



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 29922-2025

Replacing GB 29922-2013

**National food safety standard - General rules for formula foods
for special medical purposes**

食品安全国家标准 特殊医学用途配方食品通则

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1 Scope

GB 29922 is the Chinese national food safety standard for foods for special medical purposes: the formula foods given to patients who cannot eat or absorb ordinary food normally, whether as their sole source of nutrition or as a supplement. It applies to products intended for people over one year of age. The standard distinguishes nutritionally complete formula foods, which can be the sole source of nutrition; specific nutritionally complete formula foods, which do the same for a named disease or condition; and nutritionally incomplete formula foods, which meet only part of the requirement. It then sets the technical requirements: the formula must be based on the results of medical or nutritional research, and the standard fixes the raw material requirements, the energy and nutrient content, the contaminant, mycotoxin and microbiological limits, the permitted food additives and nutritional fortifiers, and the labelling. Registration of such a product in China is granted against this text. The 2025 edition, effective 2 March 2026, replaces GB 29922-2013.

This Standard applies to formula foods for special medical purposes for people aged 1 year and older.

2 Terms and definitions

2.1 Formula foods for special medical purposes Formula foods specially processed and prepared to meet the special nutritional or dietary needs of people with restricted food intake, digestive and absorption disorders, metabolic disorders, or specific disease states. These products must be consumed alone or in combination with other foods under the

guidance of a doctor or clinical nutritionist.

2.2 Complete nutritional formula foods Formula foods for special medical purposes that can serve as a single source of nutrition to meet the nutritional needs of the target population, including complete nutritional formula foods for people aged 1 ~ 10 years, complete nutritional formula foods for people aged 10 years and older, and partially nutritionally modified complete nutritional formula foods.

2.3 Specific complete nutritional formula foods Formula foods for special medical purposes that can serve as a single source of nutrition to meet the nutritional needs of target population under specific diseases or medical conditions.

2.4 Incomplete nutritional formula food Formula foods for special medical purposes that can meet some of the nutritional needs of the target population, which are not suitable as a single source of nutrition, including incomplete nutritional components (nutrient components, thickening components, dietary fiber components), incomplete nutritional formulas (electrolyte formulas, liquid formulas, preoperative carbohydrate formulas, amino acid metabolism disorder formulas), incomplete nutritional formulas for specific diseases, and other categories.

3.1 Basic requirements

3.1.1 The formulation of formula foods for special medical purposes shall be based on the medical and/or nutritional research results, and their safety and clinical application (effects) shall be scientifically proven.

3.1.2 The production conditions of formula foods for special medical purposes shall comply with relevant national regulations.

3.2 Raw material requirements

3.2.1 The raw materials used in formula foods for special medical purposes shall comply with the relevant safety standards and/or regulations, and the use of substances that endanger the health of consumers is prohibited.

3.2.2 Hydrogenated oils shall not be used in products intended for people aged 1 ~ 10 years.

3.3 Sensory requirements Sensory requirements shall be in accordance with Table 1.

3.4.1 Complete nutritional formula foods

3.4.1.1 Complete nutritional formula foods suitable for people aged 1 ~ 10 years
3.4.1.1.1 The energy content of complete nutritional formula foods suitable for people aged 1 ~ 10 years shall not be less than 250 kJ (60 kcal) per 100 mL (liquid products or products that can be dissolved into liquid in a ready-to-eat state) or per 100 g (solid or semi-solid

products for direct consumption). The calculation of energy is based on the value obtained by multiplying the protein, fat, carbohydrate, and dietary fiber content per 100 mL or per 100 g of product by their respective energy coefficients of 17 kJ/g, 37 kJ/g, 17 kJ/g, and 8 kJ/g - in kJ/100 mL or kJ/100 g for the sum of the results - then dividing by

4.184 in kcal/100 mL or kcal/100 g. If other substances provide 5% or more of the total energy, they shall be included in the total energy. 3.4.1.1.2 The protein content in complete nutritional formula foods suitable for people aged 1 ~ 10 years shall not be less than

0.5 g/100 kJ (2 g/100 kcal), of which the proportion of high-quality protein shall not be less than 50% (not applicable to complete nutritional formula foods with amino acid formula). For the inspection method of proteins, refer to GB 5009.5. 3.4.1.1.3 In complete nutritional formula foods suitable for people aged 1 ~ 10 years, the energy contribution ratio of linoleic acid shall not be less than 2.5% and the energy contribution ratio of alpha-linolenic acid shall not be less than 0.4%. For the inspection method of fatty acids, refer to GB 5009.168. 3.4.1.1.4 The vitamin and mineral content in complete nutritional formula foods suitable for people aged 1 ~ 10 years shall comply with the provisions of Table 2. 3.4.1.1.5 In addition to the components specified in Table 2, if one or more components from Table 3 are selected to be added to the product or are indicated on the label, their content shall comply with the provisions of Table 3. protein accounting for $\geq 20\%$ of the energy; high-energy-density complete nutritional formula foods are suitable for people with high-energy-density dietary needs. For liquid products or products that can be reconstituted into liquids, in ready-to-eat form, the energy density of high-energy-density complete nutritional formula foods for people aged 1 ~ 10 years is $\geq$

1.2 kcal/mL), and the energy density of high-energy-density complete nutritional formula foods for people aged 10 years and more is $\geq$

1.5 kcal/mL). The categories and main technical requirements of partially nutritionally modified complete nutritional formula foods for some people aged 1 ~ 10 years shall comply with the provisions of Appendix A of this Standard; the essential fatty acids (linoleic acid, alpha-linolenic acid), vitamins and minerals, and optional component indicators in partially nutritionally modified complete nutritional formula foods for other people aged 1 ~ 10 years shall comply with the corresponding technical requirements for complete nutritional formula foods for people aged 1 ~ 10 years. The essential fatty acids (linoleic acid, alpha-linolenic acid), vitamins, minerals and optional components in partially nutritionally modified complete nutritional formula foods for people aged 10 years and older shall meet the corresponding technical requirements for complete nutritional formula foods for people aged 10 years and older.

3.4.2 Specific complete nutritional formula food The energy and nutrient content of specific complete nutritional formula foods shall be based on the complete nutritional formula foods in

3.4.1.1 or 3.4.1.2, but may be appropriately adjusted according to the special requirements of diseases or medical conditions to meet the nutritional needs of the target population. See Appendix B for common specific complete nutritional formula foods.

3.4.2.1 For nutritional formulas that meet the requirements of the corresponding specific complete nutritional formula food standards, their safety and clinical application (effects) in specific disease or medical condition populations shall be scientifically proven.

3.4.2.2 For nutritional formulas for which there are no specific standards for complete nutritional formula foods, their safety and clinical application (effects) in specific disease or medical condition populations shall be scientifically proven based on the medical and/or nutritional research results.

3.4.3 Incomplete nutritional formula food

3.4.3.1 Common incomplete nutritional formula foods mainly include nutrient components, thickening components, dietary fiber components, electrolyte formulas, liquid formulas, preoperative carbohydrate formulas, amino acid metabolism disorder formulas, incomplete nutritional formulas for specific diseases, and others. These types of products cannot be used as a single source of nutrition to meet the nutritional needs of the target population and need to be used in combination with other foods.

3.8 Food additives and nutritional fortification substances

3.8.1 For products applicable to people aged 1 ~ 3 years, the use of food additives shall comply with the requirements of GB 2760 on the types and amounts of additives permitted in infant formula; for products applicable to other populations, the use of food additives shall comply with the types and amounts of additives permitted in the same or similar products in GB 2760.

3.8.2 The use of nutrient fortifiers shall comply with the provisions of GB 14880.

3.8.3 The mass specifications of food additives and nutritional fortifiers shall comply with the relevant standards and regulations.

3.8.4 Depending on the specific nutritional needs of the target population, one or more amino acids may be added to various formula foods for special medical purposes. The sources of the amino acids used shall comply with Appendix C, GB 14880 and other relevant regulations.

3.8.5 If live bacteria and/or other substances are added to formula foods for special medical purposes, they shall comply with relevant national regulations.

4.1 Labels

4.1.1 Product labels shall comply with the provisions of GB 13432. The labeling of nutrient