignition (%) ≤	Lead (mg/kg) ≤	Arsenic (mg/kg) ≤
7	Phenylalanine	L-phenylalanine	L-2-amino-3-phenylpropionic acid	$C_9H_{11}NO_2$	165.19	-33.0~-35.0	5.4~6.0	98.5	0.2	0.1	0.3	0.2
8	Threonine	L-threonine	L-2-amino-3-hydroxybutyric acid	$C_4H_9NO_3$	119.12	-26.0~-29.0	5.0~6.5	98.5	0.2	0.2	0.3	0.2
9	Tryptophan	L-tryptophan	L-2-amino-3-indole-1-propionic acid	$C_{11}H_{12}N_2O_2$	204.23	-30.0~-32.5	5.4~6.4	98.5	0.2	0.1	0.3	0.2
10	Tyrosine	L-tyrosine	S-amino-3 (4-hydroxyphenyl)-propionic acid	$C_9H_{11}NO_3$	181.19	-11.3~-12.1	5.0~6.5	98.5	0.2	0.2	0.3	0.2
11	Valine	L-valine	L-2-amino-3-methylbutyric acid	$C_5H_{11}NO_2$	117.15	+26.6~+28.8	5.5~6.5	98.5	0.2	0.1	0.3	0.2
[a] Non-edible animal and plant materials shall not be used as the source of monomeric amino acids.												