SRI LANKA STANDARD 651 : 2007

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SPECIFICATION FOR
INFANT FORMULA (STARTER)
(SECOND REVISION)

SRI LANKA STANDARDS INSTITUTION

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(SECOND REVISION)

SLS 651 : 2007

(Attached AMD 396 and AMD 547)

(Attached Corrigendum No 1)

Gr. 12

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SRI LANKA

Sri Lanka Standards are subject to periodical revision in order to accommodate the progress made by industry. Suggestions for improvement will be recorded and brought to the notice of the Committees to which the revisions are entrusted.

This standard does not purport to include all the necessary provisions of a contract.

SRI LANKA STANDARD
SPECIFICATION FOR INFANT FORMULA (STARTER)
(SECOND REVISION)

FOREWORD

This standard was approved by the Sectoral Committee on Agriculture and Food Products and was authorized for adoption and publication as a Sri Lanka Standard by the Council of the Sri Lanka Standard Institution on 2007-02-02.

Human milk ideally fulfils the entire requirement for growth and additionally provides unique bio-immune factors for protecting the health of infants. Breast feeding is therefore, universally regarded as the most appropriate form of nourishing the infant. However, when breast feeding is not possible, reliance has to be placed upon the alternate sources of nutrients for infant feeding. It is imperative that infant formula shall be properly formulated so that nutritional requirements for optimal growth are met adequately, and that there is minimum of physiological stress on the developing organ/ enzymic system of the infant. It is equally important to promote correct feeding practices so that appropriate use of the infant food could be made for protecting the health of the infant.

This specification for Infant Formula was first published in 1984 and revised in 1989. Taking into consideration the new thinking on infant feeding in the light of the socio-economic conditions of Sri Lanka, a revision of this specification was considered necessary. In this second revision, technological advances made in the processing of Infant Formula have been given due consideration. This specification covers only infant formula which are intended for the partial or total replacement of breast milk.

This specification is subject to the restrictions imposed under the Food Act No. 26 of 1980 and the regulations framed thereunder, wherever applicable.

For the purpose of deciding whether a particular requirement of this specification is complied with, the final value, observed or calculated, expressing the results of a test or an analysis, shall be rounded off in accordance with **CS 102**. The number of significant places retained in the rounded off value shall be the same as that of the specified value in this specification.

In the revision of this specification, the assistance derived from the recent literature on infant nutrition as well as the Sri Lanka Code for the Promotion, Protection and Support of Breast Feeding and Marketing of Designated Products (Amended Code – 2002), by Nutrition Coordination Division of the Ministry of Healthcare, Nutrition and Uva Wellassa Development, Government of Sri Lanka and Recommended International Standards for Foods for Infants (Codex Alimentarius Commission, Step 8 - 2006) are gratefully acknowledged.

1 SCOPE

1.1 This specification 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.

1.2 This specification prescribes the compositional, quality and safety requirements and methods of sampling and test for Infant Formula.

1.3 Only products that comply with the criteria laid down in the provisions of this specification would be accepted for marketing as infant formula. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first six months of life.

1.4 The application of this specification shall take into account, the recommendations made in the Sri Lanka Code for the Promotion, Protection and Support of Breast Feeding and marketing of designated products (Amended Code – 2002).

1.5 This specification does not cover formulas for special medical purposes intended for infants.

2 REFERENCE

CS 102 Presentation of numerical values
SLS 428 Random sampling methods
SLS 467 Code of practice for labelling of prepackaged foods
SLS 516 Microbiological test methods
Part 1 Aerobic plate count
Part 3 Coliforms
Part 5 *Salmonella*
SLS 735 Methods of test for milk and milk products
Part 2 Determination of titratable acidity
Part 3 Determination of moisture
Part 8 Determination of total ash/acid insoluble ash
Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC), 16th Edition, 5th Revision 1999.

3 DEFINITIONS

For the purpose of this specification, the following definitions shall apply :

3.1 infant formula (starter) : A breast – milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first six months of life upto the introduction of appropriate complementary feeding.

3.2 infant : A child not more than twelve months of age.

3.3 guidance upper level - Guidance Upper Levels (GUL) are for nutrients without sufficient information for a science – based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of infants and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they shall not be interpreted as goal values. Nutrient contents in infant formulas shall usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of infant formulas or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers shall not increase levels of nutrients to approach the GULs.

4 REQUIREMENTS

4.1 General requirements

4.1.1 Purity requirements

All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.

4.1.2 The product shall be processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.

4.1.3 Consistency and particle size

When prepared according to the label directions for use, the product shall be free of lumps and of large coarse particles and suitable for adequate feeding of infants.

4.1.4 Specific prohibitions

The product and its components shall not contain commercially hydrogenated oils and fats and shall not have been treated by ionizing radiation.

4.2 Compositional and nutritional requirements

4.2.1 Essential composition

4.2.1.1 Infant formula is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be suitable for infant feeding. The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants.

4.2.1.2 All ingredients and food additives used shall be gluten – free.

4.2.1.3 Infant formula prepared ready for consumption in accordance with instructions of the manufacturer shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal (295 kJ) of energy.

4.2.1.4 Infant formula prepared ready for consumption shall contain per 100 kcal the following nutrients with the following minimum and maximum or guidance upper levels (GUL), as appropriate.

a) Protein

TABLE 1A – Requirements for Protein

Sl. No.	Characteristic	Requirement		Method of Test
		Minimum	Maximum	
(1)	(2)	(3)	(4)	(5)
i)	Protein [1),2),3)] g/100 kcal	1.8 [4), 5)]	3.0	Appendix **B**

NOTE :

[1)] *The calculation of the protein content should be based on N x 6.38 for milk proteins and their partial protein hydrolysates. The protein levels set in any other case are based on a nitrogen conversion factor of 6.25.*

[2)] *For an equal energy value the formula must contain an available quantity of each essential and other amino acids at least equal to that contained in the reference protein (breast-milk as defined in Annex 1); nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine may be added together. The concentrations of methionine and cysteine may be added together if the ratio is less than 2 : 1 ; in the case that the ratio is between 2 : 1 and 3 : 1 the suitability of the formula has to be demonstrated by clinical testing.*

[3)] *Isolated amino acids may be added to Infant Formula only to improve its nutritional value for infants. Essential and other 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.*

[4] *The minimum value applies to cows' milk protein. For infant formula based on non-cows' milk protein other minimum values may need to be applied. For infant formula based on soy protein isolate, a minimum value of 2.25 g / 100 kcal applies.*

[5] *Infant formula based on non-hydrolysed milk protein containing less than 2 g protein / 100 kcal and infant formula based on hydrolysed protein containing less than 2.25 g protein / 100 kcal shall be clinically evaluated.*

b) Lipids

TABLE 1B - Requirements for lipids

Sl. No. (1)	Characteristic (2)	Requirement		Method of Test (5)
		Minimum (3)	Maximum (4)	
i)	Total fat, [6] g/100 kcal	4.4	6.0	Appendix **C**
ii)	Linoleic acid, g/100 kcal	0.3	1.4	
iii)	α - Linolenic acid, mg/100 kcal	50	not specified	
iv)	Ratio linoleic / α – linolenic acid	5 : 1	15 : 1	

NOTE : [6] *Lauric and myristic acids are constituents of fats, but combined shall not exceed 20 % of total fatty acids. The content of trans fatty acids shall not be higher than 3 % of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3 % of trans fatty acids is intended to allow for the use of milk fat in infant formula. The erucic acid content shall be less than 1 % of total fatty acids. The total content of phospholipids shall be less than 300 mg/100 kcal.*

c) Carbohydrates

TABLE 1C - Requirements for carbohydrates

Sl. No. (1)	Characteristic (2)	Requirement		Method of Test (5)
		Minimum (3)	Maximum (4)	
i)	Total carbohydrates, [7] g/100 kcal	9.0	14.0	Appendix **D**

NOTE : [7] *Lactose and glucose polymers shall be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinized starches gluten-free by nature may be added to infant formula up to 30 % of total carbohydrates and up to 2 g / 100 ml. (Sucrose, unless needed, and the addition of fructose as an ingredient shall be avoided in infant formula, because of potential life – threatening symptoms in young infants with unrecognized hereditary fructose intolerance).*

d) Vitamins

TABLE 1D - Requirements for vitamins

Sl. No. (1)	Characteristic (2)	Requirement		Method of Test (5)
		Minimum (3)	Maximum (4)	
i)	Vitamin A, µg RE [8] /100 kcal	60	180	Appendix **E**
ii)	Vitamin D_3, µg [9] /100 kcal	1.0	2.5	

NOTE :

[8] *expressed as retinol equivalents (RE)*

1 µg RE = 3.33 IU Vitamin A = 1 µg all – trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

[9] *Calciferol. 1µg calciferol = 40 IU vitamin D*

TABLE 1E - Requirements for vitamins

Sl. No. (1)	Characteristic (2)	Requirement		Method of Test (5)
		Minimum (3)	Guidance Upper Level (4)	
i)	Vitamin E, mg α- TE [10] /100 kcal	0.5 [11]	5	Appendix **E**
ii)	Vitamin K, µg /100 kcal	4	27	
iii)	Thiamin, µg /100 kcal	60	300	
iv)	Riboflavin, µg /100 kcal	80	500	
v)	Niacin [12] , µg /100 kcal	300	1500	
vi)	Vitamin B_6, µg /100 kcal	35	175	
vii)	Vitamin B_{12}, µg /100 kcal	0.1	1.5	
viii)	Pantothenic acid, µg /100 kcal	400	2000	
ix)	Folic acid, µg /100 kcal	10	50	
x)	Vitamin C [13] ,mg /100 kcal	10	70 [14]	
xi)	Biotin, µg /100 kcal	1.5	10	

NOTE :

[10] *1 mg α - TE (alpha – tocopherol equivalent) = 1 mg d - α - tocopherol*

[11] *Vitamin E content shall be at least 0.5 mg α –TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula : 0.5 mg α –TE / g linoleic acid (18 : 2 n – 6) ; 0.75 α –TE /g α-linolenic acid (18 : 3 n – 3) ; 1.0 mg α –TE /g arachidonic acid (20 : 4 n – 6) ; 1.25 mg α – TE /g eicosapentaenoic acid (20 : 5 n – 3) ; 1.5 mg α– TE /g docosahexaenoic acid (22 : 6 n – 3).*

[12] *Niacin refers to preformed niacin*

[13] *expressed as ascorbic acid*

[14] *This GUL has been set to account for possible high losses over shelf-life in liquid formulas ; for powdered products lower upper levels shall be aimed for.*

e) Minerals and trace elements

TABLE 1F - Requirements for minerals and trace elements

Sl. No. (1)	Characteristic (2)	Requirement			Method of Test (6)
		Minimum (3)	Maximum (4)	GUL (5)	
i)	Iron, mg /100 kcal	0.45	--	1.3	Appendix **F**
ii)	Calcium, mg /100 kcal	50	--	140	
iii)	Phosphorus, mg /100 kcal	25	--	100 [15]	
iv)	Ratio calcium / phosphorus	1 : 1	2 : 1	--	
v)	Copper [16] , µg /100 kcal	35	--	120	
vi)	Zinc, mg /100 kcal	0.5	--	1.5	
vii)	Magnesium, mg /100 kcal	5	--	15	
viii)	Sodium, mg /100 kcal	20	60	--	
ix)	Chloride, mg /100 kcal	50	160	--	
x)	Potassium, mg /100 kcal	60	180	--	
xi)	Manganese, µg /100 kcal	1	--	100	
xii)	Iodine, µg /100 kcal	10	--	60	
xiii)	Selenium, µg /100 kcal	1	--	9	

[15] *This GUL shall be accommodate higher needs with soy formula.*

[16] *Adjustment may be needed in these levels for infant formula made in regions with a high content of copper in the water supply.*

f) Other substances

TABLE 1 G - Requirements for other substances

Sl. No.	Characteristic	Requirement		
		Minimum	Maximum	GUL
(1)	(2)	(3)	(4)	(5)
i)	Choline, mg /100 kcal	7	--	50
ii)	Myo – Inositol, mg /100 kcal	4	--	40
iii)	L – Carnitine, mg /100 kcal	1.2	not specified	--

4.2.2 Optional ingredients

4.2.2.1 In addition to the compositional requirements listed under **4.2.1.4,** other ingredients may be added in order to provide substances ordinarily found in human milk and to ensure that the formulation is suitable as the sole source of nutrition for the infant or to provide other benefits that are similar to outcomes of populations of breastfed babies.

4.2.2.2 The suitability for the particular nutritional uses 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, taking into account levels in human milk.

4.2.2.3 Only L(+) lactic acid producing cultures may be used.

4.2.2.4 Fluoride shall not be added to infant formula. In any case its level shall not exceed 100 µg /100 kcal in infant formula prepared ready for consumption as recommended by the manufacturer.

4.2.2.5 The following substances may be added, in which case their content per 100 kcal in the infant formula ready for consumption shall not exceed the requirement specified in Column **3** of the Table **2**.

TABLE 2 - Requirements for optional ingredients

Sl. No. (1)	Characteristic (2)	Requirement (3)
i)	Taurine, mg /100 kcal (max)	12
ii)	Total nucleotides, mg /100 kcal (max)	5
iii)	Cytidine 5' – monophosphate (CMP), mg /100 kcal (max)	2.5
iv)	Uridine 5' – monophosphate (UMP), mg /100 kcal (max)	1.75
v)	Adenosine 5' – monophosphate (AMP), mg /100 kcal (max)	1.5
vi)	Guanosine 5' – monophosphate (GMP), mg /100 kcal (max)	0.5
vii)	Inosine 5' – monophosphate (IMP), mg /100 kcal (max)	1.0
viii)	Phospholipids, mg /100 kcal (max)	300 (or 2 g/l)
ix)	Docosahexaenoic acid [17)] (% of fatty acids) (GUL)	0.5

NOTE : [17)] *If docosahexaenoic acid (22 : 6 n – 3) is added to infant formula, arachidonic acid (20 : 4 n – 6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20 : 5 n – 3), which can occur in sources of LC – PUFA, should not exceed the content of docosahexaenoic acid.*

4.3 Food Additives

The following additives are permitted for use in the preparation of infant formula, with the restrictions stated in Column **3** of Table **3A, 3B, 3C, 3D** and **3E.**

4.3.1 Thickeners

TABLE 3 A – Thickeners

INS Number (1)	Additive (2)	Maximum level in 100 ml of the product ready for consumption (3)
412	Guar gum	0.1 g in liquid formulas containing hydrolysed protein
410	Carob bean gum (Locust bean gum)	0.1 g in all types of infant formula
1412	Distarch phosphate	0.5 g singly or in combination in soy-based infant formula only
1414	Acetylated distarch phosphate	
1413	Phosphated distarch phosphate	2.5 g singly or in combination in hydrolyzed protein and/or amino acid-based infant formula only.
1440	Hydroxypropyl starch	
407	Carrageenan	0.03 g in regular milk-and soy-based liquid infant formula only. 0.1 g in hydrolyzed protein and/or amino acid based liquid infant formula only.

4.3.2 Emulsifiers

TABLE 3 B – Emulsifiers

INS Number (1)	Additive (2)	Maximum level in 100 ml of the product ready for consumption (3)
322	Lecithins	0.5 g in all types of infant formula [18)]
471	Mono-and diglycerides	0.4 g in all types of infant formula [18)]

NOTE : *[18)] If more than one of the substances INS 322, 471 are added, the maximum level for each of those substances is lowered with the relative part as present of the other substances.*

4.3.3 Acidity Regulators

TABLE 3 C – Acidity Regulators

INS Number (1)	Additive (2)	Maximum level in 100 ml of the product ready for consumption (3)
524	Sodium hydroxide	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in **4.2.1.4 (e)** in all types of infant formula
500ii	Sodium hydrogen carbonate	
500i	Sodium carbonate	
525	Potassium hydroxide	
501ii	Potassium hydrogen carbonate	
501i	Potassium carbonate	
526	Calcium hydroxide	.
331	Sodium citrate	Limited by Good Manufacturing Practice in all types of infant formula.
332	Potassium citrate	
270	L (+) Lactic acid	
330	Citric acid	

4.3.4 Antioxidants

TABLE 3 D – Antioxidants

INS Number (1)	Additive (2)	Maximum level in 100 ml of the product ready for consumption (3)
307b	Mixed tocopherol concentrate	1 mg in all types of infant formula singly or in combination
304i	L – Ascorbyl palmitate	

4.3.5 Packaging Gases

TABLE 3 E – Packaging gases

INS Number (1)	Additive (2)	Maximum level in 100 ml of the product ready for consumption (3)
290	Carbon dioxide	Good Manufacturing Practice
941	Nitrogen	

4.4 Contaminants

4.4.1 Pesticide residues

The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

4.4.2 Other contaminants

The product shall not contain contaminants or undesirable substances (eg. biologically active substances) in amounts which may represent a hazard to the health of the infant.
The ready-to use product shall not contain more than 0.02 mg/kg of Lead.

4.5 Other requirements

The product shall also conform to the requirements given in Table **4** when tested in accordance with Column **4** of the table.

TABLE 4 – Other requirements for infant formula

Sl. No. (1)	**Characteristic** (2)	**Requirement** (3)	**Method of test** (4)
i)	Moisture, per cent by mass, (max)	3.5	SLS 735 : Part 3
ii)	Solubility, per cent by mass, (min)	98.0	Appendix G
iii)	Titratable acidity, as lactic acid, per cent by mass (max)	1.5	SLS 735 : Part 2
iv)	Acid insoluble ash, per cent by mass (max)	0.01	SLS 735 : Part 8

4.6 Microbiological limits

The product shall comply to the microbiological limits given in Table **5** when tested in accordance with Column **7** of the table.

Table 5 – Microbiological limits

SI No. (1)	Test organism (2)	Limit per gram				Method of test (7)
		n (3)	c (4)	m (5)	M (6)	
i)	Aerobic plate count	5	1	1×10^4	1×10^5	Appendix H
ii)	Coliforms	5	1	10	100	
iii)	*E.coli*	5	0	0	-	
iv)	*Salmonella*	10	0	0	-	

NOTE : *Aerobic plate count (APC) in powdered infant formula with added lactic acid producing cultures must not exceed the microbiological limits set in the Table 5 prior to the addition of the lactic acid cultures to the food.*

where,

n is the number of samples to be tested;
c is the maximum allowable number of samples yielding values between *m* and *M*;
m is the limit below which a count is acceptable for any sample; and
M is the limit above which a count is unacceptable for any sample.

5 PACKAGING

5.1 `The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. When in liquid form, the product shall be packed in hermetically sealed containers; nitrogen and carbon dioxide may be used as packing media.

5.2 The containers, including packaging materials, shall be made only of substances, which are safe and suitable for their intended uses.

6 MARKING

Each container or package shall be marked legibly and indelibly with the following :

6.1 The name of the product

6.1.1 The name of the product shall be either "Infant Formula (starter)" or any appropriate designation indicating the true nature of the product, in accordance with national usage.

6.1.2 The sources of protein in the product shall be clearly shown on the label.

6.1.3 If cows' milk is the only source of protein, the product may be labelled "Infant Formula Based on Cows' Milk".

6.1.4 A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.

6.2 Brand or Trade name, if any ;

6.3 Net content, in g or ml ;

6.4 Instructions for use and storage ;

6.4.1 Adequate directions regarding the storage of the product after the container has been opened, shall be appear on the label or in any accompanying leaflet.

6.4.2 The label shall carry clear graphic instructions illustrating the method of preparation of the product.

6.4.3 Product in powdered form shall contain a scoop to enable the use of the infant formula in accordance with the directions contained in the label on the package.(This does not apply to single serve sachets, or packages containing single serve sachets)

6.4.4 Adequate directions for the appropriate preparation and use of the product, including its storage and disposal after preparation, i.e. that formula remaining after feeding should be discarded, shall be appear on the label and/or in any accompanying leaflet.

6.4.5 Products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form shall be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling shall be in accordance with Good Hygienic Practice.

6.4.6 The directions shall be accompanied by a warning about the health hazards of in - appropriate preparation, storage and use.

6.5 Name and address of the manufacturer and packer or distributor in Sri Lanka ;

6.6 Batch or code number ;

6.7 Date of expiry ;

6.8 Date of manufacture ;

6.9 In case where infant formulae are imported in bulk and repacked, the date of manufacturer and the date of repacking ;

6.10 List of ingredients ;

6.10.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.

6.10.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names or INS number for these ingredients and additives may be included on the label.

6.11 Country of origin, in case of imported products ;

6.12 Declaration of nutritive value ;

The declaration of nutrition information shall contain the following information which should be in the following order:

a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes or per 100 milliliters of the food as sold as well as per 100 milliliters of the food ready for use, when prepared according to the instructions on the label.

b) the total quantity of each vitamin, mineral, choline as listed in **4.2.1.4** and any other ingredient as listed in **4.2.2** of this specification per 100 grammes or per 100 milliliters of the food as sold as well as per 100 milliliters of the food ready for use, when prepared according to the instructions on the label.

c) in addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

6.13 Additional labelling requirements

6.13.1 Labels shall not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words “important notice” or their equivalent ;

b) the statement “Breast milk is the best food for your baby” or a similar statement as to the superiority of breastfeeding or breast milk ;

c) a statement that the product should only be used on advice of an independent health worker as to the need for its use and the proper method of use.

6.13.2 The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula.

6.13.3 The words “humanized” “maternalized” or other similar words shall not be used.

6.13.4 Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months.

6.13.5 The products shall be labelled in such a way as to avoid any risk of confusion between infant formula (starter), follow-up formula, and formula for special medical purposes.

6.14 The marking and labeling shall also be in accordance with **SLS 467**.

7 SAMPLING

Representative sample of the product shall be drawn as prescribed in Appendix **A.**

8 METHOD OF TEST

Tests shall be carried out as prescribed in Parts **2**, **3** and **8** of **SLS 735** and Appendices **B** to **H** of this specification.

9 CRITERIA FOR CONFORMITY

A lot shall be declared as conforming to the requirements of this specification if the following conditions are satisfied :

9.1 Each container or package examined as in **A.6.1** satisfies the packaging and marking requirements.

9.2 Each individual sample tested as in **A.6.2** satisfy the relevant requirements.

9.3 Test results on the composite sample tested as in **A.6.3** satisfy the relevant requirements.

9.4 Each of the samples tested as in **A.6.4** satisfies the microbiological limits.

APPENDIX A
SAMPLING

A.1 LOT

In any consignment, all the containers or packages of same type and size belonging to one batch of manufacture shall constitute a lot.

A.2 GENERAL REQUIREMENTS OF SAMPLING

In drawing, preparing, storing and handling samples, following precautions and directions shall be observed;

A.2.1 Samples shall be drawn in a protected place not exposed to damp, air, dust or soot.

A.2.2 The sampling instruments shall be clean and dry when used. When drawing samples for microbiological examination, the sampling instruments shall be sterilized.

A.2.3 The samples shall be protected against adventitious contamination.

A.2.4 The samples shall be placed in clean and dry containers. The size of the sample containers shall be of such that they are almost completely filled by the sample. When drawing samples for microbiological examination, the sample containers shall be sterilized.

A.2.5 The sample containers shall be sealed air-tight after filling and marked with necessary details of sampling.

A.2.6 Samples shall be stored in such a manner that the temperature of the material does not vary unduly from the room temperature.

A.3 SCALE OF SAMPLING

A.3.1 Samples shall be tested from each lot for ascertaining its conformity to the requirements of this specification.

A.3.2 The number of containers or packages to be selected from a lot shall be in accordance with Table **6**.

TABLE 6 - Scale of sampling

No. of containers / packages in the lot (1)	No. of containers/ packages to be selected (2)	No. of containers/ packages to be selected as the reference sample (3)
up to 500	13	9
501 to 1 000	15	15
1 001 to 3 000	18	24
3 001 to 10 000	20	30
10 001 and above	25	45

A.3.3 The containers or packages shall be selected at random. In order to ensure randomness of selection, tables of random numbers as given in **SLS 428** shall be used.

A.4 PREPARATION OF SAMPLES

A.4.1 Microbiological examination

Ten containers or packages shall be selected from the containers or packages selected as in A.3.2. Sufficient quantity of material shall be drawn from the top, middle and bottom portions of each container or package so selected using an appropriate sampling instrument. The material obtained from each container or package shall be mixed separately under aseptic conditions to form individual samples. The individual samples so obtained shall be transferred separately into sterile sample containers and marked with necessary details of sampling.

A.4.2 Examination of general requirements

A sufficient quantity of material shall be drawn from the top, middle and bottom portions of each remaining container or package (after selecting for microbiological examination) selected as in A.3.2 using an appropriate sampling instrument. The material obtained from each container shall be mixed separately to form individual samples and transferred to separate sample containers.

A.4.3 Tests for compositional, nutritional and other requirements

An equal quantity of material shall be drawn from the top, middle and bottom portions of each remaining container or package (after selecting for microbiological examination) selected as in **A.3.2**. using an appropriate sampling instrument. The material so obtained shall be mixed together to form a composite sample and transferred to a sample container.

A.5 REFERENCE SAMPLE

If reference samples are required for tests other than microbiological examination, the number of containers / packages to be selected shall be as given in Column **3** of Table **6**. The containers / packages so selected shall be separated into three parts. One of these shall be marked for the purchaser, one for the vendor and the third for reference.

A.6 NUMBER OF TESTS

A.6.1 Each container or package selected as in **A.3.2** shall be examined for packaging and marking requirements.

A.6.2 Individual samples prepared as in **A.4.2** shall be examined for the requirements given in **4.1.1** to **4.1.4**.

A.6.3 The composite sample prepared as in **A.4.3** shall be tested for the requirements given in Table 1A, 1B, 1C, 1D, 1E, 1F and Table **4**.

NOTE : *Test for the requirements given in Table 1D, 1E, and 1F may not be necessary for routine analysis. These tests shall be carried out only if required or requested.*

A.6.4 Each of the ten samples prepared as in **A.4.1** shall be tested for *Salmonella.* Five samples shall be selected from the samples prepared as the **A.4.1** and shall be tested for aerobic plate count, coliforms and *E.coli*.

APPENDIX B
DETERMINATION OF PROTEIN

Determination of protein shall be carried out according to the method described in Codex Alimentarius Commision (CAC) / Vol. IX – Ed. 1, Part III.

APPENDIX C
DETERMINATION OF LIPIDS

Determination of total fat shall be carried out according to the method described in CAC/RM 55 – 1976 and AOAC 996.06, 992.25 .

APPENDIX D
DETERMINATION OF TOTAL CARBOHYDRATES

Determination of total carbohydrates shall be carried out according to the method described in Codex Alimentarius Commission (CAC) / Vol. IX – Ed. 1, Part III

APPENDIX E
DETERMINATION OF VITAMINS

Determination of the vitamins shall be carried out according to the methods given in the Official Methods of Analysis of the AOAC (Association of Official Analytical Chemists), 16th Edition, 5th Revision 1999 as given in Table **7**.

TABLE 7 - Methods of analysis of vitamins

Sl. No. (1)	Vitamin (2)	Method of Analysis (3)
i)	Vitamin A	992.04 - retinol isomers 992.06 - retinol 941.15 - foods in which carotenes have been added
ii)	Vitamin D	as a source of vitamin A 992.26 - D_3, milk based infant formula
iii)	Vitamin E	971.30 992.03 - Milk based infant formula
iv)	Vitamin K	999.15 (LC Method)
v)	Thiamine	986.27
vi)	Riboflavin	985.31
vii)	Vitamin B_6	985.32
viii)	Vitamin B_{12}	986.23
ix)	Pantothenic acid	992.07
x)	Folic acid	992.05
xi)	Vitamin C	985.33
xii)	Niacin and nicotinamide	985.34
xiii)	Choline	999.14 (Enzymatic Method)

APPENDIX F
DETERMINATION OF MINERALS

Determination of minerals shall be carried out according to the methods given in the Official Methods of Analysis of the AOAC (Association of Official Analytical Chemists) 16th Edition, 5th Revision 1999 as given in Table **8**

TABLE 8 – Methods of analysis of minerals .

Sl. No. (1)	Mineral (2)	Method of Analysis (3)
i)	Iron	984.24
ii)	Calcium	984.27
iii)	Phosphorus	986.24
iv)	Sodium and Potassium	984.27
v)	Iodine (milk based formula)	992.24
vi)	Chloride	986.26
vii)	Selenium	968.15

APPENDIX G
DETERMINATION OF SOLUBILITY

G.1 APPARATUS

G.1.1 *Metal dishes,* with lids

G.1.2 *Oven*, maintained at $100 \pm 2\ ^0$C

G.2 PROCEDURE

G.2.1 Shake 4 g of the sample with 32 ml of hot water (at $50\ ^0$C) for 10 seconds. Place on a water bath maintained at $50 \pm 2\ ^0$C for 5 minutes. Shake for one minute making five double excursions of 12 per second. Cool in a refrigerator. Remove the fat layer by running a needle around the cake of fat. Allow to reach room temperature.

Break up the deposit with a rod and shake the stoppered tube hard to produce apparent homogeneity. Weigh 2 ml of this solution in a dish (**G.1.1**)

G.2.2 Centrifuge the remaining solution (**G.2.1**) for 10 minutes. Weigh 2 ml of the clear solution in a dish (**G.1.1**).

G.2.3 Dry both dishes on a water bath. Heat in the oven (**G.1.2**) for 75 minutes. Cool in a desiccator and weigh.

G.3 CALCULATION

$$Solubility,\ per\ cent\ by\ mass\ =\ \frac{m_1}{m_2} x \frac{s_2}{s_1}\ x\ 100$$

where,

m_1 is the mass, in grams, of 2 ml of the sample in **G.2.1**;
m_2 is the mass, in grams, of 2 ml of the sample in **G.2.2**;
s_1 is the mass, in grams, of the dried solids corresponding to m_1 ; and
s_2 is the mass, in grams, of the dried solids corresponding to m_2

APPENDIX H
MICROBIOLOGICAL EXAMINATION

H.1 RECONSTITUTION OF THE POWDER

Weigh 10 g of the powder into a wide mouth bottle using a sterile spoon / spatula. Add 90 ml of sterile 0.1 per cent peptone water diluent previously warmed to 45 ^{0} C. Agitate mildly to wet sample completely. Soak for 120 seconds and then shake the bottle, making 25 up and down movements of about one foot in 7 seconds. Hold in a water bath at 45 ^{0} C for 15 minutes.

Gently invert the sample six times and prepare serial decimal dilutions immediately.

NOTE : *If the powder is difficult to disperse, use 1.25 per cent (m/V) sodium citrate solution in place of 0.1 per cent peptone solution.*

H.2 TESTS

H.2.1 Aerobic plate count

Proceed as described in **SLS 516 : Part 1 : 1981**, using plate count agar or yeast extract milk agar and incubating at 30 ± 1 ^{0} C for 72 ± 2 hours.

H.2.2. *Enumeration of coliforms and E.coli*

Proceed as described in **SLS 516 : Part 3 : 1982**, incubate at 30 ± 1 ^{0} C for 48 ± 2 h for coliforms.

H.2.3 *Detection of Salmonella*

Proceed as in **SLS 516 : Part 5**, using following procedure for pre enrichment :

Add 0.5 g of Brilliant green to 100 ml of distilled water and store for at least one day in advance.

Weigh 25 g of the sample aseptically. Pour it over the surface of 225 ml of sterile distilled water containing 1 ml of Brilliant green solution previously prepared. Do not shake. Allow to stand undisturbed at room temperature for 60 ± 10 minutes before incubation. Incubate at 37 ^{0}C for 16 hours to 20 hours. (Adjustment of pH is not necessary).

ANNEX I (INFORMATIVE)

Essential and other amino acids in breast milk

For the purpose of this specification the essential and other amino acids in human breast milk, expressed as mg per 100 kcal, are the following:

Arginine, mg / 100 kcal	56
Cysteine, mg / 100 kcal	38
Histidine, mg / 100 kcal	41
Isoleucine, mg / 100 kcal	92
Leucine, mg / 100 kcal	169
Lysine, mg / 100 kcal	114
Methionine, mg / 100 kcal	24
Phenylalanine, mg / 100 kcal	81
Threonine, mg / 100 kcal	77
Tryptophan, mg / 100 kcal	33
Tyrosine, mg / 100 kcal	75
Valine, mg / 100 kcal	90

AMD NO 396

AMENDMENT NO: 01 APPROVED ON 2009-08-26 TO SLS 651 : 2007

SRI LANKA STANDARD SPECIFICATION FOR INFANT FORMULA
(Second Revision)

EXPLANATORY NOTE

It was noted that the maximum acceptable limit (M) of the Aerobic Plate Count of Microbiological requirements in Sri Lanka Standard specification for Infant Formula is higher than the maximum acceptable limit of the Aerobic Plate Count given in Sri Lanka Standard specifications for Milk powder and Follow-up formula.

This amendment is issued in order to be in line with these two standards.

AMD 396

AMENDMENT NO: 01 APPROVED ON 2009-08-26 TO SLS 651 : 2007

SRI LANKA STANDARD SPECIFICATION FOR INFANT FORMULA
(Second Revision)

page 15

Clause 4.6

Microbiological limits

Table 5, SI No. i), Column (6)

Delete " $1x10^5$ " and substitute with "50 000".

AMENDMENT NO: 02 TO SLS 651:2007
SRI LANKA STANDARD SPECIFICATION FOR INFANT FORMULA (STARTER)

EXPLANATORY NOTE

The Committee was decided to rearrange the Table 3 C and Table 3 D for better clarification and easy understanding.

Amendment No: 02 approved on 2021-04-30 to SLS 651: 2007

SRI LANKA STANDARD SPECIFICATION FOR INFANT FORMULA (STARTER)

Replace the Table 3 C and Table 3 D with following Tables:

4.2 Food additives

4.3.3 *Acidity regulators*

INS Number (1)	**Additive** (2)	**Maximum number in 100 ml of the product ready for consumption** (3)
524	Sodium hydroxide	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in 4.2.1.4 (e) in all types of formula
500ii	Sodium hydrogen carbonate	0.2 g singly or in combination and within the limits for sodium, potassium and calcium in 4.2.1.4 (e) in all types of formula
500i	Sodium carbonate	
525	Potassium hydroxide	
501ii	Potassium hydrogen carbonate	
501i	Potassium carbonate	
526	Calcium hydroxide	
331	Sodium citrate	Limited by Good Manufacturing Practice in all types of infant formula
332	Potassium citrate	
270	L (+) Lactic acid	
330	Citric acid	

4.3.4 *Antioxidant*

INS Number (1)	**Additive** (2)	**Maximum number in 100 ml of the product ready for consumption** (3)
307b	Mixed tocopherol concentrate	1 mg in all types of infant formula singly or in combination
304i	L-Ascorbyl palmitate	1 mg in all types of infant formula singly or in combination

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CORRIGENDUM TO SLS 651: 2007
SRI LANKA STANDARD SPECIFICATION FOR INFANT FORMULA (STARTER)

Table 5 – Other requirements

SI No vi) Column 3

Acid insoluble ash, per cent by mass, max. 0.01 replaced to 0.1.

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SRI LANKA STANDARDS INSTITUTION

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