GB

NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

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National Food Safety Standard - General Standard for Infant Formula for Special Medical Purposes

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National Food Safety Standard - General Standard for Infant Formula for Special Medical Purposes

1 Scope

This Standard applies to infant formula for special medical purposes.

2 Normative references

The documents cited in this Standard are indispensable for the application of this Standard. For the dated references, only the versions with the dates indicated are applicable to this Standard. For the undated references, the latest version (including all the amendments) are applicable to this Standard.

3 Terms and definitions

3.1 Infant

People of 0 months ~ 12 months of age.

3.2 Infant formula for special medical purposes

A powdered or liquid formula designed for the nutritional needs of infants with special medical conditions, such as special disorders, diseases, or medical conditions. Under the guidance of a doctor or clinical dietitian, when consumed alone or in combination with other foods, the energy and nutritional ingredient can meet the growth and development needs of infants with special medical conditions of 0 months ~ 6 months of age.

4 Technical requirements

4.1 General requirements

Formulations for infant formula for special medical purposes shall be based on research results of medical and nutritional studies. The safety, nutritional adequacy, and clinical effects need to be scientifically proven. When consumed alone or in combination with other foods, the growth and development needs of infants with special medical conditions of 0 months ~ 6 months of age can be

and nutritional needs of certain infants, the energy can be adjusted accordingly. The energy is calculated by multiplying the protein, fat, and carbohydrate content per 100mL of product by the energy coefficients of 17 kJ/g, 37 kJ/g, and 17 kJ/g (the energy coefficient of dietary fiber, calculated according to 50% of energy coefficient of carbohydrate). The sum obtained is the value of kJ/100mL, and divided by 4.184, to obtain the value of kcal/100mL.

4.4.3 In general, the amount of protein, fat, and carbohydrate contained per 100kJ (100 kcal) of infant formula for special medical purposes shall meet the requirements of Table 2.

4.4.4 For infant formula for special medical purposes, except for special needs (such as lactose intolerance), the preferred carbohydrate shall be lactose and (or) glucose polymer. Only pre-gelatinized starch can be added to infant formula for special medical purposes. Fructose shall not be used.

Table 2 -- Indexes for protein, fat, and carbohydrate

Nutrients	Per 100 kJ		Per 100 kcal		Inspection method
	Minimum	Maximum	Minimum	Maximum	
Protein[a]	0.45	0.70	1.88	2.93	GB 5009.5
Fat[b]/ (g)	1.05	1.40	4.39	5.86	GB 5413.3
Of which: Linoleic acid/ (g)	0.07	0.33	0.29	1.38	GB 5413.27
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]/ (g)	2.2	3.3	9.2	13.8	-

[a] The protein content shall be calculated by multiplying nitrogen (N) ×6.25.

[b] The total amount of lauric acid and myristic acid (tetradecanoic acid) in the final product fat <20% of total fatty acids. The maximum content of trans-fatty acids <3% of total fatty acids. Erucic acid content <1% of total fatty acids. Total fatty acids refer to the sum of C4 ~ C24 fatty acids.

[c] N.S. means no special instructions.

[d] The carbohydrate content A_1 shall be calculated according to the formula (1):

$$A_1 = 100-(A_2+A_3+A_4+A_5+A_6) \quad \text{..... (1)}$$

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;

Table 5 (continued)

Optional ingredients	Per 100 kJ		Per 100 kcal		Inspection method
	Minimum	Maximum	Minimum	Maximum	
Choline/ (mg)	1.7	12.0	7.1	50.2	GB/T 5413.20
Inositol/ (mg)	1.0	9.5	4.2	39.7	GB 5413.25
Taurine/ (mg)	N.S.[a]	3	N.S.[a]	13	GB 5413.26
L-carnitine/ (mg)	0.3	N.S.[a]	1.3	N.S.[a]	-
Docosahexaenoic acid/ (% total fatty acid [b, c])	N.S.[a]	0.5	N.S.[a]	0.5	GB 5413.27
Eicosatetraenoic acid/ (% total fatty acid [b, c])	N.S.[a]	1	N.S.[a]	1	GB 5413.27

[a] N.S. means no special instructions.

[b] If docosahexaenoic acid (22:6 n-3) is added to the infant formula for special medical purposes, at least the same amount of eicosatetraenoic acid (20:4 n-6) shall be added. The amount of eicosapentaenoic acid (20:5 n-3) in long-chain unsaturated fatty acid shall not exceed that of docosahexaenoic acid.

[c] Total fatty acids refer to the sum of C4 ~ C24 fatty acids.

4.6 Other indexes: It shall meet the requirements of Table 6.

Table 6 -- Other indexes

Items		Indexes	Inspection method
Moisture/ (%) [a]	≤	5.0	GB 5009.3
Ash			
Powdered product/（%）	≤	5.0	GB 5009.4
Liquid product (based on total dry matter) / (%)	≤	5.3	
Impurity degree			
Powdered product/ (mg/kg)	≤	12	GB 5413.30
Liquid product/ (mg/kg)	≤	2	

[a] It is limited to powdered infant formula for special medical purposes.

4.7 Contaminant limits: It shall meet the requirements of Table 7.

4.10 Food additives and nutrient supplements

4.10.1 The quality of food additives and nutrient supplements shall comply with the relevant safety standards and relevant regulations.

4.10.2 The use of food additives and nutrient supplements shall comply with the provisions of GB 2760 and GB 14880.

4.11 Urease activity: The urease activity in products containing soybean ingredients shall meet the requirements of Table 10.

Table 10 -- Urease activity index

Item	Index	Inspection method
Qualitative determination of urease activity	Negative	GB/T 5413.31[a]
[a] The sampling amount of liquid infant formula for special medical purposes shall be converted according to the dry matter content.		

5 Others

5.1 Label

5.1.1 The product label shall comply with the provisions of GB 13432. The nutrients and optional ingredients shall be marked with an indication of the content of "per 100kJ".

5.1.2 The label shall clearly indicate the type of infant formula for special medical purposes (e.g., lactose-free formula) and the applicable special medical conditions. Formulas for premature/low birth weight infants shall be marked with the osmotic pressure of the product. The formula for special medical purposes, which can be eaten by infants over 6 months of age, shall be marked "When infants with special medical conditions above 6 months of age take this product, supplementary food shall be added".

5.1.3 The label shall clearly identify "Please use under the guidance of a doctor or clinical dietitian".

5.1.4 There must be no image of infants and women on the label. "Humanization", "breast milk-simulated", or similar terminology cannot be used.

5.2 Use instructions

5.2.1 The product use, preparation instructions and illustrations, storage conditions shall be clearly stated on the label. When the maximum surface area of the package is less than 100cm^2 or the product mass is less than 100g, the illustration may not be indicated.

Appendix A

(Normative)

Common infant formula for special medical purposes

Table A.1 -- Common infant formula for special medical purposes

Product category	Applicable special medical conditions	Main technical requirements of the formula
Lactose-free or low-lactose formula	Lactose intolerance infants	1. The lactose is completely or partially replaced by other carbohydrates in the formula; 2. The protein in the formula is provided by milk protein.
Formula of partially hydrolyzed milk protein	Infants with high risk of milk protein allergy	1. The milk protein shall be processed and decomposed into small molecular milk proteins, peptides, and amino acids; 2. The lactose may be completely or partially replaced by other carbohydrates in the formula.
Formula of deeply hydrolyzed milk protein or amino acid formula	Food protein-allergic infants	1. Food protein shall be not included in the formula; 2. The source of the amino acid used shall comply with the provisions of GB 14880 or Appendix B of this Standard; 3. The content of some minerals and vitamins can be adjusted appropriately.
Formula for premature/low birth weight infants	Premature/low birth weight infants	1. The content of energy, protein, and certain minerals and vitamins shall be higher than that specified in 4.4; 2. The formula for premature/low weight infants shall use medium-chain fat which is easily digested and absorbed as a partial source of fat, but medium-chain fat shall not exceed 40% of total fat.
Breast milk nutritional supplement	Premature/low birth weight infants	Essential ingredients and optional ingredients in 4.4 and 4.5 can be optionally added. The content can be adjusted appropriately according to the nutritional needs of premature/low birth weight infants and the recognized breast milk data. Combined with breast milk, the growth and development needs of premature/low birth weight infants can be met.

Appendix B

(Normative)

Monomeric amino acids which can be used in infant formula for special medical purposes

Table B.1 -- Monomeric amino acids which can be used in infant formula for special medical purposes [a]

No.	Amino acids	Compound source	Chemical name	Molecular formula	Molecular weight	Specific rotation [α]D, 20°C	pH	Purity (%) ≥	Moisture (%) ≤	Ash (%) ≤	Lead (mg/kg) ≤	Arsenic (mg/kg) ≤
1	Aspartic acid	L-aspartic acid	L-aminosuccinic acid	$C_4H_7NO_4$	133.1	+24.5 ~ +26.0	2.5 ~ 3.5	98.5	0.2	0.1	0.3	0.2
		L-magnesium aspartate	L-magnesium aminosuccinate	$2(C_4H_5NO_4)\cdot Mg$	288.49	+20.5 ~ +23.0	-	98.5	0.2	0.1	0.3	0.2
2	Threonine	L-threonine	L-2-amino-3-hydroxybutyric acid	$C_4H_9NO_3$	119.12	-26.5 ~ -29.0	5.0 ~ 6.5	98.5	0.2	0.1	0.3	0.2
3	Serine	L-serine	L-2-amino-3-hydroxypropionic acid	$C_3H_7NO_3$	105.09	+13.6 ~ +16.0	5.5 ~ 6.5	98.5	0.2	0.1	0.3	0.2
4	Glutamate	L-glutamate	α-aminoglutaric acid	$C_5H_9NO_4$	147.13	+31.5 ~ +32.5	3.2	98.5	0.2	0.1	0.3	0.2
		L-potassium glutamate	α-potassium aminoglutarate	$C_5H_8KNO_4\cdot H_2O$	203.24	+22.5 ~ +24.0	-	98.5	0.2	0.1	0.3	0.2
5	Glutamine	L-glutamine	2-amino-4-amidobutyric acid	$C_5H_{10}N_2O_3$	146.15	+6.3 ~ +7.3	-	98.5	0.2	0.1	0.3	0.2
6	Proline	L-proline	Pyrrolidine-2-carboxylic acid	$C_5H_9NO_2$	115.13	-84.0 ~ -86.3	5.9 ~ 6.9	98.5	0.2	0.1	0.3	0.2
7	Glycine	Glycine	Amino acetic acid	$C_2H_5NO_2$	75.07	-	5.6 ~ 6.6	98.5	0.2	0.1	0.3	0.2
8	Alanine	L-alanine	L-2-aminopropionic acid	$C_3H_7NO_2$	89.09	+13.5 ~ +15.5	5.5 ~ 7.0	98.5	0.2	0.1	0.3	0.2