Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020

Chapter 1

Preliminary

1. **Short title and commencement:** (1) These regulations may be called the Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020.

(2) They shall come into force on the date of their publication in the Official Gazette and Food Business Operator shall comply with all the provisions of these regulations by 1st July, 2021.

2 Definitions, - (1) In these regulations, unless the context otherwise requires, -

(a) **"Act"** means the Food Safety and Standards Act, 2006 (34 of 2006);

(b) **"Food Authority"** means the Food Safety and Standards Authority of India established under section 4 of the Act;

(c) **"Food for infants based on traditional food ingredients"** are products known to be prepared traditionally at home for feeding infants, but processed and provided in packaged forms, after six months up to twenty-four months of age;

(d) "**Food for special medical purpose intended for infants"** means a substitute for human milk or formula that is specially manufactured to meet the special nutritional requirements of infants from birth to twenty-four months with specific disorders, diseases or medical conditions;

(e) **"Follow-up formula"** means a food for infants after six months up to twenty four months of age, which is intended for use as a liquid part of the complementary diet for infants when prepared in accordance with instructions for use;

(f) **"Infant Food"** shall have the meaning assigned to it in clause (x) of sub-section (1) of Section 3 of the Act;

(g) **"Infant Milk substitute"** shall have the meaning assigned to it in clause (x) of sub-section (1) of Section 3 of the Act;

(h) **"Infant formula"** means a breast milk substitute product based on milk of cow or buffalo or other milch animals as specified under the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 or mixture thereof and other ingredients which have been proven to be suitable for infant feeding, to meet the nutritional requirements of infant during the first six months;

(i) **"Milk cereal based complementary food"** means the food for infants after 6 months up to 24 months of age, which is based on milk, cereals and /or legumes (pulses), millets, nuts and protein concentrates or protein isolates and/or defatted edible oilseed extracts and so prepared as to permit dilution with water or milk or other suitable medium;

(j) **"Processed cereal based complementary food"** means food for infants after 6 months up to 24 months of age, which is based on cereals and legumes (pulses), millets, nuts and protein isolates or protein concentrates or de-fatted edible oil seed extracts and so prepared as to permit dilution with water or milk or other suitable medium;

(k) **"Schedules"** means the Schedules to these regulations.

(2) Words and expression used herein and not defined in these regulations shall have the same meaning as assigned to them in the Act.

3. General requirements-

(1) An article of infant milk substitutes or infant foods or food for special medical purpose intended for infants, whose standards are not specified under these regulations shall be manufactured for sale, exhibited for sale or stored for sale only after obtaining approval of such article of food and its label from the Food Authority.

(2) Foods for infant nutrition shall be packed in hermetically sealed, clean and sound containers or in flexible pack made from paper, polymer and/ or metallic film as per the Food Safety and Standards (Packaging) Regulations, 2018, so as to protect the contents from deterioration. It shall be packed under inert atmosphere. The packaging material used for products covered under these regulations shall be free from Bisphenol A (BPA).

(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 the composition tables.

(4) Wherever applicable, food for infant nutrition shall use the source compounds for minerals, vitamins and other nutrients from Schedule-I(a), Schedule-I(b) and Schedule-I(c), respectively provided under these regulations.

(5) Foods for infant nutrition may 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 per cent. DHA of total fatty acids and ratio of ARA:DHA as 1:1 minimum.

Provided that 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.

Provided further that Infant Milk substitutes for preterm infants shall comply with requirements specified under the standards.

(6) Lactose and glucose polymers shall be the preferred carbohydrates for food for infant nutrition. 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.

(7) Food for infant nutrition shall be free from lumps and coarse particles, and shall be uniform in appearance. It shall be free from rancid taste and musty odour.

Provided that milk cereal based complementary food and processed cereal based complementary food may be in the form of small granules and flakes forms.

(8) Food for infant nutrition shall comply with the requirements of the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992(42 of 1992) as amended in 2003 including aspect related to advertisement, marketing and promotion of Food products covered under these regulations in accordance with the section 3, 4, 5, 7, 8, 9 and 10 of the said Act.

(9) Food for infant nutrition shall comply with the requirements of the Legal Metrology (Packaged Commodities) Rules, 2011 except for the requirement of standard pack size as per the second schedule of the aforesaid rules in case of food for special medical purpose intended for infants.

(10) Food for infant nutrition shall conform to the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011.

(11) Food for infant nutrition shall conform to the Food Safety and Standards (Prohibition and Restriction of Sales) Regulation, 2011.

(12) Food for infant nutrition shall conform to the microbiological requirements specified under Appendix B of Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

(13) Advertisements and claims of products covered under these regulations shall be in accordance with the Food Safety and Standards (Advertising and Claims) Regulations, 2018.

(14) Wherever nutritional composition has been specified in 100 gm or 100 kcal basis under specific product categories in the composition tables, the FBO's shall comply with the nutrition composition in either per 100 gm or per 100 kcal basis.

4. Labelling: The labelling of the food for infant nutrition shall be in accordance with the [1][Food Safety and Standards (Labelling and Display) Regulations, 2020], and the specific labelling requirements provided under these regulations.

(1) Without prejudice to any other provisions relating to labelling requirements contained in these regulations, every container of products covered under these regulations or any label affixed thereto shall indicate in a clear, conspicuous and in an easily readable manner, the words "IMPORTANT NOTICE" in capital letters and indicating thereunder the following particulars, namely: -

(a) a statement "MOTHER'S MILK IS BEST FOR YOUR BABY" in capital letters. The types of letters used shall not be less than five millimetres and the text of such statement shall be in the front of the pack of every container of food for infant nutrition or any label affixed thereto. The colour of the text printed or used shall be different from that of the background of the label, container as the case maybe. In case of infant food, a statement indicating "Infant food shall be introduced only after the age of six months and up to the age of two years" shall also be given.

Provided that in case of food for special medical purpose intended for infants where breastfeeding is contraindicated on medical grounds for the disease(s), disorders(s) or medical condition(s) for which the product is intended, the

labelling provision “MOTHERS’ MILK IS BEST FOR YOUR BABY” shall not be required.

(b) a statement that infant milk substitute or infant food 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;

(c) a warning that Infant milk substitute or infant food is not the sole source of nourishment of an infant;

(d) 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;

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.

(e) the approximate composition of nutrients per 100 gm or 100 ml of the product including its energy value in kilo calories or kilo joules;

(f) the storage condition specifically stating “Store in a cool and dry place in an air tight container” or the like (after opening use the contents within the period mentioned or the expiry date whichever is earlier);

(g) the feeding chart and directions for use and instruction for discarding leftover feed;

(h) instruction for use of measuring scoop (level or heaped) and the quantity per scoop (scoop to be given with pack);

(i) indicating the Batch number, Month and Year of its manufacture, Use by date or Recommended Last Consumption date or Expiry Date;

(j) the protein efficiency ratio (PER) which shall be minimum 2.5, if the product other than infant milk substitute is claimed to have higher quality protein;

(k) the specific name of the food additives and appropriate class titles, if permitted, shall also be declared;

(2) No containers or label of food for infant nutrition shall have a picture of infant or women or both. It shall not have picture or other graphic materials or phrases designed to increase the saleability or the infant milk substitute or infant food. The terms “Humanised” or “Maternalised” or any other similar words shall not be used. The package and/or any other label of infant milk substitute or infant food shall not exhibit the words, “Full Protein Food”, “Energy Food”, “Completer Food” or “Health Food” or any other similar expression.

(3) The product which contains neither milk nor any milk derivatives shall be labelled “Contains no milk or milk products or milk derivatives” in conspicuous manner.

(4) Declaration to be surrounded by line: There shall be a surrounding line enclosing the declaration where the words “unsuitable for babies” are required to be used. The distance between any part of the word “unsuitable for babies” surrounding the line enclosing these words shall not be less than 1.5 mm.

(5) A warning relating to allergen if any ingredients with known allergenicity are present;

(6) A warning against inherent contamination as under:

“Warning: Boiled and cooled water shall be used to prepare this product and any leftover product must be discarded to reduce the risk of infection”.

5. Food Additives:

(1) Food for infant nutrition shall be free from preservatives, added colours and flavours.

(2) Only the food additives listed under these regulations shall be used in the foods covered under these regulations. The articles of food may contain carry over food additives subject to compliance with the provisions specified under 3.1.1 (10) of Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

6. Hygiene: The product covered under these regulations shall be prepared and handled in accordance with the requirement specified in Schedule-IV of the Food Safety and

Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008) specified by Codex Alimentarius Commission.

Chapter 2

Infant Milk Substitute

7. Infant formula: This standard applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants during the first six months.

(1) Composition:

(a) Infant formula is a product based on milk of cow or buffalo or other milch animals as defined under the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 or mixture thereof, and other nutrients and ingredients which have been provided under these regulations.

(b) The product may be modified by partial removal or substitution of different milk solids and addition of carbohydrates; and salts such as phosphates and citrates. Only precooked and / or gelatinised starches gluten-free by nature may be added to infant formula up to 30 per cent of total carbohydrates and up to 2 gm/100ml.

(c) The infant formula may contain vegetable oils rich in polyunsaturated fatty acids to partially substitute milk fat. It may contain medium chain triglycerides. Hydrogenated vegetable oils and fats shall not be used in infant formula.

(d) The infant formula may contain fructo-oligosaccharides and/or galacto-oligosaccharides. In either case, their content shall not exceed 0.8 gm/100ml. When used in combination the percentage ratio shall be 90:10 of galacto-oligosaccharides and fructo-oligosaccharides, respectively.

(e) Infant formula may contain L(+) lactic acid producing bacteria with prior approval of the Food Authority.

(f) Infant formula ready for consumption in accordance with instructions of the manufacturer shall contain not less than 60 kcal and not more than 70kcal of energy per 100 ml.

(g) The infant formula shall also conform to the following requirements, namely:-

Sl. No.	Parameters	Requirements per 100 g	Requirements per 100 kcal
1.	Moisture, per cent by weight, Max	4.50	-
2.	Total Protein (N x 6.25[1]) per cent by weight	10.00 - 16.00	2.10 - 3.40
3.	Total fat, including milk fat[2], g Milk fat, g, Min	18.00-25.00 12.00	3.80 - 5.30 2.50
4.	a) Linoleic acid, mg b) α-Linolenic acid, mg, Min c) Ratio of Linoleic acid/α-Linolenic acid, Min.	1500.00 - 7000.00 250.00 6:1	300.00- 1500.00 50.00 6:1
5.	Carbohydrates, per cent by weight	45.00 -70.00	9.60 - 14.90
6.	Total ash, percent by weight, Max	8.50	-
7.	Ash insoluble in dilute hydrochloric acid, per cent by weight, Max	0.10	-
8.	Vitamin A (as retinol equivalent, RE), µg	350.00 - 823.00	75.00 - 175.00
9.	Vitamin D, µg	5.00 - 14.00	1.00 - 3.00
10.	Vitamin E (as alpha tocopherol equivalent), mg	2.50 - 6.00	0.50 - 1.30
11.	Vitamin K, µg	7.50 - 19.00	1.60 - 4.00
12.	Vitamin C, mg	25.00 - 75.00	5.30 - 16.00
13.	Thiamine, µg	200.00 - 517.00	42.50 - 110.00
14.	Riboflavin, µg	400.00 - 2000.00	85.10 - 425.50
15.	Niacin equivalent, mg	3.80 - 9.90	0.80 - 2.10
16.	Pyridoxine, µg	100.00 - 400.00	21.30 - 85.10
17.	Dietary Folate equivalent (DFE)[3], µg	15.00 - 56.90	3.20 - 12.10

Sl. No.	Parameters	Requirements per 100 g	Requirements per 100 kcal
18.	Pantothenic acid, mg	2.00 - 10.00	0.42- 2.12
19.	[1][Vitamin B12, µg	0.25 – 4.0	0.05 - 0.90]
20.	Biotin, µg	7.50 - 50.00	1.60 - 10.60
21.	Choline, mg, Min	32.00	6.80
22.	Sodium, mg	90.00 - 300.00	19.15 - 63.80
23.	Potassium, mg	300.00 - 900.00	63.82 - 191.48
24.	Chloride, mg	250.00 - 800.00	53.20 - 170.20
25.	Calcium, mg	250.00 - 700.00	53.20 - 148.90
26.	Phosphorous, mg	125.00 - 500.00	26.60 - 106.40
27.	Calcium : Phosphorus ratio	1:1 - 2:1	1:1 - 2:1
28.	Magnesium, mg	30.00 – 75.20	6.40 - 16.00
29.	Iron, mg	3.00 - 7.00	0.60 - 1.50
30.	Iodine, µg	90.00 – 225.60	19.15 - 48.00
31.	Copper, µg	160.00 - 470.00	34.00 - 100.00
32.	Zinc, mg	2.50 - 5.90	0.50- 1.25
33.	Manganese, µg	5.00 - 500.00	1.00 - 106.40
34.	Selenium, µg	5.00 - 17.00	1.00 - 3.60

1. Where only milk protein is used, a factor N x 6.38 may be used

2. Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20 per cent of total fatty acids. The contents of trans fatty acids shall not exceed 3 per cent of total fatty acids. The erucic acid content shall not exceed 1 per cent of total fatty acids. The total content of phopsholipids shall not exceed 300 mg/100 kcal.

3. 1 microgram DFE = 0.6 microgram folic acid

(h) **Optional Ingredients:** when prepared in accordance with instructions for use infant formula may contain other nutrients which are ordinarily found in human milk in amounts prescribed below:

Sl. No.	Nutrients	Requirements per 100 ml of the product ready for consumption
1.	Carotenes, mg, Min	0.025
2.	Amino acids (L forms), mg, Min	0.90
3.	Non-protein nitrogen, mg, Min	17.00

Sl. No.	Nutrients	Requirements per 100 ml of the product ready for consumption
4.	Nucleotides, mg, Min	1.17
5.	L-carnitine, mg, Min	0.72
6.	Lactalbumin, mg, Min	140.00
7.	Lactoferrin, mg, Min	27.00
8.	Lysozyme, mg, Min	80.00
9.	Glucosamine, mg, Min	70.00
10.	Inositol, mg, Min	2.70
11.	Citric acid, mg, Min	35.00
12.	Cholesterol, mg, Min	8.80
13.	Fucose, mg, Min	130.00
14.	Lipid phosphorous, mg, Min	0.70
15.	Prostaglandins, mg, Min	PGE 15.00 PGF 40.00
16.	Taurine, mg, Max	8.40
17.	Molybdenum, μg	0.90 - 6.50
18.	Chromium, μg	0.90 - 6.50

(2) Food additives:

(a) The following food additives may be used in the preparation of infant formula ready for consumption prepared following manufacturer's instructions, unless otherwise indicated:

Food Additive	INS No.	Recommended maximum level per 100 ml of the product ready for consumption
Thickeners		
Guar gum	412	0.1 gm in liquid formulas containing hydrolysed protein
Carob bean gum (Locust bean gum)	410	0.1gm in all types of infant formula

Food Additive	INS No.	Recommended maximum level per 100 ml of the product ready for consumption
Distarch phosphate	1412	0.5 gm singly or in combination in soy based infant formula only 2.5 gm singly or in combination in hydrolysed protein and / or amino acid based infant formula only
Acetylated distarch phosphate	1414	
Phosphated distarch phosphate	1413	
Hydroxypropyl starch	1440	
Carrageenan	407	0.03 gm (in regular milk and soy based liquid infant formula only) 0.1 gm in hydrolysed protein and / or amino acid based liquid infant formula only
Emulsifiers		
Lecithin	322	0.5 gm in all types of infant formula*
Mono- and diglycerides	471	0.4 gm in all types of infant formula*
Citric and fatty acid esters of glycerol	472c	0.9 gm in all types of liquid infant formula 0.75 gm in all types of powdered infant formula
Acidity Regulators		
Sodium hydroxide	524	0.2 gm singly or in combination and within the limits for sodium, potassium and calcium in provision (g) of sub-regulation 7(1) in all types of infant formula
Sodium hydrogen carbonate	500ii	
Sodium carbonate	500i	
Potassium hydrogen carbonate	501ii	
Potassium carbonate	501i	
Potassium hydroxide	525	
Calcium hydroxide	526	
L(+) lactic acid	270	GMP in all types of infant formula
Citric acid	330	
Sodium dihydrogen citrate	331i	
Trisodium citrate	331iii	
Potassium citrate	332	

Food Additive	INS No.	Recommended maximum level per 100 ml of the product ready for consumption
Sodium dihydrogen phosphate, disodium hydrogen phosphate and trisodium phosphate	339 i, ii and iii	45 mg as phosphorous singly or in combination and within limits for sodium, potassium and phosphorous in provision (g) of sub-regulation 7(1) in all types of infant formula
Potassium dihydrogen phosphate, dipotassium hydrogen phosphate and tripotassium phosphate	340 i, ii and iii	
Antioxidants		
Mixed tocopherol concentrate	307b	1 mg in all types of infant formula singly or in combination
Ascorbyl palmitate	304i	1 mg in all type of infant formula singly or in combination
Packaging gases		
Carbon dioxide	290	GMP
Nitrogen	941	

* If more than one of the substances INS 322, 471 are added the maximum level for each of those substance is lowered with the relative part as present of the other substances.

(b) Food additives shown in Schedule I (d) for special nutrient formulations may also be used.

[1][**(3)** where an infant formula in powder format is manufactured without use of any vegetable oil, linoleate, vitamin E, starch, specified food additive and optional ingredients, the product may be named as 'Infant Milk Food].

Chapter 3

Infant Food

8. Milk cereal based complementary Food: This standard applies to milk-cereal based complementary food in powder, small granules or flakes form intended to complement the diet of infant after six months up to twenty four months of age.

(1) Composition:

(a) Milk cereal based complementary food is based on milk of cow or buffalo or other milch animals as specified under the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 or mixture thereof, and/or other nutrients or ingredients which have been provided under these regulations.

(b) It may contain a variety of cereals, pulses, soybean, millets, fruits and vegetables or their products, egg or egg products, nuts and edible oil seeds after processing.

(c) It may also contain edible vegetable oil, defatted edible oil seed extracts, protein concentrates or protein isolates or protein hydrolysates, milk solids, various carbohydrates, and salts such as phosphates and citrates. It shall not contain hydrogenated vegetable fats and oils.

(d) The milk cereal based complementary food shall conform to the following requirements, namely:

Sl. No.	**Parameters**	**Requirements per 100 g**	**Requirements per 100 kcal**
1.	Moisture, per cent by weight, Max	5.00	-
2.	Total protein including milk protein, per cent by weight (N x 6.25), Min Milk protein (N x 6.38), per cent by weight, Min	15.00 5.00	3.20 1.00
3.	Total fat (including milk fat), per cent by weight, Min Milk fat, per cent by weight, Min	7.50 5.00	1.60 1.00
4.	Total carbohydrates, per cent by weight, Min	55.00	11.70
5.	Total ash, per cent by weight, Max	5.00	-
6.	Ash insoluble in dilute hydrochloric acid; per cent by weight, Max	0.10	-

Sl. No.	Parameters	Requirements per 100 g	Requirements per 100 kcal
7.	Crude fibre (on dry basis), per cent by weight, Max	1.00	-
8.	Vitamin A (as retinol equivalent, RE), µg	350.00 - 823.00	75.00 - 175.00
9.	Vitamin D, µg	5.00 – 14.00	1.00 - 3.00
10.	Vitamin C, mg	25.00 - 75.00	5.30 - 16.00
11.	Thiamine, mg	0.20 - 0.50	0.04 - 0.10
12.	Riboflavin, mg	0.40 - 2.00	0.08 - 0.40
13.	Niacin equivalent, mg	3.80 - 9.90	0.80 - 2.10
14.	Dietary Folate equivalent (DFE)*, µg	15.00 - 50.00	3.20 - 10.60
15.	Iron, mg	3.00 - 7.00	0.60 - 1.50
16.	Zinc, mg	2.50 - 5.90	0.50 - 1.25

*1 microgram DFE = 0.6 microgram folic acid

(e) **Optional Ingredient or Nutrient:** It may also contain optional ingredient or nutrient as below:

Sl. No.	Nutrient	Requirements per 100 g	Requirements per 100 kcal
1.	Pantothenic acid, mg	2.00 - 10.00	0.40 - 2.10
2.	Vitamin B 12, µg	0.25 - 0.70	0.05 - 0.15
3.	Vitamin K, µg	7.50 - 19.00	1.60 - 4.00
4.	Choline, mg, Max	32.00	6.80
5.	Inositol, mg	20.00 200.00	4.25 - 42.55
6.	Calcium, mg	250.00 - 700.00	53.20 - 148.90
7.	Phosphorus, mg	125.00 - 500.00	26.60 - 106.40
8.	Chloride, mg	250.00 - 800.00	53.20 - 170.20
9.	Magnesium, mg	30.00 - 75.20	6.40 - 16.00
10.	Sodium, mg	90.00 - 300.00	19.15 - 63.80

Sl. No.	Nutrient	Requirements per 100 g	Requirements per 100 kcal
11.	Selenium, µg	5.00 - 17.00	1.00 - 3.60
12.	Taurine, mg, Max	60.00	12.75
13.	L-amino acids, mg, Min	0.90	0.20
14.	L-Carnitine, mg, Min	5.00	1.00
15.	Biotin, µg	7.50 - 50.00	1.60 - 10.60
16.	Iodine, µg	90.00 - 225.60	19.15 - 48.00
17.	Potassium, mg	300.00 - 900.00	63.80 - 191.50
18.	Pyridoxine, µg	100.00 - 400.00	21.30 - 85.10

Highlighted text shows the provision published in Corrigenda dated 31.03.2021

(2) Food Additives:

(a) Following additives are permitted in the preparation of milk cereal based complementary food for infants in 100 gm of the product ready for consumption prepared following manufacturer's instructions, unless otherwise indicated.

Food Additive	INS No.	Recommended maximum Level per 100 g of the product ready for consumption
Emulsifiers		
Lecithins	322	1500 mg
Mono- and diglycerides	471	5000 mg singly or in combination
Acetic fatty acid esters of glycerol	472a	
Lactic fatty acid esters of glycerol	472b	
Citric acid fatty acid esters of glycerol	472c	
Acidity regulators		
Sodium hydrogen carbonate	500ii	GMP
Potassium hydrogen carbonate	501ii	

Food Additive	**INS No.**	**Recommended maximum Level per 100 g of the product ready for consumption**
Calcium carbonate	170i	GMP
L(+)lactic acid	270	
Citric acid	330	
Acetic acid	260	
Potassium acetate	261	
Sodium acetate	262i	
Calcium acetate	263	
Malic acid (DL)-L(+) form only	296	
Sodium lactate (solution)-L(+) form only	325	
Potassium lactate (solution)-L(+) form only	326	
Calcium lactate-L(+) form only	327	
Monosodium citrate	331i	
Trisodium citrate	331ii	
Monopotassium citrate	332i	
Tripotassium citrate	332ii	
Calcium citrate	333	
Hydrochloric acid	507	
Sodium hydroxide	524	
Potassium hydroxide	525	
Calcium hydroxide	526	
Glucono-delta-lactone	575	GMP
L(+)Tartaric acid	334	500 mg singly or in combination
Disodium tartarate	335ii	
Potassium sodium L(+) tartrate L(+) form only	337	
Ortho phosphoric acid	338	Only for pH adjustment 440 mg singly or in combination as phosphorous
Mono sodium ortho phosphate	339i	
Disodium orthophosphate	339ii	

Food Additive	**INS No.**	**Recommended maximum Level per 100 g of the product ready for consumption**
Trisodium orthophosphate	339iii	Only for pH adjustment 440 mg singly or in combination as phosphorous
Monopotassium orthophosphate	340i	
Dipotassium orthophosphate	340ii	
Tripotassium orthophosphate	340iii	
Monocalcium orthophosphate	341i	
Dicalcium orthophosphate	341ii	
Tricalcium orthophosphate	341iii	
Antioxidants		
Mixed tocopherol concentrate	306	300 mg/kg fat or oil singly or in combination
Alpha tocopherol	307	
L-ascorbylpalmitate	304	200 mg/kg fat or oil
L-ascorbic acid	300	50 mg expressed as ascorbic acid
Sodium ascorbate	301	
Potassium ascorbate	303	
Calcium ascorbate	302	20 mg expressed as ascorbic acid
Raising agent		
Ammonium carbonate	503i	GMP
Ammonium hydrogen carbonate	503ii	
Sodium carbonate	500i	
sodium hydrogen carbonate	500ii	
Thickeners		
Carob bean gum	410	1000 mg singly or in combination 2000 mg in gluten free cereal based foods
Guar gum	412	
Gum Arabic	414	
Xanthan gum	415	
Pectins (amidated and non amidated)	440	
Oxidized starch	1404	5000 mg singly or in combination
Mono starch phosphate	1410	

Food Additive	INS No.	Recommended maximum Level per 100 g of the product ready for consumption
Distarch phosphate	1412	5000 mg singly or in combination
Phosphateddistarch phosphate	1413	
Acetylated distarch phosphate	1414	
Acetylated distarchadipate	1422	
Starch acetate esterified with acetic anhydride	1420	
Starch sodium octenyl succinate	1450	
Acetylated oxidized starch	1451	
Anticaking agent		
Silicon dioxide	551	GMP
Packaging gases		
Carbon dioxide	290	GMP
Nitrogen	941	
Enzymes		
Alpha amylase	-	GMP

(b) Food additives shown in Schedule I (d) for special nutrient formulations may also be used.

9. Processed cereal based complementary Food: This standard applies to processed cereal based complementary food in powder, small granules or flakes form intended to complement the diet of infant after six months up to twenty-four months of age.

(1) Composition:

(a) Processed cereal based complementary food is a product based on variety of cereals, pulses including soybean, millets, nuts and edible oil seeds.

(b) It shall contain milled cereals and legumes combined accounting for not less than 75 per cent.

(c) The Sodium content of the product shall not exceed 100 mg per 100 kcals of the ready to eat product.

(d) It may also contain other ingredients such as protein concentrates, protein isolates, protein hydrolysates, essential amino acids, milk and milk products, eggs and egg products, edible vegetable oils, defatted edible oil seed extracts, fruits and vegetables or their products, nuts or their products, honey, corn syrup, malt and various carbohydrates. It shall not contain hydrogenated vegetable oils and fats.

Provided that products containing honey or maple syrup shall be processed in such a way as to destroy spores of *Clostridium botulimum.*

(e) It may also contain other vitamins and minerals other than the listed ones. When any of these nutrient is added, the same shall not exceed the Recommended Dietary allowances (RDA) as specified by the Indian Council of Medical Research and in case such standards are not specified, the standards laid down by Codex Alimentarious Commission, shall apply.

(f) The processed cereal based complementary food shall conform to the following requirements, namely:

Sl. No.	**Parameters**	**Requirements per 100 g**	**Requirements per 100 kcal**
1.	Moisture, per cent by weight, Max	5.00	-
2.	Total protein (N x 6.25)[1], per cent by weight, Min	15.00	3.20
3.	Total fat, per cent by weight, Max	7.50	1.60
4.	Total carbohydrates, per cent by weight, Min	55.00	11.70
5.	Total ash, per cent by weight, Max	5.00	-
6.	Ash insoluble in dilute hydrochloric acid, per cent by weight, Max	0.10	-
7.	Crude fibre (on dry basis), per cent by weight, Max	1.00	-
8.	Vitamin A (as retinol equivalent), µg	350.00 - 823.00	75.00 - 175.00
9.	Vitamin D, µg	5.00 - 14.00	1.00 - 3.00
10.	Vitamin C, mg	25.00 - 75.00	5.30 - 16.0

Sl. No.	Parameters	Requirements per 100 g	Requirements per 100 kcal
11.	Thiamine, mg	0.20 - 0.50	0.04 - 0.10
12.	Riboflavin, mg	0.40 - 2.00	0.08 - 0.40
13.	Niacin equivalent, mg	3.80 - 9.90	0.80 - 2.10
14.	Dietary Folate equivalent (DFE)[2], µg	15.00 - 50.00	3.20 - 10.60
15.	Iron, mg	3.00 - 5.65	0.60 - 1.20
16.	Zinc, mg	2.50 - 5.90	0.50 - 1.25
17.	Pantothenic acid, mg	2.00 - 10.00	0.40 - 2.10
18.	Pyridoxine, µg	100.00 - 400.00	21.30 - 85.10
19.	Vitamin B12, µg	0.25 - 0.70	0.05 - 0.15
20.	Biotin, µg	7.50 - 50.0	1.60 - 10.60
21.	Choline, mg, Min	32.00	6.80
22.	Inositol, mg	20.00 - 200.00	4.25 - 42.55
23.	Selenium, µg	5.00 - 17.00	1.00 - 3.60

1. Where the product is intended to be mixed with water or milk before consumption, the minimum content of protein shall be 15 per cent by weight. Protein Efficiency Ratio (PER) of processed cereal based complementary food shall not be less than 70 per cent of that of casein which is 2.5. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture and only in the proportions necessary for that purpose. Only natural forms of L-amino acids shall be used.

2. 1 microgram DFE = 0.6 microgram folic acid

(2) Food Additives:

(a) Following additives are permitted in the preparation of processed cereal based complementary food for infants in 100 g of the product ready for consumption prepared following manufacturer's instructions unless otherwise indicated.

Food Additive	INS No.	Recommended maximum level per 100 g of the product ready for consumption
Emulsifiers		
Lecithins	322	1500 mg

Food Additive	**INS No.**	**Recommended maximum level per 100 g of the product ready for consumption**
Mono- and diglycerides	471	5000 mg singly or in combination
Acetic fatty acid esters of glycerol	472a	
Lactic fatty acid esters of glycerol	472b	
Citric acid fatty acid esters of glycerol	472c	
Acidity regulators		
Sodium hydrogen carbonate	500ii	GMP
Potassium hydrogen carbonate	501ii	
Calcium carbonate	170i	
L(+)lactic acid	270	
Citric acid	330	
Acetic acid	260	
Potassium acetate	261	
Sodium acetate	262i	
Calcium acetate	263	
Malic acid (DL)-L(+) form only	296	
Sodium lactate (solution)-L(+) form only	325	
Potassium lactate (solution)-L(+) form only	326	
Calcium lactate-L(+) form only	327	
Monosodium citrate	331i	
Trisodium citrate	331ii	
Monopotassium citrate	332i	
Tripotassium citrate	332ii	

Food Additive	**INS No.**	**Recommended maximum level per 100 g of the product ready for consumption**
Calcium citrate	333	GMP
Hydrochloric acid	507	
Sodium hydroxide	524	
Potassium hydroxide	525	
Calcium hydroxide	526	
Glucono-delta-lactone	575	GMP
L(+)Tartaric acid	334	500 mg singly or in combination
Disodium tartarate	335ii	
Potassium sodium L(+) tartrate L(+) form only	337	
Ortho phosphoric acid	338	Only for pH adjustment 440 mg singly or in combination as phosphorous
Mono sodium ortho phosphate	339i	
Disodium orthophosphate	339ii	
Trisodium orthophosphate	339iii	
Monopotassium orthophosphate	340i	
Dipotassium orthophosphate	340ii	
Tripotassium orthophosphate	340iii	
Monocalcium orthophosphate	341i	
Dicalcium orthophosphate	341ii	
Tricalcium orthophosphate	341iii	
Antioxidants		
Mixed tocopherol concentrate	306	300 mg/kg fat or oil singly or in combination
Alpha tocopherol	307	
L-ascorbylpalmitate	304	200 mg/kg fat or oil

Food Additive	INS No.	Recommended maximum level per 100 g of the product ready for consumption
L-ascorbic acid	300	50 mg expressed as ascorbic acid
Sodium ascorbate	301	
Potassium ascorbate	303	
Calcium ascorbate	302	20 mg expressed as ascorbic acid
Raising agent		
Ammonium carbonate	503i	GMP
Ammonium hydrogen carbonate	503ii	
Sodium carbonate	500i	
sodium hydrogen carbonate	500ii	
Thickeners		
Carob bean gum	410	1000 mg singly or in combination 2000 mg in gluten free cereal based foods
Guar gum	412	
Gum Arabic	414	
Xanthan gum	415	
Pectins (amidated and non amidated)	440	
Oxidized starch	1404	5000 mg singly or in combination
Mono starch phosphate	1410	
Distarch phosphate	1412	
Phosphateddistarch phosphate	1413	
Acetylated distarch phosphate	1414	
Acetylated distarchadipate	1422	
Starch acetate esterified with acetic anhydride	1420	
Starch sodium octenyl succinate	1450	
Acetylated oxidized starch	1451	

Food Additive	INS No.	Recommended maximum level per 100 g of the product ready for consumption
Anticaking agent		
Silicon dioxide	551	GMP
Packaging gases		
Carbon dioxide	290	GMP
Nitrogen	941	
Enzymes		
Alpha amylase	-	GMP

(b) Food additives shown in Schedule I (d) for special nutrient formulations may also be used.

(3) The processed cereal based complementary foods for use in specific conditions, where protein needs to be restricted and where other cereals like wheat, soya, legumes and milk cannot be used, such processed cereal based complementary foods shall be prepared with single cereal like rice or ragi, which shall have the minimum protein content of 6 to 9 per cent, such products shall be conspicuously labelled, "mono grain based complementary foods for use in specific conditions under medical guidance only".

10. Follow-up Formula: This standard applies to the composition of Follow-up formula in powder or liquid form for infant after six months up to twenty four months of age. The product shall be nutritionally adequate to contribute to normal growth and development when used in accordance with its directions for use. Follow-up formula, in powdered form requires water for preparation.

(1) Composition:

(a) Follow-up formula is a product based on milk of cow or buffalo or other milch animals as specified under the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 or mixture thereof, and other nutrients and ingredients provided under these regulations.

(b) The follow-up formula shall have protein content minimum of 3 g per 100 kcal derived from whole or skimmed milk or with minor modification that does not substantially impair the vitamin or mineral content of milk and which

represents a minimum of 90 per cent of total protein. The product may contain vegetable proteins.

(c) The quality of protein shall not be less than 85 per cent of casein. Essential amino acids may be added to follow-up formula to improve its nutritional value. Essential amino acids may be added to improve protein quality only in amounts necessary for that purpose. Only L forms of amino acids shall be used.

(d) Fat not less than 3 gm and not more than 6 gm per 100kcal. Linoleic acid in fat shall not be less than 300 mg per 100 kcal. Partially hydrogenated oils and fats shall not be used in follow-up formula. Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20 per cent of total fatty acids. The content of trans fatty acids shall not exceed 3 per cent of total fatty acids. The erucic acid content shall not exceed 1 per cent of total fatty acids.

(e) The product shall contain nutritionally available carbohydrates suitable for feeding in such quantities so as to adjust the product to the energy density given below:

100 ml of ready-to-use formula when prepared in accordance with instructions for use shall provide 60 to 85 kcal of energy. Only precooked and / or gelatinised starches gluten-free by nature may be added.

(f) It may also contain other vitamins and minerals other than the listed ones. When any of these nutrient is added, the same shall not exceed the Recommended Dietary Allowances (RDA) as specified by the Indian council of Medical Research and in case such standards are not specified, the standards laid down by Codex Alimentarius Commission, shall apply.

(g) It may also contain optional ingredients permitted under Infant Formula.

(h) The follow-up shall conform to the following requirements, namely:

Sl. No.	**Parameters**	**Requirements per 100 g**	**Requirements per 100 kcal**
1.	Moisture, percent by weight, Max	4.50	-
2.	Total ash, per cent by weight, Max	8.50	-
3.	Ash insoluble in dilute hydrochloric acid, per cent by weight, Max	0.10	-

Sl. No.	Parameters	Requirements per 100 g	Requirements per 100 kcal
4.	Vitamin A (as retinol equivalent), µg	350.00 - 823.00	75.00 - 175.00
5.	Vitamin D, µg	5.0 - 14.00	1.00 - 3.00
6.	Vitamin E (as alpha-tocopherols), mg	2.50 - 6.00	0.50 - 1.30
7.	Vitamin K, µg	7.50 - 19.00	1.60 - 4.00
8.	Vitamin C, mg	25.0 - 75.00	5.30 - 16.00
9.	Thiamine, µg	200.00 - 517.00	42.55 - 110.00
10.	Riboflavin, µg	400.00 - 2000.00	85.10 - 425.50
11.	Niacin, equivalent mg	3.80 - 9.90	0.80 - 2.10
12.	Pyridoxine, µg per 100 g	100.00 - 400.00	21.30 - 85.10
13.	Dietary Folate equivalent (DFE)*, µg	15.00 - 50.00	3.20 - 10.60
14.	Pantothenic acid, mg	2.00 - 10.00	0.40 - 2.10
15.	[1][Vitamin B12, µg	0.25 - 4.0	0.05 - 0.90]
16.	Choline, mg, Min	32.00	6.80
17.	Biotin, µg	7.50 - 19.0	1.60 - 4.00
18.	Sodium, mg	90.00 - 300.00	19.15 - 63.80
19.	Potassium, mg	300.00 - 900.00	63.80 - 191.50
20.	Chloride, mg	250.00 - 800.00	53.20 - 170.20
21.	Calcium, mg	405.00 - 800.00	86.20 - 170.20
22.	Phosphorus, mg	270.00 - 500.00	57.45 - 106.40
23.	Magnesium, mg	30.00 - 75.20	6.40 - 16.00
24.	Iron, mg	3.00 - 7.00	0.60 - 1.50
25.	Iodine, µg	90.00 – 225.60	19.15 - 48.00
26.	Copper, µg	160.00 - 470.00	34.00 - 100.00
27.	Zinc, mg	2.50 - 5.90	0.50 - 1.25
28.	Manganese, µg	5.00 - 50.00	1.00 - 10.60
29.	Selenium, µg	5.00 - 17.00	1.00 - 3.60
30.	Inositol, per 100 ml of the product prepared in accordance with the	40.00	8.50

Sl. No.	Parameters	Requirements per 100 g	Requirements per 100 kcal
	manufacturer's instructions, mg, Max		
31.	Taurine, mg, Max	60.00	12.75
32.	Essential Amino acids, per 100 ml of the product prepared in accordance with the manufacturer's instructions, mg, Min	0.90	0.19

*1 microgram DFE = 0.6 microgram folic acid

Highlighted text shows the provision published in Corrigenda dated 31.03.2021

(2) Food Additives:

(a) The following additives may be used in the preparation of follow up formula ready for consumption prepared following manufacturer's instructions, unless otherwise indicated.

Food Additive	INS No.	Recommended maximum level per 100 ml of Product Ready-for consumption
Thickening agent		
Guar gum	412	0.1 g
Locust bean gum (carob bean gum)	410	0.5 g singly or in combination
Distarch phosphate	1412	
Acetylated distarch phosphate	1414	
Phosphateddistarch phosphate	1413	

Food Additive	**INS No.**	**Recommended maximum level per 100 ml of Product Ready-for consumption**
Acetylated distarchadipate	1422	2.5 g singly or in combination in hydrolyzed protein and / or amino acid based products only
Carrageenan	407	0.03 g singly or in combination in milk and soy based products only 0.1 g singly or in combination in hydrolyzed protein and / or amino acid based liquid products only
Pectins	440	1 g
Emulsifiers		
Lecithin	322(i)	0.5 g
Mono- and diglycerides	471	0.4 g
[1][Acidity regulators]		
Sodium hydrogen carbonate	500ii	GMP within the limits for sodium in clause (h) of sub-regulation (1) of regulation 10
Sodium carbonate	500i	
Sodium citrate	331i	
Potassium hydrogen carbonate	501ii	
Potassium carbonate	501i	
Potassium citrate	332i	
Sodium hydroxide	525	
Potassium hydroxide	525	
Calcium hydroxide	526	
L(+) lactic acid L(+) lactic acid producing cultures	270	
Citric acid	330	
Antioxidants		
Mixed tocopherol concentrate	307b	3 mg singly or in combination
Alpha tocopherol	307a&c	

Food Additive	INS No.	Recommended maximum level per 100 ml of Product Ready-for consumption
L-ascorbylpalmitate	304	5 mg singly or in combination expressed as ascorbic acid
L-ascorbic acid	300	
Sodium ascorbate	301	
Calcium ascorbate	302	
[1][Packaging gases		
Carbon dioxide	290	GMP]
Nitrogen	941	

(b) Food additives shown in Annexure I (d) for special nutrient formulations may also be used.

11. Food for Infants based on traditional food ingredients: This standard applies to food prepared using traditional food ingredients intended for infants after 6 months up to 24 months of age.

(1) Composition:

(a) The composition of such foods shall be based on traditional food ingredients such as rice, rice flour, wheat flour, semolina, pulses and other cereals, spices, fruits, dry fruits and vegetables, milk, ghee, egg and egg products.

(b) Ingredients used shall be safe and comply with all the applicable provisions of Food safety and Standard Regulations, 2011.

(c) Such foods shall be either in the form "Ready to Use" or to be reconstituted with medium such as milk, water, curd or any other medium appropriate for infant. Clear instructions for use shall be provided on the label.

(d) These shall be manufactured adopting necessary and appropriate technologies during the process and packaging so that they retain their nutritional and other physical and sensory attributes.

(2) If required, the food additives specified for milk cereal based complementary food under these regulations may be used.

(3) The products shall bear prominently the term “Traditional Food for Infants” on the front of the pack label.

(4) Explanatory note: A non-exhaustive examples of foods for infants based on traditional foods are:

(a) Cooked lentils, cereals, dry fruits, grains mashed to a pasty form, sweetened with sugar or jaggery or honey;
(b) Cooked vegetables mashed to a pasty form either sweetened or with little ghee;
(c) Ragi malt mix;
(d) Semolina or sooji based foods with either milk or curd or ghee.

Chapter 4

Food for special medical purpose intended for infants

12. Food for special medical purpose intended for infants: This standard applies to food for special medical purpose intended for infants from birth to 24 months in liquid or powdered form intended for use, where necessary, as a substitute for human milk or formula in meeting the special nutritional requirements arising from the disorders, diseases or medical conditions for whose dietary management the product has been formulated.

(1) Composition:

(a) Food for special medical purpose intended for infants is a product based on ingredients (from known and well established sources) suitable for human consumption.

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

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

(d) Optional ingredients: In addition to the compositional requirements to provide substances ordinarily found in human milk or required other ingredients, optional ingredients as specified under infant formula may be added to ensure that the formulation is suitable as the sole source of nutrition for the infant and for the dietary management of the disease, disorder or medical condition of the infant.

(e) The suitability for the intended special medical purpose, the suitability for the particular nutritional use of infants and the safety of these substances shall be scientifically demonstrated. The formula shall contain sufficient amounts of these substances to achieve the intended effect.

(2) No food business operator shall advertise the infant formula for special medical purpose intended for infants.

(3) Food Additives: The food for special medical purpose intended for infants shall comply with additives provisions specified in sub-regulation (2) of regulation 7 relating to additives for infant formula and sub-regulation (2) of regulation 10 relating to additives for follow up formula, as applicable. Food additives shown in Schedule I (d) for special nutrient formulations may also be used.

13. Preterm infant milk substitute: The preterm infant milk substitute is required for babies born before 37 weeks only and till they attain 40 weeks of age or as prescribed by physician.

(1) The preterm infant milk substitutes shall meet the following requirements:

Sl. No.	Nutrient	Requirements per 100 kcal	Requirements per kg/day
1.	Fluids	-	135.00-200.00
2.	Energy, kcal	-	110.00-130.00
3.	Total protein, g	3.20-4.10	3.50-4.50
4.	Total fat, g	4.40-6.00	4.80-6.60
	Linoleic acid, mg	350.00-1400.00	385.00-1540.00
	α-Linolenic acid, mg(Min)	50.00	55.00
5.	Docosahexaenoic acid (DHA), mg	11.00-27.00	12.00-30.00
6.	Eicosapentaenoic acid (EPA), mg(Max)	18.00	20.00
7.	Arachidonic acid (ARA), mg	16.00-39.00	18.00-42.00
8.	Carbohydrate, g	10.50-12.00	11.60-13.20
9.	Sodium, mg	63.00-105.00	69.00-115.00
10.	Potassium, mg	71.00-177.00	78.00-195.00
11.	Chloride, mg	95.00-161.00	105.00-177.00
12.	Calcium, mg	109.00-182.00	120.00-200.00
13.	Phosphate, mg	55.00-127.00	60.00-140.00
14.	Magnesium, mg	7.30-13.60	8.00-15.00
15.	Iron, mg	1.80-2.70	2.00-3.00
16.	Zinc, mg	1.30-2.30	1.40-2.50
17.	Copper, µg	90.00-210.00	100.00-230.00
18.	Selenium, µg	4.50-9.00	5.00-10.00

19.	Manganese, µg	0.90-13.60	1.00-15.00
20.	Iodine, µg	9.00-50.00	10.00-55.00
21.	Chromium, ng	27.00 – 2045.00	30.00-2250.00
22.	Molybdenum, µg	0.27-4.50	0.30-5.00
23.	Thiamin, µg	127.00-273.00	140.00-300.00
24.	Riboflavin, µg	181.00-364.00	200.00-400.00
25.	Niacin, mg	0.90-5.00	1.00-5.50
26.	Pantothenic acid, mg	0.45-1.90	0.50-2.10
27.	Pyridoxine, µg	45.00-273.00	50.00-300.00
28.	Cobalamin, µg	0.09-0.73	0.10-0.80
29.	Folic acid, µg	32.00-91.00	35.00-100.00
30.	L-Ascorbic acid, mg	18.00-50.00	20.00-55.00
31.	Biotin, µg	1.50-15.00	1.70-16.50
32.	Vitamin A, µg retinol equivalents	365.00-1000.00	400.00-1100.00
33.	Vitamin D, IU	100-350	800.00-1000.00
34.	Vitamin E, mg alpha tocopherol equivalents	2.00-10.00	2.20-11.00
35.	Vitamin K, mcg	4.00-25.00	4.40-28.00
36.	Choline, mg	7.30-50.00	8.00-55.00
37.	Inositol, mg	4.00-48.00	4.40-53.00

Highlighted text shows the provision published in Corrigenda dated 31.03.2021

(2) The containers of infant milk substitute meant for preterm baby or labels affixed thereto shall indicate the following additional information, namely: -

(a) the words "**FOR THE PRETERM BABY (BORN BEFORE 37 WEEKS)"** in capital and bold letters along with the product name in central panel;

(b) a statement **"RECOMMENDED TO BE TAKEN UNDER MEDICAL ADVICE ONLY"** in capital and bold letters.

14. Lactose free infant milk substitutes:

(1) In addition to the nutrient requirements specified for Infant formula (*except milk fat*) and follow-up formula lactose free infant milk substitute shall also meet the following requirements:

(a) Soy-protein based, lactose free formula shall have soy protein and glucose, dextrose, dextrin/maltodextrin, maltose and/ or sucrose as carbohydrates.

(b) Lactose-free cow/buffalo milk-based formulas shall have carbohydrate as glucose, dextrose, dextrin/maltodextrin, maltose and sucrose. It may also contain caseinates, milk protein concentrates, isolates and hydrolysates.

(c) Lactose content shall not exceed 0.05 per cent by weight.

(d) The fat content derived from vegetable oils shall not be less than 18 per cent by weight.

(2) The container of infant milk substitute for lactose intolerant infants or label affixed thereto shall indicate conspicuously "**LACTOSE-FREE**" in capital and bold letters.

(3) An advisory warning **"RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY"** shall appear on the label in capital and bold letters. The label shall also bear the following statements, namely: -

(a) "Lactose free infant milk substitute shall only be used in case of diarrhoea in infants due to lactose intolerance"

(b) "The lactose free infant milk substitute shall be withdrawn if there is no improvement in symptoms of intolerance".

15. Hypoallergenic infant milk substitutes:

(1) In addition to the nutrient requirements specified for infant formula and follow-up formula except for milk fat and milk protein, the hypoallergenic infant milk substitutes shall also meet the following requirement:

(a) Protein used shall be extensively hydrolysed whey protein or casein or contain only free amino acids.

(2) The product which contains neither milk nor any milk derivatives shall be labelled "CONTAINS NO MILK OR MILK PRODUCTS" in conspicuous manner.

(3) The container of infant milk substitute meant for infants with allergy to cow / buffalo/other milch animal (as specified under the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011) milk protein shall indicate conspicuously "**HYPOALLERGENIC FORMULA**" and statement "**RECOMMENDED TO BE TAKEN UNDER MEDICAL ADVICE ONLY**" in capital and bold letters on the label.

16. Foods for Infants with Inborn Errors of Metabolism (IEM): This standard applies to food intended for the specific dietary management of disease or a condition of infants with specific inborn error(s) of metabolism. This food is intended to be given under medical supervision.

(1) Description:

(a) A food for infant with IEM is a food which is formulated or processed to be consumed orally or administered enterally through a tube and is intended for the specific dietary management of a disease or a condition with distinctive nutritional requirements, based on well-established scientific principles, studies and medical evaluation.

(b) It is specially processed and formulated with nutrients desirable for the infant suffering from a specific IEM. The product shall exclude the ingredients/nutrients that

are harmful to the diseased infant. The essential characteristic involves a specific modification of the content or nature of proteins, fats or carbohydrates.

(c) It is intended for the dietary management of an infant who, because of therapeutic or chronic needs has restricted, limited or impaired capacity to ingest, digest, absorb or metabolize ordinary foodstuffs or infant formula or certain nutrients or who needs specific nutrients established by medical observations.

(d) Such foods fulfill unique nutritional needs of the infant with IEM through specific modifications or alterations and processing of the food components.

(e) The Food Authority shall specify the IEM conditions as approved by it after undertaking proper scientific evaluation. No food business operator shall manufacture, sell, market, or import products for IEM conditions except those specified by the Food Authority from time to time.

(2) Composition:

(a) The composition of food for infants with IEM shall be based on sound medical and nutritional principles. The nutritional safety and adequacy of the food shall be scientifically demonstrated to support the growth and development of infants with IEM. Their use shall be demonstrated by scientific evidence to be beneficial in the dietary management of the infants for whom it is intended.

(b) Ingredients used in such food shall be suitable and safe and shall comply with all the applicable provisions of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011. The product may have ingredients such as milk, carbohydrates, vegetable oils, hydrolysed proteins, amino acids, or any other ingredients required for the infants with IEM provided they are safe, desirable and nutritionally beneficial for infants with IEM.

(c) The product may also have ingredients that are scientifically and medically proven to be necessary for such foods. However, prior approval of the authority has to be taken.

(d) It may contain vitamins and minerals stated in infant formula; provided such nutrients are safe, desirable and not harmful for infants suffering from IEM. Vitamins, minerals and amino acids for infants suffering from IEM may be added at levels greater than RDA specified based on scientific or medical needs and under strict medical supervision.

(3) Labelling:

(a) The words '**FOOD FOR SPECIAL MEDICAL PURPOSE'** shall be printed in capital and bold letters in the immediate proximity of the name or brand name of the product.

(b) The statement "For the nutrition management of ..... (specific IEM disease(s), disorder(s) or medical condition(s) for which the product is intended, and for which it has been shown to be effective) shall be appearing on the label.

(c) An advisory warning **"RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY"** shall appearing on the label in capital and bold letters in an area separated from other written, printed or graphic information.

(d) Information on osmolality or osmolarity and/or acid-base balance shall be given when appropriate.

(e) Such foods in which essential characteristic involves a specific modification of the content or nature of proteins, fats or carbohydrates shall bear a description of this modification and information on the amino acid, fatty acid or carbohydrate profile when necessary.

(f) A prominent statement indicating whether the product is intended or not as the sole source of nutrition shall appear on the label.

(g) Information of the nature of animal or plant proteins or protein hydrolysates shall be provided.

(h) Feeding instructions, including the method of administration and serving size if applicable, shall be given on the label.

(i) A complete statement concerning adequate precautions, known side effects, contraindications and product-drug interaction, as applicable shall be given on the label.

(J) A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful shall be given on the label.

(k) If the product has been formulated for a specific age group, it shall carry a prominent statement to that effect.

(l) A statement specifying the nutrient(s) which have been reduced, omitted, increased or otherwise modified, relative to normal requirements and the rationale for the reduction, omission, increase or other modification shall appear on the label.

(m) A warning that the product is not for parenteral use shall appear on the label.

Schedule I(a)

Advisory list of mineral salts for use in foods for infant nutrition under the provisions of the regulations

Sl. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
1.	**Calcium (Ca)**		
(1)	Calcium carbonate	JECFA (1973), FCC, USP, BP, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Calcium chloride	JECFA(1975), FCC, USP, BP, IP	
(3)	Calcium citrate (Tricalciumdi citrate)	JECFA(1975), FCC, USP, IP	
(4)	Calcium gluconate	JECFA (1998), FCC USP, BP, IP	
(5)	Calcium glycerophosphate	FCC, BP, IP	
(6)	Calcium L- lactate	JECFA (1974), FCC, USP, BP, IP	
(7)	Calcium hydroxide	JECFA (1975), FCC, USP, BP, JP	
(8)	Calcium phosphate, monobasic (Calcium dihydrogen phosphate)	JECFA(1996), FCC, IP	
(9)	Calcium phosphate, dibasic (Calcium hydrogen phosphate)	JECFA(1975), FCC, BP, IP	

Sl. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
(10)	Calcium phosphate, tribasic (Tricalcium diphosphate)	JECFA(1973), FCC, BP, IP	
(11)	Calcium oxide	JECFA(1975), FCC, IP	MCCF, PCCF, FSMP
(12)	Calcium sulphate	FCC, JECFA(1975), IP	FSMP
2.	**Phosphorus (P)**		
(1)	Calcium phosphate, monobasic	FCC, JECFA(1996), IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Calcium phosphate, dibasic	FCC, JECFA(1975), IP	
(3)	Calcium phosphate, tribasic	FCC,JECFA(1973), IP	
(4)	Magnesium phosphate, dibasic	FCC, IP	
(5)	Magnesium phosphate, tribasic	FCC, IP	
(6)	Potassium phosphate, monobasic	FCC, IP	
(7)	Potassium phosphate, dibasic	FCC, IP	
(8)	Sodium phosphate, dibasic	FCC, IP	
(9)	Phosphoric acid	FCC, IP	
3.	**Chloride (Cl)**		
(1)	Calcium chloride	FCC, JECFA(1975), IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Choline chloride	FCC, IP	
(3)	Magnesium chloride	FCC, IP	
(4)	Manganese chloride	FCC, IP	
(5)	Potassium chloride	FCC, IP	
(6)	Sodium chloride	FCC, IP	
(7)	Hydrochloric acid (Food grade)	IP	
4.	**Iron (Fe)**		
(1)	Ferrous carbonate, stabilized with saccharose	DAB, IP	MCCF, PCCF, FSMP
(2)	Ferrous citrate	FCC, IP	
(3)	Ferrous fumarate	FCC, USP, DAB, BP, IP	
(4)	Ferrous gluconate	FCC, JECFA(1999), USP, DAB, BP, IP	

Sl. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
(5)	Ferrous lactate	JECFA(1989), FCC, IP	IF, MCCF, PCCF, FUF, FSMP
(6)	Ferrous succinate	MI, IP	
(7)	Ferrous sulphate	FCC, JECFA(1999), USP, BP, DAB, IP	
(8)	Ferric ammonium citrate	JECFA(1984), FCC, IP	
(9)	Ferric citrate	FCC, IP	
(10)	Ferrous bisglycinate	JECFA (2003), IP	
(11)	Sodium ferric pyrophosphate Ferric diphosphate	FCC, IP	
(12)	Ferric orthophosphate	FCC, IP	
(13)	Hydrogen reduced iron	FCC, DAB, IP	MCCF, PCCF, FSMP
(14)	Electrolytic iron	FCC, IP	
(15)	Carbonyl iron	FCC, IP	
(16)	Ferric saccharate	DAB, IP	
(17)	Sodium ferric diphosphate	FCC, IP	
5.	**Magnesium (Mg)**		
(1)	Magnesium hydroxide carbonate	JECFA(1979), USP, BP, IP	
(2)	Magnesium chloride	FCC, JECFA(1979), USP, BP, IP	
(3)	Magnesium oxide	FCC, JECFA(1973), USP, BP, IP	
(4)	Magnesium phosphate, dibasic	FCC, JECFA(1982), IP	

Sl. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
	(Magnesium hydrogen phosphate)		IF, MCCF, PCCF, FUF, FSMP
(5)	Magnesium phosphate, tribasic (Trimagnesium phosphate)	FCC, JECFA(1982), IP	
(6)	Magnesium sulphate	FCC, USP, BP, IP	
(7)	Magnesium carbonate	JECFA (1973), FCC, USP, BP, IP	IF, MCCF, PCCF, FUF, FSMP
(8)	Magnesium hydroxide	JECFA (1975), FCC, USP, BP, IP	
(9)	Magnesium salts of citric acid	USP,IP	
(10)	Magnesium gluconate	JECFA(1998), FCC, IP	
(11)	Magnesium lactate	JECFA (1983), JP	MCCF, PCCF, FSMP
(12)	Magnesium glycerol-phosphate	PhEur, IP	
(13)	Magnesium acetate	PhEur, IP	FSMP
6.	**Sodium (Na)**		
(1)	Sodium bicarbonate	FCC, JECFA(1975), USP, IP	IF, MCCF, FUF, FSMP
(2)	Sodium carbonate	FCC, JECFA(1975), USP, IP	
(3)	Sodium chloride	FCC, USP, BP, IP	
(4)	Sodium citrate (Trisodium citrate)	JECFA(1975), USP, BP, DAB, IP	
(5)	Sodium gluconate	FCC, JECFA(1995), USP, IP	
(6)	Sodium L- lactate	JECFA(1974), FCC, USP, BP, IP	

Sl. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
(7)	Sodium phosphate, monobasic (sodium dihydrogen phosphate	JECFA(1963), FCC, USP, IP	
(8)	Sodium phosphate, dibasic (Disodium hydrogen phosphate)	JECFA(1975), FCC, USP, BP, IP	
(9)	Sodium phosphate, tribasic (Trisodium phosphate)	FCC, JECFA (1975), IP	
(10)	Sodium sulphate	JECFA (2000), FCC, USP, BP, IP	
(11)	Sodium hydroxide	JECFA (1975), FCC, USP, BP, IP	IF, MCCF, FUF, FSMP
7.	**Potassium (K)**		
(1)	Potassium bicarbonate	FCC, JECFA(1979), USP, BP, IP	IF, MCCF, FUF, FSMP
(2)	Potassium carbonate	FCC, JECFA(1975), USP, BP, IP	
(3)	Potassium chloride	FCC, JECFA(1979), USP, BP, IP	IF, MCCF, PCCF, FUF, FSMP
(4)	Potassium citrate (Tripotassium citrate)	FCC, JECFA(1975), USP, BP, IP	
(5)	Potassium glycerol phosphate	FCC, IP	PCCF, FSMP
(6)	Potassium gluconate	JECFA(1978), FCC, USP, IP	IF, MCCF, PCCF, FUF, FSMP
(7)	Potassium phosphate, monobasic (Potassium dihydrogen phosphate)	FCC, JECFA(1982), BP, IP	IF, FUF, FSMP
(8)	Potassium phosphate, dibasic (Dipotassium hydrogen phosphate)	FCC,JECFA(1982),BP, IP	
(9)	Potassium hydroxide	JECFA(1975), FCC, BP, IP	IF, FUF, FSMP

Sl. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
(10)	Potassium phosphate tribasic	JECFA(1982), IP	IF, FUF, FSMP
(11)	Potassium L-Lactate	JECFA(1974, FCC, IP	IF, MCCF, PCCF, FUF, FSMP
8.	**Copper (Cu)**		
(1)	Copper gluconate (Cupric gluconate)	FCC, USP, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Cupric carbonate	MI, IP	
(3)	Cupric citrate	FCC, USP, IP	
(4)	Copper sulphate (Cupric sulphate)	JECFA(1973), FCC, USP,DAB, IP	
9.	**Iodine (I)**		
(1)	Potassium iodide	FCC, USP, BP, DAB, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Sodium iodide	USP, BP, DAB, IP	
(3)	Potassium iodate	FCC, IP	IF, MCCF, FUF, FSMP
(4)	Sodium iodate	FCC, IP	FSMP
10.	**Zinc (Zn)**		
(1)	Zinc acetate	USP, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Zinc chloride	USP, BP, DAB, IP	
(3)	Zinc oxide	FCC, USP, DAB, BP, IP	
(4)	Zinc sulphate	FCC, USP, BP, IP	
(5)	Zinc gluconate	FCC, USP, IP	IF, MCCF, PCCF, FUF, FSMP
(6)	Zinc lactate	FCC, IP	

Sl. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
(7)	Zinc carbonate	USP, IP	FSMP
(8)	Zinc citrate (zinc citrate dihydrate or zinc citrate trihydrate)	USP, IP	IF, MCCF, PCCF, FUF, FSMP
11.	**Manganese (Mn)**		
(1)	Manganese(II) carbonate	MI, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Manganese(II) chloride	FCC, IP	
(3)	Manganese(II) citrate	FCC, IP	
(4)	Manganese sulphate	FCC, USP, IP	
(5)	Manganese (II) gluconate	FCC, IP	
(6)	Manganese (II) glycerol-phosphate	FCC, IP	MCCF, PCCF, FSMP
12.	**Selenium**		
(1)	Sodium selenate	MI, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Sodium selenite	PhEur, USP, MP, MI, IP	
(3)	Sodium hydrogen selenite	DVFA, IP	FSMP
13.	**Chromium (Cr)**		
(1)	Chromium(III) sulphate	USP, MI, IP	IF, FSMP
(2)	Chromium(III) chloride	USP, MI, IP	IF, FSMP
14.	**Molybdenum (MoVI)**		
(1)	Sodium molybdate	PhEur, IP	IF, FSMP
(2)	Ammonium molybdate	FCC, USP, IP	IF, FSMP

Schedule I(b)

Advisory list of vitamin compounds for use in food for infant nutrition under the provisions of the regulations

Sl. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
1.	**Vitamin A**		
(1)	trans Retinol	FCC, USP, PhEur, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Retinyl acetate	FCC, USP, PhEur, IP	
(3)	Retinyl palmitate	FCC, USP, PhEur, IP	
2.	**Provitamin A**		
(1)	Beta-carotene	JECFA(1987), FCC, USP, PhEur, IP	IF, MCCF, PCCF, FUF, FSMP
3.	**Vitamin D**		
(1)	Vitamin D_2(Ergocalciferol)	FCC, USP, PhEur, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Vitamin D_3 (Cholecalciferol)	FCC, USP, BP, DAB, IP	
4.	**Vitamin E**		
(1)	D-alpha-Tocopherol	JECFA(2000), FCC, USP, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	DL-alpha-Tocopherol	JECFA(1986), FCC, USP, IP	
(3)	D-alpha-Tocopheryl acetate	FCC, USP, BP, PhEur, IP	
(4)	DL-alpha-Tocopheryl acetate	FCC, USP, BP, PhEur, IP	
(5)	D-alpha-Tocopheryl acid succinate	FCC, USP, PhEur, IP	FSMP
(6)	DL-alpha Tocopheryl acid succinate	MP, MI, USP, PhEur, IP	

Sl. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
(7)	DL-alpha-Tocopheryl polyethylene glycol succinate	FCC, USP, IP	FSMP
5.	**Vitamin C**		
(1)	L-Ascorbic acid	JECFA(1973), FCC, USP, BP, PhEur, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Calcium-L-ascorbate	JECFA(1981), FCC, USP, PhEur, IP	
(3)	6-Palmitoyl-L-ascorbic acid (Ascorbyl palmitate)	JECFA(1973), FCC, USP, BP, PhEur, IP	
(4)	Sodium-L-ascorbate	JECFA(1973), FCC, USP, PhEur, IP	
(5)	Potassium-L-ascorbate	FCC, IP	
6.	**Vitamin B_1**		
(1)	Thiamin chloride hydrochloride	FCC, USP, PhEur, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Thiamin mononitrate	FCC, USP, BP, PhEur, IP	
7.	**Vitamin B_2**		
(1)	Riboflavin	JECFA(1987), FCC, USP, BP,IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Riboflavin-5-phosphate sodium	JECFA (1987), USP, BP, PhEur, IP	
8.	**Niacin**		
(1)	Nicotinic acid amide (Nicotinamide)	FCC, USP, PhEur, BP, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Nicotinic acid	FCC, USP, BP, PhEur, IP	
9.	**Vitamin B_6**		
(1)	Pyridoxine hydrochloride	FCC, USP, BP, PhEur, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Pyridoxal 5-phosphate	MI, FCC, USP, IP	

Sl. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
10.	**Folic acid**		
(1)	N-Pteroyl-L-glutamic acid	FCC, USP, PhEur, IP	IF, FUF, MCCF, PCCF, FSMP
(2)	Calcium-L-methyl-folate	JECFA(2005), IP	FSMP
11.	**Pantothenic acid**		
(1)	Calcium-D-pantothenate	FCC, USP, PhEur, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Sodium-D-pantothenate	DAB, IP	
(3)	D-Panthenol	FCC, USP, PhEur, IP	
(4)	DL-Panthenol	FCC, USP, PhEur, IP	
12.	**Vitamin B_{12}**		
(1)	Cyanocobalamin	FCC, USP, BP, PhEur, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Hydroxo-cobalamin	USP, PhEur, IP	
13.	**Vitamin K_1**		
(1)	Phytomenadione (2-Methyl-3-phytyl-1,4-naphtho-quinine/ Phylloquinone/phyto nadione)	FCC, USP, PhEur, BP, IP	IF, MCCF, PCCF, FUF, FSMP
14	**Vitamin K2**		
(1)	Menaquinone	USP	IF, MCCF, PCCF, FUF, FSMP
15	**Biotin**		

Sl. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
(1)	D-biotin	FCC, USP, PhEur, IP	IF, MCCF, PCCF, FUF, FSMP

Highlighted text shows the provision published in Corrigenda dated 31.03.2021

Schedule I(c)

Advisory list of amino acids and other nutrients for use in foods for infant nutrition under the provisions of the regulations

S. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
1.	**Amino acids**		
(1)	L-Arginine	FCC, USP, PhEur, BP, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	L-Arginine hydrochloride	FCC, USP, PhEur, BP, IP	
(3)	L-Cystine	FCC, USP, PhEur, IP	
(4)	L-Cystine dihydrochloride	MI, IP	
(5)	L-Cysteine	DAB, IP	
(6)	L-Cysteine hydrochloride	FCC, PhEur, IP	
(7)	L-Histidine	FCC, USP, PhEur, IP	
(8)	L-Histidine hydrochloride	FCC, PhEur, DAB, IP	
(9)	L-Isoleucine	FCC, USP, PhEur, IP	
(10)	L-Isoleucine hydrochloride	FCC, USP, IP	

S. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
(11)	L-Leucine	FCC, USP, PhEur, IP	IF, MCCF, PCCF, FUF, FSMP
(12)	L-Leucine hydrochloride	MI, FCC, USP, IP	
(13)	L-Lysine	USP, IP	
(14)	L-Lysine mono hydrochloride	FCC, USP, PhEur, IP	
(15)	L-Methionine	FCC, USP, PhEur, IP	
(16)	L-Phenylalanine	FCC, USP, PhEur, IP	
(17)	L-Threonine	FCC, USP, PhEur, IP	
(18)	L-Tryptophan	FCC, USP, PhEur, IP	
(19)	L-Tyrosine	FCC, USP, PhEur, IP	
(20)	L-Valine	FCC, USP, PhEur, IP	
(21)	L-Alanine	FCC, USP, PhEur, IP	FSMP
(22)	L-Arginine-L-aspartate	PhEur, IP	
(23)	L-Aspartic acid	FCC, USP, PhEur, IP	
(24)	L-Citrulline	USP, IP	
(25)	L-Glutamic acid	JECFA(1987), USP, FCC, PhEur, IP	
(26)	L-Glutamine	FCC, USP, PhEur, IP	

S. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
(27)	Glycine	FCC, USP, PhEur, IP	FSMP
(28)	L-Ornithine	MI, FCC, IP	
(29)	L-Ornithine monohydrochloride	DAB, IP	
(30)	L-Proline	FCC, USP, PhEur, IP	
(31)	L-Serine	USP, PhEur, IP	
(32)	N-Acetyl-L-cysteine	USP, PhEur, IP	
(33)	N-Acetyl-L-methionine	FCC,IP	FSMP (Only for use in infants above 12 months)
(34)	L-Lysine acetate	FCC, USP, MP, PhEur, IP	FSMP
(35)	L-Lysine-L-aspartate	Jap Food Stan, IP	
(36)	L-Lysine-L-glutamate dihydrate	Jap Food Stan, IP	
(37)	Magnesium L-aspartate	PhEur, IP	
(38)	Calcium L-glutamate	JECFA, FCC, Jap Food Stan, IP	
(39)	Potassium L-glutamate	JECFA, FCC, Jap Food Stan, IP	
2.	**Carnitine**		
(1)	L-Carnitine	FCC, USP, PhEur, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	L-Carnitine hydrochloride	FCC, IP	

S. No.	Nutrient source	Purity requirements by	Use in foods for infant nutrition
(3)	L-Carnitine tartrate	FCC, PhEur, IP	IF, FUF, FSMP
3.	**Taurine**		
(1)	Taurine	USP, IP, JP	IF, FUF, FSMP
4.	**Choline**		
(1)	Choline	FCC, USP, IP	IF, MCCF, PCCF, FUF, FSMP
(2)	Choline chloride	FCC, IP	
(3)	Choline citrate	USP, IP	
(4)	Choline hydrogen tartrate	DAB, IP	
(5)	Choline bitartrate	FCC, USP, DAB, IP	
5.	**Inositols**		
(1)	Myo-inositol	FCC, IP	IF, MCCF, PCCF, FUF, FSMP
6.	**Nucleotides**		
(1)	Adenosine 5-monophosphate (AMP)	FSANZ, IP	IF, FUF, FSMP
(2)	Cytidine 5-mono phosphate (CMP)	FSANZ, IP	
(3)	Guanosine 5-mono phosphate (GMP)	JECFA (1985), IP	
(4)	Inosine 5-mono phosphate (IMP)	JECFA (1974), IP	
(5)	Disodium Uridine 5-monophosphate salt	FSANZ, IP	
(6)	Disodium Guanosine 5-mono phosphate salt	FCC, JECFA, FSANZ, IP	
(7)	Disodium inosine 5-mono phosphate salt	FCC, JECFA, FSANZ, IP	

Free, hydrated and anhydrous forms of amino acids and the hydrochloride, sodium and potassium salts of amino acids may be used for Food for Special Medical Purpose.

Schedule I(d)
Advisory list of food additives for special nutrient formulations under the provisions of the regulations

For reasons of stability and safe handling, some vitamins and other nutrients have to be converted into suitable preparations. For this purpose, the food additives included in respective specific standards may be used. In addition, the following food additives may be used as nutrient carriers.

Additive/Carrier	INS No.	Recommended maximum level in Ready-to-Use foods for infant nutrition (mg/kg)
Gum Arabic-(gum acacia)	414	10
Silicon dioxide	551	10
Mannitol (for vitamin B_{12} dry rubbing, 0.1% only)	421	10
Starch sodium octenyl succinate	1450	100
Sodium L-ascorbate (in coating of nutrient preparations containing polyunsaturated fatty acids)	301	75

Abbreviations:

BP: British Pharmacopoeia

DAB: Deutsches Arzneibuch

DVFA: Danish Veterinary and Food administration

FCC: Food Chemicals Codex

FSANZ: Food Standards Australia and New Zealand

FSMP: Foods for Special Medical Purposes

FUF: Follow up Formula

IF: Infant formula

IP: Indian Pharmacopoeia

Jap Food Stan: Japanese Food Standard

JECFA: FAO/WHO Joint Expert Committee on Food Additives.

JP: The Pharmacopeia of Japan

MCCF: Milk cereal based complementary food

MI: Merck Index

MP: Martindale Pharmacopoeia

PCCF: Processed cereal based complementary food

PhEur: Pharmacopeia Europeia

USP: The United States Pharmacopeia

Note: The principal regulations were published in the Gazette of India, Extraordinary Part III, Section 4, *vide* notification number F. No. Stds/03/Notification (IFR)/FSSAI-2017, dated 4th December, 2020 and subsequently amended *vide* notification number:

1. F.No. Std/SP-05/T(IFR-01), dated 30th August, 2022.