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Indian Standard

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शिशु दुग्ध विकल्प — विशिष्टि

(दूसरा पुनरीक्षण)

Infant Milk Substitutes — Specification

(Second Revision)

ICS 67.100.99

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FOREWORD

This Indian Standard (Second Revision) 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, when breast feeding is not possible, reliance has to be placed upon the alternate sources of nutrients for infant feeding. It is imperative that infant milk substitutes should be properly formulated so that nutritional requirements for optimal growth of the infant are met adequately, and that there is minimum of physiological stress on the developing organs and enzymatic system of the infant. It is equally important to promote correct feeding practices, so that appropriate use of the infant milk substitute could be made for protecting the health of the infant. Under the *Infant Milk Substitutes, Feeding Bottles and Infant Foods* (*Regulation of Production, Supply and Distribution*) *Act,* 1992, various types of foods for infants being marketed in our country have been placed under the following two categories:

a) Infant milk substitutes, and

b) Infant foods.

'Infant milk substitute' means any food being marketed or otherwise represented as partial or total replacement for mother's milk and covers infant formula and infant milk food. Whereas 'infant food' means any food being marketed or otherwise represented as a complement to mother's milk to meet the growing nutritional needs of the infant after the age of six months and up to the age of two years. Infant foods cover follow up formula, milk cereal based complementary foods and processed cereal based complementary foods.

Earlier, the requirements of infant milk substitutes were covered under separate standards, namely, IS 1547 : 1985 'Infant milk food' and IS 11156 : 1985 'Infant formulae'. In order to align with the *Infant Milk. Substitutes Feeding Bottles and Infant Foods* (*Regulation of Production Supply and Distribution*) *Act,* 1992, these standards were revised and amalgamated into one comprehensive standard, IS 14433 (Part 1) : 1997 'Infant milk substitutes — Specification: Part 1 Milk protein based'; and IS 1547 and IS 11156 were consequently withdrawn. IS 14433 (Part 1) covered infant milk substitutes which were milk protein based and Part 2 of the standard was intended to cover vegetable protein based infant milk substitutes, which however was not formulated. IS 14433 (Part 1) was subsequently revised and published as IS 14433 : 2007 'Infant milk substitutes — Specification (*first revision*)' cancelling IS 14433 (Part 1) : 1997. The first revision was brought out to include requirements for lactose free infant milk substitutes, lactose and sucrose free infant milk substitutes and sucrose free infant milk substitutes which involve substitution of milk protein by soya protein. In the first revision, requirements for hypoallergenic infant milk substitutes were also included and the chemical and microbiological requirements for the products were updated and the requirements were harmonized with the *Food Safety and Standards Act*, 2006 and the Rules and Regulations framed thereunder.

A scheme for labelling environment friendly products known as ECO-Mark was also introduced in the first revision at the instance of the Ministry of Environment and Forests, Government of India. 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.

Amendments were later issued to IS 14433 : 2007 in August 2007, May 2008, December 2012, May 2013 and December 2016.

(*Continued on third cover*)

Indian Standard

INFANT MILK SUBSTITUTES — SPECIFICATION

(Second Revision)

1 SCOPE

This standard prescribes the types, requirements, methods of test and sampling for 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

For the purpose of this standard, the following definitions shall apply.

3.1 Infant Milk Food — A breast milk substitute product based on milk (*see* **4** of IS 13688) which has been proven to be suitable for infant feeding to meet the nutritional requirements of infant during the first six months. The milk may be modified by the partial removal/substitution of different milk solids, carbohydrates, salts such as phosphates, citrates; vitamins and minerals.

3.2 Infant Formula — A breast milk substitute product based on milk (*see* **4** of IS 13688) and other ingredients which has been proven to be suitable for infant feeding, to meet the nutritional requirements of infant during the first six months. The product may be modified by the partial removal/substitution of milk fat with edible vegetable oils rich in polyunsaturated fatty acids and/or by different milk solids, either singly or in a suitable combination; carbohydrates; salts such as phosphates and citrates; vitamins and minerals. The product may be in liquid or powdered form. Vegetable oils rich in polyunsaturated fatty acids may be added to partially substitute milk fat to an extent that the product shall contain a minimum of 12 percent by mass of milk fat.

3.3 Infant — A child not more than 12 months of age.

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

3.5 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

Infant milk substitutes shall be of the following two types:

a) *Type I* — Infant milk food, and
b) *Type II* — Infant formula.

5 REQUIREMENTS

5.1 Description

The product shall be white or white with a greenish tinge to light cream 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 scorched particles in the product shall not exceed 15 mg (equivalent to Disc B) when tested as per the method given in IS 13500.

5.3 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 per cent of total carbohydrate.

NOTE — For the purpose of the above clause, record of the addition may be maintained by the manufacturer since analytical methods have not been established for these.

5.4 Type I infant milk substitute/infant milk food shall be free from starch and added antioxidants.

5.5 Type II infant milk substitute/infant formula may contain the following optional ingredients:

a) Only precooked and/or gelatinised starches gluten-free by nature up to 30 percent of total carbohydrates and up to 2 g/100 ml;

b) Vegetables oils may be added to partially substitute milk fat to an extent that the product shall contain a minimum of 12 percent by weight of milk fat. The vegetable oils added shall be rich in polyunsaturated fatty acids. It may contain medium chain triglycerides. Hydrogenated vegetable oils and fats shall not be used; and

c) Fructo-oligosaccharides and/or galacto-oligosaccharides, not exceeding 0.8 g/100 ml in either case; when used in combination, the percentage ratio shall be 90 : 10 of galacto-oligosaccharides and fructo-oligosaccharides, respectively.

5.6 Type I and Type II infant milk substitutes ready for consumption in accordance with instructions of the manufacturer shall contain not less than 60 kcal and not more than 70 kcal of energy per 100 ml.

5.7 Optional Ingredients

Type II infant milk substitutes may contain in addition to the vitamin and minerals listed in Table 2, other nutrients ordinarily found in human milk in amounts prescribed in Table 1.

5.7.1 Type II infant milk substitutes may also contain algal and fungal oil as sources of Docosahexaenoic Acid (DHA) and Arachidonic acid (ARA) from *Crypthecodiniumcohnii*, *Mortierellaalpina*, *Schizochytrium* sp., and *Ulkenia* sp. or fish oil at the level of maximum 0.5 percent DHA of total fatty acids and ratio of ARA : DHA as 1 : 1 minimum.

NOTE — DHA content shall not be less than 0.2 per cent of total fatty acids, if a claim related to the addition of DHA is made.

Table 1 Optional Ingredients

(*Clause* 5.7)

Sl No.	Nutrients	Requirement per 100 ml of the Product Ready for Consumption	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Carotenes, mg, *Min*	0.025	IS 17671
ii)	Amino acids (L-form), mg, *Min*	0.90	AOAC 2018.06
iii)	Non-protein nitrogen, mg, *Min*	17.00	ISO 8968-4
iv)	Nucleotides, mg, *Min*	1.17	IS 16641
v)	L-Carnitine, mg, *Min*	0.72	IS 17668
vi)	Lactalbumin, mg, *Min*	140.00	*See* Note 2
vii)	Lactoferrin, mg, *Min*	27.00	*See* Note 2
viii)	Lysozyme, mg, *Min*	80.00	ISO 27105
ix)	Glucosamine, mg, *Min*	70.00	*See* Note 2
x)	Inositol, mg, *Min*	2.70	IS 16649* or any other validated international method
xi)	Citric acid, mg, *Min*	35.00	IS 12757
xii)	Cholesterol, mg, *Min*	8.80	*See* Note 2
xiii)	Fucose, mg, *Min*	130.00	*See* Note 2
xiv)	Lipid phosphorus, mg, *Min*	0.70	AOAC 923.07
xv)	Prostaglandins, mg, *Min*	PGE 15.00 PGF 40.00	*See* Note 2
xvi)	Taurine, mg, *Max*	8.40	AOAC 2018.06* or AOAC 997.05
xvii)	Molybdenum, µg	0.90-6.50	ISO 20649
xviii)	Chromium, µg	0.90-6.50	ISO 20649

NOTES

1 When any of the above nutrients is added, the amount of these added nutrients shall be declared on the label. A variation of minus 10.0 per cent from the declared value of the nutrients or nutritional ingredients on the label shall be allowed.

2 Any validated international method may be used.

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

5.8 Food Additives

5.8.1 Type I Infant milk substitute shall not contain food additives.

5.8.2 The following food additives may be used in the preparation of Type II infant milk substitute ready for consumption prepared following manufacturer's instructions, unless otherwise indicated:

Food Additives	Maximum Level in 100 ml of the Product Ready-for-Consumption
Thickeners	
Guar gum	0.1 g in liquid formulas containing hydrolysed protein
Locust bean gum (carob bean gum)	0.1 g in all types of infant formula
Distarch phosphate	0.5 g singly or in combination in soy based infant formula only; 2.5 g singly or in combination in hydrolysed protein and/or amino acid based infant formula only
Acetylated distarch phosphate	
Phosphated distarch phosphate	
Hydroxy propyl starch	
Carrageenan	0.03 g (in regular milk and soy based liquid infant formula only); 0.1 g in hydrolyzed protein and/or amino acid based liquid infant formula only)
Emulsifiers	
Lecithin	0.5 g in all types of infant formula*
Mono- and diglycerides	0.4 g in all types of infant formula*
Citric and fatty acid esters of glycerol	0.9 g in all types of liquid infant formula 0.75 g in all types of powdered infant formula
Acidity Regulators	
Sodium hydroxide	0.2 g singly or in combination and within the limits for sodium, potassium and calcium specified in Table 2 in all types of infant formula
Sodium hydrogen carbonate	
Sodium carbonate	
Potassium hydrogen carbonate	
Potassium carbonate	
Potassium hydroxide	
Calcium hydroxide	
L (+) lactic acid L (+) lactic acid producing cultures	GMP in all types of infant formula
Potassium citrate	
Citric acid	
Sodium dihydrogen citrate	
Trisodium citrate	
Potassium citrate	
Sodium dihydrogen phosphate, disodium hydrogen phosphate and trisodium phosphate	45 mg as phosphorus singly or in combination and within limits for sodium, potassium and phosphorus in Table 2 in all types of infant formula
Potassium dihydrogen phosphate, dipotassium hydrogen phosphate and tripotassium phosphate	

Food Additives	Maximum Level in 100 ml of the Product Ready-for-Consumption
Antioxidants	
Mixed tocopherols concentrate	1 mg in all types of infant formula singly or in combination
L-Ascorbyl palmitate	
Packaging Gases	
Carbon dioxide	GMP
Nitrogen	

**If more than one of the substances (lecithin and monoglycerides/diglycerides) are added the maximum level for each of those substance is lowered with the relative part as present of the other substances.*

5.8.3 For reasons of stability and safe handling, some vitamins and other nutrients have to be converted into suitable preparations. For this purpose, the following food additives may be used as nutrient carriers in Type II infant milk substitutes:

Additive/Carrier	Recommended Maximum Level in Ready-to-Use foods for Infant Nutrition (mg/kg)
Gum Arabic (gum acacia)	10
Silicon dioxide	10
Mannitol (for vitamin B_{12} dry rubbing, 0.1 percent only)	10
Starch sodium octenyl succinate	100
Sodium L-ascorbate (in coating of nutrient preparations containing polyunsaturated fatty acids)	75

5.9 Quality of Ingredients

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

5.9.2 The vitamins, minerals and other nutrients shall be of food grade. Wherever applicable, infant milk substitutes 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 phosphate monobasic (calcium dihydrogen phosphate), calcium phosphate dibasic (calcium hydrogen phosphate), calcium phosphate tribasic (tricalcium diphosphate);

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 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;

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;

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 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;
10) *Zinc (Zn)* — Zinc acetate, zinc chloride, zinc oxide, zinc sulphate, zinc gluconate, zinc lactate, 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;
12) *Selenium* — 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-alpha-tocopherol, DL-alpha-tocopherol, D-alpha-tocopheryl acetate, DL-alpha-tocopheryl acetate;
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* — 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;
13) *Biotin (Vitamin H)* — D-biotin;
14) *Vitamin* B_{12} — Cyanocobalamin, hydroxo-cobalamin; and
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
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*; *and*
20) *L-Valine.*

d) Carnitine
1) *L-Carnitine*;
2) *L-Carnitine hydrochloride*; *and*
3) *L-Carnitine tartarate*.

e) Taurine
1) *Taurine*

f) Choline
1) *Choline*;
2) *Choline chloride*;
3) *Choline citrate*;
4) *Choline hydrogen tartrate*; *and*
5) *Choline bitartrate*.

g) Inositols
1) *Myo-inositol*

h) Nucleotides
1) *Adenosine 5-monophosphate (AMP)*;
2) *Cytidine 5-mono phosphate (CMP)*;
3) Guanosine 5-mono phosphate (GMP);
4) *Inosine 5-mono phosphate (IMP)*;
5) *Disodium Uridine 5-monophosphate salt*;
6) *Disodium Guanosine 5-mono phosphate salt*; *and*
7) *Disodium inosine 5-mono phosphate salt*.

5.10 The product shall also conform to the requirements given in Table 2 (either per 100 g or 100 kcal basis) and Table 3.

Table 2 Requirements for Infant Milk Substitutes (Type I and Type II)

(*Clauses* 5.7 *and* 5.10)

Sl No.	Characteristic	Requirements per 100 g	Requirements per 100 kcal	Method of Test, Ref to
(1)	(2)	(3)	(4)	(5)
i)	Moisture, percent by mass, *Max*	4.50	–	IS 11623 for reference purpose IS 16072 for routine purpose
ii)	a) Total protein (N × 6.25), percent by mass	10.00 - 16.00	2.10 - 3.40	IS 11917
	b) Milk protein (N × 6.38), percent by mass, *Min* (only for Type I)	12.00	2.50	
iii)	Fat[1], percent by mass			IS 11721
	a) Total fat, including milk fat (for Type II)	18.00 - 25.00	3.80 - 5.30	
	b) Milk fat[3], *Min*	18.00 (Type I) 12.00 (Type II)	3.80 (Type I) 2.50 (Type II)	
iv)	a) Linoleic acid, mg	1500.00 - 7000.00	300.00 - 1500.00	Annex B or
	b) α-Linolenic acid, mg, *Min*	250.00	50.00	ISO 16958*
	c) Ratio of linoleic acid and α-linolenic acid, *Min* (only for Type II)	6 : 1	6 : 1	
v)	Carbohydrates, percent by weight	45.00 - 70.00	9.60 - 14.90	Annex C of IS 1656
vi)	Total ash, percent by mass, *Max*	8.50	–	Annex C
vii)	Acid insoluble ash, percent by mass, *Max*	0.10	–	Annex D
viii)	Solubility index, ml/100 g, *Max*	2.0	–	IS 12759
ix)	Vitamin A (as retinol equivalent, RE), µg	350.00 - 823.00	75.00 - 175.00	IS 16639
x)	Vitamin D, µg	5.00 - 14.00	1.00 - 3.00	IS 17177
xi)	Vitamin E (as α-tocopherol equivalent), mg (only for Type-II)	2.50 - 6.00	0.50 - 1.30	IS 16639
xii)	Vitamin K, µg	7.50 - 19.00	1.60 - 4.00	IS 21446
xiii)	Vitamin C, mg	25.00 - 75.00	5.30 - 16.00	IS 5838 or IS 17176*
xiv)	Thiamine, µg	200.00 - 517.00	42.50 - 110.00	IS 17669
xv)	Riboflavin, µg	400.00 - 2000.00	85.10 - 425.50	IS 17669
xvi)	Niacin equivalent, mg	3.80 - 9.90	0.80 - 2.10	IS 17669
xvii)	Vitamin B_6 (pyridoxine), µg	100.00 - 400.00	21.30 - 85.10	IS 17669
xviii)	Dietary folate equivalent (DFE)[3], µg	15.00 - 56.90	3.20 - 12.10	AOAC 2013.13
xix)	Pantothenic acid, mg	2.00 - 10.00	0.42 - 2.12	IS 16642
xx)	Vitamin B_{12}, µg	0.25 - 4.50	0.05 - 0.90	IS 16640* or AOAC 2014.02
xxi)	Biotin, µg	7.50 - 50.0	1.60 - 10.60	IS 17670
xxii)	Choline, mg, *Min*	32.00	6.80	IS 17668
xxiii)	Iron, mg	3.00 - 7.00	0.60 - 1.50	AOAC 985.35 or ISO 15151 or ISO 21424*
xxiv)	Sodium, mg	90.00 - 300.00	19.15 - 63.80	IS 12760 or ISO 15151 or ISO 21424*
xxv)	Potassium, mg	300.00 - 900.00	63.82 - 191.48	IS 12760 or ISO 15151 or ISO 21424*
xxvi)	Chloride, mg	250.00 - 800.00	53.20 - 170.20	IS 11763 or AOAC 2016.03*
xxvii)	Calcium, mg	250.00 - 700.00	53.20 - 148.90	IS 12760 or ISO 15151 or ISO 21424*

Table 2 (*Concluded*)

Sl No.	Characteristic	Requirements per 100 g	Requirements per 100 kcal	Method of Test, Ref to
(1)	(2)	(3)	(4)	(5)
xxviii)	Phosphorus, mg	125.00 - 500.00	26.60 - 106.40	IS 12756 or ISO 15151 or ISO 21424*
xxix)	Calcium: phosphorus ratio	1:1 - 2:1	1:1 - 2:1	Sl. No. xxvii divided by Sl. No. xxviii
xxx)	Magnesium, mg	30.00 - 75.20	6.40 - 16.00	IS 12760 or ISO 15151 or ISO 21424*
xxxi)	Iodine, µg	90.00 - 225.60	19.15 - 48.00	IS 17379
xxxii)	Copper, µg	160.00 - 470.00	34.00 - 100.00	**15** of IS 1699 or ISO 15151 or ISO 21424*
xxxiii)	Zinc, mg	2.50 - 5.90	0.50 - 1.25	**15** of IS 1699 or ISO 15151 or ISO 21424*
xxxiv)	Manganese, µg	5.00 - 500.00	1.00 - 106.40	ISO 15151 or ISO 21424*
xxxv)	Selenium, µg	5.00 - 40.00	1.00 - 9.00	IS 15303 or ISO 15151 or ISO 20649*

NOTES

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

2 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. (i) to (iii) (except fatty acid profile), (v) to (ix) and (xxiii) are to be carried out.

3 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 Table 2.

[1] Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20 per cent of total fatty acids. The erucic acid content when determined as per ISO 16958 shall not exceed 1 per cent of total fatty acids. The total content of phospholipids shall not exceed 300 mg/100 kcal. The method given in ISO 16958 shall be used for this purpose. The contents of trans fatty acids when determined as per the method given in Annex F of IS 10633 shall not exceed 3 per cent of total fatty acids (except in Type I infant milk substitutes).

[2] In case of Type II infant milk substitutes, since there is no reliable methods at present for the estimation of separate contents of milk fat (12 percent min) and vegetable fat in the total fat, records of their addition shall be maintained by the manufacturer. However, the product shall not have less than 18 percent total fat when tested as per IS 11721.

[3] 1 microgram DFE = 0.6 microgram folic acid.

Table 3 Microbiological Requirements for Infant Milk Substitutes (Type I and Type II)

(*Clause* 5.10)

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 E.

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.

5.11 The pesticide residues, antibiotic and veterinary drug residues, naturally occurring toxins 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.

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

5.13 Hygienic Conditions

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

5.14 Optional Requirement for ECO-Mark

5.14.1 *General Requirements*

5.14.1.1 The product shall conform to the requirements prescribed under **5.1** to **5.13**.

5.14.1.2 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.

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

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

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

5.14.1.6 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.

Table 4 Limits of Heavy Metals and Other Contaminants or Toxic Substances

(*Clause* 5.12)

Sl No.	Contaminant/Toxin	Limit	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Lead, ppm, *Max*	0.2 0.02 (ready-to-use Type II infant milk substitutes)	IS 12074 or AOAC 2015.01*
ii)	Arsenic, ppm, *Max*	0.05	IS 11124 or AOAC 2015.01*
iii)	Tin, ppm, *Max*	5.0	ISO 14377
iv)	Cadmium, ppm, *Max*	0.1	**15** of IS 1699 or AOAC 2015.01*
v)	Melamine, ppm, *Max*	1.0 (Type I and Type II) 0.15 (Liquid Type II)	IS 16195

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

5.14.2 *Specific Requirements*

5.14.2.1 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.

5.14.2.2 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 used for the product shall be free from Bisphenol A (BPA).

6.1.2 The product shall be packed in quantities as stipulated under *Legal Metrology* (*Packaged Commodities*) *Rules*, 2011 as well as 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) Directions for storage;
j) Composition — Indicating the approximate composition of nutrients per 100 g or per 100 ml of the product as well as the energy value in kilocalories or kilojoules;
k) In case fish oil is used, it shall be mentioned on the label;
m) Feed chart and directions for use;
n) Instructions for discarding leftover feed;
p) Instructions for use of measuring scoop (level or heaped) and the quantity per scoop (scoop to be given with pack);
q) Statement in bold letters: "IMPORTANT NOTICE: MOTHER'S MILK IS BEST FOR YOUR BABY;
r) A statement that infant milk substitute shall be used only on the advice of a health worker as to the need for its use and the proper method of its use;
s) A warning that Infant milk substitute is not the sole source of nourishment of an infant;
t) A statement indicating instruction for appropriate and hygienic preparation including cleaning of utensils, bottles and teats and warning against health hazards of inappropriate preparations as under:

u) **Warning/Caution** — Careful and hygienic preparation of infant foods or infant milk substitute is most essential for health. Do not use fewer scoops than directed since diluted feeding will not provide adequate nutrients needed by your infant. Do not use more scoops than directed since concentrated feed will not provide the water needed by your infant; and

v) Any other requirements as stipulated under *Food Safety and Standards* (*Labelling and Display*) *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.

ANNEX A

(*Clause* 2)

LIST OF REFERRED STANDARDS

IS No./Other Publication	*Title*
1699 : 1995	Methods of sampling and test for food colours (*second revision*)
1656 : 2022	Milk-cereal based complementary foods — Specification (*fifth revision*)
2491 : 2013	Food hygiene — General principles — Code of practice (*third revision*)
5402 (Part 1) : 2021/ ISO 4833-1 : 2013	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
10171 : 1999	Guide on suitability of plastics for food packaging (*second revision*)
10633 : 2017	Vanaspati — Specification (*third 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*)
11124 : 1984	Method for atomic absorption spectrophotometric determination of arsenic
11623 : 2008/ ISO 5537 : 2004	Dried milk — Determination of moisture content (Reference Method) (*first 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*)
11917 : 2018/ ISO 8968-1 : 2014	Milk and milk products — Determination of nitrogen content — Kjeldahl principle and crude protein calculation (*first revision*)
12074 : 1987	Method for determination of lead by atomic absorption spectrophotometer

IS No./Other Publication	*Title*
12756 : 2019/ ISO 2962 : 2010	Cheese and processed cheese products — Determination of total phosphorus content — Molecular absorption spectrometric method (*first revision*)
12757 : 2012/ ISO/TS 2963 : 2006	Cheese and processed cheese products — Determination of citric acid content — Enzymatic method
12759 : 2019/ ISO 8156 : 2005	Dried milk and dried milk products — Determination of insolubility index (*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*)
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
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
16072 : 2012	Determination of moisture content in milk powder and similar products (Routine method)
16195 : 2014/ISO/TS 15495 : 2010	Milk, milk products and infant formulae — Guidelines for the quantitative determination of melamine and cyanuric acid by LC-MS/MS
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)
16641 : 2018/ ISO 20638 : 2015	Infant formula — Determination of nucleotides by liquid chromatography
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)

IS No./Other Publication	*Title*
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
17671 : 2021/ ISO 23443 : 2020	Infant formula and adult nutritionals — Determination of beta-carotene lycopene and lutein by reversed-phase ultra-high performance liquid chromatography RP-UHPLC
IS/ISO 21446 : 2019	Infant formula and adult nutritionals — Determination of trans and total cis trans Vitamin K_1 content — Normal phase HPLC
ISO 8968-4 : 2001	Milk — Determination of nitrogen content — Part 4: Determination of non-protein-nitrogen content
ISO 14377 : 2002	Canned evaporated milk — Determination of tin content — Method using graphite furnace atomic absorption spectrometry
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 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.
ISO 27105 : 2016	Milk and cheese — Determination of hen's egg white lysozyme content by high performance liquid chromatography

ANNEX B

[*Table* 2, *Sl No.* (iv)]

METHOD OF DETERMINATION OF LINOLEIC ACID

B-0 GENERAL

The method is of special application to determination of linoleic and linoleic acid in products containing little or no other polyunsaturated acids.

B-1 DEFINITION

Polyunsaturated fatty acids in which the double bonds are not conjugated are spectroscopically transparent in the ultra-violet region of the spectrum, that is, they show no absorption bands. On conjugation, linoleic acid, linolenic acid and any higher unsaturated constituents show ultra-violet absorption bands at specific wavelengths. Provided the behaviour of pure sample of these acids under the same standardized conditions has been determined, the amount of each acid present can be calculated. The calculation takes into account the fact that in a mixture of linoleic and linolenic acids (or as esters and soaps), all the triple conjugation shall arise from the linolenic acid whereas the double conjugation arises from both linoleic and linolenic acids.

B-2 PRINCIPLE

The fatty acid mixture under test is heated with a reagent prepared from glycerol and caustic potash under standard conditions, and the reacted mixture is diluted with alcohol to a fixed volume. The ultra-violet absorption of the solution is then measured in a spectrophotometer at 234 and 268mμ and the linoleic and linolenic acids calculated.

B-3 REAGENTS

B-3.1 Glycerol /Potassium Hydroxide Reagent — Add 17.5 to 17.7 g potassium hydroxide to 100 ml (126 g) of glycerine and heat the mixture in an open stainless steel beaker to 200 °C stirring with a thermometer to drive off water. Small pellet of potassium hydroxide is preferable and should be taken from a recently opened or a previously used but well-sealed bottle. On reaching 200 °C, remove the source of heat and allow to cool. The strength should be 10.9 to 11.0 percent (*m/m*) potassium hydroxide. The reagent should always be freshly prepared before use.

B-3.2 Ethyl Alcohol — Obtained from industrial methylated spirit by fractional distillation over potassium hydroxide in a suitable fractionating column. Collect the distillate in three main fractions and reserve the middle fraction for use in the test, after having checked the transmittance at 234 to 268 nm. Between 60 to 70 percent transmittance at these wavelengths is considered satisfactory.

B-4 APPARATUS

B-4.1 Suitable Spectrophotometer

B-4.2 Heat-resistant Glass Boiling Tubes, 15 × 2.5 cm.

B-4.3 Oil-bath, capable of being maintained at 180 ± 0.5 °C.

B-4.4 Small Tubes, about 20 × 10 mm, closed at one end (iodine value tubes).

B-4.5 Solid Stem Thermometer, reading up to 200 °C.

B-4.6 Graduated Flasks, 50 ml.

B-5 PROCEDURE

The procedure for determination of linoleic and linolenic acids in products containing little or no other polyunsaturated acid is provided as Table B-1.

B-6 CALCULATION

B-6.1 Calculate the *E* (1 percent, 1 cm) values at 234 nm (or the relevant diene peak maximum wave length) and at 268 nm as follows:

$$E\ (1\ \text{percent}, 1\ \text{cm}) = \frac{\text{Observed optical density}}{C \times L}$$

where,

C = concentration of sample solution in gram per 100 ml, and

L = light path length of absorption cell in centimetres.

B-6.1.1 Calculate the percent linoleic and linolenic acids according to the following:

Linoleic acid, percent = 0.113 *E* (1percent, 1 cm) 234 nm − 0.127 *E* (1 percent, 1 cm) 268 nm

Linolenic acid, percent = 0.187 *E* (1 percent, 1 cm) 268 nm

NOTE — If results are required to be calculated to a glyceride basis, multiply by 1.05 in each case.

Table B-1 Procedure for Determination of Linoleic and Linolenic Acids

(*Clause* B-5)

Sl No.	Step	Precaution	Explanatory Note
(1)	(2)	(3)	(4)
i)	Weigh 11g glycerol/potassium hydroxide reagent into each of three 15 × 2.5 cm glass boiling tubes.	± 0.01 g	Two of these are for duplicate determinations and the third a control
ii)	Immerse these in an oil-bath heated to 180 ± 0.5 °C.	See that the liquid in the tubes is entirely covered.	—
iii)	Take the temperature by means of a thermometer arranged so that the bulb lies centrally in the liquid in control tube.	The bath shall be steady at 180 °C at the time of Inserting the tubes.	Undue heating of the reagent promotes attack on the glass tubes, causing turbidity, and also affecting the precision of the test.
iv)	Weigh accurately into each of two iodine value tubes about 0.1g of fatty material.	—	—
v)	Place one of these each into two of the boiling tubes containing the reagent. Place an empty tube into the control.	—	—
vi)	As the addition is made to an individual tube, remove it from the batch and swirl vigorously for 30 seconds.	—	With fatty acids, the saponification proceeds easily but If neutral glyceride oils are being tested, saponification does not take place readily, and low results may be obtained, caused by oxidation and polymerization at 180 °C.
		—	If even a small amount of free fatty acid is present, the saponification proceeds satisfactorily, presumably owing to the immediate formation of a little soap which promotes emulsification of the phases
		In case of difficulty experienced from this cause, add 0.1 g of pure stearic acid (± 0.05 g) in both the test control tubes.	Isomerisation will then proceed smoothly.
vii)	Return each tube to the bath and maintain if at 180 °C for exactly 30 min.	—	—
viii)	Remove each tube precisely at the end of this period, cool a little and add 10 to 20 ml alcohol.	—	—
ix)	Swirl vigorously, while maintaining it in a warm condition	—	—
x)	Transfer each solution to a 50 ml graduated flask, washing it with about 20 ml alcohol.	—	—
xi)	Cool each flask to room temperature and make up to volume with alcohol.	—	—
xii)	Dilute each suitably (*see* Table B-2) with alcohol and with the control dilution in the reference cell. Determine the ultra-violet absorption over the range of 225-300 nm.	Silica absorption cells shall be used. The whole curve is not essential but it is advisable to see that there are no abnormalities present of a material of unknown origin is being examined.	For samples containing large proportions of linoleic and/or linolenic acids, the diene peak maximum may be found to shift from 234 nm to 232 or 231 nm. Accordingly, peak maximum wavelength should be determined for such samples. Samples of marine origin will show peaks at 301, 315, 345 nm and even longer wavelengths. The presence of acids causing these peaks renders the formulae given below invalid. The diene wavelength shift is very likely caused by formation of different mixtures of conjugated geometric isomers.
xiii)	Calculate percent linoleic and linolenic acids as indicated below.	—	—

NOTE — Natural fats (other than a few exceptions, such as, tung oil) contain no conjugated acids. The ultra-violet absorption of fatty acids derived from natural fats before isomerization is usually negligible and ultra-violet measurement need only be carried out after isomerization. In the case of tung oil fatty acids and certain processed oil fatty acids, for example, acids from partially hydrogenated oils where a measurable amount of conjugation is present, examination shall be carried out before isomerization.

Table B-2 Dilutions Required for Original Sample Solution

(*Table* B-1)

Sl No.	Material	For Reading at 234 nm			For Reading at 268 nm		
		Volume of original solution to be taken	To be diluted to	Percent sample in solution	Volume of original solution to be taken	To be diluted to	Percent sample in solution
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
i)	Bonegreases, follows and derived fatty acids, oleines of iodine value than 90	2 ml	25 ml	0.016	2 ml	25 ml	0.016
ii)	Groundnut oil and derived fatty acids, oleines of iodine value greater than 90	1 ml	25 ml	0.008	1 ml	25 ml	0.008
iii)	Linoleic acid and its esters, sunflower seed tobacco seed, nigerseed oils, etc. and derived fatty acids	1 ml then 1 ml (A)	25 ml (A) 25 ml	0.000 64	2 ml	25 ml	0.016
iv)	Soybean oil and derived fatty Acids	1 ml then 1 ml	25 ml (A) 25 ml	0.000 64	1 ml	25 ml	0.008
v)	Linolenic acid and its esters, linseed oil, etc, and derived fatty acids	2 ml then 1 ml (A)	25 ml (A) 25 ml	0.000 64	2 ml then 1 ml (A)	25 ml (A)	0.000 64
vi)	Tall oil fatty acids	Dilutions should be prepared as given for linolelc acid and its esters, etc, but a correction should be made, by subtracting from the calculated linoleic acid content half the percentage of resin acids found.					

ANNEX C

[*Table* 2, *Sl No.* (vi)]

DETERMINATION OF TOTAL ASH

C-1 APPARATUS

C-1.1 Flat Bottom Dish, of stainless steel, porcelain, Silica or platinum.

C-1.2 Muffle Furnace, maintained at 550 ± 20 °C.

C-1.3 Desiccator

C-2 PROCEDURE

Weigh accurately 3 g of the material in the dish, previously dried in an air-oven and weighed. Heat the dish gently on a flame at first and then strongly in a muffle furnace till grey ash results. Cool the dish in a desiccator and weigh. Heat the dish again for 30 min in the muffle furnace. Cool the dish in a desiccator and weigh. Repeat this process of heating for 30 min, cooling and weighing until the difference between two successive weighings is less than 1 mg. Record the lowest mass.

NOTE — Preserve the dish containing the ash for the determination of acid insoluble ash (*see* **C-3**).

C-3 CALCULATION

Total ash, percent by mass =

$$\frac{100\,(M_2 - M)}{M_1 - M}$$

where

M = mass of the empty dish, in g;

M_1 = mass of the dish with the material taken for the test, in g; and

M_2 = mass of the dish with the ash, in g.

ANNEX D

[*Table* 2, *Sl No.* (vii)]

DETERMINATION OF ACID INSOLUBLE ASH

D-1 APPARATUS

D-1.1 Flat-Bottom Dish, of stainless steel, porcelain, silica or platinum.

D-1.2 Muffle Furnace, maintained at 550 ± 20 °C.

D-1.3 Desiccator

D-2 REAGENT

D-2.1 Dilute Hydrochloric Acid, *5* N prepared from concentrated hydrochloric acid.

D-3 PROCEDURE

To the ash contained in the dish (*see* Note under **C-2**), add 25 ml of dilute hydrochloric acid. Cover with a watch-glass and heat on a water bath for 10 min. Allow to cool and filter the contents of the dish through a Whatman filter paper No. 42 or its equivalent. Wash the filter paper with water until the washings are free from the acid and return it to the dish. Keep it in an oven maintained at 100 ± 2 °C for about 3 h. Ignite in a muffle furnace at 550 ± 20 °C for 1 h. Cool the dish in a desiccator and weigh. Heat the dish again at 550 ± 20 °C for 30 min, cool in a desiccator and weigh. Repeat this process for heating for 30 min, cooling and weighing until the difference between two successive weighings is less than 1 mg. Record the lowest mass.

D-4 CALCULATION

Acid insoluble ash, percent by mass =

$$\frac{100\,(M_2 - M)}{M_1 - M}$$

where

M = mass of the empty dish, in g;

M_1 = mass of the dish with the material taken for the test, in g; and

M_2 = mass of the dish with the acid insoluble ash, in g.

ANNEX E

[*Table 3*]

SAMPLING PLAN FOR MICROBIOLOGICAL REQUIREMENTS

E-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; and

M = Microbiological limit that separates unsatisfactory from satisfactory in a 3-class sampling plan.

E-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 ≤ m 2. Unsatisfactory, if one or more of the values observed are > m or more than c values are > m	1. Satisfactory, if all the values observed are ≤ m 2. Acceptable, if a maximum of c values are between m and M and the rest of the values are observed as ≤ m 3. Unsatisfactory, if one or more of the values observed are > M or more than c values are > m

ANNEX F

(*Clause* 7)

SAMPLING OF INFANT MILK SUBSTITUTES

F-1 GENERAL REQUIREMENTS

F-1.0 In drawing, preparing, storing and handling Samples the following precautions and directions shall be observed.

F-1.1 Samples shall be taken in a protected place not exposed to damp air, dust or soot.

F-1.2 The sampling instrument shall be clean and dry when used. When taking samples for microbiological examination, it shall be sterile.

F-1.3 Precautions shall be taken to protect the samples, the material being sampled, the sampling instrument and the containers for samples from adventitious contamination.

F-1.4 The samples shall be placed in clean and dry glass containers. The sample containers shall be of such a size that they are almost completely filled by the sample. The sample containers shall in addition be sterile when they are used for samples for microbiological examination.

F-1.5 Each container shall be sealed air-tight after fining and marked with full details of sampling, batch or code number, name of the manufacturer and other important particulars of the consignment.

F-1.6 Samples shall be stored in such a manner that the temperature of the material does not vary unduly from the normal temperature.

F-2 SCALE OF SAMPLING

F-2.1 Lot

F-2.1.1 All the containers in a single consignment of one type of material drawn from a single batch of manufacture shall constitute a lot. If the consignment is declared to consist of different batches of manufacture, the batches shall be marked separately and the group of containers in each batch shall constitute separate lots.

F-2.1.2 Samples shall be tested for each lot as certain in g its conformity to the requirements of this standard.

F-2.2 The number of containers to be selected from the lot shall depend on the size of the lot and shall be as given in Table F-1.

Table F-1 Scale of Sampling for Containers of 400 g and Above

(*Clauses* F-2.2 *and* F-3.1)

Sl No.	Number of Containers in the Lot	Number of Containers to be Selected		
		Total	Group A	Group B
(1)	(2)	(3)	(4)	(5)
i)	50-100	3	2	1
ii)	101-300	5	3	2
iii)	301-500	7	4	3
iv)	501 and above	9	5	4

NOTES

1 The scale of sampling for containers of 200 g shall be as agreed to between the purchaser and the supplier.

2 The scale of sampling for less than 50 containers of 400 gin a lot shall be as agreed to between the purchaser and the supplier.

F-2.3 The containers shall be chosen at random from the lot. In order the ensure the randomness of selection, procedures as given in IS 4905 may be followed.

F-3 TEST SAMPLESAND REFEREE SAMPLES

F-3.1 The number of containers selected according to col 3 of Table F-1 shall be randomly divided into two groups, Group A and Group B under col 4 and 5. The number of containers in Group A shall be used for testing characteristics other than microbiological and the containers in Group B shall be used for testing microbiological specifications.

F-3.2 Draw with the suitable sampling instrument approximately equal quantity or material from different parts of each container in Group A till about 300 g of material is obtained. The quantity of material so obtained shall be thoroughly mixed and divided into three equal parts. Each part so obtained shall constitute an individual sample representing the container and shall be transferred immediately to thoroughly clean and dry sample container, sealed air-tight and labeled with the particulars given in **F-1.5**. The individual sample so obtained shall be divided into three sets in such a way that each set has a sample representing each selected container. One of these sets shall be marked

for the purchaser, another for the vendor and the third for the referee.

F-3.3 From the material from each selected container, remaining after the individual sample has been taken, approximately equal quantities of material shall be taken and mixed thoroughly so as to form a composite sample weighing about 300 g. This composite sample shall be divided into three equal parts and transferred to clean add dry containers sealed air-tight and labelled with the particulars as given in **F-1.5**. One of these composite samples shall be for the purchaser, another for the vendor and the third for the referee.

F-3.4 From each of the container in Group B, draw with a suitable sampling instrument which is sterile; at least 150 g of material and mix thoroughly in aseptic conditions to form a sample for microbiological examination. Divide sample (taking care not to bring any microbiological contamination in the material) into three equal parts. Each part so obtained shall constitute a sample representing the container and shall be transferred to sterile glass containers and shall be sealed air-tight and labelled with the particulars given in **F-1.5**. They shall be marked, in addition, with the words, 'For Microbiological Examination'. The sample so obtained shall be divided into three sets in such a way that each set has a sample representing each selected container. One of these sets shall be marked for the purchaser, another for the vendor and the third for the referee.

F-3.5 Referee Sample

Referee sample shall consist of a set of individual samples (*see* **F-3.1**), 8 composite samples (*see* **F-3.2**) and a set of samples for microbiological examination (*see* **F-3.3**) marked for this purpose and shall bear the seals of the purchaser and the vendor. These shall be kept at a place as agreed to between the two so as to be used in case of dispute.

F-4 NUMBER OF TESTS

F-4.1 Tests for determination of moisture, total milk protein, milk fat, total fat, total ash, acid insoluble ash and insolubility index as given in Table 2 shall be conducted on each of the samples constituting a set of individual samples.

F-4.2 Tests for microbiological specifications shall be conducted on each of the samples constituting a set of test samples labelled with the words 'For Microbiological Examination'.

F-4.3 Tests other than those given in **F-4.1** and **F-4.2** shall be conducted on the composite sample.

ANNEX G

(*Foreword*)

COMMITTEE COMPOSITION

Dairy Products and Equipment Sectional Committee, FAD 19

Organization	*Representative(s)*
National Dairy Research Institute, Karnal	Dr Manmohan Singh Chauhan (***Chairman***)
All India Food Processors Association, New Delhi	Dr K. L. Gaba Mr Vijay Gaur (*Alternate*)
Bihar State Cooperative Milk Producers' Federation Ltd, (COMPFED), Patna	Mr Sushil Kumar Mr Rupesh Raj (*Alternate*)
Confederation of Indian Food Trade and Industry, New Delhi	Ms Varsha Yadav Dr Anirudha Chhonkar (*Alternate*)
Confederation of Indian Industry, New Delhi	Ms Neha Aggarwal Ms Arti Gupta (*Alternate*)
Centre for Analysis and Learning in Livestock and Food (CALF), Anand	Dr Rajesh Nair Dr Rajeev Chawla (*Alternate*)
Directorate of Marketing and Inspection, Faridabad	Dr D. M. Govind Reddy Shri Rahul Singh (*Alternate*)
Export Inspection Council of India, New Delhi	Dr J. S. Reddy Mr Kumar Narender (*Alternate*)
Envirocare Labs Pvt Ltd, Thane	Dr Nilesh Amritkar Dr Priti Amritkar (*Alternate*)
Food Safety and Standards Authority of India, New Delhi	Dr Monica Puniya Ms Tripti Tayal (*Alternate*)
Gujarat Cooperative Milk Marketing Federation Ltd, Anand	Mr Sameer Saxena Mr Sayan Banerjee (*Alternate*)
IDMC Ltd, Anand	Mr Devender Gupta Mr Prakash Maheshwari (*Alternate*)
Indian Dairy Association, New Delhi	Dr G. S. Rajorhia Dr Satish Kulkarni (*Alternate*)
Indian Stainless Steel Development Association, Gurugram	Mr Rohit Kumar Mr Rajat Aggarwal (*Alternate*)
Jupitor Glass Works, New Delhi	Mr Karan Nangia Mr Amreek Singh Puri (*Alternate*)
Ministry of Fisheries, Animal Husbandry and Dairying, Department of Animal Husbandry and Dairying, New Delhi	Shri Goutam Kumar Deb Shri Ajit Kumar K. (*Alternate*)
Mother Dairy Fruit and Vegetable Ltd, Delhi	Ms Nita Sen Mr Shailender Kumar (*Alternate*)
National Dairy Development Board, Anand	Mr S. D. Jaisinghani Mr Suresh Pahadia (*Alternate*)
National Dairy Research Institute, Karnal	Dr Vivek Sharma Dr Rajesh Kumar Bajaj (*Alternate*)
National Institute of Food Technology Entrepreneurship and Management (NIFTEM), Sonipat	Dr P. K. Nema

Organization	*Representative(s)*
National Institute of Nutrition, Hyderabad	Dr B. Santosh Kumar Dr Sylvia Fernandez Rao (*Alternate*)
Punjab State Coop. Milk Producers' Federation Limited	Dr Sanjeev Kumar Sharma
Rajasthan Co-op Dairy Federation (RCDF) Ltd, Jaipur	Mr J. D. Singh
Tamil Nadu Co-op Milk Producers' Federation Limited, Chennai	Mr S. R. Sankar Mr S. Jeyachandran (*Alternate*)
Tetra Pak India Pvt Ltd, Pune	Mr Shashikant Ramnath Suruse Mr Sameer Singh Suhail (*Alternate*)
Vimta Labs Limited, Hyderabad	Dr Jagadeesh Kodali Dr Muni Nagendra Prasad Poola (*Alternate*)
BIS Directorate General	Shrimati Suneeti Toteja, Scientist 'E' and Head (FAD) [Representing Director General (*Ex-officio*)]

Member Secretary

Dr Bhawana
Scientist 'D' (FAD), BIS

Panel for Revision of Indian Standards on Infant Foods, FAD 19-FAD 24 Joint Panel 10

Organization	*Representative(s)*
National Dairy Research Institute, Karnal	Dr A. K. Singh (***Convenor***)
Abbott India Ltd, Mumbai	Ms Arti G. Shankar
Central Institute of Agricultural Engineering, Bhopal	Dr Manoj Tripathi
Danone India Limited, Delhi	Mr Vijay Gaur
Food Safety and Standards Authority of India, New Delhi	Mr Sunil Bakshi
Gujarat Cooperative Milk Marketing Federation Ltd, Anand	Mr Sameer Saxena
National Dairy Research Institute, Karnal	Dr Naresh Goyal
National Institute of Nutrition, Hyderabad	Dr B. Santosh Kumar
National Institute of Technology, Rourkela	Dr Mohd Khalid Gul
Nestle India Limited, Gurugram	Dr Anirudha Chhonkar

(*Continued from second cover*)

This second revision has been brought out to harmonize the requirements of Infant Milk Substitutes with the *Food Safety and Standards (Foods for Infant Nutrition) Regulations*, 2020. Major changes include:

a) Product description has been updated;
b) Requirements for pre-mature/low birth weight infant milk substitute, lactose free infant milk substitutes, lactose and sucrose free infant milk substitute, sucrose free infant milk substitute and hypoallergenic infant milk substitute have been removed;
c) List of permitted optional ingredients has been updated;
d) List of permitted food additives as well as their levels have been updated;
e) Referred test methods have been updated;
f) Chemical and microbiological requirements have been updated; and
g) Labelling clause has been modified.

A separate standard is being formulated for 'Food for special medical purpose intended for infants' in line with the *Food Safety and Standards* (*Foods for Infant Nutrition*) *Regulations*, 2020 which covers the requirements for infant milk substitute that is specially manufactured to meet the special nutritional requirements of infants from birth to twenty-four months with specific disorders, such as preterm infant milk substitute, lactose free infant milk substitutes and hypoallergenic infant milk substitutes.

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 G.

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.

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Review of Indian Standards

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This Indian Standard has been developed from Doc No.: FAD 19 (18814).

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