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Report Name: Formulas for Special Medical Purposes Intended for Infants Draft Standard Notified

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Report Highlights:

On March 6, 2023, China notified the National Food Safety Standard: Formulas for Special Medical Purposes Intended for Infants (GB25596-xxxx) to the WTO SPS as G/SPS/N/CHN/1268. This Draft Standard will replace the existing National Food Safety Standard: Formulas for Special Medical Purposes Intended for Infants (GB25596-2010). Comments on the measure may be submitted to China's SPS Enquiry Point (sps@customs.gov.cn) by May 5, 2023. There is currently no published date for implementation of the final standard. This report contains an unofficial English translation of the draft standard.

Summary: The National Food Safety Standard: Formulas for Special Medical Purposes Intended for Infants (GB25596-2010) was published on December 21, 2010 and implemented on January 1, 2012. It is a national, mandatory food safety standard that applies to both domestic and imported products. On March 6, 2023, China notified the National Food Safety Standard: Formulas for Special Medical Purposes Intended for Infants (GB25596-xxxx) to the WTO SPS as G/SPS/N/CHN/1268. This Draft Standard will replace the existing National Food Safety Standard: Formulas for Special Medical Purposes Intended for Infants (GB25596-2010). Comments on the measure may be submitted to China's SPS Enquiry Point (sps@customs.gov.cn) by May 5, 2023. There is currently no published date for implementation of the final standard. This report contains an unofficial English translation of the draft standard.

The Forward of the draft standard lists a number of changes in the draft revision from the current standard. Exporters should work with their Chinese importers and partners to closely monitor the standard revision process, provide their comments on issues of interest, and ensure compliance with the final standard.

(Begin Unofficial Translation)

National Standard of the People's Republic of China

GB 25596-XXXX

National Food Safety Standard

Formulas for Special Medical Purposes Intended for Infants

(Draft for comments)

Issued on XX-XX-XXXX **Implemented on XX-XX-XXXX**

Issued by the National Health Commission of the People's Republic of China and State Administration for Market Regulation

Foreword

The Standard replaces GB 25596-2010 (the National Food Safety Standard - Formulas for Special Medical Purposes Intended for Infants).

When compared with GB 25596-2010, the Standard mainly has following changes:

- Terms and definitions are modified.

- The necessary components are modified, and the minimum or maximum values for some nutrients are adjusted or added.

-The choline is changed into necessary ingredients from optional ingredients.

-The limit indicators of pollutant are modified;

-The limit indicators of mycotoxin are modified;

- The microbial limit indicators are modified;

-Appendix A is modified, six categories are added on the basis of the original product categories, and the technical indicators are clarified;

- Appendix B is modified.

National Food Safety Standard

Formulas for Special Medical Purposes Intended for Infants

1 Scope

The Standard applies to infant formula for special medical purposes for infants aged 0 ~ 12 months.

2 Terms and definitions

2.1 Infant Formula for Special Medical Purposes

Refers to the formula designed and produced to meet the dietary nutritional requirements of infants with special medical conditions such as special disorders, diseases or medical conditions. This kind of food shall be eaten alone or in combination with other foods under the guidance of doctors or clinical nutritionists.

3 Technical requirements

3.1 General requirements

3.1.1 Formulations for infant formula for special medical purposes shall be based on research results of medical and nutritional studies, and their safety, nutritional adequacy, and clinical effects need to be scientifically proven.

3.1.2 The category and primary technical requirements of common infant formula for special medical purposes shall conform to Appendix A of the Standard.

3.1.3 The processing technology of infant formula for special medical purposes shall comply with all applicable national standards.

3.2 Requirements on Materials

3.2.1 Materials used in products shall comply with corresponding safety standards and or relevant provisions, and materials which will cause harm to nutrition and health of infants shall not be used.

3.2.2 Materials and food additives shall not contain glutelin.

3.2.3 Hydrogenated oil and fat shall not be used.

3.2.4 Materials treated with radiation shall not be used.

3.3 Sensory Requirements

The color, luster, taste, smell, texture and soakage of infant formula for special medical purposes shall be consistent with characteristics of corresponding products, and there shall be no visible foreign matters in the case of normal vision.

3.4 Essential Ingredients

3.4.1 The energy, nutritional components, and content of infant formula for special medical purposes shall be based on the necessary components specified in the Standard, but can be appropriately adjusted in light of the special nutritional needs of infants with such conditions as special disorders, diseases or medical conditions and in accordance with product categories and main technical requirements listed in Appendix A in order to meet the nutritional needs of infants with special medical conditions.

3.4.2 In a ready-to-eat state, the product should include 250 kJ (60 kcal) - 314 kJ (75 kcal) of energy in every 100 mL. The energy is calculated by multiplying the content of protein, fat and carbohydrate in each 100 mL of product by the energy coefficients of 17 kJ/g, 37 kJ/g and 17 kJ/g (the energy coefficient of dietary fiber is 8 kJ/g), and then dividing the sum (a value in kilojoule /100 milliliter (kJ /100 mL)) by 4.184 to obtain a value in kilocalorie /100 milliliter(kcal/100 mL).

3.4.3 The protein content, fat content and carbohydrate content per 100kJ (100 kcal) in products shall be consistent with provisions of Table 1.

3.4.4 For infant formula for special medical purposes, except for special needs (such as lactose intolerance), the preferred carbohydrate shall be lactose. Glucose polymer can be added as appropriate (among which starch may be added only after being pre-gelatinized), and no levulose or saccharose shall be used as a source of carbohydrates.

Table 1 Indexes for protein, fat, and carbohydrate

Nutrients	Index				Inspection method
	Per 100 kJ		Per 100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Protein [a]/(g)	0.43	0.84	1.8	3.5	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 toα-linolenic acid	5:1	15:1	5:1	15:1	-
Carbohydrate [d]/(g)	2.2	3.3	9.0	14.0	-

[a] The protein content shall be calculated by multiplying nitrogen (N) x6.25; L mono-amino acids and their salts can be selectively added according to the special nutritional needs of infants with special disorders, diseases or medical conditions, whose source shall be consistent with provisions of Appendix B.

[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] NS 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;

A_5-Ash content, g/100g;

A_6-Dietary fiber content (Based on the addition amount of oligosaccharide and/or polysaccharide), g/100g.

3.4.5 Vitamins: shall be consistent with provisions of Table 2.

Table 2 Vitamin Indexes

Nutrients	Index				Inspection method
	Per 100 kJ		Per 100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Vitamin A/ (μg RE) [a]	14	43	60	180	GB 5009.82
Vitamin D (μg) [b]	0.48	1.20	2.0	5.0	
Vitamin E / (mg a-TE) [c]	0.12	1.20	0.5	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)	8.4	41.8	35	175	GB 5009.154
Vitamin B_{12}/ (μg)	0.024	0.359	0.10	1.50	GB 5413.14
Nicotinic acid (nicotinamide)/(μg)[d]	96	359	400	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)	0.36	2.39	1.5	10.0	GB 5009.259
Choline /(mg)	4.8	23.9	20	100	GB 5413.20

a RE is retinol equivalent. 1μg RE=1μg alltrans retinol (vitamin A) =3.33 IU vitamin A. Vitamin A only includes preformed retinol, and doesn't include any carotene components when Vitamin A activity is calculated and claimed.

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

c 1 mg d-α- tocopherol=1 mg α-TE (α- tocopherol equivalent);1 mg dl-α- tocopherol=0.74 mg a-TE (α-tocopherol equivalent)

3.4.6 Mineral substances: shall be consistent with provisions of Table 3.

Table 3 Indexes for Mineral Substances

Nutrients	Index				Inspection method
	Per 100 kJ		Per 100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Na/(mg)	N.S.[a]	20	N.S.[a]	84	GB 5009.91
K/(mg)	17	54	70	225	
Cu/(μg)	8.4	28.7	35	120	GB5009.13
Mg/(mg)	1.2	3.6	5.0	15.0	GB5009.241
Fe/(mg)	0.10	0.48	0.42	2.00	GB5009.90
Zn/(mg)	0.12	0.36	0.50	1.50	GB5009.14
Mn/(μg)	0.24	23.90	1.0	100.0	GB5009.242
Ca/(mg)	12	43	50	180	GB5009.92
P/(mg)	6	26	25	110	GB5009.87
Ratio of calcium to phosphorus	1:1	2:1	1:1	2:1	-
Iodine /(μg)	3.6	14.1	15	59	GB5009.267
Cl/(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. means no special instructions.					

3.5 Optional Ingredients

3.5.1 In addition to essential ingredients in 3.4, when one or multiple ingredients in Table 4 are selected to be added in products or to be indicated on labels, their content shall be consistent with provisions of Table 4.

3.5.2 When other substances except those in Table 4 and Appendix B are added to products, relevant provisions in China shall be met.

Table 4 Indexes for Optional Ingredients

Optional ingredients	Index				Inspection method
	Per 100 kJ		Per 100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Chromium / (μg)	0.4	2.4	1.5	10.0	GB 5009.123
Molybdenum / (μg)	0.4	2.4	1.5	10.0	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	N.S	1.3	N.S.	GB 29989
Docosahexaenoic acid (DHA)[a]/(mg)	3.6	9.6	15	40	GB5009.168
Eicosatetraenoic acid (AA/ARA) /(mg)	N.S.[b]	19.1	N.S. [b]	80	GB5009.168
[a.] If docosahexaenoic add (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) shall not exceed that of docosahexaenoic acid. [b.] N.S. means no special instructions.					

3.6 Other indexes: It shall meet the requirements of Table 5.

Table 5 Other indexes

Items		Index	Inspection method
Moisture /(%) [a]	≤	5.0	GB 5009.3
Ash Solid product/(%) Liquid product (based on total dry matter)/(%)	≤ ≤	5.0 5.3	GB 5009.4
Impurity degree Solid product/ (mg/kg) Liquid product / (mg/8L)	≤ ≤	12 2	GB 5413.30
[a.] It is limited to powdered solid product.			

3.7 Contaminant limit: It shall meet the requirements of GB2762.

3.8 Mycotoxin Limit: It shall meet the requirements of GB 2761.

3.9 Microbial Limit

3.9.1 Pathogen limit in solid products shall be consistent with provisions of GB 29921, and other microbial limit shall be consistent with provisions of Table 6.

3.9.2 Liquid products shall meet commercial sterility requirements and be tested with the methods specified in GB 4789.26.

Table 6 Indexes of Microbial Limit

Items	Sampling plan [a] and limit (it is expressed as CFU/g or CFU/mL except that it is specified otherwise.)				Inspection method
	n	c	m	M	
Total bacterial count [b]	5	2	1000	10000	GB 4789.2
Coli group	5	2	10	100	GB 4789.3plate counting method

[a.] Analysis and treatment for samples are conducted according to GB 4789.1 and GB 4789.18.

[b.] It is not applicable to products to which active probiotics (aerobic bacteria and anaerobic bacteria) are added [viable count of each kind of active probiotics shall be $\geq 10^6$ CFU/g (mL)].

3. 10 Food additives and nutrient supplements

3. 10.1 The use of food additives and nutrient supplements shall comply with the provisions of GB 2760 and GB 14880.

3. 10.2 The quality of food additives and nutrient supplements shall comply with the relevant safety standards and relevant regulations.

3.11 Urease activity: Urease activity in products with soybean and soybean protein products as the main source of protein shall be consistent with provisions of Table 7.

Table 7 Urease activity index

Items	Index	Inspection method
Qualitative determination of urease activity	Negative	GB 5413.31[a]

[a.] The sampling quantity of liquid products shall be converted according to dry matter content.

4 Others

4.1 Label

4.1.1 Content indicated on the label shall be consistent with GB 13432 and/or relevant provisions. Content “per 100 kJ (100 kcal)” for essential ingredients and optional ingredients shall be indicated.

4.1.2 The label shall clearly indicate the product category (such as lactose-free formula), applicable people with special medical conditions and osmotic pressure.

4.1.3 The label of anti-reflux formula shall indicate the viscosity of the product.

4.1.4 The formula for special medical purposes, which can be consumed 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."

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

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

4.2 Use instructions

4.2.1 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.

4.2.2 It shall give warnings on the hazard to health resulting from improper preparation or use.

4.3 Packaging

Carbon dioxide and/or nitrogen conforming to national food safety standard may serve as packaging medium.

Appendix A

Common infant formula for special medical purposes

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

Product category	Applicable people with special medical conditions	Main technical requirements of the formula
Lactose-free or low-lactose formula	Lactose intolerance infants	1. The lactose shall be completely or partially replaced by other available carbohydrates in the formula; 2. The lactose content in the solid lactose-free formula food shall be lower than 0.5g/100g; The lactose content in solid low-lactose formula food should be less than 2g/100g. Liquid products can be converted according to dilution multiple; 3. The protein in the formula is provided by milk protein.
Formula of partially hydrolyzed milk protein	Infants with functional gastrointestinal discomfort, and can be selectively used for infants with high risk of milk protein allergy.	1. Protein in the formula is provided by milk protein; 2. All milk proteins in the product are processed and decomposed into small molecular milk proteins, peptide segments and amino acids; 3. Lactose can be completely or partially replaced by other available carbohydrates in the formula.
Formula of deeply hydrolyzed milk protein	Infants with food protein allergy or gastrointestinal dysfunction.	1. The product shall contain 250 kJ (60 kcal)~418 kJ (100 kcal) of energy per 100mL in the ready-to-eat state; 2. The protein in the formula is provided by deeply hydrolyzed milk protein; 3. All milk proteins in the product are decomposed into short peptides and amino acids through processing; 4. Lactose can be completely or partially replaced by other available carbohydrates in the formula; 5. The content of some nutrients can be adjusted appropriately, and the adjusted range of nutrient content shall conform to the provisions in Table A.1.1.
Amino acid formula	Infants with food protein allergy or gastrointestinal dysfunction.	1. The energy per 100mL of the product shall be 250 kJ (60 kcal)~418 kJ (100 kcal) in the ready-to-eat state; 2. The protein in the formula is provided by amino acids; 3. The sources of amino acids used shall conform to the provisions in Appendix B of this standard; 4. Lactose can be completely or partially replaced by other

		available carbohydrates in the formula; 5. The content of some nutrients can be adjusted appropriately, and the adjusted range of nutrient content shall conform to the provisions in Table A.1.1.
Amino acid metabolism disorder formula	Infants with amino acid metabolism disorder	1. The energy per 100mL of the product in the ready-to-eat state shall be 250 kJ (60 kcal)~418 kJ (100kcal); 2. The protein in the formula is provided by amino acids, and its source shall comply with the provisions of Appendix B of this standard; 3. The types and contents of amino acids that shall be restricted in formula foods with common amino acid metabolic disorders are shown in Table A.1.2; 4. Lactose can be completely or partially replaced by other available carbohydrates in the formula; 5. The content of some nutrients can be adjusted appropriately, and the adjusted range of nutrient content shall comply with the provisions in Table A.1.1.
Premature/low birth weight infant formula	Premature/low birth weight infants	1. The energy per 100mL of the product in the ready-to-eat state shall be 250 kJ (60 kcal)~465 kJ (111 kcal); 2. Medium-chain fat shall be used as part of the source of fat, and the medium-chain fat shall not exceed 40% of the total fat; 3. The content of some nutrients can be adjusted appropriately, and the adjusted range of nutrient content shall comply with the provisions in Table A.1.3.
Breast milk nutritional supplement	Premature/low birth weight infants	1. The essential components and optional components in 3.4 and 3.5 can be selectively added, and their contents can be appropriately adjusted according to the nutritional needs of premature/low birth weight infants and the recognized breast milk data. The combination with breast milk can meet the requirements of the maximum and minimum values of energy and nutrients in the formula of premature/low birth weight infants. 2. The protein can be hydrolyzed.
Ketogenic formula	Infants with refractory epilepsy, other suitable medical conditions	1. The mass ratio of fat to (protein + carbohydrate) ranges from 1:1 to 4:1; 2. The maximum fat and the minimum carbohydrate are not limited.

Anti-reflux formula	Infants with frequent gastroesophageal reflux	1. The pregelatinized high amylopect in such as potato starch and rice starch or a thickener special for this formula are added; 2. When adding high amylopectin, the addition amount of starch is 9-25g/100g, and it can be added separately or mixed.
Abnormal fat metabolism formula	Infants with fatty acid transport, metabolism and absorption disorders	1. Medium-chain fat shall be used as part of the source of fat; 2. The content of medium-chain fat shall not be less than 50% of total fat.
High-energy formula	Infants with high consumption, growth retardation and limited liquid intake caused by diseases.	1. The energy content of the product per 100mL in the ready-to-eat state shall be 314kJ(75kcal) -565kJ (135kcal); 2. The content of protein shall be not less than 0.53g/100kJ(2.2g/100kcal); 3. The protein in the formula is provided by milk protein or amino acid. Milk protein can be whole protein or hydrolyzed protein.
Protein components	Infants needing to be supplemented with protein	1. The protein in the product is provided by milk protein, which can be whole protein or hydrolyzed protein; 2. The content of protein in whole protein products shall not be less than 90g/100g; The content of protein in partially hydrolyzed products shall be greater than 80 g/100g (based on dry matter); The content of protein in the deep hydrolysis product shall be greater than 65 g/100 g (based on dry matter). 3. No additional ingredients shall be added (except those necessary for the process); 4. It shall be used in conjunction with other foods.
Medium-chain fat components	Infants needing additional medium-chain fatty acids	1. Vegetable oil with high medium-chain fat content; 2. The content of medium-chain fat shall not be less than 95% of total fat; 3. No additional ingredients shall be added (except those necessary for the process); 4. It shall be used in conjunction with other foods.

Table A.1.1 Adjustable nutritional indicators of milk protein deep hydrolysis formula, amino acid formula or amino acid metabolism disorder formula.

Nutrients to be adjusted	Index			
	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Protein/ (g) [a]	0.45	1.41	1.8	5.9
Carbohydrate/ (g)	2.2	3.66	9.0	15.3
Vitamin B_1/ (μg)	9.8	71.7	41	300
Vitamin B_2/ (μg)	14	119	58	500
Vitamin B_6/ (μg)	8.5	75	35	314
Nicotinic acid (nicotinamide)/ (μg)[b]	96	750	400	3138
Folic acid/ (μg)	1.0	12	4.2	50
Pantothenic acid / (μg)	70	478	293	2000
Vitamin C/ (mg)	1.9	16.7	8	70
Biotin / (μg)	0.4	5	1.7	20.90
Zinc / (mg)	0.12	0.6	0.5	2.50
Calcium/ (mg)	12	60	50	251
Manganese / (μg)	0.24	50	1.0	209
Copper / (μg)	4.8	28.7	20	120
Iodine / (μg)	1.2	14	5	59
Selenium / (μg)	0.25	2.00	1.0	8.6

Table A.1.2 Common amino acid metabolic disorders and the types and content requirements of amino acids that shall be restricted

Common amino acid metabolic disorders	Types of amino acids that shall be restricted	Amino acid content that shall be restricted in formula food mg/g protein equivalent
Phenylketonuria	Phenylalanine	≤ 1.5
MSUD	Leucine, isoleucine, valine	≤ 1.5[a]
Propionaemia/methylmalonacidemia	Methionine, Threonine and Valine	≤ 1.5[a]
	Isoleucine	≤ 5
Tyrosinemia	Phenylalanine and tyrosine	≤1.5[a]
Hypercystinuria	Methionine	≤1.5
Glutaralemia type I	lysine	≤1.5
	Tryptophan	≤8
Isovalerate	Ieucine	≤1.5

Urea circulation disorder	Non-essential amino acids (alanine, arginine, aspartic acid, asparagine, glutamic acid,	≤1.5[a]
[a] refers to the content of single amino acid.		

Table A.1.3 Nutritional indicators adjusted for premature/low birth weight infants formula

Nutrients to be adjusted	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Protein/ (g)	0.48	0.98	2.0	4.1
Fat/ (g)	0.84	1.90	3.5	8.0
Carbohydrate (g)	0.69	3.3	2.9	14.0
Vitamin A/ (μg RE)	14	177	60	741
Vitamin D/(μg)	0.48	2.18	2.0	9.1
Vitamin E /(mg α-TE)	0.12	2.39	0.5	10.0
Vitamin B2/(μg)	19	148	80	619
Vitamin B6/(μg)	8.4	75.0	35	314
Nicotinic acid (nicotinamide)/(μg)	96	1195	400	5000
Folic acid /(μg)	2.4	21.5	10	90
Biotin /(μg)	0.36	8.8	1.5	36.8
Sodium /(mg)	N.S.[b]	25	N.S.[b]	105
Copper /(μg)	8.4	59.8	35	250
Magnesium /(mg)	1.2	4.1	5.0	17.2
Iron /(mg)	0.10	0.87	0.42	3.64
Zinc /(mg)	0.12	0.65	0.50	2.72
Calcium /(mg)	12	60	50	251
Phosphorus /(mg)	6	30	25	126
Selenium/ (μg)	0.48	2.15	2.0	9.0
Inositol /(mg)	1.0	17.7	4	74

Appendix B

(Normative)

Monomeric amino acids and their salts 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 and their salts [a]

No.	Amino Acid	Source of Chemical Compound	Chemical Name	Molecular Formula	Relative molecular mass	Specific rotation [α]D,20℃	pH	Purity % ≥	Water content (%)	Ash content (%) ≤	Lead (mg/kg) ≤	Arsenic (mg/kg) ≤
1	Aspartic acid	L-aspartic acid	L-aminosuccinic acid	$C_4H_7NO_4$	133.1	+24.0~+26.0	2.5~3.5	98.5	0.2	0.1	0.3	0.2
		L-magnesium aspartate	L-aspartic acid magnesium	$2(C_4H_6NO_4)$-Mg-$2H_2O$	324.5	+22.0~+23.0	6.0-8.0	98.5	10-14	-	0.3	0.2
2	Threonine	L-threonine	L-2-amino-3-hydroxybutyric	$C_4H_9NO_3$	119.12	-26.0~29.0	5.0~6.5	98.5	0.2	0.2	0.3	0.2
3	Serine	L-serine	L-2-amino-3-	$C_3H_7NO_3$	105.09	+14.0~+15.6	5.5~6.5	98.5	0.2	0.1	0.3	0.2
4	Glutamic acid	L-glutamic acid	a-aminoglutaric acid	$C_5H_9NO_4$	147.13	+31.5~+32.5	3.0-3.5	98.5	0.3	0.1	0.3	0.2
		L-potassium glutamate	a-potassium aminoglutaric acid	$C_5H_8KNO_4$-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	4.8-5.8	98.5	0.3	0.2	0.3	0.2
6	Proline	L-proline	Pyrrolidine-2-carboxylic acid	$C_5H_9NO_2$	115.13	-84.5~86.0	5.9~6.9	98.5	0.3	0.2	0.3	0.2
7	Glycine	Glycine	Aminoacetic 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	+14.0~+15.0	5.5~7.0	98.5	0.2	0.1	0.3	0.2
9	Cystine	L-cystine	L-3,3'- disulfide bis (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
10	Valine	L-valine	L-2-amino-3-methylbutyric	$C_5H_{11}NO_2$	117.15	+26.6~+28.8	5.5~6.5	98.5	0.2	0.1	0.3	0.2
11	Methionine	L-methionine	2-amino-4-methylthio butanoic	$C_5H_{11}NO_2S$	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-methylthio butanoic acid	$C_7H_{13}NO_3S$	191.25	-18.0- -22.0	-	98.5	0.5	0.1	0.3	0.2
12	Leucine	L-leucine	L-2-amino-4-methylvaleric	$C_6H_{13}NO_2$	131.17	+14.9 ~+16.0	5.5~6.5	98.5	0.2	0.2	0.3	0.2
13	Isoleucine	L-isoleucine	L-2-amino-3-methylvaleric	$C_6H_{13}NO_2$	131.17	+38.9~+41.8	5.5~6.5	98.5	0.2	0.2	0.3	0.2

No.	Amino Acid	Source of Chemical Compound	Chemical Name	Molecular Formula	Relative molecular mass	Specific rotation [α]D,20℃	pH	Purity % ≥	Water content (%)	Ash content (%) ≤	Lead mg/kg ≤	Arsenic mg/kg ≤
14	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
15	Phenylalanin	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
16	Lysine hydrochloride	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	$C_6H_{14}N_2O_2C_2H_4O_2$	206.24	+8.5~+10.0	6.5~7.5	98.5	0.3	0.2	0.3	0.2
17	Arginine	L-arginine	L-2-amino-5-guanidine valeric	$C_6H_{14}N_4O_2$	174.2	+26.9~+27.9	10.5~12.0	98.5	0.5	0.2	0.3	0.2
		L-arginine hydrochloride	L-2-amino-5-guanidine valerate hydrochloride	$C_6H_{14}N_4O_2$-HCl	210.66	+21.5~+23.5	4.7-6.2	98.5	0.2	0.1	0.3	0.2
18	Histidine	L-histidine	a-amino β-imidazolyl propionic	$C_6H_9N_3O_2$	155.15	+12.0~+12.8	7.0~8.5	98.5	0.2	0.2	0.3	0.2
		L-histidine hydrochloride	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
19	Tryptophan	L-tryptophan	L-2-amino-3-indolyl-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
20	Cysteine	L-Cysteine	L-α-amino-β-hydrophobic	$C_3H_7NO_2S$	121.16	+8.3~+9.5	4.5~5.5	98.5	0.5	0.1	0.3	0.2
		L- cysteine hydrochloride	L-2-amino -3- hydrophobic propionic acid hydrochloride	$C_3H_7NO_2S$-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- hydrophobicpropionic acid	$C_3H_7NO_2SECI$	157.62	+5.6~+8.9	1.5-2.0	98.5	2.0	0.1	0.3	0.2

[a] It is forbidden to use non-edible animal and plant raw materials as a source of monomer amino acids.

(End Unofficial Translation)

Attachments:

No Attachments.