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National Food Safety Standard

General Rule on Formulated Foods for Special Medical Purposes

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National Standard for Food Safety

General Rule on Formulated Foods for Special Medical Purposes

1. Scope

This standard is applicable to formulated foods for special medical purposes which are suitable for people above 1 year.

2. Terms and definitions

2.1 Formulated foods for special medical purposes

As especially formulated foods that are produced to meet the special requirements for nutrient or meals of people who suffer from eating limitation, disorder of digestion and absorption, metabolic disorders or special disease state, these products shall be eaten individually or with other foods under the guidance of doctors or clinical dietitians.

2.1.1 Full nutritional formula foods

Formulated foods for special medical purposes that can meet the requirements of target groups for nutrition as a single nutrition source.

2.1.2 Specific full nutritional formula foods

Formulated foods for special medical purposes that can meet the requirements of target groups for nutrition under the condition of specified diseases or medical conditions as a single nutrition source.

2.1.3 None-full-nutritional formula foods

Formulated foods for special medical purposes that can meet the requirements of target groups for nutrition and are not suitable to be used as a single nutrition source.

3 Technical requirements

3.1 Basic requirements

Formulated foods for special medical purposes shall be based on the medical and/or nutritional research results with scientifically verified security and clinical effects. Their production condition shall also be in accordance with relevant national regulations.

3.2 Requirements for materials

Formulated foods for special medical purposes shall be made of raw materials which meet the requirements of relevant standards and/or regulations. Those which jeopardize consumers' health shall be forbidden.

3.3 Sensory requirements

The colors, tastes, smells, textures and dissolving ability of formulated foods for special medical purposes shall be in accordance with their characteristics and include no visible extraneous matters.

3.4 Nutritional ingredients

3.4.1 Full nutritional formula foods suitable for people aged from 1 to 10 years

3.4.1.1 Full nutritional formula foods suitable for people aged from 1 to 10 years shall contain 250 kJ (60 kcal) of energy or more in every 100 mL of their liquid products or reconstituted foods under their immediately-edible condition,or in every 100 g of their immediately edible non-liquid products. To calculate the energy, we can multiply the content of protein, fat and carbohydrate in every 100 mL or 100 g of products by their respective energy coefficients, i.e. 17 kJ/g, 37 kJ/g and 17 kJ/g（energy coefficients of dietary fiber, to be calculated with 50% of carbohydrate energy coefficient). Their sums are the values of kJ/100mL or kJ/100g , which can be divided by 4.184 to be the values of kcal/100mL or kcal/100g.

3.4.1.2 Full nutritional formula foods suitable for people aged from 1 to 10 years shall contain 0.5g/100kJ（2g/100kcal) of protein or more, in which quality protein shall account for 50% or more.Please see GB 5009.5 for the way to test protein.

3.4.1.3 In the full nutritional formula foods suitable for people aged from 1 to 10 years, the energy supply ratio of linoleic acid shall be 2.5% or more and that of -linolenic acid shall be 0.4% or more.Please see GB 5413.27 for the way to test aliphatic acid.

3.4.1.4 In the full nutritional formula foods suitable for people aged from 1 to 10 years, the content of vitamins and mineral substances shall be in accordance with Table 1.

3.4.1.5 Except for the ingredients specified in Table 1, if one or more ingredients in Table 2 are added or shown in the products, their content shall be in accordance with Table 2.

Table 1 Vitamin and mineral substance index (people aged from 1 to 10 years)

Nutrient	Every 100kJ		Every 100kca		Test method
	Minimum	Maximum	Minimum	Maximum	
Vitamin A/(μg RE) [a]	17.9	53.8	75	225	GB 5413.9 or GB/T 5009.82
Vitamin D/(μg)[b]	0.25	0.75	1.05	3.14	GB 5413.9
Vitamin E/(mg α-TE) [c]	0.15	N.S[e]	0.63	N.S.	GB 5413.9 or GB/T 5009.82
Vitamin K1 /(μg)	1	N.S.	4	N.S.	GB 5413.10 or GB/T 5009.158
Vitamin B1/(mg)	0.01	N.S.	0.05	N.S.	GB 5413.11 or GB/T 5009.84
Vitamin B2/(mg)	0.01	N.S.	0.05	N.S.	GB 5413.12
Vitamin B6 /(mg)	0.01	N.S.	0.05	N.S.	GB 5413.13 or GB/T 5009.154

Nutrient	Every 100kJ		Every 100kca		Test method
	Minimum	Maximum	Minimum	Maximum	
Vitamin B12 /(μg)	0.04	N.S.	0.17	N.S.	GB 5413.14
Nicotinic acid （nicotinamide） /(mg) [d]	0.11	N.S.	0.46	N.S.	GB 5413.15 or GB/T 5009.89
Folic acid/(μg)	1.0	N.S.	4	N.S.	GB 5413.16 or GB/T 5009.211
Pantothenic acid/(mg)	0.07	N.S.	0.29	N.S.	GB 5413.17 or GB/T 5009.210
Vitamin C/(mg)	1.8	N.S.	7.5	N.S.	GB 5413.18
Biotin/(μg)	0.4	N.S.	1.7	N.S.	GB 5413.19
Sodium/(mg)	5	20	21	84	GB 5413.21 or GB/T 5009.91
Potassium/(mg)	18	69	75	289	GB 5413.21 or GB/T 5009.91
Copper/(μg)	7	35	29	146	GB 5413.21 or GB/T 5009.13
Magnesium/(mg)	1.4	N.S.	5.9	N.S.	GB 5413.21 or GB/T 5009.90
Iron/(mg)	0.25	0.5	1.05	2.09	GB 5413.21 or GB/T 5009.90
Zinc /(mg)	0.1	0.4	0.4	1.5	GB 5413.21 or GB/T 5009.14
Manganese/(μg)	0.3	24	11	100.4	GB 5413.21 or GB/T 5009.90
Calcium/(mg)	17	N.S.	71	N.S.	GB 5413.21 or GB/T 5009.92
Phosphorus/(mg)	8.3	46.2	34.7	193.5	GB 5413.22 or GB/T 5009.87
Iodine/(μg)	1.4	N.S.	5.9	N.S.	GB 5413.23
Chlorine/(mg)	N.S.	52	N.S.	218	GB 5413.24
Selenium/(μg)	0.5	2.9	2.0	12.0	GB 5009.93

[a] RE is the retinol equivalent. 1μg RE =3.33 IU of Vitamin A=1μg of alltrans retinol (Vitamin A).Vitamin A only includes preformed retinol. No carotenoid ingredients are included when the activity of Vitamin A is calculated and claimed.

[b] Calciferol, 1μg of Vitamin D=40 IU of Vitamin D

[c] 1 mgα-TE (α-tocopherol equivalent)=1 mg of d-α–tocopherol

[d] Nicotinic acid doesn't include the precursor form.

[e] N.S. means no specification.

Table 2 Selectable ingredient index (people aged from 1 to 10 years)

Selectable ingredient [a]	Every 100kJ		Every 100kca		Test method
	Minimum	Maximum	Minimum	Maximum	
Chromium/(μg)	0.4	5.7	1.8	24	GB/T 5009.123
Molybdenum/(μg)	1.2	5.7	5	24	—
Fluorine/(mg)	N.S.[b]	0.05	N.S.	0.2	GB/T 5009.18
Choline/(mg)	1.7	19.1	7.1	80	GB/T5413.20
Inositol/(mg)	1	9.5	4.2	39.7	GB 5413.25
Taurine/(mg)	N.S.	3.1	N.S.	13	GB 5413.26 or GB/T 5009.169
L-carnitine/(mg)	0.3	N.S.	1.3	N.S.	—
Docosahexaenoic Acid(%Total fatty acid c)	N.S.	0.5	N.S.	0.5	GB 5413.267 or GB/T 5009.1698
Eicosatetraenoic Acid(%Total fatty acid c)	N.S.	1	N.S.	1	GB 5413.27
Nucleotide/(mg)	0.5	N.S.	2	N.S.	—
Dietary fiber/(g)	N.S.	0.7	N.S.	2.7	GB 5413.6 or GB/T 5009.88

[a] Compound origins of fluorine are sodium fluoride and potassium fluoride. Please see the allowed origin in C.2 of GB 14880 for nucleotide and dietary fiber. For other compound origins, please see GB 14880.
[b] N.S. means no specification.

3.4.2 Full nutritional formula foods suitable for people aged above 10 years

3.4.2.1 Full nutritional formula foods suitable for people aged above 10 years shall contain 295 kJ (70 kcal) of energy or more in every 100 mL of their liquid products or reconstituted foods under their immediately-edible condition, or in every 100 g of their immediately edible non-liquid products. To calculate the energy, we can multiply the content of protein, fat and carbohydrate in every 100 mL or 100 g of products by their respective energy coefficients, i.e. 17 kJ/g, 37 kJ/g and 17 kJ/g（energy coefficients of dietary fiber, to be calculated with 50% of carbohydrate energy coefficient). Their sums are the values of kJ/100mL or kJ/100g , which can be divided by 4.184 to be the values of kcal/100mL or kcal/100g.

3.4.2.2 Full nutritional formula foods suitable for people aged from 1 to 10 years shall contain 0.7g/100kJ（3g/100kcal) of protein or more, in which quality protein shall account for 50% or more. Please see GB 5009.5 for the way to test protein.

3.4.2.3 In the full nutritional formula foods suitable for people aged above 10 years, the energy supply ratio of linoleic acid shall be 2.0% or more and that of-linolenic acid shall be 0.5% or more. Please see GB 5413.27 for the way to test aliphatic acid.

3.4.2.4 In the full nutritional formula foods suitable for people aged above 10 years, the content of vitamins and mineral substances shall be in accordance with Table 3.

3.4.2.5 Except for the ingredients specified in Table 3, if one or more ingredients in Table 4 are added or shown in the products, their content shall be in accordance with Table 4.

Table 3 Vitamin and mineral substance index （people aged above 10 years）

Nutrient	Every 100kJ		Every 100kca		Test method
	Minimum	Maximum	Minimum	Maximum	
Vitamin A/(μg RE) [a]	9.3	53.8	39.0	225	GB 5413.9 or GB/T 5009.82
Vitamin D/(μg) [b]	0.19	0.75	0.80	3.14	GB 5413.9
Vitamin E/(mg α-TE) [c]	0.15	N.S [e]	0.80	N.S.	GB 5413.9 or GB/T 5009.82
Vitamin K1 /(μg)	1	N.S.	4.40	N.S.	GB 5413.10 or GB/T 5009.158
Vitamin B1/(mg)	0.02	N.S.	0.07	N.S.	GB 5413.11 or GB/T 5009.84
Vitamin B2/(mg)	0.02	N.S.	0.07	N.S.	GB 5413.12
Vitamin B6 /(mg)	0.02	N.S.	0.07	N.S.	GB 5413.13 or GB/T 5009.154
Vitamin B12 /(μg)	0.043	N.S.	0.13	N.S.	GB 5413.14
Nicotinic acid （nicotinamide） /(mg) [d]	0.05	N.S.	0.20	N.S.	GB 5413.15 or GB/T 5009.89
Folic acid/(μg)	5.3	N.S.	22.2	N.S.	GB 5413.16 or GB/T 5009.211
Pantothenic acid/(mg)	0.07	N.S.	0.29	N.S.	GB 5413.17 or GB/T 5009.210
Vitamin C/(mg)	1.3	N.S.	5.6	N.S.	GB 5413.18
Biotin/(μg)	0.5	N.S.	2.2	N.S.	GB 5413.19
Sodium/(mg)	20	N.S	83	N.S.	GB 5413.21 or GB/T 5009.91
Potassium/(mg)	27	N.S	111	N.S.	GB 5413.21 or GB/T 5009.91
Copper/(μg)	11	120	44	500	GB 5413.21 or GB/T 5009.13

Nutrient	Every 100kJ		Every 100kca		Test method
	Minimum	Maximum	Minimum	Maximum	
Magnesium/(mg)	4.4	N.S.	18.3	N.S.	GB 5413.21 or GB/T 5009.90
Iron/(mg)	0.20	0.55	0.83	2.30	GB 5413.21 or GB/T 5009.90
Zinc /(mg)	0.1	0.45	0.4	2.2	GB 5413.21 or GB/T 5009.14
Manganese/(μg)	6.0	2146.0	25.0	611.0	GB 5413.21 or GB/T 5009.90
Calcium/(mg)	13	N.S.	56	N.S.	GB 5413.21 or GB/T 5009.92
Phosphorus/(mg)	9.6	N.S.	40.0	N.S.	GB 5413.22 or GB/T 5009.87
Iodine/(μg)	1.6	N.S.	6.7	N.S.	GB 5413.23
Chlorine/(mg)	N.S.	52	N.S.	218	GB 5413.24
Selenium/(μg)	0.8	5.3	3.3	22.0	GB 5009.93

[a] RE is the retinol equivalent. 1μg RE =3.33 IU of Vitamin A=1μg of alltrans retinol (Vitamin A). Vitamin A only includes preformed retinol. No carotenoid ingredients are included when the activity of Vitamin A is calculated and claimed.

[b] Calciferol, 1μg of Vitamin D=40 IU of Vitamin D

[c] 1 mgα-TE （α-tocopherol equivalent）=1 mg of d-α–tocopherol

[d] Nicotinic acid doesn't include the precursor form.

[e] N.S. means no specification.

Table 4 Selectable ingredient index (people aged above 10 years)

Selectable ingredient [a]	Every 100kJ		Every 100kca		Test method
	Minimum	Maximum	Minimum	Maximum	
Chromium/(μg)	0.4	13.3	1.8	55.6	GB/T 5009.123
Molybdenum/(μg)	1.3	12.0	5.6	2450.0	—
Fluorine/(mg)	N.S.[b]	0.05	N.S.	0.20	GB/T 5009.18
Choline/(mg)	5.3	39.8	22.2	166.7	GB/T5413.20
Inositol/(mg)	1.0	33.5	4.2	140.0	GB 5413.25
Taurine/(mg)	N.S.	4.8	N.S.	20.0	GB 5413.26 or GB/T 5009.169
L-carnitine/(mg)	0.3	N.S.	1.3	N.S.	—
Nucleotide/(mg)	0.5	N.S.	2.0	N.S.	—
Dietary fiber/(g)	N.S.	0.7	N.S.	2.7	GB 5413.6 or GB/T 5009.88
[a] Compound origins of fluorine are sodium fluoride and potassium fluoride. Please see the allowed origin in C.2 of GB 14880 for nucleotide and dietary fiber. For other compound origins, please see GB 14880. [b] N.S. means no specification.					

3.4.3 Specific full nutritional formula foods

The energy and nutrient content of specific full nutritional formula foods shall be based on the full nutritional formula foods in 3.4.1 or 3.4.2, but can be properly adjusted according to the special requirements of diseases or medical condition for nutrients to meet the nutrition requirements of target groups. Please see the common specific full nutritional formula foods in Appendix A.

3.4.4 None-full-nutritional formula foods

The common none-full-nutritional formula foods include nutrient ingredients, electrolyte formula, thickening ingredients，liquid formula and formula of amino acid metabolism disorder. Technical indicators of all products shall be in accordance with the requirements of Table 5. Unable to satisfy the nutrition requirements of target groups as a single nutrition source, such products shall be consumed with other foods. So their nutrient content shall not be required. None-full-nutritional formula foods shall be consumed in accordance with the special condition or requirements of individual patients under the guidance of doctors or clinical dietitians.

Table 5 Key technical requirements for common none-full-nutritional formula foods

Product category		Main technical requirements for formulas
Nutrient ingredients	Protein (amino acid) ingredients	1. It comprises protein and/or amino acid； 2. One or more amino acids, protein hydrolysates, peptides or quality integral protein can be chosen as protein sources.
	Fat (aliphatic acid) ingredients	1.It comprises fat and/or aliphatic acid; 2. LCT, MCT or other fat (aliphatic acid） origins in accordance with laws and regulations can be chosen.
	Carbohydrate ingredients	1. It comprises carbohydrate； 2. Monosaccharide, disaccharide, oligosaccharide or polysaccharide, maltodextrin, glucose polymers or other raw materials in accordance with laws and regulations shall be chosen as the origins of carbohydrate.
Electrolyte formula		1. It shall be based on carbohydrate; 2. An appropriate amount of electrolyte shall be added.
Thickening ingredients		1. It shall be based on carbohydrate; 2. One or more thickeners shall be added; 3. Dietary fibers can be added.
Liquid formula		1. It shall be based on carbohydrate and protein; 2. Various vitamins and mineral substances can be added; 3. Dietary fibers can be added.
Formula of amino acid metabolism disorder		1. It is mainly made of amino acid but contains little amino acid which is related to amino acid. See the amino acid types and content requirements limited in common amino acid metabolism disorder formula foods at Table 6. 2. An appropriate amount of fat, carbohydrate, vitamins, mineral substance and/or other substances； 3. It shall meet patients' requirement for some of the vitamins and mineral substances while meeting their requirement for some of the protein (amino acid).

Table 6 Amino acid types and content limited in common amino acid metabolism disorder formula foods

Common amino acid metabolism disorder	Amino acid types limited in formulated foods	Amino acid types limited in formulated foods mg/g
Phenylketonuria	Phenylalanine	≤1.5
Maple syrup urine disease	Leucine, isoleucine, valine	≤1.5[a]
Propionic acidemia/methylmalonic acidemia	Methionine, threonine, valine	≤1.5[a]
	Isoleucine	≤1.5
Tyrosinemia	Phenylalanine, tyrosine	≤1.5[a]
homocystinuria	Methionine	≤1.5
Glutaric Acidemia Type I	Lysine	≤1.5
	Tryptophan	≤18
Isovaleric acidemia	Leucine	≤1.5
Urea cycle disorders	Non-essential amino acid (alanine, arginine, aspartic acid, asparaginate, glutamic acid, glutamine, glycine, proline, serine)	≤1.5[a]
[a] means content of single amino acids		

3.5 Limited quantity of pollutants

Limited quantity of pollutants shall be in accordance with Table 7.

Table 7 Limited quantity of pollutants (to be calculated with solid products)

Items	Index		Test method
Lead/(mg/kg) ≤	0.15	0.5[a]	GB 5009.12
Nitrate(calculated by NaNO3) /≤ (mg/kg)[b]	100		GB 5009.33
Nitrite(calculated by NaNO2)≤ /(mg/kg)[c]	2		
[a] Products only suitable for people aged above 10 years. [b] Not suitable for products containing vegetables and fruits. [c] Only suitable for dairy-based products (containing no soybean)			

3.6 Limited quantity of mycotoxin

Mycotoxin shall be in accordance with Table 8.

Table 8 Limited quantity of mycotoxin (to be calculated with solid products)

Items	Index	Test method
Aflatoxin M1（μg/kg）a ≤ Aflatoxin B1（μg/kg）b ≤	0.5 0.5	GB 5009..24
a Only suitable for dairy and lactoprotein products b Only suitable for soybean and soybean protein products		

3.7 Limited quantity of microorganism

Limited quantity of microorganism in solid formulated foods for special medical purposes shall be in accordance with Table 9. Microbiological indicators for liquid formulated foods for special medical purposes shall be in accordance with commercial standard of sterility and be tested according to GB/T 4789.26.

Table 9 Limited quantity of microorganism

Items	**Sampling plana quantity limit（demonstrated with CFU/g if not being specified）**				**Test method**
	n	c	m	M	
Aerobic bacterial count [b,c]	5	2	1000	10000	GB 4789.2
Coliform	5	2	10	100	GB4789.3 plate counting method
Salmonella	5	0	0/25g	-	GB 4789.4
Staphylococcus aureus	5	2	10	100	GB 4789.10 plate counting method
[a] Samples shall be analyzed and processed in accordance with GB 4789.1. [b] Products which are not suitable to include active bacteria (aerobiotic and anaerobic probiotics) (viable count of activated probiotics in products shall be 106 CFU/g (mL) or more) [c] Products only suitable for people aged from 1 to 10 years.					

3.8 Food additives and nutrition enhancers

3.8.1 The usage of food additives in products suitable for people aged from 1 to 10 years shall be in accordance with additive types and usage for infant formula foods in GB 2760. The usage of food additives in products suitable for people aged above 10 shall be in accordance with additive types and usage for the same or similar products in GB 2760.

3.8.2 Nutrient supplements shall be applied in accordance with GB 14880.

3.8.3 Specification and quality of food additives and nutrient supplements shall be in accordance with relevant standards and regulations.

3.8.4 One or more amino acids can be added to the formulated foods for special medical purposes according to people's special requirement for nutrition. The origin of amino acids shall be in accordance with Appendix B and/or GB 14880.

3.8.5 Other substances that are added to formulated foods for special medical purposes shall be in accordance with the relevant national regulations.

4 Others

4.1 Labels

4.1.1 Product labels shall be in accordance with GB 13432. The label" every 100 kJ （/100kJ）"shall be added to the label of nutrient and selectable ingredients.

4.1.2 The formula or nutritional features of products shall be described in the label, as well as the product types,target users and the warning" unsuitable for non-target people".

4.1.3 The warning "to be used under the guidance of doctors or clinical dietitians" shall be placed in the striking area of the label.

4.1.4 The warning "this product shall not be used for parenteral nutrition support or intravenous injection"shall be shown in the label.

4.2 Instructions for use

4.2.1 The usage, explanation and diagram of formulation, and the storage condition of relevant products shall be definitely specified on the label. Such a diagram may not be used when the largest superficial area of the package is less than 100 cm2 or the product weight is less than 100 g.

4.2.2 Hazard to health due to improper formulation or misuse shall be demonstrated in the instructions.

4.3 Packages

Food-grade carbon dioxide and/or nitrogen whose purity is 99.9% or more can be used as the packing medium.

Appendix A

Common specific full nutritional formula foods

A.1 Full nutritional formula foods for diabetes

A.2 Full nutritional formula foods for diseases of respiratory system

A.3 Full nutritional formula foods for nephrosis

A.4 Full nutritional formula foods for tumors

A.5 Full nutritional formula foods for liver disease

A.6 Full nutritional formula foods for the muscle attenuation syndrome

A.7 Full nutritional formula foods for trauma, infection, surgery and other stress situations

A.8 Full nutritional formula foods for inflammatory bowel diseases

A.9 Full nutritional formula foods for food protein allergy related

A.10 Full nutritional formula foods for intractable epilepsy

A.11 Full nutritional formula foods for gastrointestinal malabsorption and pancreatitis

A.12 Full nutritional formula foods for fatty acid metabolism disorder

A.13 Full nutritional formula foods for obesity and defatting surgery

Appendix B Amino acids that can be used for formulated foods for special medical purposes

See the amino acids that can be used in formulated foods for special medical purposes at Table B.1.

Table B.1 Amino acids that can be used for formulated foods in special medical purposes

S/R Number	Amino acid[a,b]	Compound source	Chemical name	Molecular formula	Molecular weight	Specific rotation [α]D,20℃	pH	Purity % ≥	Moisture % ≤	Ash % ≤	Lead mg/kg ≤	Arsenic mg/kg ≤
1	Aspartic acid	L-aspartic acid	L-Asparaginic acid	C4H7NO4	133.1	+24.5~+26.0	2.5~3	98.5	0.2	0.1	0.3	0.2
		L-magnesium	L-magnesium aspartic	2(C4H6NO4) Mg	288.49	+20.5~+23.0	—	98.5	0.2	0.1	0.3	0.2
2	Threoni	L-threonine	L-2-amino-3-hydroxyb	C4H9NO3	119.12	-26.5~-29.0	5.0~6	98.5	0.2	0.1	0.3	0.2
3	Serine	L-serine	L-2-amino-3-hydracryli	C3H7NO3	105.09	+13.6~+16.0	5.5~6	98.5	0.2	0.1	0.3	0.2
4	Glutamic acid	L-glutamic acid	α-aminoglutaric acid	C5H9NO4	147.13	+31.5~+32.5	3.2	98.5	0.2	0.1	0.3	0.2
		L-potassium	α-potassium	C5H8KNO4·H2O	203.24	+22.5~+24.0	—	98.5	0.2	0.1	0.3	0.2
		L-calcium	α-calcium	C10H16CaN2O8 ·	404.39	+27.4~+29.2	6.6	98.5	0.2	0.1	0.3	0.2
5	Glutami	L-glutamine	2-amino-4-butanoic	C5H10N2O3	146.15	+6.3~+7.3	—	98.5	0.2	0.1	0.3	0.2
6	Proline	L-proline	Pyrrolidine-2-carboxyli	C5H9NO2	115.13	-84.0~-86.3	5.9~6	98.5	0.2	0.1	0.3	0.2
7	Glycine	Glycine	Amino acetic acid	C2H5NO2	75.07	—	5.6~6	98.5	0.2	0.1	0.3	0.2
8	Alanine	L-alanine	L-2-aminopropionic	C3H7NO2	89.09	+13.5~+15.5	5.5~7	98.5	0.2	0.1	0.3	0.2
9	Cystine	L-cystine	L-3,3'-dithiobis（ 2-aminopropionic	C6H12N2O4S2	240.3	-215~-225	5.0~6.5	98.5	0.2	0.1	0.3	0.2
		L-cysteine	L-α-amino-β-thiohydra	C3H7NO2S	121.16	+8.3~+9.5	4.5~5	98.5	0.2	0.1	0.3	0.2
		L-cysteine	L-cysteinyl	C3H7NO2S·HCl·H	175.63	+5.0~+8.0	—	98.5	0.2 b	0.1	0.3	0.2
		N-acetyl-L-cysteine	N-acetyl-L-α-amino-β-thiohydracrylic acid	C5H9NO3S	163.20	+21~+27	2.0~2.8	98.0	0.2	0.1	—	—
10	Valine	L-valine	L-2-amino-3-isovaline	C5H11NO2	117.15	+26.7~+29.0	5.5~7	98.5	0.2	0.1	0.3	0.2
11	Methionine	L-methionine	2-amino-4-methyl	C5H11NO2S	149.21	+21.0~+25.0	5.6~6	98.5	0.2	0.1	0.3	0.2
		N-acetyl-L-met	N-acetyl-2-amino-4-m	C7H13NO3S	191.25	-18.0~ -22.0	—	98.5	0.2	0.1	0.3	0.2
12	Leucine	L-leucine	L-2-amino-4-methyl	C6H13NO2	131.17	+14.5 ~+16.5	5.5~6	98.5	0.2	0.1	0.3	0.2

Table B.1 （to be continued）

S/R Number	Amino acid a,b	Compound source	Chemical name	Molecular formula	Molecular weight	Specific rotation [α]D,20℃	pH	Purity % ≥	Moisture % ≤	Ash % ≤	Lead mg/kg ≤	Arsenic mg/kg ≤
13	Isoleucine	L-isoleucine	L-2-amino-3-methyl pentanoic acid	C6H13NO2	131.17	+38.6~+41.5	5.5~7.0	98.5	0.2	0.1	0.3	0.2
14	Tyrosine	L-tyrosine	S-amino-3（4-hydroxycyclohexyl phenyl ketone）-propionic acid	C9H11NO3	181.19	-11.0~-12.3	—	98.5	0.2	0.1	0.3	0.2
15	Phenylalanine	L-phenylalanine	L-2-amino-3-phenylpropionic acid	C9H11NO2	165.19	-33.2~-35.2	5.4~6.0	98.5	0.2	0.1	0.3	0.2
16	Lysine	L-lysine hydrochloride	L-lysine monohydrochloride	C6H14N2O2·HCl	182.65	+20.3~+21.5	5.0~6.0	98.5	0.2	0.1	0.3	0.2
		L-lysine acetate	L-Lysine monoacetate	C6H14N2O2·C2H4O2	206.24	+8.5~+10.0	6.5~7.5	98.5	0.2	0.1	0.3	0.2
		L-lysine	L-2,6-diamino caproic acid	C6H14N2O2·H2O	164.2	+25.5 ~+27.0	9.0 ~10.5	98.5	0.2	0.1	0.3	0.2
		L-lysine-L-glutamic acid	L-2,6-diamino caproic acid α-amino glutarate	C11H23N3O6·2H2O	329.35	+27.5~+29.5	6.0~7.5	98.0	0.2	0.1	0.3	0.2
		L-lysine-aspartic acid	L-2,6-diamino caproic acid L- amino succinate	C10H21N3O6	279.30	+24.0 ~+26.5	5.0~7.0	98.0	0.2	0.1	0.3	0.2
17	Arginine	L-arginine	L-2-amino-5-guanidyl valeric acid	C6H14N4O2	174.2	+26.0~+27.9	10.5~12.0	98.5	0.2	0.1	0.3	0.2
		L-arginine hydrochloride	L-2-amino-5-guanidyl valeric acid hydrochloride	C6H14N4O2·HCl	210.66	+21.3~+23.5	—	98.5	0.2	0.1	0.3	0.2
		L -arginine-aspartic acid	L-2-amino-5-guanidyl valeric acid- L-aspartic acid	C10H21N5O6	307.31	+25.0 ~+27.0	6.0~7.0	98.5	0.2	0.1	0.3	0.2