IS 14433 (2007): Infant milk substitutes [FAD 19: Dairy Products and Equipment]

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भारतीय मानक

शिशु दुग्ध के वैकल्पिक आ।ार — विशिष्टि

(पहला पुनरीक्षण)

Indian Standard

INFANT MILK SUBSTITUTES — SPECIFICATION

(First Revision)

ICS 67.100.99

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

January 2007 Price Group 6

AMENDMENT NO. 1 AUGUST 2007
TO
IS 14433 : 2007 INFANT MILK SUBSTITUTES — SPECIFICATION

(First Revision)

(*Page* 2, *clause* **6.2**, *informal table*, *col* 1) — Insert 'L (+) Lactic acid producing cultures' after 'L (+) Lactic acid'.

(*Page* 2, *clause* **6.2**, *informal table*, *col* 1) — Insert the following at the end:

'Antioxidants (Mixed tocopherols concentrate and L-Ascorbyl palmitate)	}	1 mg in all types of infant formulae'

[*Page* 3, *clause* **6.10.1**(a), *line* 1] — Substitute '2.25 g/100 kcal to 2.75 g/100 kcal' *for* '2.25 g/100 kcal/J to 2.75 g/100 kcal/J'.

[*Page* 4, *clause* **6.10.3**(a)] — Substitute 'whey or casein' *for* 'casein'.

(FAD 19)

Reprography Unit, BIS, New Delhi, India

AMENDMENT NO. 2 MAY 2008
TO
IS 14433 : 2007 INFANT MILK SUBSTITUTES — SPECIFICATION

(First Revision)

[*Page* 5, *Table* 1, *Sl No.* (xxi), *col* 2] — Substitute 'Calcium, mg/100 g, *Min*' *for* 'Calcium, mg/100'.

(FAD 19)

Reprography Unit, BIS, New Delhi, India

Dairy Products and Equipments Sectional Committee, FAD 19

FOREWORD

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

This standard was first published in 1997 and this revision is being undertaken 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 and therefore the division of the standard into two parts is rendered unnecessary. In this revision, requirements for hypoallergenic infant milk substitutes has also been included and the chemical and microbiological requirements for hypoallergenic infant milk substitutes has also been included and the chemical and microbiological requirements updated. In view of the above inclusions and updations, the standard is harmonized with the standards for infant milk substitutes laid down under the *Prevention of Food Adulteration Rules*, 1955.

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 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, 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.

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) 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. With the publication of this standard, IS 14433 (Part 1) : 1997 stand cancelled.

The first revision of IS 14433 is being undertaken 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 and therefore the division of the standard into two parts is rendered unnecessary. In this revision, requirements for hypoallergenic infant milk substitutes has also been included and the chemical and microbiological requirements updated. In view of the above inclusions and updations, the standard is harmonized with the standards for infant milk substitutes laid down under the *Prevention of Food Adulteration Rules*, 1955.

While formulating this standard, due consideration has been given to the relevant rules prescribed by the Government of India, namely *Prevention of Food Adulteration Rules*, 1955; *Infant Milk Substitutes, Feeding Bottles and*

(*Continued on third cover*)

Indian Standard

INFANT MILK SUBSTITUTES — SPECIFICATION

(First 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 the standards indicated.

3 TERMINOLOGY

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

3.1 Infant Milk Food — The material as prepared by spray drying of the milk of cow or buffalo or a mixture thereof. The milk may be modified by the partial removal/substitution of different milk solids, carbohydrates such as sucrose, dextrose and dextrins/ maltodextrins, maltose and lactose, salts such as phosphates, citrates; vitamins A, D, E, B group, C, and other vitamins, minerals such as iron, copper, zinc, iodine and others.

3.2 Infant Formula — The material as prepared by spray drying of the milk of cow or buffalo or a mixture thereof. The milk 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 such as sucrose, dextrose and dextrins/maltodextrins, maltose and lactose; salts such as phosphates, citrates; vitamins A, D, E, B, group C, and other vitamins; minerals such as iron, copper, zinc, iodine and others.

NOTE — Infant formula meant for premature infants (born before 37 weeks) or infants with low birth weight (less than 2 500 g) and suitably modified with addition of proteins, whey proteins, minerals so as to achieve the required whey: casein ratio; calcium: phosphorus ratio along with other requirements, as given in the standard, shall be termed as Premature/Low birth weight infant milk substitute.

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

3.4 Routine Tests — 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

4.1 The material shall be of the following two types:

a) *Type I* — Infant milk food, and

b) *Type II* — Infant formula including:

1) Infant formula;

2) Pre-mature/Low birth weight infant milk substitute;

3) Lactose free infant milk substitute, lactose and sucrose free infant milk substitute and sucrose free infant milk substitute; and

4) Hypoallergenic infant milk substitute.

5 DESCRIPTION

The product shall be white or white with a greenish tinge to light cream in colour, free from lumps and shall be uniform in appearance.

6 REQUIREMENTS

6.1 Type I Infant milk substitute shall be free from starch and added antioxidants while in Type II, ready to drink infant milk substitute, lecithin (*see* IS 5055) and ascorbyl palmitate (*see* IS 13462) may be used up to a maximum limit of 0.5 g/100 ml and 1 mg/100 ml respectively and shall be free from starch. 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.

6.2 Type I Infant milk substitute shall not contain food additives. Type II Infant milk substitute may contain food additives listed below:

Food Additives	*Maximum Level in 100 ml of the Ready-to-Drink Product*
*p*H-Adjusting Agents:	
Sodium hydroxide Sodium hydrogen carbonate Sodium carbonate Potassium hydroxide Potassium hydrogen carbonate Potassium carbonate Calcium hydroxide	Limited by good manufacturing practice and within the limits for sodium and potassium in all types of infant formulae
Sodium citrate Potassium citrate L (+) Lactic acid Citric acid	Limited by good manufacturing practice in all types of infant formulae

6.3 The flavour of the product in dry condition or of the reconstituted feed shall be fresh and sweet. The material shall not have any rancid taste or musty odour (*see* IS 10641).

6.4 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.

6.5 In Type II Infant milk substitutes, vegetable oils added shall be rich in polyunsaturated fatty acids. It shall also contain a minimum linoleate (linoleic acid in form of glycerides) content of 1.398 g per 100 g of the product when determined as per the method given in Annex A of IS 6387. The product shall also contain a minimum of 0.70 IU of vitamin E per 100 kcal, when determined as per the method given in IS 7235.

6.6 Type II Infant milk substitutes may contain in addition to the vitamin and minerals listed under **3.2**, other nutrients when required in order to provide nutrients ordinarily found in human milk such as:

a) Carotenes : Not less than 0.25 mg/l
b) Fluorine : Not less than 0.107 mg/l
c) Aminoacids : Not less than 9 mg/l (only L forms of aminoacids should be used)
d) Non-protein nitrogen : Not less than 173 mg/l
e) Nucleotides : Not less than 11.7 mg/l
f) Carnitine : Not less than 11.27 µg/l
g) Lactalbumin : Not less than 1.4 g/l
h) Lactoferrin : Not less than 0.27 g/l
j) Lysozyme : Not less than 0.8 g/l
k) Fucose : Not less than 1.3 g/l
m) Glucosamine : Not less than 0.7 g/l
n) Inositol : Not less than 0.39 g/l
p) Citric acid : Not less than 0.35 g/l
q) Cholesterol : Not less than 88 mg/l
r) Lipid Phosphorus : Not less than 7 mg/l
s) Prostaglandins : Not less than PGE 150 mg/l
Not less than PGF 400 mg/l

When any of these nutrients is added, the amount of these added nutrients shall be declared on the label, which should not be less than mentioned. It may contain medium chain triglycerides, taurine, molybdenum and chromium.

6.7 Quality of Ingredients

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

6.7.2 The vitamins and minerals shall be of food grade. Iron salts should be such so as to ensure high bio-availability of iron. The source of mineral salts and vitamin compounds may be used from:

a) *Minerals*

1) *Calcium* (Ca) — Calcium carbonate, calcium chloride, calcium citrate, calcium phosphate monobasic, calcium phosphate dibasic, calcium phosphate tribasic;
2) *Phosphorous* (P) — Calcium phosphate monobasic, calcium phosphate dibasic, calcium phosphate tribasic, magnesium phosphate dibasic, potassium phosphate dibasic;
3) *Chloride* (Cl) — Calcium chloride, choline chloride, magnesium chloride, manganese chloride, sodium chloride, sodium chloride iodized;
4) *Iron* (Fe) — Ferrous citrate, ferrous lactate, ferrous sulphate, ferric pyrophosphate;
5) *Magnesium* (Mg) — Magnesium chloride, magnesium oxide, magnesium phosphate dibasic;
6) *Sodium* (Na) — Sodium bicarbonate, sodium chloride, sodium chloride iodized, sodium citrate, sodium phosphate monobasic;
7) *Potassium* (K) — Potassium phosphate dibasic;
8) *Copper* (Cu) — Cupric citrate, cupric sulphate;
9) *Iodine* (I) — Potassium iodide, sodium iodide;
10) *Zinc* (Zn) — Zinc sulphate; and
11) *Manganese* (Mn) — Manganese chloride, manganese sulphate.

b) *Vitamins*

1) *Vitamin* A — Retinyl acetate, retinyl palmitate, retinyl propionate

2) *Provitamin* A — Beta-carotene;
3) *Vitamin* D — *Vitamin* D_2 — Ergocalciferol, *Vitamin* D_3 — Cholecalciferol, cholecalciferol-cholesterol;
4) *Vitamin* E — d-alpha-tocopherol, dl-alpha-tocopherol, d-alpha-tocopheryl acetate, dl-alpha-tocopheryl acetate, d-alpha-tocopheryl succinate, dl-alpha-tocopheryl succinate;
5) *Thiamin* (*Vitamin* B_1) — Thiamin chloride hydrochloride, thiamin mononitrate;
6) *Riboflavin* (*Vitamin* B_2) — Riboflavin, Riboflavin 5' — phosphate sodium;
7) *Niacin* — Nicotinamide, nicotinic acid;
8) *Vitamin* B_6 — Pyridoxine hydrochloride;
9) *Biotin* (*Vitamin* H) — d-biotin;
10) *Folacin* — Folic acid;
11) *Pantothenic acid* — Calcium pantothenate, panthenol;
12) *Vitamin* B_{12} — Cyanocobalamin, hydroxycobalamin;
13) *Vitamin* K — Phytylmenaquinone;
14) *Vitamin* C — Ascorbic acid, sodium ascorbate, calcium ascorbate, ascorbyl-6-palmitate;
15) *Choline* — Choline bitartrate, choline chloride;
16) *Inositol*; and
17) *Selenium* — Sodium selenite.

6.8 Hygienic Conditions

The material shall be manufactured and packed under hygienic conditions (*see* IS 2491).

6.9 Bacteriological Requirements

6.9.1 *Bacterial Count*

The bacterial colony count per gram of the product shall not be more than 10 000 when determined according to the method prescribed in IS 5402.

6.9.2 *Coliform Count*

Coliform bacteria shall be absent per 0.1 g of the product when determined according to the method prescribed in IS 5401.

6.9.3 *Escherichia coli*

Escherichia coli shall be absent per 0.1 g of the product when tested as per the method prescribed in IS 5887 (Part 1).

6.9.4 *Staphylococcus aureus*

Staphylococcus aureus shall be absent per 0.1 g of the product when tested as per the method prescribed in IS 5887 (Part 2).

6.9.5 *Salmonella and Shigella*

Salmonella and *Shigella* shall be absent per 25 g of the product when tested as per the method prescribed in IS 5887 (Part 3) and IS 5887 (Part 7) respectively. (*see* Note).

NOTE — The requirements for *Salmonella* and *Shigella* shall be tested in a laboratory situated away from the production area.

6.9.6 *Yeast and Mould Count*

Yeast and mould shall be absent per 0.1 g of the product when tested as per IS 5403.

6.10 The Infant milk substitutes shall also conform to requirements given in Table 1.

6.10.1 The low birth weight infant milk substitute shall meet the requirements prescribed below in addition to the requirements prescribed for Type II Infant milk substitute under **6** and Table 1.

a) Protein content shall be 2.25 g/100 kcal/J to 2.75 g/100 kcal/J, when determined as per the method prescribed in IS 7219.
b) Mineral content shall not be less than 0.5 g/100 kcal. The Calcium: Phosphorus ratio shall be 2:1 when determined as per the methods prescribed in IS 5949 and IS 12756 respectively. Sodium, Potassium and Chloride combined together shall not be less than 40 milliequivalent per litre when determined as per the methods prescribed in IS 12760 and IS 11763.
c) Whey: Casein ratio shall be 60:40. Essential amino acids should include taurine, cystine, tyrosine and histidine.

NOTES

1 1 kJ = 0.238 846 kcal or 1 kcal = 4.186 8 kJ.

2 For the conversion of the values of requirements of the characteristics from percent by mass (per 100 g) to the value per 100 kcal, the total kcal content of the food shall be based upon the values of 4 kcal/g of carbohydrates and per g of proteins; and 9 kcal/g of fat. Carbohydrates may be determined as per the method prescribed under Annex C of IS 1656.

3 The Committee, is in the process of identifying the method of test for determination of whey: 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.

6.10.2 Lactose free infant milk substitute, lactose and sucrose free infant milk substitute and sucrose free infant milk substitute shall also meet the requirements prescribed below in addition to the requirements prescribed for Type II Infant milk substitute under **6** and Table 1, provided that in these three products edible vegetable oil may be used in place of milk fat and lecithin may be used as emulsifier:

a) Soy protein-based, lactose-free formula shall have soy-protein and carbohydrate as glucose, dextrose, dextrin/maltodextrins, maltose and/or sucrose; and

b) Lactose-free cow's/buffalo's milk-based formulas shall have carbohydrate as glucose, dextrose, dextrin/maltodextrins, maltose and sucrose.

6.10.3 The hypoallergenic infant milk substitute shall meet the requirements prescribed below in addition to the requirements prescribed for Type II Infant milk substitute under 6 and Table 1.

a) The protein shall be hydrolyzed casein.

b) 100 percent free aminoacids as a protein source.

6.11 Optional Requirements for ECO-Mark

6.11.1 *General Requirements*

6.11.1.1 The product shall conform to the requirements prescribed under **6.1** to **6.10**.

6.11.1.2 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 alongwith the authorization if required under *Environment (Protection) Act*, 1986 and the Rules made thereunder to the Bureau of Indian Standards, while applying for the ECO-Mark and the product shall also be in accordance with the *Prevention of Food Adulteration Act*, 1954 and the Rules made thereunder. Additionally, *FPO*, 1955 (*Fruit Product Order*) framed under *Essential Commodities Act*, 1966, *Standards of Weights and Measures Act*, 1977 and 1985 requirements wherever applicable, has to be compiled with.

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

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

6.11.1.5 The date of manufacture and date of expiry shall be declared on the product package by the manufacturer.

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

6.11.1.7 The pesticide residues (if any) in the product shall not exceed the limit as prescribed in *PFA Act*, 1954 and the Rules made thereunder.

6.11.1.8 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.

6.11.2 *Specific Requirements*

6.11.2.1 The material used inside the metal cap of the product shall conform to the relevant Indian Standards of food grade plastics as permitted under the *Prevention of Food Adulteration Act*, 1954 and the Rules made thereunder. Caps and closures shall not be treated as labels.

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

6.11.2.3 Product shall be free from Aflatoxins when tested in accordance with the method prescribed in Appendix J of IS 4684.

7 PACKING AND MARKING

7.1 Packing

The product shall be packed in hermetically sealed, clean and sound metal containers (*see* IS 11078) or in a flexible pack 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).

7.1.1 The product shall be packed in nitrogen or a mixture of nitrogen and carbon dioxide.

7.2 The product shall be packed in quantities as stipulated under the *Standards of Weights and Measures (Packaged Commodities) Rules*, 1977 as well as in accordance with requirements under *PFA Act*, 1954 and Rules 1955.

7.3 Marking

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

a) Name of the material, and brand name, if any;

b) Type of material;

c) Name and address of the manufacturer;

d) Batch or Code number;

e) Month and year of manufacturing or packing;

f) Net mass (*see* 7.2);

g) Date before which the contents should be consumed be indicated by marking the words 'Use before..... (month and year)';

h) *Composition* — Indicating the approximate composition of nutrients per 100 g of the product as well as the energy value in joules;

j) Feed chart and directions for use; and

k) Any other requirements as stipulated under *PFA Rules* 1955, *Infant Milk Substitutes, Feeding Bottles and Infant Foods Act*, 1992 *and Rules* 1993; and *Standards of Weights and Measures (Packaged Commodities) Rules*, 1977.

Table 1 Requirements for Infant Milk Substitutes

(*Clauses* 6.10, 6.10.1 *and* 6.10.2)

Sl No.	Characteristic	Requirement		Method of Test, Ref to
		Type 1	Type 2	
(1)	(2)	(3)	(4)	(5)
i)	Moisture, g/100 g, *Max*	4.5	4.5	IS 11623
ii)	Total Milk Protein, g/100 g:			IS 7219
	Min	12.0	10.0	
	Max	—	16.0	
iii)	Fat			
	a) Milk fat, g/100 g, *Min*	18.0	12.0	IS 11721
	b) Total fat, g/100 g, *Min*	—	18.0	do
iv)	Total ash, g/100 g, *Max*	8.5	8.5	Annex B
v)	Acid, insoluble ash, g/100 g, *Max*	0.1	0.1	Annex C
vi)	Solubility			IS 12759
	a) Solubility index, ml/100 g, *Max*	2.0	2.0	
	b) Solubility, percent by mass, *Min*	98.5	98.5	
vii)	Vitamin A (as retinol), µg/100 g, *Min*	350	350	IS 5886
viii)	Iron, mg/100 g, *Min*	5.0	5.0	Annex D
ix)	Heavy metals			
	a) Lead, mg/kg, *Max*	0.2	0.2	IS 12074
	b) Arsenic, mg/kg, *Max*	0.05	0.05	IS 11124
	c) Tin, mg/kg, *Max*	5.0	5.0	Clause 17 of IS 2860
	d) Cadmium, mg/kg, *Max*	0.1	0.1	Clause 15 of IS 1699
x)	Added vitamin D (expressed as chole-calciferol), µg/100 g, *Min*	4.5	4.5	IS 5835
xi)	Thiamine, µg/100 g, *Min*	185	185	IS 5398
xii)	Niacin, µg/100 g, *Min*	1 160	1 160	IS 5400
xiii)	Riboflavin, µg/100 g, *Min*	275	275	IS 5399
xiv)	Vitamin B_6 (pyridoxine), µg/100 g, *Min*	160	160	IS 7530
xv)	Vitamin B_{12}, µg/100 g, *Min*	0.7	0.7	IS 7529
xvi)	Folic acid µg/100 g, *Min*	20	20	IS 7234
xvii)	Pantothenic acid, mg/100 g, *Min*	1.4	1.4	IS 9840
xviii)	Biotin, µg/100 g, *Min*	7.0	7.0	IS 9820
xix)	Vitamin C, mg/100 g, *Min*	35	35	IS 5838
xx)	Vitamin K, µg/100 g, *Min*	18	18	[1]
xxi)	Calcium, mg/100	230	230	IS 5949
xxii)	Phosphorus, mg/100g, *Min*	115	115	IS 12756
xxiii)	Iodine, µg/100 g, *Min*	20	20	Clause A-2 of IS 7224
xxiv)	Copper, µg/100 g,			
	Min	280	280	Clause 15 of IS 1699
	Max	1 500	1 500	
xxv)	Manganese, µg/100 g, *Min*	20	20	Clause 35 of IS 3025
xxvi)	Zinc, mg/100 g,			
	Min	2.5	2.5	Clause 15 of IS 1699
	Max	5.0	5.0	
xxvii)	Sodium, mg/100 g, *Min*	90	90	IS 12760
xxviii)	Potassium, mg/100 g, *Min*	370	370	do
xxix)	Chloride, mg/100 g, *Min*	250	250	IS 11763
xxx)	Magnesium, mg/100 g, *Min*	22	22	IS 5949
xxxi)	Choline, mg/100 g, *Min*	32	32	[1]
xxxii)	Selenium µg/100 g, *Min*	14	14	IS 3025 (Part 56) or IS 15303
xxxiii)	Vitamin E (as α-tocopherol compounds) IU/100 g, *Min*	—	3.15	IS 7235

NOTES

1 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 from Sl No. (i) to (viii) are to be carried out.

2 The Indian Standards on methods for test indicated in col 5 from Sl No. (x) to (xviii) are given for guidance only as they are under revision at present. As there is no other suitable and easily workable method at present, the manufacturers would be required to maintain a record showing the quantity of these 'added vitamins', added to each batch.

3 In case of Type II infant milk substitutes, since there is no reliable method 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.

[1] Test method to be specified. Till such time test methods are prescribed, factory records shall be maintained of the additions per batch.

7.3.1 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'

7.3.2 *BIS Certification Marking*

The product may also be marked with the Standard Mark.

7.3.2.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

7.3.2.2 *ECO-Mark*

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

8 SAMPLING

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

ANNEX A

(*Clause* 2)

LIST OF REFERRED INDIAN STANDARDS

IS No.	*Title*
1070 : 1992	Reagent grade water (*third revision*)
1656 : 1997	Milk-cereal based weaning foods — Specification (*third revision*)
1699 : 1995	Methods of sampling and test for food colours (*second revision*)
2491 : 1998	Food hygiene — General principles — Code of practice (*second revision*)
2860 : 1964	Methods of sampling and test for processed fruits and vegetables
3025 : 1964	Method of sampling and test (physical and chemical) for water used in industry
3025 (Part 56) : 2003	Methods of sampling and test (physical and chemical) for water and wastewater: Part 56 Selenium
4684 : 1975	Specification of edible groundnut flour (expeller pressed) (*first revision*)
4905 : 1968	Method for random sampling
5055 : 1996	Lecithin, food grade (*first revision*)
5398 : 1969	Method for estimation of thiamine (vitamin B_1) in foodstuffs
5399 : 1969	Methods for estimation of riboflavin (vitamin B_2) in foodstuffs
5400 : 1969	Methods for estimation of nicotinic acid (Niacin) in foodstuffs
5401 (Part 1) : 2002	Microbiology — General guidance for the enumeration of coliforms: Part 1 Colony count technique (*first revision*)
5402 : 2002	Microbiology — General guidance for the enumeration of micro-organisms — Colony count technique at 30°C (*first revision*)
5403 : 1999	Method for yeast and mould count of foodstuffs (*first revision*)
5835 : 1970	Method for estimation of vitamin D in foodstuffs
5838 : 1970	Method for estimation of vitamin C in foodstuffs
5886 : 1970	Methods for estimation of carotenes and vitamin A (Retinol) in foodstuffs
5887	Methods for detection of bacteria responsible for food poisoning:
(Part 1) : 1976	Isolation, identification and enumeration of *Escherichia coli* (*first revision*)
(Part 2) : 1976	Isolation, identification and enumeration of *Staphylococcus aureus* and faecal streptococci (*first revision*)
(Part 3) : 1999	General guidance on methods for the detection of *Salmonella* (*second revision*)

IS No.	Title
(Part 5) : 1976	Isolation, identification and enumeration of vibrio cholerae and vibrio parahaemolyticus (*first revision*)
(Part 7) : 1999	General guidance on methods for isolation and identification of *Shigella*
5949 : 1990	Method for volumetric determination of calcium and magnesium using EDTA (*first revision*)
6387 : 1987	Vegetable protein infant food with milk (*first revision*)
7219 : 1973	Method for determination of proteins in food and feed ingredients
7224 : 2006	Iodized salt (*first revision*)
7234 : 1974	Method for estimation of folic acid in foodstuffs
7235 : 1974	Estimation of tocopherols (vitamin E) in foodstuffs
7529 : 1975	Method for estimation of vitamin B_{12} in foodstuffs
7530 : 1975	Method for estimation of pyridoxine (vitamin B_6) in foodstuffs
9820 : 1981	Method for estimation of biotin in foodstuffs
9840 : 1981	Method for estimation of pantothenic acid in foodstuffs
10171 : 1999	Guide on suitability of plastics for food packaging (*second revision*)
10641 : 1983	Recommended methods for determination of aroma and taste thresholds
11078 : 1993	Round open top sanitary cans for milk powder (*first revision*)
11124 : 1984	Method for atomic absorption spectrophotometric determination of arsenic
11623 : 1986	Method for determination of moisture content in milk powder and similar products
11721 : 2005	Dried milk and dried milk products — Determination of fat content — Gravimetric method (Reference method) (*first revision*)
11763 : 2005	Cheese and processed cheese products — Determination of chloride content — Potentiometric titration method (*second revision*)
12074 : 1987	Method for determination of lead by atomic absorption spectrophotometry
12756 : 1989	Cheese and cheese products — Determination of total phosphorus content by molecular absorption spectrometric method
12759 : 1989	Dried milk and dried milk products — Determination of insolubility index
12760 : 1989	Dried milk — Determination of sodium and potassium contents — Flame emission spectrometric method
13462 : 1992	Ascorbyl palmitate, food grade
13500 : 1992	Spray dried milk powders — Scorched particles — Determination
15303 : 2003	Determination of antimony, iron and selenium in water by electrothermal atomic absorption spectrometric method

ANNEX B

[*Table* 1, *Sl No.* (iv)]

DETERMINATION OF TOTAL ASH

B-1 APPARATUS

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

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

B-1.3 Desiccator

B-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).

B-3 CALCULATION

$$\text{Total ash, percent by mass} = \frac{100\,(M_2 - M)}{M_1 - M}$$

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 C

[*Table* 1, *Sl No.* (v)]

DETERMINATION OF ACID INSOLUBLE 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 REAGENT

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

C-3 PROCEDURE

To the ash contained in the dish (*see* Note under **B-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.

C-4 CALCULATION

$$\text{Acid insoluble ash, percent by mass} = \frac{100\,(M_2 - M)}{M_1 - M}$$

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 D

[*Table* 1, *Sl No.* (viii)]

DETERMINATION OF IRON

D-0 GENERAL

The determination of iron may be carried out either by the spectrophotometric method at **D-1** or by Wong's spectrocolorimetric method at **D-2**. In case of a dispute, the spectrophotometric method at **D-1** shall be used.

D-1 SPECTROPHOTOMETRIC METHOD

D-1.1 Glassware, including pipettes, should be cleaned with re-distilled nitric acid and thoroughly rinsed with re-distilled water. Portions of glassware which come in contact with the material should not be permitted to come in contact with any surface that may cause contamination, for example, table tops, racks, iron stand, operators' hands, etc.

D-1.2 All the reagents should be stored in neutral ground glass-stoppered bottles.

D-1.3 Apparatus

D-1.3.1 *Volumetric Flasks,* 100-ml and 25-ml.

D-1.3.2 *One-Mark Graduated Flask*, 100-ml capacity.

D-1.3.3 *Separating Funnel*, 125-ml capacity.

D-1.3.4 *Graduated Glass Measuring Cylinder (Stoppered)*, 25-ml capacity.

D-1.3.5 *A Suitable Spectrophotometer or Photoelectric Colorimeter*, adjusted for transmission at 485 nm.

D-1.4 Reagents

D-1.4.1 *Hydrochloric Acid*, 20 percent (*m/m*).

D-1.4.2 *Re-distilled Nitric Acid*, sp gr 1.42.

D-1.4.3 *Concentrated Hydrochloric Acid*, sp gr 1.16.

D-1.4.4 *Distilled Water* (*see* IS 1070).

D-1.4.5 *Bromine Water,* a saturated solution of bromine in water.

D-1.4.6 *Dilute Hydrochloric Acid,* 1:1 (*m/m*).

D-1.4.7 *Potassium Persulphate Solution,* 2 percent (*m/m*) in distilled water (*see* IS 1070), prepared freshly every few days and stored under refrigeration.

D-1.4.8 *Potassium Thiocyanate Solution,* 20 percent (*m/m*) in distilled water (*see* IS 1070), prepared freshly every few days and stored under refrigeration.

D-1.4.9 *Isobutyl Alcohol*, boiling point 106°C to 107°C, re-distilled in neutral glass apparatus (reagent recovered by simple distillation is not satisfactory for reuse).

D-1.4.10 *Anhydrous Sodium Sulphate*

D-1.5 Preparation of the Standard Curve

D-1.5.1 Weigh accurately 1.000 g of iron wire into a clean, dry, iron-free beaker. Dissolve it in hydrochloric acid, sufficient to dissolve it, to which 1 to 2 ml of nitric acid have been added. Carefully evaporate to dryness and dissolve the residue in the minimum amount of concentrated hydrochloric acid. Transfer it to a 100-ml volumetric flask and dilute to volume.

D-1.5.2 From the above stock solution, prepare a working standard of 10 micrograms iron per millilitre by diluting with distilled water (*see* IS 1070). Add a few drops of bromine water prior to adjusting to volume. Draw a standard curve by developing the colour on increments of the working standard in the range of 0 to 60 micrograms of iron by taking in a 25-ml volumetric flask, 5 ml of concentrated hydrochloric acid, the required quantity of standard iron solution and making up to the volume by distilled water (*see* IS 1070). Proceed as in **D-1.6.2**.

D-1.6 Procedure

D-1.6.1 Weigh accurately 3 to 5 g of the material in a silica, porcelain or platinum dish. Char the sample at low heat. Place the charred sample in a muffle furnace at 550 ± 20°C for a period of about 5 h for ashing. After cooling, dissolve the ash by adding 5 ml of dilute hydrochloric acid and heating the mixture to a gentle boil for 3 min. Allow the contents to cool to room temperature. Transfer the contents to a 100-ml one-mark graduated flask and dilute to volume with distilled water (*see* IS 1070).

D-1.6.2 Transfer 25-ml aliquot of the prepared solution to a 125-ml separating funnel and add exactly 5 ml of concentrated hydrochloric acid. Add 1 ml of potassium persulphate solution and swirl the separating funnel to ensure complete mixing. Then add 10 ml of potassium thiocyanate solution to develop the colour. Add 25 ml of isobutyl alcohol and shake for 2 min. Draw off and discard the aqueous layer. Invert and then slowly revolve the funnel to dislodge any water particles sticking to the walls of the separating funnel. Allow to stand for 10 min. After this period draw off the small amount of water which has separated from the alcohol layer and then transfer

this alcohol layer to a dry 25-ml graduated measuring cylinder. Add about 0.1 g anhydrous sodium sulphate to the contents of this cylinder and agitate it to ensure the removal of suspended particles of water from the alcohol extract.

D-1.6.3 Determine the transmittance of the alcohol extract in a spectrophotometer or photo-electric calorimeter at 485 nm set with a reagent blank at 100 percent transmittance. The reagent blank is prepared in the same manner as the sample.

NOTE — If the colour is too intense to read (in excess of 50 micrograms) repeat the determination, using a smaller aliquot of the prepared sample. It is important that the volume ratio and prepared sample — blank relationship be kept constant. The difference in the aliquot size should be made up by the addition of the reagent blank solution. For example, if a 15-ml aliquot is used in place of the usual 25-ml, correct the difference in volume by adding 10 ml of the reagent blank.

D-1.7 Calculation

Find out the amount of iron present, in terms of micrograms in the solution, by plotting the intensity reading on the standard curve previously drawn (*see* **D-1.5.2**) and calculate the quantity of iron as mg per 100 g of sample.

D-2 WONG'S SPECTROCOLORIMETRIC METHOD

D-2.1 Principle

Iron is determined colorimetrically making use of the fact that ferric iron gives a blood red colour complex with potassium thiocyanate whose intensity is measured at 500 nm.

D-2.2 Reagents

D-2.2.1 *Sulphuric Acid,* 30 percent (*m/v*).

D-2.2.2 *Potassium Persulphate Solution,* 7 percent (*m/v*). Dissolve 7 g potassium persulphate in distilled water (*see* IS 1070), and make volume upto 100-ml.

D-2.2.3 *Potassium Thiocyanate Solution,* 40 percent (*m/v*). Dissolve 40 g potassium thiocyanate in distilled water (*see* IS 1070). Add 4 ml acetone and make up the volume to 100-ml.

D-2.2.4 *Standard Iron Solution* — Dissolve pure iron or ammonium ferrous sulphate and make appropriate dilution so as to get a solution of iron concentration of 20 µg/ml.

D-2.3 Procedure

D-2.3.1 *Preparation of Sample Solution* — *See* **D-1.6.1**.

D-2.3.2 *Estimation of Iron*

Transfer suitable volume (2 to 4 ml) of the prepared sample solution (*see* **D-2.3.1**) into the measuring cell using pipette. Add the required quantity of distilled water (*see* IS 1070) so that the total volume is 6.5 ml. Add 1 ml sulphuric acid, 1 ml potassium persulphate solution and 1.5 ml of potassium thiocyanate solution. Shake well and measure the optical density (O.D.) of the developed colour within 20 min, colorimetrically, at 500 nm using a suitable Spectrocolorimeter. Similarly, find out the standard optical density (O.D.) using standard iron solution (*see* **D-2.2.4**) in place of prepared sample solution.

D-2.4 Calculation

Calculate the quantity of iron as milligram per 100 g of sample using the following formulae:

$$\text{Iron, mg/100 g} = \frac{\text{Standard Conc.}}{\text{Standard O.D.}} \times \frac{\text{Sample O.D.}}{\text{Aliquot taken}} \times \frac{\text{Volume made}}{\text{Sample taken}} \times \frac{100}{1\,000}$$

ANNEX E

(*Clause* 8)

SAMPLING OF INFANT MILK SUBSTITUTES

E-1 GENERAL REQUIREMENTS

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

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

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

E-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.

E-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.

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

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

E-2 SCALE OF SAMPLING

E-2.1 Lot

E-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.

E-2.1.2 Samples shall be tested for each lot ascertaining its conformity to the requirements of this standard.

E-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 2.

Table 2 Scale of Sampling for Containers of 400 g and Above

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 g in a lot shall be as agreed to between the purchaser and the supplier.

E-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.

E-3 TEST SAMPLES AND REFEREE SAMPLES

E-3.1 The number of containers selected according to col 3 of Table 2 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.

E-3.2 Draw with the suitable sampling instrument approximately equal quantity of 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 labelled with the particulars given in **E-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.

E-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 **E-1.5**. One of these composite samples shall be for the purchaser, another for the vendor and the third for the referee.

E-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 **E-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.

E-3.5 Referee Sample

Referee sample shall consist of a set of individual samples (*see* **E-3.1**), a composite sample (*see* **E-3.2**) and a set of samples for microbiological examination

(*see* **E-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 a dispute.

E-4 NUMBER OF TESTS

E-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 1 shall be conducted on each of the samples constituting a set of individual samples.

E-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'.

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

(*Continued from second cover*)

Infant Foods (*Regulation of Production, Supply and Distribution*) *Act*, 1992 *and Rules* 1993; and 'Third Schedule' of the *Standards of Weights and Measures* (*Packaged Commodities*) *Rules*, 1977.

NOTE — The various statutory rules indicated were valid at the time of publication of this standard. Since the statutory Rules and Acts are updated from time-to-time, this standard is subject to the restrictions imposed under these Acts and Rules wherever applicable.

A scheme for labelling environment friendly products known as ECO-Mark has been introduced at the instance of the Ministry of Environment and Forests (MEF), Government of India. The ECO-Mark shall be administered by the Bureau of Indian Standards (BIS) under the *BIS Act*, 1986 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.

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 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act,* 1986 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards : Monthly Additions'.

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