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IS 15757: 2007

भारतीय मानक

अनुसरित फार्मूला — अनुपूरक आहार — विशिष्टि

Indian Standard

FOLLOW-UP FORMULA — COMPLEMENTARY FOODS — SPECIFICATION

ICS 67.100.99

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

AMENDMENT NO. 1 AUGUST 2007 TO IS 15757: 2007 FOLLOW-UP FORMULA — COMPLEMENTARY FOODS — SPECIFICATION

[Page 3, Table 1, Sl No. (vii), col 3] — Substitute '350' for '75'.

(FAD 19)

Reprography Unit, BIS, New Delhi, India

AMENDMENT NO. 2 MAY 2008 TO IS 15757: 2007 FOLLOW-UP FORMULA COMPLEMENTARY FOODS — SPECIFICATION

[Page 3, Table 1, Sl No. (xxv), col 2] — Substitute 'Calcium, mg/100 g, Min' for 'Calcium, mg/100'.

(FAD 19)

Reprography Unit, BIS, New Delhi, India

AMENDMENT NO. 3 NOVEMBER 2012 TO

IS 15757: 2007 FOLLOW-UP-FORMULA—COMPLEMENTARY FOODS—SPECIFICATION

(*Page* 3, *Table* 1, *Sl.No.* (i), *col* 4) — Substitute 'IS 11623 for reference purpose and IS 16072 for routine purpose' *for* 'IS 11623'.

(*Page* 5, *Annex* A) — Insert the following at the end:

'IS No. Title

16072:2012 Determination of moisture content in milk powder

and similar products (Routine method).'

FOREWORD

This Indian Standard 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.

Follow-up formula complementary foods is used as a liquid part of the weaning diet for infants after the age of six months and upto the age of two years. Formulation of a standard on follow-up formula was considered necessary to ensure that the composition of the product is such that it is nutritionally adequate to contribute to normal growth and development of infants.

The standard is harmonized with the standards for follow-up formula laid down under the *Prevention of Food Adulteration*, 1955.

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.

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.

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.

Indian Standard

FOLLOW-UP FORMULA — COMPLEMENTARY FOODS — SPECIFICATION

1 SCOPE

This standard prescribes the requirements, methods of test and sampling for follow-up formula-complementary foods intended for infants at the weaning stage after the age of six months and up to the age of two years.

2 REFERENCES

The Indian 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

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

3.1 Follow-Up Formula-Complementary Food

Follow-up formula-complementary food is the product prepared by spray drying of the milk of cow or buffalo or a mixture thereof. It may contain vegetable protein. Follow-up formula based on milk shall be prepared from nutrients mentioned at 5.2 below except that a minimum of 3 g/100 available Calories (or 0.7 g/100 kJ) of protein shall be derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin or mineral content of the milk and which represents a minimum of 90 percent of the total protein.

Follow-up formula is used as a liquid part of the complementary diet for infants after the age of six months and up to the age of two years. When prepared in accordance with the instructions for use, 100 ml of the ready-for-consumption product shall provide not less than 60 kcal (or 250 kJ) and not more than 85 kcal (or 355 kJ).

3.2 Routine Tests

Tests carried out on each lot to check the essential requirements which are likely to vary during production.

3.3 Type Test

The tests to prove conformity to the requirements of this standard. These 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 DESCRIPTION

The follow-up formula-complementary when in liquid form, is suitable for use either directly or diluted with water before feeding, as appropriate. In powdered form it requires water for preparation and it shall be free from lumps and shall be uniform in appearance.

5 REQUIREMENTS

- 5.1 Follow-up formula-complementary food shall be free from starch and added colour and flavour. It shall be free from dirt and extraneous matter and free from scorched particles. It shall also be free from any material which is harmful to human health.
- 5.2 Follow-up formula shall contain the following nutrients indicated below:
 - a) Protein shall not be less than 3.0 g/100 available calories (or 0.7 g/100 available kilojoules) and not more than 5.5 g/100 available calories (or 1.3 g/100 available kilojoules). The nutritional quality of protein shall be equivalent to that of casein or a greater quantity of other protein in inverse proportion to its nutritional quality. The quality of the protein shall not be less than 85 percent of that of casein. Essential amino acids may be added to follow-up formula to improve its nutritional value. Only L forms of amino acids shall be used.
 - b) Fat shall not be less than 4 g/100 calories (0.93 g/100 available kilojoules) and not more than 6 g/100 calories (1.4 g/100 available kilojoules). Linoleic acid (in the form of glyceride) shall not less than 310 mg/100 calories (or 74.09 mg/100 available kilojoules) when determined as per the method given in Annex A of IS 6387.

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- c) The product shall contain nutritionally available carbohydrates suitable for the feeding of the older infant and young child in such quantities as to adjust the product to the energy density in accordance with the requirements given at 3.1.
- 5.3 The product may also contain other nutrients when required to ensure that the product is suitable to form part of a mixed feeding scheme intended for use after six months of age. When any of these nutrients is added, the food shall contain not less than Recommended Dietary Allowance (RDA) amounts of these nutrients.
- 5.4 The product may contain food additives listed below:

Food Additives	Maximum Level in 100 ml of the Product Ready-for-Consumption			
(1)	(2)			
pH-Adjusting Agents				
Sodium hydrogen carbonate Sodium carbonate Sodium citrate Potassium hydrogen carbonate Potassium carbonate Potassium citrate Sodium hydroxide Calcium hydroxide Potassium hydroxide L (+) Lactic acid Citric acid	Limited by good manufacturing practice and within the limits for sodium			
Antioxidants				
Mixed tocopherols concentrate α-tocopherol	3 mg, singly or in combination			
L-Ascorbyl palmitate	5 mg, singly or in combination			

5.5 Quality of Ingredients

- 5.5.1 All ingredients used shall be clean, of good quality, safe and suitable for ingestion by infants.
- 5.5.2 The vitamins and minerals shall be of food grade. Iron salts should be such so as to ensure high bioavailability of iron. The source of mineral salts and vitamin compounds may be used from the list given in 6.7.2 of IS 14433.

5.6 Hygienic Conditions

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

5.7 Flavour and Odour

The flavour and odour of the follow-up formulacomplementary food in the powder form or when reconstituted with water shall be fresh and sweet (see IS 10641). It shall not have a rancid taste or a musty odour.

5.8 Bacteriological Specifications

5.8.1 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.

5.8.2 Coliform Count

The coliform bacteria shall be absent per 0.1 g of the product when determined according to the method prescribed in IS 5401 (Part 1).

5.8.3 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).

5.8.4 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).

5.8.5 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

5.8.6 Yeast and Mould Count

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

5.9 The follow-up formula shall also comply with the requirements given in Table 1.

5.10 Optional Requirements for ECO-Mark

5.10.1 General Requirements

- 5.10.1.1 The product shall conform to the requirements prescribed under 5.1 to 5.10.
- 5.10.1.2 The manufacturers 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

Table 1 Requirements for Follow-Up Formula-Complementary Food (Clause 5.9)

SI No.	Characteristic	Requirement Type 1	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Moisture, g/100 g, Max	4.5	IS 11623
ii)	Total milk protein, g/100 g:		
	Min	13.5	IS 7219
	Мах	24.75	
iii)	Total fat, g/100 g:		
	Min	18.0	IS 11721
	Max	27.0	
	Linoleate g/100 g, Min	1.398	IS 6387
iv)	Total ash, g/100 g, Max	8.5	Annex B of IS 14433
v)	Acid insoluble ash, g/100 g, Max	0.1	Annex C of IS 14433
vi)	Solubility:		
	a) Solubility index, ml/100 g, Max	2.0	IS 12759
	b) Solubility, percent by mass, Min	98.5	
vii)	Vitamin A (as retinol), μg/100 g, Min	75	IS 5886
viii)	Iron, mg/100 g, <i>Min</i>	5.0	Annex D of IS 14433
ix)	Added vitamin D	4.5	IS 5835
	(expressed as chole-calciferol) μg/100 g, Min		
x)	Thiamine μg/100 g, Min	180	IS 5398
xi)	Riboflavin µg/100 g, Min	270	IS 5399
xii)	Niacin μg/100 g, Min	1125	IS 5400
xiii)	Vitamin B ₆ (pyridoxine) μg/100 g, Min	202.50	IS 7530
xiv)	Folic acid µg/100 g, Min	20.0	IS 7234
xv)	Pantothenic acid, mg/100 g, Min	1.35	IS 9840
xvi)	Vitamin B ₁₂ μ g /100 g, <i>Min</i>	0.675	IS 7529
xvii)	Biotin, μg/100 g, Min	6.75	IS 9820
xviii)	Vitamin C, mg/100 g, Min	36	IS 5838
xix)	Vitamin E (as α-tocopherol compounds) IU/100 g, Min	3.15	IS 7235
xx)	Vitamin K, μg/100 g, Min	18	D
xxi)	Choline, mg/100 g, Min	32	1)
xxii)	Sodium, mg/100 g, Min	90	IS 12760
xxiii)	Potassium, mg/100 g, Min	360	IS 12760
xxiv)	Chloride, mg/100 g, Min	247.50	IS 11763
xxv)	Calcium, mg/100	405	IS 5949
xxvi)	Phosphorus, mg/100g, Min	270	IS 12756
xxvii)	Magnesium, mg/100 g, Min	27	IS 5949
xxviii)	Iodine, µg/100 g, Min	22.50	Clause A-2 of IS 7224
xxix)	Copper, μg/100 g:		
	Min	280	Clause 15 of IS 1699
	Max	1 500	
xxx)	Zinc, mg/100 g:		
	Min	2.5	Clause 15 of IS 1699
	Мах	5.0	
xxxi)	Manganese, μg/100 g, Min	20	Clause 35 of IS 3025
xxxii)	Selenium μg/100 g, Min	14	1)
xxxiii)	Heavy metals:		
	a) Lead, mg/kg, Max	0.2	IS 12074
	b) Arsenic, mg/kg, Max	0.05	IS 11124
	c) Tin, mg/kg, Max	5.0	Clause 17 of IS 2860
	d) Cadmium, mg/kg, Max	0.1	Clause 15 of IS 1699

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 SI No. (i) to (viii) are to be carried out.

² The Indian Standards indicated in col 4 from SI No. (ix) to (xvii) 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.

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

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 (Fruit Product Order), 1955 framed under Essential Commodities Act, 1966, Standards of Weights and Measures Act, 1977 and 1985 requirements wherever applicable, has to be complied with

- **5.10.1.3** The product/packaging may also display in brief the criteria based on which the product has been labelled environment friendly.
- **5.10.1.4** The material used for product packing shall be recyclable or biodegradable.
- 5.10.1.5 The date of manufacture and date of expiry shall be declared on the product package by the manufacturer.
- 5.10.1.6 The product shall be microbiologically safe when tested as per IS 5887 (Part 5) and should be free from bacterial and fungal toxins.
- **5.10.1.7** The pesticide residues (if any) in the product shall not exceed the limit as prescribed in *PFA Act*, 1954 and the Rules made thereunder.
- 5.10.1.8 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.

5.10.2 Specific Requirements

- 5.10.2.1 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.
- 5.10.2.2 The percentage of fruit juice/pulp, if any added shall be mentioned on the product package.
- **5.10.2.3** No synthetic food colour and artificial sweetener shall be added or used in the product.
- 5.10.2.4 Product shall be free from aflatoxins when tested in accordance with the method prescribed in Appendix J of IS 4684.

6 PACKING AND MARKING

6.1 Packing

The follow-up formula-complementary food 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).

- **6.1.1** The product shall be packed in nitrogen or a mixture of nitrogen and carbon dioxide.
- 6.1.2 The product shall be packed in quantities as stipulated under Standards of Weights and Measures (Packaged Commodities) Rules, 1977 as well as in accordance with requirements under Prevention of Food Adulteration Act, 1954 and Rules, 1955.

6.2 Marking

- **6.2.1** The containers shall bear legibly and indelibly the following information:
 - a) Name of the material, and brand name, if any;
 - b) Name and address of the manufacturer:
 - c) Batch or Code number:
 - d) Month and year of manufacturing or packing;
 - e) Net mass (see 6.1.1);
 - f) Date before which the contents should be consumed be indicated by marking the words 'Use before......(month and year)';
 - g) Composition Indicating the approximate composition of nutrients per 100 g of the product as well as the energy value in joules;
 - i) 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.

6.2.2 BIS Certification Marking

The product may also be marked with the Standard Mark.

6.2.2.1 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.

6.2.2.2 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 E of IS 14433.

ANNEX A

(Clause 2)

LIST OF REFERRED INDIAN STANDARDS

IS No.	Title	IS No.	Title
1699 : 1995	Methods of sampling and test for food colours (second revision)	(Part 3): 1999	General guidance on methods for the detection of Salmonella (second revision)
2491 : 1998	Food hygiene — General principles — Code of practice (second revision)	(Part 5): 1976	Isolation, identification and enumeration of vibrio cholerae and
2860 : 1964	Methods of sampling and test for processed fruits and vegetables		vibrio parahaemolyticus (first revision)
3025 : 1964	Method of sampling and test (physical and chemical) for water used in industry	(Part 7) : 1999	General guidance on methods for isolation and identification of Shigella
4684 : 1975	Specification of edible groundnut flour (expeller pressed) (first revision)	5949 : 1990	Method for volumetric determination of calcium and magnesium using EDTA (first revision)
5398 : 1969	Method for estimation of thiamine (vitamin B ₁) in foodstuffs	6387 : 1987	Vegetable protein infant food with milk (first revision)
5399 : 1969	Methods for estimation of riboflavin (vitamin B ₂) in foodstuffs	7219 : 1973	Method for determination of proteins in food and feed ingredients
5400 : 1969	Methods for estimation of nicotinic	7224 : 2006	lodized salt (first revision)
5401	acid (Niacin) in foodstuffs Microbiology — General guidance	7234 : 1974	Method for estimation of folic acid in foodstuffs
(Part 1): 2002	for the enumeration of coliforms: Part 1 Colony count technique (first	7235 : 1974	Estimation of tocopherols (vitamin E) in foodstuffs
5402 : 2002	revision) Microbiology — General guidance	7529 : 1975	Method for estimation of vitamin B ₁₂ in foodstuffs
	for the enumeration of micro- organisms — Colony count technique	7530 : 1975	Method for estimation of pyridoxine (vitamin B_6) in foodstuffs
5403 : 1999	at 30°C (first revision) Method for yeast and mould count of	9820 : 1981	Method for estimation of biotin in foodstuffs
5835 : 1970	foodstuffs (first revision) Method for estimation of vitamin D	9840 : 1981	Method for estimation of pantothenic acid in foodstuffs
5838 : 1970	in foodstuffs Method for estimation of vitamin C	10171 : 1999	Guide on suitability of plastics for food packaging (second revision)
5886 : 1970	in foodstuffs Methods for estimation of carotenes and vitamin A (Retinol) in	10641 : 1983	Recommended methods for determination of aroma and taste thresholds
5887	foodstuffs Methods for detection of bacteria	11078 : 1993	Round open top sanitary cans for milk powder (first revision)
	responsible for food poisoning:	11124 : 1984	Method for atomic absorption
(Part 1): 1976	Isolation, identification and enumeration of Escherichia coli (first		spectrophotometric determination of arsenic
(Part 2) : 1976	revision) Isolation, identification and	11623 : 1986	Method for determination of moisture content in milk powder and similar products
·	enumeration of Staphylococcus aureus and faecal streptococci (first revision)	11721 : 2005	Dried milk and dried milk products — Determination of fat content —

IS 15757: 2007

IS No.	Title	IS No.	Title
	Gravimetric method (Reference method) (first revision)		content by molecular absorption spectrometric method
11763 : 2005	Cheese and processed cheese products — Determination of chloride content — Potentiometric	12759 : 1989	Dried milk and dried milk products — Determination of insolubility index.
	titration method (second revision)	12760 : 1989	Dried milk — Determination of
12074 : 1987	Method for determination of lead by atomic absorption spectrophotometry	•	sodium and potassium contents — Flame emission spectrometric method
12756 : 1989	Cheese and cheese products — Determination of total phosphorus	14433 : 2007	Infant milk substitutes — Specification (first revision)

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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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Amendments Issued Since Publication

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