



PRODUCT SPECIFICATION SHEET

F-75 Therap.milk 200 ml

Material nr.: S0000261

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1. General Description

Ready to use F-75 Therapeutic diet. For phase 1 treatment of Severe Acute Malnutrition (SAM). Each unit of 200ml, is packed in an aseptic carton.

2. Intended Use

The F-75 liquid therapeutic diet is intended for the initial phase of treatment of children diagnosed with Severe Acute Malnutrition (SAM). It is intended to stabilize the child's metabolism and support rehydration.

The F-75 liquid therapeutic milk has an energy density of approximately 75 kcal/ 100ml. F 75 must be used under medical supervision. A cautious approach is required because of child's fragile physiological state and reduced homeostatic capacity. Hence, F-75 is not designed for weight gain. (WHO. Guideline: Updates on the management of severe acute malnutrition in infants and children. Geneva: *World Health Organization*; 2013:4)

3. Target Population

Children diagnosed with SAM, in the initial or stabilisation phase of their treatment.

4. Technical Specifications

4.1 General quality

Milk based white or pale yellowish, free from impurities or coloured particles

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.

4.2 Ingredients

milk powder, refined vegetable oil, sugar, maltodextrin, milk derivates, emulsifier (lecithin) vitamins and minerals (optionally premix can be used).

4.3 Nutritional Composition

Macronutrients in g per 100ml

Energy: 75 (70-80) kcal
Protein: 1 (0.75-1.5) g
Lipids: 2.5 (2.0-3.0) g
n-6 fatty acid: 3 -10 % max of total energy; 0.50 -1.70 g per 100 ml
n-3 fatty acid: 0.3- 2.5 % of total energy; 0.05- 0.40 g per 100 ml
Carbohydrate: 12 (10.5-14) g
Lactose: 1.24 g maximum
Ash: 0.70 g maximum
Osmolarity: 240-320 mMol /L

All therapeutic foods approved for the initial feeding or stabilisation phase of treatment of children with severe acute malnutrition must provide at least 50% of protein in the form of dairy protein. For the purposes of conversion from unit weight to unit energy, protein and carbohydrate are assumed to contribute 4 kcal/g and lipids 9 kcal/g.

Minerals per 100ml

Sodium: 17 mg maximum
Potassium: 122-156 mg
Calcium: 50-100 mg
Phosphorus: 50-100 mg
Magnesium: 8.5-11 mg
Iron: 0.05 mg maximum
Zinc: 1.8-3.0 mg
Copper: 0.2-0.3 mg
Selenium: 3.5-7.0 mcg
Iodine: 12.3-24.5 mcg

Vitamins per 100ml

Vitamin A: 0.1-0.3 mg

Vitamin C: 9 mcg minimum
Vitamin D3: 2.5-5.0 mcg
Vitamin E: 3.3-6.5 mg
Vitamin K: 2.5 mcg minimum
Ascorbic acid: 10 mg minimum
Thiamine: 0.08 mg minimum
Riboflavin: 0.3 mg minimum
Niacin: 0.8 mg minimum
Pantothenic acid: 0.5 mg minimum
Vitamin B6: 0.1 mg minimum
Folic acid: 35 mg minimum
Vitamin B12: 0.3 mcg minimum
Biotin: 10 mcg minimum

4.4 Formulation and Starting materials

F-75 shall be manufactured referencing the formula described in the WHO document: Management of severe malnutrition: a manual for physicians and other senior health workers World health organization, 1999 (refer to Table 7, Table 8 and Appendix 4).
<http://www.who.int/nutrition/publications/severemalnutrition/9241545119/en/>

The product must provide at least 50% of protein in the form of dairy protein. 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 a characteristic milk taste and smell. It shall be white as cream, and 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.

Applicable codex references for ingredients can be found in this link:
<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 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 choose judiciously 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 fatty acids. Hydrogenated vegetable oils are not to be used.

Applicable reference

1. CXS 210 -1999: Standard for Named Vegetable Oils.
2. Code of Practice for the reduction of 3-Monochloropropane-1-2- DIOL Esters (3-MCPDEs) and GLYCICIDL 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) Advisory lists of Nutrient Compounds for use in foods for Special Dietary uses for Infants and Young Children.

http://www.fao.org/input/download/standards/300/CXG_010e_2015.pdf

Another list of acceptable vitamin compounds can be found in Annex 3 of the COMMISSION DIRECTIVE 2006/141/EC of 22 December 2006 on infant formulae, 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. Vitamins and minerals shall be in such forms that they are easily absorbed by patients with SAM who are often achlorhydric. The added minerals shall be water-soluble and shall not form insoluble components when mixed together. Iron salts are not to be added.

The liquid therapeutic diet shall have a mineral composition that will not alter the acid-base metabolism of patients with SAM. In particular, it shall have a moderate positive non-metabolisable base sufficient to eliminate the risk of metabolic acidosis. The non-metabolisable base can be estimated using the formula:

Estimated absorbed millimoles (sodium+potassium+calcium+magnesium) minus (phosphates + chlorides) See: http://www.who.int/maternal_child_adolescent/documents/a91065/en/

Added minerals shall be in the form of water-soluble salts. Minerals used shall be in forms that are known to be bioavailable. Nitrite and nitrate salts shall not be used. Recommended forms of minerals can be found in Appendix 4, Management of Severe Malnutrition a manual for senior health workers. <http://www.who.int/nutrition/publications/severemalnutrition/9241545119/en/>
http://apps.who.int/iris/bitstream/10665/44295/1/9789280641479_eng.pdf?ua=1

4.5.5 Flavouring

The use of artificial flavourings is not permitted; only natural flavourings may be used. Natural flavourings are defined in CAC/GL 29-1987 General Requirements for Natural Flavourings and in Regulation of the European parliament and of the Council (EC) N° 1334/2008. https://www.fsai.ie/uploadedFiles/Req%201334_2008.pdf

4.5.6 Antioxidants

The use of artificial antioxidants is not permitted, only natural antioxidants such as ascorbyl palmitate or mixed tocopherols may be used.

4.5.7 Other additives

Essential L-amino acids, choline, taurine, carnitine, inositol, carotene and other semi-essential or biologically valuable nutrients may be added to meet the specification 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 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 (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 aseptic cartons.

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.

5.2 Primary label

Labels must have adequate information to permit identification, safe transport, storage and use of the product throughout its shelf life. The label is to be white with black printing. Labels should be printed directly on container/packaging.

Ink/colour: The writing on primary and secondary packs must be in indelible ink, in black on white. The labelling shall be in English, Arabic and French. One of these languages may be replaced by a local language as requested by UNICEF.

The primary package shall contain the following information

- Generic name: F-75 Therapeutic Milk
- Clear statement: For the initial phase (or stabilisation phase) of treatment of children with Severe Acute Malnutrition, not suitable for long-term feeding of well-nourished children. Use under medical supervision.
- Applicable warnings (such as handling product leftovers, how long the milk 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 g of powder and 100 ml of reconstituted diet.
- 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.

Labelling must comply with the WHA *International Code of Marketing for breastmilk substitutes*.

Applicable reference

https://www.who.int/nutrition/publications/code_english.pdf

5.3 Secondary packaging

The 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.

5.4 Secondary packaging Label

Carton label shall contain this information

- Generic name: F-75 Therapeutic Milk (or Therapeutic formula F-75)
- A clear statement: For initial phase (or Phase 1) of treatment of Children with Severe Acute Malnutrition
- Any applicable warnings
- Name and address of the manufacturer and packer, or distributor, or importer, or exporter, or vendor and country of origin
- Gross weight
- Number of aseptic containers per carton
- Batch number clearly identified and printed
- Date of manufacture
- Use by date clearly identified and printed
- Storage conditions and maximum stacking height (e.g., 2 meters maximum)
- An image indicating that boxes should not be stood on



5.5 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 and drying 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. 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. www.fao.org/input/download/standards/23/CXP_001e.pdf 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.

Other Applicable standards 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 Process validation

The coefficient of variation shall be as low as possible, and always <5%. For calculator refer to WFP method:

<http://foodqualityandsafety.wfp.org/coefficient-of-variation-calculator>

6.3 Traceability

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

6.4 Batch Size

The batch size shall be defined as one bulk mix.

7. Product Safety

Therapeutic milk 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 regard to 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 starting 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.

7.2 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.

1) NOTE: No composite sample. Maximum pooling authorized is 4 pooled samples of 375g (25g from 15 units), only if the laboratory method has been validated and accredited for that method.

2) NOTE: No composite sample. One pooled sample of 300g (10g from 30 units) authorized, only if the laboratory method has been validated and accredited for that method.

7.3 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.

3) NOTE: No composite sample. No pooled samples.

4) NOTE: For ISO 21528-1: One pooled sample of 300g (10g from 30 units) authorized, only if the laboratory method has been validated and accredited. In case of positive result, another test using the ISO 21528-2 is mandatory (no composite sample, no pooled samples authorized for ISO 21528-2).

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 starting materials used)

Ochratoxin A <0.5ppb

Aflatoxin B1 <0.1ppb

Aflatoxin M1 <0.025ppb

Patulin <10ppb

Deoxynivalenol <200ppb

Zearalenone <20ppb

Fumonisin <200ppb

Applicable reference

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

Pyrethroids <10 ppb

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

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 fensulfotion, its oxygen analogue and their sulfone, expressed as fensulfotion)

Fentin, expressed as triphenyltin cation

Haloxfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)

Hexachlorobenzene

Nitrofen

Ometholate

Terbufos (sum of terbufos, ist sulfoxide and sulfone, expressed as terbufos)

Aldrin and dieldrin, expressed as dieldrin, Endrin

Applicable reference

1. CXM 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 <0.092mg/kg

Cadmium <0.043mg/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 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 F 75

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 finished product analysis in order to prove that the batch complies with the specification. In the case a 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 is used, then individual analysis of each component is expected. The principal tests listed below must be performed in order to check if the quality of F-75 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 100 ml

Energy: 70 – 80 kcal
Protein: 4.0-7.0% total energy
Lipids: 25-35% total energy
Lactose: 1.24 g maximum

Vitamin A: 0.1 – 0.3 mg
Potassium: 122-156 mg
Sodium: 17 mg maximum
Iron: 0.05 mg maximum
Osmolarity: 240-320 mOsmol/L (freezing point depression)

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 (to cover e.g., heavy metals and pesticides).

Shelf life

Shelf life unopened: 12 months from date of manufacture.

Storage and Transport Information

Supplier must indicate storage and transport temperature conditions. Do not store above 30 °C is preferred.

Supplier shall provide Weight of carton, around: 5.48 kg/ carton

Supplier shall provide gross volume of carton, around: 6.0 dm³ / carton

Supplier must include other important instructions e.g Protect from direct sunlight

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 “Nutritional Products”

FOR MORE INFORMATION

CPHHQ-SD- Nutrition Supplies lsd.nutritionssupplies@unicef.org

[Technical resources for nutrition products | UNICEF Supply Division](#)