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Report Highlights:

On March 27, 2025, the People’s Republic of China's (China's) National Health Commission (NHC) and the State Administration for Market Regulation (SAMR) jointly released the final National Food Safety Standard Formulas for Special Medical Purposes Intended for Infants (GB 25596-2025) applicable for infants aged 0 to 12 months, and it will enter into force on March 16, 2027. China notified the draft standard to the WTO on March 6, 2023. This report provides unofficial translation of the final standard. Stakeholders should conduct their own review of the regulation.

FAS China provides this analysis and reporting as a service to the United States agricultural community, and to our farmers, ranchers, rural communities, and agribusiness operations in support of a worldwide agricultural information system and a level playing field for U.S. agriculture.

Summary:

On March 27, 2025, the People's Republic of China's (China's) National Health Commission (NHC) and the State Administration for Market Regulation (SAMR) jointly released the National Food Safety Standard Formulas for Special Medical Purposes Intended for Infants (GB 25596-2025).

On March 6, 2023, China notified the draft National Food Safety Standard of Formulas for Special Medical Purposes Intended for Infants to the WTO under G/SPS/N/CHN/1268. This standard applies to formula foods for special medical purposes intended for infants aged 0 to 12 months old and regulates the requirements of ingredients, nutritional components, contaminants, labeling, and packaging for the products produced and sold in China.

The final standard will enter into force on March 16, 2027, and will replace the current implementing standard of GB 25596-2010 which entered into force since January 2012. This report provides an unofficial translation of the final standard. Stakeholders should conduct their own review of the regulation.

BEGIN TRANSLATION

National Food Safety Standard
Formulas for Special Medical Purposes Intended for Infants
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 indicators of contaminants limits are modified,
- The indicators of mycotoxin limits are modified,
- The microbial limits 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 formula foods for special medical purposes for infants aged 0 ~ 12 months.

2 Terms and Definitions

2.1 Formula foods for special medical purposes intended for infants

Refers to the formula foods specially prepared and produced to meet the dietary nutritional needs of infants with special medical conditions such as restricted feeding, digestive and absorption issues, and metabolic disorders. This kind of food shall be eaten alone or in combination with other foods under the guidance of physicians or clinical nutritionists.

3 Technical Requirements

3.1 General requirements

3.1.1 The formulas for infant formulas 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.

3.1.1.1 The categories, applicable population of special medical conditions, primary technical requirements of common infant formulas for special medical purposes shall conform to Appendix A of the Standard.

3.1.1.2 Other special infant formulas for special medical purposes that are clinically needed should comply with the requirements of 3.1.1.

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

3.2 Requirements of ingredients

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 Ingredients and food additives shall not contain gluten.

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, taste, smell, texture, and reconstitution properties of infant formulas for special medical purposes shall be consistent with characteristics of corresponding products, and there shall be no visible foreign matters.

3.4 Essential ingredients

3.4.1 The energy, nutritional components, and content of infant formulas for special medical purposes shall be based on the necessary components specified in this 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) to 314 kJ (75 kcal) of energy in every 100 mL of product. The energy is calculated by multiplying the content of protein, fat, and carbohydrate in every 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 content of protein, fat, and carbohydrate per 100 kJ (100 kcal) in products shall follow the provisions in Table 1.

Table 1: Indicators for protein, fat, and carbohydrate

Nutrients	Indicator				Testing 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 to α-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 as nitrogen (N) x 6.25; L mono-amino acids can be selectively added according to the special nutritional needs of infants with special disorders, diseases, or medical conditions, shall be consistent with provisions of Appendix B.

[b] The total amount of lauric acid and myristic acid (myristanoic acid) in fat of the final product ≤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 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 - Water 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.

3.4.4 For infant formulas for special medical purposes, except for special needs (such as lactose intolerance), the preferred carbohydrate source shall be lactose. Glucose polymer may be added as appropriate (among which starch may be added only after being pre-gelatinized), and fructose or saccharose shall not be used as sources of carbohydrates.

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

Table 2 Vitamin Indicators

Nutrients	Indicator				Testing 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	GB 5009.296
Vitamin E / (mg a-TE) [c]	0.12	1.20	0.5	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	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 5009.285
Nicotinic acid (nicotinamide) [d]/ μg	96	359	400	1 500	GB 5009.89
Folic acid /μg	2.4	12.0	10	50	GB 5009.211
Pantothenic acid /μg	96	478	400	2 000	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 all trans 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).

[d] Niacin does not include precursor forms.

3.4.6 Minerals: shall comply with provisions in Table 3.

Table 3: Minerals Indicators

Nutrients	Indicators				Testing method
	Per 100 kJ		Per 100 kcal		
	Minimum	Maximum	Minimum	Maximum	
Sodium/ mg	N.S.[a]	20	N.S.[a]	84	GB 5009.91
Potassium/ mg	17	54	70	225	
Copper / μg	8.4	28.7	35	120	GB5009.13
Magnesium / mg	1.2	3.6	5.0	15.0	GB5009.241
Iron / mg	0.10	0.48	0.42	2.00	GB5009.90
Zinc/ mg	0.12	0.36	0.50	1.50	GB5009.14
Manganese / μg	0.24	23.90	1.0	100.0	GB5009.242
Calcium / mg	12	43	50	180	GB5009.92
Phosphorus / 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
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. 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 comply with provisions in Table 4.

3.5.2 When other substances are added to products in addition to Table 4 and Appendix B, relevant national regulations shall be met.

Table 4: Indicators for Optional Ingredients

Optional ingredients	Indicators				Testing 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 5009.297
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 5009.300
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 formulas 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 indicators

It shall meet the requirements of Table 5.

Table 5: Other Indicators

Items		Indicator	Testing method
Water content [a] / %	≤	5.0	GB 5009.3
Ash			GB 5009.4
Solid product/ %	≤	5.0	
Liquid product (based on total dry matter) [b]/ %	≤	5.3	
Impurity degree			GB 5413.30
Solid product/ (mg/kg)	≤	12	
Liquid product / (mg/8L)	≤	2	

[a] limited to solid products.
[b] liquid products after mixing breast milk nutritional supplements with breast milk should meet the ash content requirements.

3.7 Contaminant limits

It shall comply with provisions of GB 2762[1].

3.8 Mycotoxin limits

It shall comply with provisions of GB 2761[2].

3.9 Microbial limits

3.9.1 Pathogen limits in solid products shall be consistent with provisions of GB 29921[3], and other microbial limits shall be consistent with provisions of Table 6.

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

Table 6: Microbial Limits Indicators

Items	Sampling plan [a] and limits (it is expressed as CFU/g or CFU/ mL except that it is specified otherwise.)				Testing method
	n	*c*	*m*	*M*	
Total bacterial count [b]	5	2	1 000	10 000	GB 4789.2
Coliform group	5	2	10	100	GB 4789.3 plate counting method
[a] Collection 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 strains (aerobic bacteria and anaerobic bacteria) are added [active strains count shall be ≥10^6 CFU/g (mL)].					

3. 10 Food additives and nutritional fortification substances

3.10.1 The use of food additives and nutritional fortification substances shall comply with the provisions of GB 2760[4] and GB 14880[5].

3.10.2 The quality of food additives and nutritional fortification substances shall comply with the corresponding safety standards and relevant regulations.

[1] National Food Safety Standard Maximum Levels of Contaminants in Foods (GB2762-2022).

[2] National Food Safety Standard Maximum Levels of Mycotoxins in Foods (GB2761-2017).

[3] National Food Safety Standard for Limits of Pathogens in Pre-packaged Foods (GB29921-2021).

[4] National Food Safety Standard Usage Standard for Food Additives (GB2760-2024).

[5] National Food Safety Standard Use of Nutritional Fortification Substances (GB14880-2012).

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 Indicators

Items	Indicator	Testing method
Qualitative determination of urease activity	Negative	GB 5009.183 [a]
[a.] The sampling quantity of liquid products shall be converted according to the content of dry matter.		

4 Others

4.1 Label

4.1.1 Content indicated on the label shall be consistent with GB 13432[6] and/or relevant provisions. Content “per 100 kJ” 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 pressures.

4.1.3 The label of anti-reflux formula shall indicate the preparation temperature, storage time, and other parameters of the products, as well as the viscosity of the product after preparation.

4.1.4 The formula for special medical purposes, which can be consumed by infants over 6 months of age shall be marked “When the product is consumed by infants over 6 months old with special medical conditions, supplementary food shall be added.”

4.1.5 The label shall clearly indicate “Please use under the guidance of a physician or clinical nutritionist.”

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

[6] National Food Safety Standard Labeling of Prepackaged Foods for Special Dietary Uses (GB13432-2013).

4.2 Use instructions

4.2.1 Instructions and illustrations for usage and preparation, and products storage conditions shall be clearly stated on the label. When the maximum surface area of the packaging is less than 100 cm^2 or the product mass is less than 100 g, the illustration may not be indicated.

4.2.2 Warnings should be given regarding possible health hazards caused by improper preparation and use.

4.3 Packaging

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

Appendix A
Common Infant Formulas for Special Medical Purposes

Common infant formulas for special medical purposes are shown in Table A.1.

Table A.1: Common Infant Formulas for Special Medical Purposes

Product category	Applicable population with special medical conditions	Main technical requirements of the formula
Lactose-free or low-lactose formula	Lactose intolerance infants	a) The lactose shall be completely or partially replaced by other available carbohydrates in the formula; b) 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. Lactose content in liquid products can be converted according to dilution multiples; c) The protein in the formula is provided by milk protein.
Partially hydrolyzed milk protein formula	Infants with functional gastrointestinal discomfort and can be selectively used for infants with high risk of milk protein allergy	a) Protein in the formula is provided by milk protein; b) All milk proteins in the product are processed and decomposed into amino acids, peptide segments, and small molecular milk proteins; c) Lactose can be completely or partially replaced by other available carbohydrates in the formula.
Deeply hydrolyzed milk protein formula	Infants with food protein allergy or gastrointestinal dysfunction	a) The product shall contain 250 kJ (60 kcal) ~ 418 kJ (100 kcal) of energy per 100 mL in the ready-to-eat state; b) The protein in the formula is provided by milk protein; c) All milk proteins in the formula are deeply hydrolyzed, mainly broken down into short peptides and amino acids; d) Lactose can be completely or partially replaced by other available carbohydrates in the formula; e) The content of some nutrients can be adjusted appropriately, and the adjusted range of nutrients content shall comply with the provisions in Table A.2.
Amino acid formula	Infants with food protein allergy or gastrointestinal dysfunction	a) The product shall contain 250 kJ (60 kcal) ~ 418 kJ (100 kcal) of energy per 100 mL in the ready-to-eat state; b) The protein in the formula is provided by amino acids; c) Amino acids used in the products shall be inconsistent with provisions of Appendix B;

		d) Lactose can be completely or partially replaced by other available carbohydrates in the formula; e) The content of some nutrients can be adjusted appropriately, and the adjusted range of nutrients content shall comply with the provisions in Table A.2.
Amino acid metabolism disorder formula	Infants with amino acid metabolism disorder	a) The product shall contain 250 kJ (60 kcal) ~ 418 kJ (100 kcal) of energy per 100 mL in the ready-to-eat state; b) The protein in the formula is provided by amino acids, and its source shall comply with the provisions of Appendix B of this Standard; c) The types and content of amino acids that shall be restricted in formula foods with common amino acid metabolic disorders are shown in Table A.3; d) Lactose can be completely or partially replaced by other available carbohydrates in the formula; e) The content of some nutrients can be adjusted appropriately, and the adjusted range of nutrient content shall comply with the provisions in Table A.2.
Premature/low birth weight infant formula	Premature/low birth weight infants	a) The product shall contain 250 kJ (60 kcal) ~465 kJ (111 kcal) of energy per 100 mL in the ready-to-eat state; b) 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; c) The content of some nutrients can be adjusted appropriately, and the adjusted range of nutrient content shall comply with the provisions in Table A.4; d) The protein in the formula is provided by a single source of high-quality protein. Milk protein can be whole protein or hydrolyzed protein.
Breast milk nutritional supplement	Premature/low birth weight infants	a) The essential components and optional components in 3.4 and 3.5 can be selectively added, and their content 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. b) The protein is provided by milk protein, may be whole protein or hydrolyzed protein.
Ketogenic formula	Infants with refractory epilepsy	a) The mass ratio of fat to (protein + carbohydrate) ranges from 1:1 to 4:1; b) The maximum value for fat and linoleic acid, and the minimum value for carbohydrate are not limited; c) The protein in the formula is provided by a single source of high-quality protein.
Anti-reflux	Infants with frequent	a) Adding pregelatinized forms of high-amylopectin starch and/or thickeners;

formula	gastroesophageal reflux	c) When adding high-amylopectin starch, the addition amount of starch is (9 g - 25 g)/100 g. d) The protein in the formula is provided by a single source of high-quality protein.
Abnormal fat metabolism formula	Infants with fatty acid transport, metabolism, and absorption disorders	a) Medium-chain fat shall be used as part of the source of fat; b) The content of medium-chain fat shall not be less than 50% of total fat. c) The protein in the formula is provided by a single source of high-quality protein.
High-energy formula	Infants with high consumption, growth retardation, and limited liquid intake caused by diseases	a) The product shall contain 314kJ (75kcal) -565 kJ (135 kcal) of energy per 100 mL in the ready-to-eat state; b) The content of protein shall be not less than 0.53 g/100 kJ (2.2 g/100 kcal); c) The protein in the formula is provided by a single source of high-quality protein or amino acid. Milk protein can be whole protein or hydrolyzed protein.
Protein components	Infants needing to be supplemented with additional protein	a) The protein in the formula is provided by a single source of high-quality protein. Milk protein can be whole protein or hydrolyzed protein. b) The content of protein in whole protein products shall not be less than 90 g/100 g; The content of protein in partially hydrolyzed and deeply hydrolyzed products shall be greater than 80 g/100 g (based on dry matter); c) No additional ingredients shall be added (except those necessary for the process); d) It shall be used in conjunction with other foods.
Medium-chain fat components	Infants needing additional medium-chain fatty acids	a) From vegetable oil with relatively high medium-chain fat content; b) The content of medium-chain fat shall not be less than 95% of total fat; c) No additional ingredients shall be added (except those necessary for the process); d) It shall be used in conjunction with other foods.

Table A.2: Nutrients Indicators of Formulas for Milk Protein Deep Hydrolyzed, Amino Acid, or Amino Acid Metabolism Disorder that Should be Adjusted

Nutrients need to be adjusted [a]	Indicator			
	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Protein/ g	0.45	1.41	1.8	5.9
Carbohydrate/ g	2.2	3.7	9.0	15.3
Vitamin B_1/ μg	10	72	41	300

Vitamin B_2/ μg	14	119	58	500
Vitamin B_6/ μg	8.5	75.0	35	314
Nicotinic acid (nicotinamide)/ μg	96	750	400	3 138
Folic acid/ μg	1.0	12.0	4	50
Pantothenic acid / μg	70	478	293	2 000
Vitamin C/ mg	1.9	16.7	8	70
Biotin / μg	0.41	5.00	1.7	20.9
Zinc / mg	0.12	0.60	0.50	2.50
Calcium/ mg	12	60	50	251
Manganese / μg	0.24	50.00	1.0	209.0
Copper / μg	4.8	28.7	20	120
Iodine / μg	1.2	14.1	5	59
Selenium / μg	0.25	2.06	1.0	8.6
[a] Formulas for rare diseases with amino acid metabolism disorders, appropriate adjustments may be made to the content of some nutrients based on the provisions of 3.1.1.				

Table A.3: Common Amino Acid Metabolic Disorders, Types and Content Requirements of Amino Acids that Should be Restricted

Common amino acid metabolic disorders	Types of amino acids that shall be restricted	Amino acid content that shall be restricted in formula foods/ (mg/g) protein equivalent
Phenylketonuria	Phenylalanine	≤ 1.5
Maple Syrup Urine Disease	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
Isovaleric acidemia	Leucine	≤1.5
Urea circulation disorder	Non-essential amino acids (alanine, arginine, aspartic acid, asparagine, glutamic acid, glutamine,Glycine, proline and serine)	≤1.5[a]
[a] refers to the content of single amino acid.		

Table A.4: Nutrients Indicators of Formulas for Premature/Low Birth Weight Infants that Should be Adjusted

Nutrients need 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	0.7	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 B_2/ μg	19	148	80	619
Vitamin B_6/ μg	8.4	75.0	35	314

Nicotinic acid (nicotinamide)/ µg	96	1 195	400	5 000
Folic acid / µg	2.4	21.5	10	90
Biotin / µg	0.36	8.80	1.5	36.8
Sodium / mg	N.S.[a]	25	N.S.[a]	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
[a] N.S. refers to no specific instruction.				

Appendix B

Requirements for Monomeric Amino Acids that Could be Used in Infant Formulas for Special Medical Purposes

Please refer to Tabel B.1 for the requirements for monomeric amino acids that can be used in infant formulas for special medical purposes.

Table B.1: Monomeric Amino Acids Used in Infant Formulas for Special Medical Purposes [a]

No.	Amino Acid	Source of Chemical Compound
1	Aspartic acid	*L*-aspartic acid
		L-magnesium aspartate
2	Threonine	*L*-threonine
3	Serine	*L*-serine
4	Glutamic acid	*L*-glutamic acid
		L-potassium glutamate
5	Glutamine	*L*-glutamine
6	Proline	*L*-proline
7	Glycine	Glycine
8	Alanine	*L*-alanine
9	Cystine	*L*-cystine
		L- cysteine
		L-cysteine hydrochloride monohydrate
10	Valine	*L*-valine
11	Methionine	*L*-methionine
		N-acetyl-*L*-methionine

12	Leucine	*L*-leucine
13	Isoleucine	*L*-isoleucine
14	Tyrosine	*L*-tyrosine
15	Phenylalanine	*L*-phenylalanine
16	Lysine	*L*-lysine hydrochloride
		L-lysine acetate
17	Arginine	*L*-arginine
		L-arginine hydrochloride
18	Histidine	*L*-histidine
		L-Histidine hydrochloride monohydrate
19	Tryptophan	*L*-tryptophan
[a] Non-edible animal and plant ingredients shall not be used as sources of monomeric amino acids.		

END TRANSLATION

Attachments:

GB 25596-2025.pdf