भारतीय मानक **IS 17945 : 2022**
Indian Standard

शिशुओं के लिए विशेष चिकित्सीय प्रयोजन हेतु आहार — विशिष्टि

Food for Special Medical Purpose Intended for Infants — Specification

ICS 67.100.99

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Dairy Products and Equipment Sectional Committee, FAD 19

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Dairy Products and Equipment Sectional Committee had been approved by the Food and Agriculture Division Council.

Human milk ideally fulfils the need for growth and additionally provides unique bio-immune factors for protecting the health of infants. Breast feeding is, therefore, universally regarded as the most appropriate form of nourishing the infant. However, sometimes, infants may have to be fed with alternate sources of nutrients to meet special nutritional requirements of infants with specific disorders, diseases or medical conditions. This standard is being formulated to cover the requirements for food for special medical purpose intended for infants, which is substitute for human milk or formula that is specially manufactured to meet the special nutritional requirements of infants from birth to twenty-four months with specific disorders, diseases or medical conditions. These include preterm infant milk substitute, lactose free infant milk substitutes and hypoallergenic infant milk substitutes. The requirements are harmonized with the *Food Safety and Standards (Foods for Infant Nutrition) Regulations*, 2020.

Earlier the requirements of pre-mature low birth weight infant milk substitute, lactose free infant milk substitutes, lactose and sucrose free infant milk substitutes, sucrose free infant milk substitutes and hypoallergenic infant milk substitutes were covered under IS 14433 : 2007 'Infant milk substitutes — Specification (*first revision*)'. In the second revision of IS 14433 brought out in 2022, the requirements of these special types of infant milk substitutes have been removed and are now covered in this standard.

A scheme for labelling environment friendly products known as ECO-Mark has been introduced in the standard. The ECO-Mark shall be administered by the Bureau of Indian Standards (BIS) under the *BIS Act*, 2016 as per the Resolution No. 71 dated 20 February 1991 and No. 425 dated 28 October 1992 published in the Gazette of the Government of India. For a product to be eligible for marking with the ECO-Mark, it shall also carry the Standard Mark of BIS for quality besides meeting additional environment friendly (EF) requirements given in the standard, which are based on the Gazette Notification No. GSR 624 (E) dated 6 September 1995 for labelling beverages, infant foods and processed fruits and vegetable products as Environment Friendly Products, published in the Gazette of the Government of India.

In the formulation of this standard, due consideration has been given to the provisions of the *Food Safety and Standards Act*, 2006 and the Rules and Regulations framed thereunder; *Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992 and Rules 1993* and the *Legal Metrology (Packaged Commodities) Rules*, 2011. However, this standard is subject to the restrictions imposed under these, wherever applicable.

The composition of the Committee responsible for formulation of the standard is given in Annex C.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

FOOD FOR SPECIAL MEDICAL PURPOSE INTENDED FOR INFANTS — SPECIFICATION

1 SCOPE

This standard prescribes the types, requirements, methods of test and sampling for food for special medical purpose intended for infants (preterm infant milk substitutes, lactose free infant milk substitutes and hypoallergenic infant milk substitutes).

2 REFERENCES

The standards listed in Annex A contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

3 TERMINOLOGY

3.0 For the purpose of this standard, the following definitions shall apply:

3.1 Food for Special Medical Purpose Intended for Infants — A substitute for human milk or formula, in liquid or powdered form that is specially manufactured to meet the special nutritional requirements of infants from birth to twenty four months with specific disorders, diseases or medical conditions for whose dietary management the product has been formulated.

3.2 Routine Tests — The tests carried out on each lot to check the essential requirements which are likely to vary during production.

3.3 Type Test — The tests to prove conformity to the requirements of this standard. They are intended to approve the formulation and quality of the product at least in the beginning of marketing or certification or both. These tests are also conducted periodically to supplement the routine tests or whenever the basic formula or method is changed.

4 TYPES

4.1 Food for special medical purpose intended for infants shall be of the following three types:

a) Preterm infant milk substitutes;
b) Lactose free infant milk substitutes; and
c) Hypoallergenic infant milk substitutes.

5 REQUIREMENTS

5.1 Description

The product shall be white or white with a greenish tinge to light cream to light yellow in colour, free from lumps and coarse particles; and shall be uniform in appearance. It shall also be free from dirt, and extraneous matter, preservatives, added colour and flavour and from any material which are harmful to infant's health. The flavor of the product in dry condition or of reconstituted feed shall be fresh and sweet. It shall be free from rancid taste and musty odour (*see* IS 10641).

5.2 The composition of food for special medical purpose intended for infants shall be based on sound medical and nutritional principles. The nutritional safety and adequacy of the formula shall be scientifically demonstrated to support the growth and development of the infants for whom it is intended as appropriate for the specific products and indications. Their use shall be demonstrated by scientific evidence to be beneficial in the dietary management of the infants for whom it is intended.

5.3 The energy content and nutrient composition of the food for special medical purpose intended for infants except preterm infant milk substitute shall be based on the requirements for infant formula and follow-up formula, as applicable based on intended age group, specified under this standard except for the compositional provisions which must be modified to meet the especial nutritional requirements arising from disease(s), disorder(s) or medical condition(s) for whose dietary management the product is specifically formulated, labelled and presented.

5.4 The scorched particles in the product shall not exceed 15 mg (equivalent to Disc B) when tested as per the method given in IS 13500.

5.5 Lactose and glucose polymers shall be the preferred carbohydrates for infant milk substitutes. Sucrose and/or fructose shall not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20 percent of total carbohydrate.

NOTE — For the purpose of this clause, since there is no analytical method available at present for the estimation of added sucrose/fructose, records of their addition shall be maintained by the manufacturer.

5.6 Optional Ingredients

In addition to the compositional requirements to provide substances ordinarily found in human milk or required other ingredients, optional ingredients permitted for Type II Infant milk substitutes as per IS 14433 may be added to ensure that the formulation is suitable as the sole source of nutrition for the infant and for the dietary management of the disease, disorder or medical condition of the infant. Provided further that preterm infant milk substitutes shall comply with requirements specified under this standard.

5.7 Food Additives

The product may contain food additives specified for Type II infant milk substitutes under **5.8.2** and **5.8.3** of IS 14433 and for follow-up formula under **4.6.1** and **4.6.2** of IS 15757, as applicable.

5.8 Quality of Ingredients

5.8.1 All ingredients used shall be clean, of good quality, safe and suitable for ingestion by infants.

5.8.2 The vitamins, minerals and other nutrients shall be of food grade. Wherever applicable, food for special medical purpose for infants shall use the source compounds for minerals, vitamins and other nutrients as follows:

a) Minerals

1) Calcium (Ca) — Calcium carbonate, calcium chloride, calcium citrate (tricalciumdi citrate), calcium gluconate, calcium glycerophosphate, calcium L-lactate, calcium hydroxide, calcium sulphate, calcium phosphate monobasic (calcium dihydrogen phosphate), calcium phosphate dibasic (calcium hydrogen phosphate), calcium phosphate tribasic (tricalcium diphosphate), calcium oxide;

2) Phosphorous (P) — Calcium phosphate monobasic, calcium phosphate dibasic, calcium phosphate tribasic, magnesium phosphate dibasic, magnesium phosphate tribasic, potassium phosphate monobasic, potassium phosphate dibasic, sodium phosphate dibasic, phosphoric acid;

3) Chloride (Cl) — Calcium chloride, choline chloride, magnesium chloride, manganese chloride, potassium chloride, sodium chloride, hydrochloric acid (food grade);

4) Iron (Fe) — Ferrous carbonate (stabilized with saccharose), ferrous citrate, ferrous fumarate, ferrous gluconate, ferrous succinate, ferrous lactate, ferric ammonium citrate, ferric citrate, ferrous bisglycinate, sodium ferric pyrophosphate ferric diphosphate, ferric orthophosphate, ferrous sulphate, hydrogen reduced iron, electrolytic iron, carbonyl iron, ferric saccharate, sodium ferric diphosphate;

5) Magnesium (Mg) — Magnesium hydroxide carbonate, magnesium chloride, magnesium oxide, magnesium phosphate dibasic (magnesium hydrogen phosphate), magnesium phosphate tribasic (Trimagnesium phosphate), magnesium carbonate, magnesium sulphate, magnesium hydroxide, magnesium salts of citric acid, magnesium gluconate, magnesium lactate, magnesium glycerol-phosphate, magnesium acetate;

6) Sodium (Na) — Sodium bicarbonate, sodium carbonate, sodium chloride, trisodium citrate, sodium gluconate, sodium L-lactate, sodium phosphate monobasic (sodium dihydrogen phosphate), sodium phosphate dibasic (disodium hydrogen phosphate), sodium phosphate tribasic (trisodium phosphate), sodium sulphate, sodium hydroxide;

7) Potassium (K) — Potassium bicarbonate, potassium carbonate, potassium chloride, potassium citrate (tripotassium citrate), potassium glycerol phosphate, potassium gluconate, potassium phosphate monobasic (potassium dihydrogen phosphate), potassium phosphate dibasic (dipotassium hydrogen phosphate), potassium hydroxide, potassium phosphate tribasic, potassium L-Lactate;

8) Copper (Cu) — Copper gluconate (cupric gluconate), cupric carbonate, cupric citrate, copper sulphate (cupric sulphate);

9) Iodine (I) — Potassium iodide, sodium iodide, potassium iodate, sodium iodate;

10) Zinc (Zn) — Zinc acetate, zinc chloride, zinc oxide, zinc sulphate, zinc gluconate, zinc lactate, zinc carbonate, zinc citrate (zinc citrate dihydrate or zinc citrate trihydrate);

11) Manganese (Mn) — Manganese(II) carbonate, manganese(II) chloride, manganese(II) citrate,

manganese sulphate, manganese (II) gluconate, manganese (II) glycerolphosphate;

12) Selenium (Se) — Sodium selenate, sodium selenite, sodium hydrogen selenite;

13) Chromium (Cr) — Chromium(III) sulphate, chromium(III) chloride; and

14) Molybdenum (MoVI) — Sodium molybdate, ammonium molybdate

b) Vitamins

1) Vitamin A — Retinyl acetate, retinyl palmitate, trans-retinol;
2) Provitamin A— Beta-carotene;
3) Vitamin D — Vitamin D_2 (ergocalciferol), vitamin D_3 (cholecalciferol);
4) Vitamin E — D-α-tocopherol, DL-α-tocopherol, D-α-tocopheryl acetate, DL-α-tocopheryl acetate, D-α-tocopheryl acid succinate, DL-α-tocopheryl acid succinate, DL-α-tocopheryl polyethylene glycol succinate;
5) Vitamin K_1 — Phytomenadione (2-methyl-3-phytyl-1,4-naphthoquinine/phylloquinone/phytonadione);
6) Vitamin K_2 — Menaquinone;
7) Thiamin (Vitamin B_1) — Thiamin chloride hydrochloride, thiamin mononitrate;
8) Riboflavin (Vitamin B_2) — Riboflavin, riboflavin-5-phosphate sodium;
9) Niacin — Nicotinic acid amide (nicotinamide), nicotinic acid;
10) Pantothenic acid — Calcium-D-pantothenate, D-panthenol, sodium-D-pantothenate, DL-Panthenol;
11) Vitamin B_6 — Pyridoxine hydrochloride; pyridoxal-5-phosphate;
12) Folic acid – N-pteroyl-L-glutamic acid, calcium-L-methyl-folate;
13) Biotin (vitamin H) — D-biotin;
14) Vitamin B_{12} — Cyanocobalamin, hydroxo-cobalamin;
15) Vitamin C — L-ascorbic acid, sodium-L-ascorbate, calcium-L-ascorbate, potassium-L-ascorbate, 6-palmitoyl-L-ascorbic acid (ascorbyl palmitate).

c) Amino acids

Free, hydrated and anhydrous forms of amino acids and the hydrochloride, sodium and potassium salts of the following amino acids:

1) L-Arginine
2) L-Arginine hydrochloride
3) L-Cystine
4) L-Cystine dihydrochloride
5) L-Cysteine
6) L-Cysteine hydrochloride
7) L-Histidine
8) L-Histidine hydrochloride
9) L-Isoleucine
10) L-Isoleucine hydrochloride
11) L-Leucine
12) L-Leucine hydrochloride
13) L-Lysine
14) L-Lysine mono hydrochloride
15) L-Methionine
16) L-Phenylalanine
17) L-Threonine
18) L-Tryptophan
19) L-Tyrosine
20) L-Valine
21) L-Alanine
22) L-Arginine-L-aspartate
23) L-Aspartic acid
24) L-Citrulline
25) L-Glutamic acid
26) L-Glutamine
27) Glycine
28) L-Ornithine
29) L-Ornithine monohydrochloride
30) L-Proline
31) L-Serine
32) N-Acetyl-L-cysteine
33) N-Acetyl-L-methionine (only for use in infants above 12 months)
34) L-Lysine acetate
35) L-Lysine-L-aspartate
36) L-Lysine-L-glutamate dihydrate
37) Magnesium L-aspartate
38) Calcium L-glutamate
39) Potassium L-glutamate

d) Carnitine

1) L-Carnitine
2) L-Carnitine hydrochloride
3) L-Carnitine tartarate

e) Taurine

1) Taurine

f) Choline

1) Choline
2) Choline chloride
3) Choline citrate
4) Choline hydrogen tartrate

5) Choline bitartrate

g) Inositols

1) Myo-inositol

h) Nucleotides

1) Adenosine 5-monophosphate (AMP)
2) Cytidine 5-monophosphate (CMP)
3) Guanosine 5-monophosphate (GMP)
4) Inosine 5-mono phosphate (IMP)
5) Disodium uridine 5-monophosphate salt
6) Disodium guanosine 5-monophosphate salt
7) Disodium inosine 5-monophosphate salt

5.9 Lactose Free Infant Milk Substitutes — In addition to the energy and nutrient requirements specified for infant formula/Type-II infant milk substitutes (*see* IS 14433, except milk fat) and follow-up formula (*see* IS 15757) as applicable based on the intended age group, lactose free infant milk substitutes shall also meet the following requirements:

a) Soy based lactose free formula shall have soy protein and glucose, dextrose, dextrin/maltodextrin, maltose and/or sucrose as carbohydrates;
b) Lactose-free cow/buffalo milk-based formulas shall have carbohydrate as glucose, dextrose, dextrin/maltodextrin, maltose and sucrose. It may also contain caseinates, milk protein concentrates, isolates and hydrolysates;
c) Lactose content shall not exceed 0.05 percent by mass; and
d) The fat content derived from vegetable oils shall not be less than 18 percent by mass.

5.10 Hypoallergenic Infant Milk Substitutes — In addition to the energy and nutrient requirements specified for infant formula/Type-II infant milk substitutes (*see* IS 14433) and follow-up formula (*see* IS 15757), except for milk fat and milk protein, as applicable based on the intended age group, the hypoallergenic infant milk substitutes shall also meet the following requirements:

a) Protein used shall be extensively hydrolysed whey protein or casein; or
b) Only free amino acids shall be used as protein source.

5.11 Preterm Infant Milk Substitutes — The preterm infant milk substitute is required for babies born before 37 weeks only and till they attain 40 weeks of age or as prescribed by physician. The product shall also conform to the requirements given in Table 1 and whey protein:casein ratio shall be 60:40 (*see* Note).

NOTE — The Committee, is in the process of identifying the method of test for determination of whey protein : casein ratio. Till such time the method of test is identified, the manufactures would be required to maintain records showing compliance with the stated requirement.

Table 1 Requirements for Preterm Infant Milk Substitutes
(*Clause* 5.11)

Sl No.	Nutrient	Requirements per 100 kcal	Requirements per kg body weight of infant/day	Method of Test, Ref to
(1)	(2)	(3)	(4)	(5)
i)	Energy, kcal	–	110.00-130.00	Energy calculation shall be based upon the values of 4 kcal/g of Carbohydrates and per g of proteins; and 9 kcal/g of fat.
ii)	Total protein, g	3.20-4.10	3.50-4.50	IS 7219
iii)	a) Total fat, g	4.40-6.00	4.80-6.60	IS 11721
	b) Linoleic acid, mg	350.00-1400.00	385.00-1540.00	Annex B of IS 14433 or ISO 16958*
	c) α-Linolenic acid, mg (*Min*)	50.00	55.00	- do -

Table 1 (*Continued*)

Sl No.	Nutrient	Requirements per 100 kcal	Requirements per kg body weight of infant/day	Method of Test, Ref to
(1)	(2)	(3)	(4)	(5)
iv)	Docosahexaenoic acid (DHA), mg	11.00-27.00	12.00-30.00	ISO 16958
v)	Eicosapentaenoic acid (EPA), mg, *Max*	18.00	20.00	ISO 16958
vi)	Arachidonic acid (ARA), mg	16.00-39.00	18.00-42.00	ISO 16958
vii)	Carbohydrate, g	10.50-12.00	11.60-13.20	Annex C of IS 1656
viii)	Sodium, mg	63.00-105.00	69.00-115.00	IS 12760 or ISO 15151 or ISO 21424*
ix)	Potassium, mg	71.00-177.00	78.00-195.00	- do -
x)	Calcium, mg	109.00-182.00	120.00-200.00	- do -
xi)	Phosphate, mg	55.00-127.00	60.00-140.00	IS 12756 or ISO 15151 or ISO 21424*
xii)	Chloride, mg	95.00-161.00	105.00-177.00	IS 11763 or AOAC 2016.03*
xiii)	Magnesium, mg	7.30-13.60	8.00-15.00	IS 12760 or ISO 15151 or ISO 21424*
xiv)	Iron, mg	1.80-2.70	2.00-3.00	AOAC 985.35 or ISO 15151 or ISO 21424*
xv)	Zinc, mg	1.30-2.30	1.40-2.50	**15** of IS 1699 or ISO 15151 or ISO 21424*
xvi)	Copper, µg	90.00-210.00	100.00-230.00	- do -
xvii)	Selenium, µg	4.50-9.00	5.00-10.00	IS 15303 or ISO 15151 or ISO 20649*
xviii)	Manganese, µg	0.90-13.60	1.00-15.00	ISO 15151 or ISO 21424*
xix)	Iodine, µg	9.00-50.00	10.00-55.00	IS 17379
xx)	Chromium, ng	27.00 – 2045.00	30.00-2 250.00	ISO 20649
xxi)	Molybdenum, µg	0.27-4.50	0.30-5.00	ISO 20649
xxii)	Thiamin, µg	127.00-273.00	140.00-300.00	IS 17669
xxiii)	Riboflavin, µg	181.00-364.00	200.00-400.00	IS 17669
xxiv)	Niacin equivalent, mg	0.90-5.00	1.00-5.50	IS 17669
xxv)	Pantothenic acid, mg	0.45-1.90	0.50-2.10	IS 16642
xxvi)	Pyridoxine, µg	45.00-273.00	50.00-300.00	IS 17669
xxvii)	Cobalamin, µg	0.09-0.73	0.10-0.80	IS 16640* or AOAC 2014.02
xxviii)	Folic acid, µg	32.00-91.00	35.00-100.00	AOAC 2013.13
xxix)	L-Ascorbic acid (vitamin C), mg	18.00-50.00	20.00-55.00	IS 5838 or IS 17176*
xxx)	Biotin, µg	1.50-15.00	1.70-16.50	IS 17670
xxxi)	Vitamin A, µg retinol equivalents	365.00-1000.00	400.00-1 100.00	IS 16639
xxxii)	Vitamin D, IU	100-350	800.00-1 000.00	IS 17177
xxxiii)	Vitamin E, mg, α-tocopherol equivalents	2.00-10.00	2.20-11.00	IS 16639

Table 1 (*Concluded*)

Sl No.	Nutrient	Requirements per 100 kcal	Requirements per kg body weight of infant/day	Method of Test, Ref to
(1)	(2)	(3)	(4)	(5)
xxxiv)	Vitamin K, µg	4.00-25.00	4.40-28.00	IS 21446
xxxv)	Choline, mg	7.30-50.00	8.00-55.00	IS 17668
xxxvi)	Inositol, mg	4.00-48.00	4.40-53.00	IS 16649

NOTES
1 The compositional requirements under Col (3) shall be complied with, while requirements under Col (4) are for guidance purpose only.
2 1 IU of Vitamin D = 0.025 µg Vitamin D.
3 In case of dispute, the method indicated by '*'shall be the referee method.
4 For the purpose of Type tests, all tests mentioned above are to be carried out and for the purpose of Routine tests, the tests given at Sl No. ii), iii), x), xi), xiv) and xxxi) are to be carried out.
5 A variation of minus 10.0 per cent from the declared value of the nutrients or nutritional ingredients on the label shall be allowed. The nutrient levels shall not exceed maximum limits as specified in this Table.

5.12 Food for special medical purpose intended for infants shall conform with the microbiological requirements given in Table 2.

Table 2 Microbiological Requirements for Food for Special Medical Purpose Intended for Infants
(*Clause* 5.12)

Sl No.	Characteristic	Requirement				Method of test, Ref to
		Sampling Plan		Limit (cfu)		
		n	c	m	M	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
(i)	Aerobic plate count	5	2	5×10^2/g	5×10^3/g	IS 5402 (Part 1)
(ii)	*Staphylococcus aureus* (Coagulase positive)	5	0	<10/g	–	IS 5887 (Part 8/ Sec 1* or 2)
(iii)	Yeast and mould count	5	0	<10/g	–	IS 5403 or IS 16069-1* for liquid product or IS 16069-2* for powdered product
(iv)	*Salmonella sp*.	60	0	Absent/25 g	–	IS 5887(Part 3/Sec 1)
(v)	*Listeria monocytogenes*	10	0	Absent/25 g	–	IS 14988 (Part 1)
(vi)	*Bacillus cereus*	5	2	1×10^2/g	5×10^2/g	IS 5887 (Part 6)
(vii)	Sulphite reducing *Clostridia*	5	2	10/g	1×10^2/g	ISO 15213
(viii)	Enterobacteriaceae	10	0	Absent/10 g	–	IS 17112 (Part 1)
(ix)	*Enterobacter sakazakii* (*Cronobacter sp*.)	30	0	Absent/10 g	–	ISO 22964

NOTES
1 For sampling plan, *see* Annex B.
2 In case of dispute, the method indicated by '*' shall be the referee method.
3 The requirement for *Salmonella* shall be tested in a laboratory situated away from the production area.

5.13 The pesticide residues, antibiotic and veterinary drug residues and other contaminants, if any, in the raw materials used in the manufacture of the product shall not exceed the limits as prescribed in the *Food Safety and Standards (Contaminants, Toxins and Residues) Regulations*, 2011.

5.14 Heavy metals and other contaminants or toxic substances (melamine), if any, in the product shall not exceed the limits specified in Table 4 of IS 14433.

5.15 Hygienic Conditions

The product shall be processed, packed, stored and distributed under strict hygienic conditions as prescribed in IS 2491.

5.16 Optional Requirement for ECO-Mark

5.16.1 *General Requirements*

5.16.1.1 The product shall conform to the requirements prescribed under **5.1** to **5.15**.

5.16.1.2 The manufacturer shall produce the consent clearance as per the provisions of *Water (PCP) Act*, 1974, *Water (PCP) Cess Act*, 1977 and *Air (PCP) Act*, 1981 along with the authorization if required under *Environment (Protection) Act*, 1986 and the Rules made thereunder to the Bureau of Indian Standards, while applying for the ECQ-Mark and the product shall also be in accordance with the *Food Safety and Standards Act, 2006* and the Rules and Regulations made thereunder. Additionally, the *Legal Metrology (Packaged Commodities) Rules*, 2011 have to be complied with.

5.16.1.3 The product/packaging may also display in brief the criteria based on which the product has been labelled environment friendly.

5.16.1.4 The material used for product packing shall be recyclable or biodegradable.

5.16.1.5 The product shall be microbiologically safe when tested as per IS 5887 (Part 5) and should be free from bacterial and fungal toxins.

5.16.1.6 The product package or leaflet accompanying it may display instruction of proper use, storage and transport (including refrigeration temperature compliance) so as to maximize the product performance, safety and minimize wastage.

5.16.2 *Specific Requirements*

5.16.2.1 The material used inside tile metal cap of the product shall conform to the relevant Indian Standards of food grade plastics as permitted under the *Food Safety and Standards Act*, 2006 and the Rules and Regulations made there under. Caps and closures shall not be treated as labels.

5.16.2.2 No synthetic food colour and artificial sweetener shall be added or used in the product.

6 PACKING AND MARKING

6.1 Packing

6.1.1 The product shall be packed in hermetically sealed, clean and sound metal containers (*see* IS 11078) or in a flexible pack made from paper, polymer and/or metallic film so as to protect it from deterioration. In case plastic material is used for flexible packaging, only food grade plastic shall be used (*see* IS 10171). The packaging material shall be free from Bisphenol A (BPA), when tested as per ISO 18857-2 : 2009 or EN 13130-13*.

NOTE — In case of dispute, the method indicated by '*' shall be the referee method.

6.1.2 The product shall be packed in accordance with requirements under *the Food Safety and Standards (Packaging) Regulations*, 2018.

6.2 Marking

6.2.1 The containers shall bear legibly and indelibly with the following information:

a) Name of the product, and brand name, If any;
b) Type of product;
c) Name and address of the manufacturer;
d) Batch or lot or Code number;
e) Month and year of manufacturing or packing;
f) Net quantity;
g) Date before which the contents should be consumed be indicated by marking the words 'Use by date/recommended last consumption date/Expiry date …….(month and year)';
h) An advisory warning "RECOMMENDED TO BE TAKEN UNDER MEDICAL ADVICE ONLY" in capital and bold letters;
j) A warning that Infant milk substitute is not the sole source of nourishment of an infant;
k) A statement indicating instruction for appropriate and hygienic preparation including cleaning of utensils, bottles and teats and warning against health hazards of inappropriate preparations;
m) A statement "FOR THE PRETERM BABY (BORN BEFORE 37 WEEKS)" for pre-term infant milk substitutes;
n) In case the product is for lactose intolerant infants, the words "LACTOSE-FREE" shall be conspicuously labelled on the container in capital and bold letters;

p) In case the product contains neither milk nor any milk derivatives, the words "CONTAINS NO MILK OR MILK PRODUCTS" shall be conspicuously labelled on the container in capital and bold letters;
q) In case the product is for infants with allergy to milk protein of cow/buffalo/other milch animal (as specified under **4** of IS 13688), the words "HYPOALLERGENIC FORMULA" shall be conspicuously labelled on the container in capital and bold letters;
r) Feed chart and directions for use;
s) Instructions for discarding leftover feed;
t) Instructions for use of measuring scoop (level or heaped) and the quantity per scoop (scoop to be given with pack)
u) Directions for storage;
w) Composition – Indicating the approximate composition of nutrients per 100 g or per 100 ml of the product as well as the energy value in kcal or kilo joules; and
y) Any other requirements as stipulated under *Food Safety and Standards (Labelling and Display) Regulations*, 2020; the *Food Safety and Standards (Foods for Infant Nutrition) Regulations*, 2020; *Infant Milk Substitutes, Feeding Bottles and Infant Foods Act*, 1992 and *Rules* 1993; and *Legal Metrology (Packaged Commodities) Rules*, 2011.

6.2.1.1 In case of flexible packs, a cautionary notice to the following effect shall be printed on the container: 'On opening, transfer the contents of the pack to a clean air tight container. After each use, replace the lid tightly and store in a cool dry place.'

6.2.2 *BIS Certification Marking*

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

6.2.3 *ECO-Mark*

The Product may also be marked with the ECO-Mark, the details of which may be obtained from the Bureau of Indian Standards.

7 SAMPLING

Representative samples of the material shall be drawn and tested for conformity to this standard as prescribed in Annex F of IS 14433.

ANNEX A
(*Clause* 2)

LIST OF REFERRED STANDARDS

IS No./ Other Publication	*Title*
1656 : 2022	Milk-cereal based complementary foods — Specification (*fifth revision*)
1699 : 1995	Methods of sampling and test for food colours (*second revision*)
2491 : 2013	Food hygiene — General principles — Code of practice *(third revision)*
5402 (Part 1) : 2021	Microbiology of the food chain — Horizontal method for the enumeration of microorganisms: Part 1 Colony count at 30°C by the pour plate technique
5403 : 1999	Method for yeast and mould count of foodstuffs and animal feeds (*first revision)*
5838 : 1970	Methods for estimation of vitamin C in foodstuffs
5887	Methods for detection of bacteria responsible for food poisoning
(Part 3/Sec 1) : 2020/ISO 6579-1 : 2017	Horizontal method for the detection, enumeration and serotyping of *Salmonella*, Section 1 Detection of *Salmonella* spp. (*third revision*)
(Part 5) : 1976	Isolation, identification and enumeration of *Vibrio cholerae* and *Vibrio parahaemolyticus* (*first revision*))
(Part 6) : 2012/ISO 7932 : 2004	Horizontal method for the enumeration of presumptive *Bacillus cereus* — Colony count technique at 30°C (*first revision*)
(Part 8/Sec 1) : 2002/ISO 6888-1 : 1999	Horizontal method for enumeration of coagulase-positive Staphylococci (*Staphylococcus aureus* and other species), Section 1 Technique using Baird-Parker agar medium
(Part 8/Sec 2) : 2002/ISO 6888-2 : 1999	Horizontal method for enumeration of coagulase-positive Staphylococci (*Staphylococcus aureus* and other species), Section 2 Technique using rabbit plasma fibrinogen agar medium
7219 : 1973	Method for determination of protein in foods and feeds
10171 : 1999	Guide on suitability of plastics for food packaging (*second revision*)
10641 : 1983	Recommended methods for determination of aroma and taste thresholds
11078 : 2012	Round open top sanitary cans for milk powder — Specification (*second revision*)
11721 : 2013/ISO 1736 : 2008	Dried milk and dried milk products — Determination of fat content — Gravimetric method (reference method) (*second revision*)
11763 : 2011/ISO 5943 : 2006	Cheese and processed cheese products — Determination of chloride content — Potentiometric titration method (*third revision*)
12756 : 2019/ISO 2962:2010	Cheese and processed cheese products — Determination of total phosphorus content — Molecular absorption spectrometric method (*first revision*)
12760 : 2012/ISO 8070 : 2007	Milk and milk products — Determination of calcium, sodium, potassium and magnesium contents — Atomic absorption spectrometric method (*first revision*)
13500 : 1992	Spray dried milk powders scorched particles – Determination
13688 : 2020	Packaged pasteurized milk — Specification (*second revision*)
14433 : 2022	Infant milk substitutes — Specification (*second revision*)
14988 (Part 1) : 2020/ISO 11290-1 : 2017	Microbiology of the food chain — Horizontal method for detection and enumeration of *Listeria monocytogenes* and of *Listeria* spp: Part 1 Detection method (*first revision*)
15303 : 2003	Determination of antimony, iron and selenium in water by electrothermal atomic absorption spectrometric method
15757 : 2022	Follow-up formula — Complementary foods — Specification (*first revision*)
16069	Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of yeasts and moulds
(Part 1) : 2013/ISO 21527-1 : 2008	Colony count technique in products with water activity greater than 0.95
(Part 2) : 2013/ISO 21527-2 : 2008	Colony count technique in products with water activity less than or equal to 0.95
16639 : 2018/ISO 20633 : 2015	Infant formula and adult nutritionals — Determination of vitamin E and vitamin A by normal phase high performance liquid chromatography

16640 : 2018/ISO 20634 : 2015	:	Infant formula and adult nutritionals — Determination of vitamin B_{12} by reversed phase high performance liquid chromatography (RP - HPLC)
16642 : 2018/ISO 20639 : 2015	:	Infant formula and adult nutritionals — Determination of pantothenic acid by ultra high performance liquid chromatography and tandem mass spectrometry method (UHPLC - MS/MS)
16649 : 2018/ISO 20637 : 2015	:	Infant formula and adult nutritionals — Determination of Myo - Inositol by liquid chromatography and pulsed amperometry
17112 (Part 1) : 2019/ISO 21528-1 : 2017	:	Microbiology of the food chain — Horizontal method for the detection and enumeration of enterobacteriaceae: Part 1 Detection of enterobacteriacea
17176 : 2019/ISO 20635 : 2018	:	Infant formula and adult nutritionals — Determination of vitamin C by (ultra) high performance liquid chromatography with ultraviolet detection ((U) HPLC-UV)
17177 : 2019/ISO 20636 : 2018	:	Infant formula and adult nutritionals — Determination of vitamin D by liquid chromatography mass spectrometry
17379 : 2020/ISO 20647 : 2015	:	Infant formula and adult nutritionals — Determination of total iodine — Inductively coupled plasma mass spectrometry (ICP-MS)
17668 : 2021/ISO 21468 : 2020	:	Infant formula and adult nutritionals — Determination of free and total choline and free and total carnitine — Liquid chromatography tandem mass spectrometry (HPLC-MSMS)
17669 : 2021/ISO 21470 : 2020	:	Infant formula and adult nutritionals — Simultaneous determination of total vitamins B_1, B_2, B_3 and B_6 Enzymatic digestion and LC-MSMS
17670 : 2021/ISO 23305 : 2020	:	Fortified milk powders, infant formula and adult nutritionals — Determination of total biotin by liquid chromatography coupled with immunoaffinity column clean-up extraction
IS/ISO 21446 : 2019	:	Infant formula and adult nutritionals — Determination of trans and total cis trans Vitamin K_1 content – Normal phase HPLC
ISO 15151 : 2018	:	Milk, milk products, infant formula and adult nutritionals — Determination of minerals and trace elements — Inductively coupled plasma atomic emission spectrometry (ICP-AES) method
ISO 15213 : 2003	:	Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of sulfite-reducing bacteria growing under anaerobic conditions
ISO 16958 : 2015	:	Milk, milk products, infant formula and adult nutritionals — Determination of fatty acids composition — Capillary gas chromatographic method
ISO 18857-2 : 2009	:	Water quality — Determination of selected alkylphenols — Part 2: Gas chromatographic-mass spectrometric determination of alkylphenols, their ethoxylates and bisphenol A in non-filtered samples following solid-phase extraction and derivatisation
ISO 20649:2015		Infant formula and adult nutritionals — Determination of chromium, selenium and molybdenum — Inductively coupled plasma mass spectrometry (ICP-MS)
ISO 21424 : 2018	:	Milk, milk products, infant formula and adult nutritionals — Determination of minerals and trace elements — Inductively coupled plasma mass spectrometry (ICP-MS) method
ISO 22964 : 2017	:	Microbiology of the food chain — Horizontal method for the detection of *Cronobacter* spp.
EN 13130-13 : 2005	:	Materials and articles in contact with foodstuffs – Plastics substances subject to limitation — Part 13: Determination of 2,2-bis(4-hydroxyphenyl) propane (Bisphenol A) in food simulants

ANNEX B
(*Table* 2)

SAMPLING PLAN FOR MICROBIOLOGICAL REQUIREMENTS

B-1 SAMPLING PLAN FOR MICROBIOLOGICAL REQUIREMENTS

The terms *n*, *c*, *m* and *M* used in this standard have the following meaning:

n = Number of units comprising a sample.
c = Maximum allowable number of units having microbiological counts above m for 2- class sampling plan and between *m* and *M* for 3- class sampling plan.
m = Microbiological limit that separates unsatisfactory from satisfactory in a 2- class sampling plan or acceptable from satisfactory in a 3-class sampling plan.
M = Microbiological limit that separates unsatisfactory from satisfactory in a 3-class sampling plan.

B-2 INTERPRETATION OF RESULTS

2-Class Sampling Plan (where n, c and m are specified)	*3-Class Sampling Plan (where n, c, m and M are specified)*
1. Satisfactory, if all the values observed are $\leq m$	1. Satisfactory, if all the values observed are $\leq m$
2. Unsatisfactory, if one or more of the values observed are > *m* or more than *c* values are > *m*	2. Acceptable, if a maximum of *c* values are between *m* and *M* and the rest of the values are observed as $\leq m$
	3. Unsatisfactory, if one or more of the values observed are > *M* or more than *c* values are > *m*

ANNEX C
(*Foreword*)

COMMITTEE COMPOSITION

Dairy Products and Equipment Sectional Committee, FAD 19

Organization	*Representative(s)*
National Dairy Research Institute, Karnal	DR DHEER SINGH (***Chairperson***) PROF M. S. CHAUHAN (***Former Chairperson***)
All India Food Processors Association, New Delhi	DR K. L. GABA SHRI VIJAY GAUR (*Alternate*)
Bihar State Cooperative Milk Producers' Federation Limited, (COMPFED), Delhi	SHRI SUSHIL KUMAR SHRI RUPESH RAJ (*Alternate*)
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Confederation of Indian Industry, New Delhi	MS NEHA AGGARWAL MS ARTI GUPTA (*Alternate*)
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Envirocare Labs Private Limited, Thane	DR NILESH AMRITKAR DR PRITI AMRITKAR (*Alternate*)
Export Inspection Council of India, New Delhi	DR J. S. REDDY SHRI KUMAR NARENDER (*Alternate*)
Food Safety and Standards Authority of India, New Delhi	DR MONICA PUNIYA MS TRIPTI TAYAL (*Alternate*)
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ICMR-National Institute of Nutrition, Hyderabad	DR B SANTOSH KUMAR DR SYLVIA FERNANDEZ RAO (*Alternate*)
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National Dairy Research Institute, Karnal	DR VIVEK SHARMA DR RAJESH KUMAR BAJAJ (*Alternate*)
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Panel for Revision of Indian Standards on Infant Foods, FAD 19-FAD 24 Joint Panel 10

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