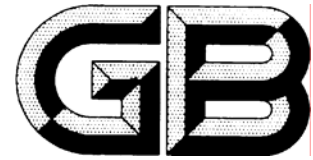


ICS 67.100.10
X 82



National Standard of P.R.C.

GB ××××—××××

Substitute for GB10767-1997, GB10765-1997, GB10766-1997

Infant formula and formulas for special medical purpose intended for infants

(Draft)

××××-××-×× Publish

××××-××-×× Implement

**Published by National Standardization
Committee**

Infant Formula and Formulas for Special Medical Purpose Intended for Infants (0-12 months of age)

Preamble

In A. Infant Formula of this standard, 4.3.7 and 4.4 is recommended while others are mandatory; B. Formulas for Special Medical Purpose Intended for Infants is recommended.

This standard is not equivalent to Standard for Infant Formula Codex Stan 72-1981 by CAC of FAO/ WHO and revised draft of Infant Formula and Formulas for Special Medical Purpose Intended for Infants[Codex Stan ?- 2007] and is in reference to Nutrient Reference Intake by Chinese Nutrition Society-2000

This standard is an integration and revision of GB10767-1997 (General Technical Conditions for Infant formula and Infant Supplementary Farina), GB10765-1997 (Infant Formula Milk Power I), GB10766-1997 (Infant Formula Milk Power II, III). This standard is in substitution for GB10767-1997, GB10765-1997, GB10766-1997.

Compared with GB10767-1997, GB10765-1997, GB10766-1997, the main changes of this standard are as follows:

- It integrates the above three standards into one standard and the name of standard is changed into Infant Formula.
- It is divided into two sections. Section A refers Infant Formula and Section B deals with Formulas for Special Medical Purpose Intended for Infants.

–

Annex A~E of this standard are normative annex.

Major drafting unit of this standard:

Major drafter of this standard:

A. Infant Formula

1 Scope

This section of standard contains the technical requirements for Infant Formula for infant not more than 12 months of age.

This section of standard applies to the manufacture, circulation, supervision and management of Infant Formula.

2 Normative reference

The clauses of the following files become the clauses of this standard by reference. As for the dated reference files, all of the subsequent revisions (except corrections) or revised edition do not apply to this standard. However, it is encouraged for the parties that reach agreement according to this standard to study whether the latest editions of these files could be used. As for the undated reference files, the latest editions apply to this standard.

GB 2763	Pesticide Residue Tolerance in the Food	
GB/T 4789.1	Microbiological Examination of Food Hygiene	General
GB/T 4789.2	Microbiological Examination of Food Hygiene	Determination of the Total Colony
GB/T 4789.3	Microbiological Examination of Food Hygiene	Determination of Coliform
GB/T 4789.4	Microbiological Examination of Food Hygiene	Test of Salmonella
GB/T 4789.10	Microbiological Examination of Food Hygiene	Counting and Test of Staphylococcus aureus
GB/T 4789.30	Microbiological Examination of Food Hygiene	Test of Mononucleosis Listeria spp
GB/T 4789.x	Microbiological Examination of Food Hygiene	Test of Colon Bacillus
GB/T 5009.1	Test Method of Food Hygiene Physical-chemical Part General	
GB/T 5009.11	Determination of Total Arsenic and Inorganic Arsenic in Food	
GB/T 5009.12	Determination of Lead in Food	
GB/T 5009.15	Determination of Cadmium in Food	
GB/T 5009.18	Determination of Fluorine in Food	
GB/T 5009.24	Determination of Aflatoxin M ₁ and B ₁ in Food	
GB/T 5413.1	Infant Formula and Milk Powder	Determination of Protein (Integrated into: 5009.5)
GB/T 5413.3	Infant Formula and Milk Powder	Determination of Fat
GB/T 5413.5	Infant Formula and Milk Powder	Determination of Lactose, Sucrose and Total Sugar
GB/T 5413.6	Infant Formula	Determination of Insoluble Dietary Fibre (Integrated into: 5009)

GB/T 5413.7	Infant Formula and Milk Powder	Determination of Ash (Integrated into:5009)
GB/T 5413.8	Infant Formula and Milk Powder	Determination of Water (Integrated into:5009)
GB/T 5413.9	Infant Formula and Milk Powder	Determination of Vitamin A, D, E (Integrated into:5009)
GB/T 5009.×	Infant Formula and Milk Powder	Determination of Vitamin K
GB/T 5413.11	Infant Formula and Milk Powder	Determination of Vitamin B ₁
GB/T 5413.12	Infant Formula and Milk Powder	Determination of Vitamin B ₂
GB/T 5413.13	Infant Formula and Milk Powder	Determination of Vitamin B ₆
GB/T 5413.14	Infant Formula and Milk Powder	Determination of Vitamin B ₁₂
GB/T 5413.15	Infant Formula and Milk Powder	Determination of Nicotinic Acid and Nicotinamide
GB/T 5413.16	Infant Formula and Milk Powder	Determination of Folic Acid (Activity of Folate)
GB/T 5413.17	Infant Formula and Milk Powder	Determination of Pantothenic Acid
GB/T 5413.18	Infant Formula and Milk Powder	Determination of Vitamin C (Integrated into: 5009.159)
GB/T 5413.19	Infant Formula and Milk Powder	Determination of Free Biotin
GB/T 5413.21	Infant Formula and Milk Powder	Determination of Calcium, Iron, Zinc, Sodium, Potassium, Magnesium, Copper and Manganese (Integrated into: 5009)
GB/T 5413.22	Infant Formula and Milk Powder	Determination of Phosphorus (Integrated into: 5009.87)
GB/T 5413.23	Infant Formula and Milk Powder	Determination of Iodine
GB/T 5009.×	Infant Formula and Milk Powder	Selenium
GB/T 5009.×	Infant Formula and Milk Powder	Sinkaline
GB/T 5009.×	Infant Formula and Milk Powder	Phaseomannite
GB/T 5009.×	Infant Formula and Milk Powder	Carnitine
GB/T 5009.×	Infant Formula and Milk Powder	Taurine
GB/T 5009.×	Infant Formula and Milk Powder	Nucleic Acid
GB/T 5009.×	Infant Formula and Milk Powder	Docosahexenoic Acid
GB/T 5009.×	Infant Formula and Milk Powder	Eicosatetraenoic Acid
GB/T 5413.31	Infant Formula and Milk Powder	Qualitative Reaction of Urease

GB/T 5413.32 milk powder

Determination of Nitrate and Nutrite

GB 13432 General Standard for the Labeling of Prepackaged Foods for Special Dietary Uses

3. Term and definition

The following terms and definitions apply to this standard

3.1 Infant formula

Infant formula means a breast-milk substitute specially processed only by physical means with the cow milk (or other edible animal milk) and its fabricated product and bean and its fabricated product as the major material and added vitamins, mineral substances and other accessories of the right amount to satisfy the nutritional requirements of infants during the first six months of life.

3.2 Infant

The term infant means a person not more than 12 months of age.

3.3 Guidance upper levels

Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress.

4. Requirement

4.1 Requirement of Raw Material

4.1.1 The raw and auxiliary materials should accord with the requirements of corresponding national standard or industry standard. All ingredients and food additives should be gluten-free.

4.1.2 Hydrogenated oil and fat should not be used.

4.1.3 The irradiated raw and auxiliary materials should not be used.

4.1.4 The pesticide residue of raw and auxiliary materials should be accord with GB 2763.

4.2 Sensory Requirement

The color, taste, smell, structural state and solubility of the product should accord with the quality requirement of corresponding product. There should not be foreign matter visible at normal eyesight.

4.3 Substances

4.3.1 The ingredients in infant formula should be suitable for infant feeding and necessary for the growth and development of infant.

4.3.2 Infant formula prepared ready for consumption shall contain per 100kJ (100 kcal) the