



GB 25596-2025

# National Food Safety Standard General Rules of Infant Formula Foods for Special Medical Purposes

食品安全国家标准 特殊医学用途婴儿配方食品通则

National Health Commission of the People's  
Republic of China

State Administration for Market Regulation

Release Date: Mar.16, 2025  
Implementation Date: Mar.16, 2027

Translated by ChemLinked

## Disclaimer

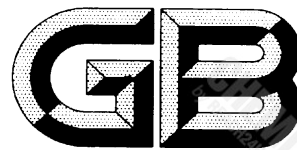
ChemLinked provides translation services to assist clients in understanding the content of regulatory documents. We strive for the accuracy and reliability of our translations, but we do not warrant the accuracy, completeness, or suitability of the translated content.

Clients are responsible for the risks inherent in utilizing our translation services and should consult with professional legal advisors as required. ChemLinked disclaims any liability for any losses or damages arising from the use of our translation services.

### **Nondisclosure:**

You may not disclose this document to anyone else without the written permission of ChemLinked.

For further clarification and questions, you can read our [Privacy Policies](#) or contact us at [contact@chemlinked.com](mailto:contact@chemlinked.com)



## National Standard of the People's Republic of China

GB 25596-2025

### National Food Safety Standard General Rules of Infant Formula Foods for Special Medical Purposes

食品安全国家标准

特殊医学用途婴儿配方食品通则

Date of publication: 2025-03-16

Date of implementation: 2027-03-16

Issued by:

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

## Preface

This standard replaces GB 25596-2010 National Food Safety Standard General Rules of Infant Formula Foods for Special Medical Purposes.

Compared with GB 25596-2010, the main changes of this standard are as follows:

- Modified terms and definitions;
- Modified the essential ingredients, and adjusted or added the minimum or maximum values of some nutrients;
- Modified choline from an optional ingredient to an essential ingredient;
- Modified the indicators of contaminant limits;
- Modified the indicators of mycotoxin limits;
- Modified the indicators of microorganism limits;
- Modified Annex A, and added six types in addition to the original product types, and clarified the technical indicators;
- Modified Annex B.

## National Food Safety Standard

### General Rules of Infant Formula Foods for Special Medical Purposes

#### 1 Scope

This standard applies to infant formula foods for special medical purposes for infants aged 0 to 12 months.

#### 2 Terms and Definitions

##### 2.1 Infant formula foods for special medical purposes

They refer to formula foods specially processed and prepared to meet the nutritional or dietary needs of infants with special medical conditions such as restricted food intake, digestion and absorption disorders, metabolic disorders, or specific disease states. This food type shall be eaten alone or in combination with other foods under the guidance of a doctor or a clinical nutritionist.

#### 3 Technical Requirements

##### 3.1 General requirements

3.1.1 The formulas for infant formula foods for special medical purposes shall be based on the results of medical and nutritional research, and their safety, nutritional adequacy, and clinical effects shall be scientifically confirmed.

3.1.1.1 The types of common infant formula foods for special medical purposes, applicable populations with special medical conditions, and main technical requirements of the formula shall comply with the provisions of Annex A.

3.1.1.2 Other infant formula foods for special medical purposes that are clinically needed should comply with the provisions of 3.1.1.

3.1.2 The processing of infant formula foods for special medical purposes should comply with relevant national regulations.

##### 3.2 Requirements of ingredients

3.2.1 The ingredients used in the product shall comply with the corresponding safety standards



Free



Free trial



Standard



Corporate



Special

# SUBSCRIBE TO CHEMLINKED NOW

## REMOVE FOOD REGULATORY BARRIERS EXPEDITE GLOBAL MARKET ACCESS

- In-time regulatory information and market access requirements
- Supported by local and experienced technically adept technical team
- Strategic partnerships with competent authorities and industrial associations worldwide
- Customized consulting service for complete compliance solutions.

## OUR SERVICES



### Information & Knowledge

News, Reports, Expert Analysis  
Pedia-articles



### Solutions

Regulatory Compliance Service, On-demand  
Translation, Advertisement Service, Tailor-made  
Service, E-commerce Solution



### Databases

Regulatory Database, English Translations  
Inventories/Lists



### Training

Webinars, Online Course  
Offline Events