PRODUCT SPECIFICATION SHEET

Ready to Use Infant Formula (RUIF)

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1. General Description

RUIF is a breast milk substitute in liquid form. It is an infant formula comprising of added fat, carbohydrates, vitamins, and minerals preferably in 200ml aseptic cartons, pack of multiples of 6 /carton.

2. Intended use

For use in infants who cannot be breastfed or are partially breastfed in situations of orphans, emergency or medical conditions that make it not possible for a mother to breastfeed.

3. Target population

Infants up to the age of 6 months

4. Technical specifications

4.1 General quality

Creamy off white to yellow colour, free from dark flecks and phase separation. Ingredients: water, whey powder / milk powder, vegetable oil, glucose, maltodextrin, lactose, lecithin, L-taurine, L-carnitine, minerals, and vitamins.

4.2 Physical/organoleptic characteristics

1. Is of medium viscosity, free flowing and has a uniform consistency and appearance. Possesses a white to light cream colour and is uniformly coloured throughout.
2. Is free from gelation, which includes such factors as surface ripple, unevenness of flow, and lumpiness. Is free from creaming (the separation of fat), protein agglomeration (the cohesion of microscopic protein particles of sufficient size to be visible), and extraneous material. Is free from coarse milk solids precipitate or sedimentation. Is smooth, uniform, free from lumps, or graininess.
3. Has normal characteristic odour and taste, free from rancidity and other undesirable odours and tastes.
4. Is a commercially sterile product. Is ready-to-use from the primary container. It supplies the labelled nutritional requirements.

4.3 Ingredients

The main components of the therapeutic milk are: water, milk powder, refined vegetable oil, sucrose, maltodextrin, vitamin and mineral premix. For flavourings, antioxidants and other additives see 4.5.5 to 4.5.6

4.4 Nutritional composition per 100 ml

As per the *CXS 72-1981: Standard for Standard for Infant formula and Formulas for Special Medicinal Purposes intended for Infants.*

4.5 Formulation and Raw materials

The product shall be a homogenous liquid that does not separate into oil/liquid phases or leave a solid sediment upon standing in a refrigerator with occasional gentle stirring. The product should have characteristic milk taste and smell. It shall be white as cream, shall not have a rancid, pungent, or unpleasant taste or smell.

All ingredients, including optional ingredients, shall be clean, of good quality, safe and with minimal fibre which should be removed when necessary. All ingredients and food additives shall be gluten free.
Relevant reference link for raw materials codex standards:
http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/

4.5.1 Milk

Full cream milk powder
Skimmed milk powder and/or
Whey powder (NB: may produce a bitter taste)

Applicable reference

1. CXS 207-1999: Standard for Milk Powders and Cream Powder.
2. CXS 289-1995: Standard for Whey Powders

4.5.2 Carbohydrates

Carbohydrates used shall be gluten free and readily soluble in water. Lactose or fructose shall not be added. Glucose or lactose polymers are the preferred sources of carbohydrate and should be pre-gelatinized (e.g., maltodextrin).

Applicable reference

1. CXS 212 – 1999: Standard for Sugars

4.5.3 Oil

Edible refined vegetable oil. The manufacturer shall judiciously choose the type of oil and establish specifications for oil to ensure that the specifications in finished product are met (with particular attention to requirements for omega 3 and omega 6 fats. Hydrogenated vegetable oils not to be used.

Applicable reference

1. CXS 210 -1999: Standard for Named Vegetable Oils
2. Code of Practice for the reduction of 3-Monochloroprane-1-2- DIOL Esters (3-MCPDEs) and GLYCYCIDL Esters (GEs) in Refined Oils and Food Products made with refined oils.
3. Trans-fat: CXS 72-1981 Standard for Infant Formula and Formulas for Special Medical Purposes intended for Infants, rev 2007

4.5.4 Vitamins and minerals

The used nutrient compounds shall comply with the criteria established in CAG/GL 10 – 1979 (Rev. 2008 last amendment 2015). Acceptable vitamin compounds can be found in Annex 3 of the COMMISSION DIRECTIVE 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC. http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006L0141
If the manufacturer uses a mineral and vitamin premix(es), they must source it from a specialized premix manufacturer.

4.5.5 Antioxidants

The use of artificial antioxidants is not permitted. Only natural antioxidants such as ascorbyl palmitate or mixed tocopherols may be used, as per the Codex Standard for Infant formula. *http://www.fao.org/input/download/standards/288/CXS_072e_2015.pdf*

4.5.6 Other additives

Essential L-amino acids, choline, taurine, carnitine, inositol carotene and other semi-essential or biologically valuable nutrients may be added at levels considered to be safe for children with severe malnutrition.

4.6 Shelf-life

The product shall retain the above-mentioned specifications for at least 9 - 12 months from date of manufacture when stored in dry conditions at a temperature of 30°C, supported by real time

shelf-life data. Shelf-life studies shall be conducted in accordance with the UNICEF/MSF *Requirements for stability study for Therapeutic Food.*

5. Packaging

5.1 Primary packaging (aseptic carton)

All packaging material being in contact with food or intended to come in contact with food, including inks and glue shall be of food-contact grade. Product shall be packed in sterile conditions.

Packaging must be free of damage such as, but not limited to: tears, cuts, holes, and abrasions through one or more layers, leakage of any seal. The closure seal must be free of wrinkles and occluded maters.

-Applicable warnings (such as handling product leftovers, how long the product can be kept at room temperature and in the refrigerator, use by date after opening, etc.)
-Breastfeeding logo and a message: *Breastfeeding is recommended for at least the first 24 months and exclusively until 6 months*
-List of ingredients (starting materials used) in descending order quantity
-Nutritional composition per 100 ml.
-Name and address of the manufacturer and packer, or distributor, or importer, or exporter, or vendor and country of origin
-Net weight
-Batch number clearly identified and visible
-Date of manufacture
-Best before date clearly identified and visible
-Storage conditions
-Instruction to ‘’Discard any feed that has not been consumed within two hours”.

5.2 Secondary packaging

The aseptic cartons shall be placed in strong, export carton boxes. Carton boxes shall be shock and puncture resistant. Cartons shall be of a sturdy quality and provide protection of the goods for carriage by air, sea and/or road to final destination worldwide, including remote locations under adverse climatic and storage conditions, and high humidity - for example an ECT (Edge Crush test*) > 11kN/m with minimum 60% remaining with 90% humidity at the highest recommended storage temperature.

Additional references

1. Recommended guideline for food hygiene in rooms where the RUIF is stored ISO/TS 22002-1:2013 – Prerequisite programs for food safety. Part 3. – Catering

2. World Health Organization 2007 Safe preparation, storage, and handling of powdered infant formula: guidelines. “World Health Organization in collaboration with Food and Agriculture Organization of the United Nations.”

5.3 Secondary packaging

Carton label shall contain this information

-Product name
- Any applicable warnings
-Name and address of the manufacturer or packer, or distributor, or importer, or exporter, or vendor and country of origin
- Gross weight
- Number of milk aseptic cartons per carton
- Batch code clearly identified and printed out
- Date of manufacture
- Use by date clearly identified and printed out
- Storage conditions and maximum stacking height (e.g., 2 meters maximum)
- An image indicating that boxes should not be stood on

5.4 Palletisation

Cartons shall be securely closed, stacked (cross stacked, if possible, to maximize stacking strength) on one-way pallets and wrapped with stretch/shrink. Please see UNICEF supply division Packing Specifications (non-CPH destinations)

https://www.unicef.org/supply/documents/packing-packaging-and-labelling-specifications-non-copenhagen-destinations

6. Processing requirements

6.1 General

All processing shall be carried out in a manner that minimizes loss of nutritive value, particularly protein quality and vitamin content.
Products must be manufactured in accordance with the CAC/RCP 66 – 2008: Code of Hygienic Practice for Powdered Formulae for Infants and Young Children.
http://www.fao.org/input/download/standards/11026/CXP_066e.pdf and CAC/RCP 1-1969, Rev. 4-2003: Recommended International Code of Practice. General Principles of Food

Hygiene. http://www.fao.org/3/w8088e/w8088e04.htm other applicable codex references and GMPs (Good manufacturing practices). The producer must have a food safety policy in place and an effective food safety management system based on a Hazard Analysis and Critical Control Points (HACCP) approach. Prerequisite programs including environmental monitoring programs must be implemented.

Applicable reference

1. ISO 22000:2005 - Food Safety Management Systems – Requirements for any Organization in the Food Chain.
2. ISO/TS 22002-1:2009 – Prerequisite Programs for Food Safety. Part 1. – Food Manufacture.

The manufacturer must elaborate and implement an analytical plan of the finished product, starting materials and the processing environment. All analytical test procedures must be described in sufficient detail, e.g., the sampling plan, acceptance/release criteria, analytical methods. ISO 17025 certified laboratories shall preferably be used. Refer to section 9 for the minimum analyses to be performed for each batch.

6.2 Traceability

A complete traceability system must be in place. For every batch code, the manufacturer must be able to identify full history of the finished products (composition, sources and batches of raw materials used, processing parameters, analytical results, quantity produced and dispatched, customers and sites where delivered).

6.3 Batch Size

The batch size shall be defined as one bulk mix.

7. Product Safety

RUIF shall be free from objectionable matter. It shall not contain any toxic substances originating from microorganisms or any other poisonous or deleterious substances, including anti-nutritional factors, heavy metals or pesticide residues in amounts that may represent a hazard to health. It shall not contain detectable levels of residues of antibiotics or other veterinary drugs used in animal husbandry.

7.1 Microbiological criteria

Manufacturers are responsible for ensuring the compliance of finished products with the microbiological criteria as specified. In regards of limitations of the end-product testing the compliance shall be ensured through the design of an appropriate food safety control system and verification of the effectiveness of the applied control measures through appropriate auditing methods, including review of monitoring records, deviations and assuring that critical

control points (CCPs) are kept under control and good hygienic practices (GHPs) are adhered to. These activities can be supplemented, as necessary, by appropriately documented microbiological sampling and analysis plans. The microbiological testing shall include, as appropriate, analysis of samples taken from raw materials, environment, production line and finished product. Environmental samples shall be taken from both: the points considered as most likely to cause product contamination and being most contaminated.
Where results of monitoring the control measures and surveillance or verification indicate that the product batch, lot or consignment, or its part is unsafe (not in compliance with the set microbiological criteria), it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

7.1.2 Food Safety Criteria

The criteria set out in Annex 1 *Code of Hygienic Practice for powdered formulae for Infants and Young Children CAC/RCP 66-2008*[3] using ISO 6579 and ISO 22964 or other validated methods applied to the finished product (powder form) after primary packing completed or anytime thereafter up to the point when the primary packaging is opened. The batch shall not be released if there is a failure to meet these criteria.

7.1.3 Food hygiene criteria

The safe production of these products is dependent on maintaining a high level of hygiene control. The criteria for process hygiene as set out in *Code of Hygienic Practice for powdered formulae for Infants and Young Children CAC/RCP 66-2008*[3] are intended to be used by the manufacturer as a means of ongoing assessment of its hygiene programs. As such these tests are not intended to be used for assessing the safety of a specific batch of product, but instead are intended to be used for verification of the hygiene programs.

Applicable references

1. FAO/WHO Expert Meeting on Enterobacter sakazakii and Other Microorganisms in Powdered
   Infant Formula. Enterobacter sakazakii and other microorganisms in powdered infant formula: meeting report http://www.fao.org/3/a-y5502e.pdf
2. ICMSF (International Commission on Microbiological Specifications for Foods). 1986. Microorganisms in foods 2. Sampling for microbiological analysis: Principles and specific applications. 2nd ed.
   Toronto: University of Toronto Press. ICMSF : https://www.icmsf.org/publications/software-downloads/

8. Chemical and other Safety

8.1 Contaminants

Nitrates < 200mg NO3-/kg
Nitrites < 2mg NO2-/kg
Aluminium < 0.6mg/kg
Melamine < 1mg/kg

Mycotoxins (as per Codex standard when applicable for the raw materials used)

Ochratoxin A <0.5ppb
Aflatoxin B1 <0.1ppb
Aflatoxin M1 <0.025ppb
Patulin<10ppb
Deoxynivalenol <200ppb
Zearalenone <20ppb
Fumonisins <200ppb

Applicable reference

1. CAC/RCP 49-2001: Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals.
2. CXS 228-2001: General Methods of Analysis for Contaminants.
3. CXS 193-1995: Codex General Standard for Contaminants and Toxins in Food.

8.2 Pesticides

In general, pesticide levels must be below 10 ppb. Verifying pesticide levels are below accepted limits is the responsibility of the manufacturer.

Carbamates <10 ppb
Organochlorines<10 ppb
Organophosphates <10 ppb
Pyrethroides <10 ppb

The maximum residue levels of specific pesticides or their metabolites in milk set in below shall not be exceeded:

Substance and Maximum residue level (mg/kg)
Cadusafos: 0.006
Demeton-S-methyl/demeton-S.methyl sulfone/
oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl) 0.006
Ethoprophos 0.008
Fipronil (sum of fipronil and fipronil-deslfinyl, expressed as finpronil) 0.004
Propineb/propylenethiourea (sum of propined and propylenethiourea) 0.006

The following pesticides shall not be used in the agricultural production intended for the production of therapeutic formulae:

Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone, expressed as disulfoton)
Fensulfotion (sum o fensulfothion, its oxygen analogue and their sulfone, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation
Haloxfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)
Hexachlorobenzene
Nitrofen
Terbufos (sum of terbufos, ist sulfoxide and sulfone, expressed as terbufos)
Aldrin and dieldrin, expressed as dieldrin, Endrin

Applicable reference

1. CXS 229-1993, REV.1-2003: Analysis of Pesticide Residues: Recommended Methods

8.3 Heavy metals*

Verifying that heavy metal levels are below accepted limits is the responsibility of the manufacturer. Examples of heavy metals that must be controlled include, but are not limited to:

Arsenic <0.052mg/kg
Cadmium <0.112mg/kg
Lead <0.2mg/kg
Mercury<0.037mg/kg
Tin <105mg/kg

**Based on 5 kg child with SAM and PTWI, CXS 193- 1995: General Standard for Contaminants and Toxins in Food and feed.*

8.4 Hydrocarbons

Benzo[a]pyrene <1ppb

8.5 Radioactivity

Radioactive contamination can occur when using milk powder derived from cows that have eaten contaminated feed. This risk is managed by using certified radioactivity free milk products. The nuclear radiation level shall meet the values valid in the area of consumption. If limits are not defined, the value must not exceed 370Bq/kg (Cs 134 & Cs136).
The product and its components shall not be treated by ionizing radiation.

8.6 GMO (Genetically Modified Organisms)

UNICEF requires the information regarding the presence/absence of GMO to be declared.

8.7 Other contaminants

The product shall meet the codex CXS 72 – 1981: Requirements for other contaminants (residues of hormones, antibiotics, and pharmacologically active substances.)

9. Minimum requirement for release of RUIF

Certificate of Analysis (CoA) is required for every batch supplied against UNICEF Supply Division Purchase Orders. It shall be forwarded prior to its shipment. The manufacturer is expected to perform the necessary finish product analysis in order to prove that the batch complies with the specification. In case vitamin and mineral premix is used it may be adequate to test for tracers as indicated above. In case single addition of vitamins and minerals are used, then individual analysis of each component is expected.

A Certificate of Analysis must be provided for each batch. The principal tests listed below must be performed in order to check if the quality of the formula meets above requirements. Additional analyses shall be defined in case of further quality assessment.
List of the minimum tests results for Certificate of Analysis and reference data are listed below:

Microbiological food safety criteria set in 7.1.2 and food hygiene criteria set in 7.1.3.

Nutrient values per 100ml

Energy: 60-70 kcal
Protein: 1.1-2.1g
Lipids: 2.6 – 4.2 g
Vitamin C: 6 mg minimum
Vitamin A: 36 – 126 mcg RE
Potassium: 36 - 126mg
Sodium: 12 – 42 mg
Iron: 0.27 mg minimum

The manufacturer shall conduct at least one complete finished product analysis annually in order to verify that the finished product is manufactured according to this specification.

Shelf life

12 months
Supplier should indicate instruction for use for the RUIF milk: After opening, store remainder in the carton in a refrigerator. Once formula is in the baby bottle or feeding cup the formula should

be used immediately. Any formula remaining in the cup after feeding should be discarded. Once opened, use contents of carton within 24 hours. Use before expiry date indicated on the top of the carton.

Storage and transportation

Store and transport in cool, dry conditions, below 30 degrees C.

Useful Resources

1. Contaminants Reference Table
2. Stability study template for Nutritional Products
3. Interagency Requirements for stability study
4. Interagency Specialised Food Manufacturer Quality Questionnaire.
5. Interagency Specialised food Product Questionnaire
6. Technical Requirements for Nutritional Products

FOR MORE INFORMATION

CPHHQ-SD- Nutrition Supplies |sd.nutritionsupplies@unicef.org

Technical resources for nutrition products | UNICEF Supply Division