Save the Children

Date of issue: 20th Nov. 2017
Written by: Alice Burrell
Authorized by: Charlotte d'Elloy

PRODUCT SPECIFICATION SHEET

F-75 THERAPEUTIC MILK

F-75 Therapeutic Milk	
1) General Description	Milk based powder for treatment of severe acute malnutrition (SAM), with added vegetable fats, carbohydrates, vitamins and minerals to prepare a liquid diet with energy density characteristics of approximately 75 kcal/100ml, specially formulated for the initial feeding or starter phase in the treatment of severe acute malnutrition. It is not designed to promote weight gain. F-75 may be used in climatic extremes from the arctic to tropical zones and may be the sole source of food, except for water and breast milk, during the period of use. The product must be in powder form (milk based powder), to be mixed with water. As of September 2017, F-75 may be found in both sachets and tins (transition to tins as sole mode of packaging): • One sachet of F-75 is mixed with 0.5 L of boiled water cooled down to 70°C, to obtain about 0.6 L of F-75 therapeutic milk with energy density of approx. 75 kcal/100ml. • One tin of F-75 can be mixed with 2.2 L of boiled water, cooled to 70 °C, but can also be made up in smaller quantities as required.
2) Item description	**Taste and smell**: clean, fresh dairy smell. Typical of milk. **Appearance**: White or slightly yellowish fine powder, free from Impurities, coloured particles. **Dispersibility:** The reconstituted diet must be a homogenous liquid that does not separate into oil/water phases or leave solid sediment upon standing over a 6-hour period with occasional gentle stirring. **Texture:** Powder, free from caking or lumps.
3) Nutritional composition (1)	**Energy:** 428 (422-440) kcal/100gr Powder 75 (70 – 80) kcal/100ml **Protein**: 5% (4-7%) of total energy 6.2 (5.0-7.5) g/100g powder **Carbohydrate:** 64% (57 – 69%) of total energy 66.6 (59.2-73.9) g/100g powder **Lipids:** 32% (25-35%) of total energy 14.6 (12.1-17.2) g/100mg powder n-6 fatty acid: 6.5 (3-10) % of total energy n-3 fatty acid: 1.5 (0.3-2.5) % of total energy **Moisture content:** 4% maximum

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	Ash:	3.2-3.5 g/100g powder
	Lactose	7.3 (6.0-8.5) g/100g powder 1.4%/100ml maximum
	Osmolarity	300 mOsmol/litre (280-300)
	Solubility index:	Maximum 1ml
	Burnt particles:	Maximum 15 (i.e. disc B minimum)
	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.	
Vitamins /100 gr powder[1]	Vitamin A:	Between 0.8 mg and 1.6 mg
	Vitamin D3:	Between 15 µg and 20 µg
	Vitamin E:	Between 20 mg and 25 mg
	Vitamin K:	Between 15 µg and 30 µg
	Thiamine:	0.5 mg minimum
	Riboflavin:	1.6 mg minimum
	Ascorbic acid:	50 mg minimum
	Vitamin B6:	0.6 mg minimum
	Vitamin B12:	1.6 µg minimum
	Folic acid:	200 µg minimum
	Nicotinic acid:	5 mg minimum
	Pantothenic acid:	3 mg minimum
	Biotin:	60 µg minimum
Minerals /100 gr powder[1]	Sodium:	87 mg maximum
	Potassium:	Between 737 mg and 938 mg
	Calcium:	Between 300 mg and 600 mg
	Phosphorus:	Between 300 mg and 600 mg
	Magnesium:	Between 48 mg to 64 mg
	Iron:	0.3 mg maximum
	Zinc:	Between 11 mg and 18 mg
	Copper:	Between 1.4 mg and 1.8 mg
	Selenium:	Between 20 µg and 40 µg
	Iodine:	Between 70 µg and 140 µg
4) Shelf life	24 months from manufacturing date, when stored in a dry place below 30°C. Unless specifically authorised in writing, products must be of fresh production i.e. less than 4 months old at the time of delivery. **Sachet** Once opened, to be used or discarded within 24 hours. **Tin** Once opened, to be used or discarded within 4 weeks.	

[1] MSF Product Specification Sheet: F75 Therapeutic Formula (last revision 28/01/2014)
UNICEF supply catalogue;

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5) Raw material	Therapeutic milk F-75 contains milk powder, refined vegetable oil, sugar, malto-dextrine, milk derivatives, vitamin and mineral complex. All ingredients, including optional ingredients, shall be clean, of good quality, safe and with excessive fibre removed where necessary. All ingredients and food additives shall be gluten free. • **Milk** Acceptable sources of milk: - Full cream milk powder - Skimmed milk powder - Whey powder (will not be used for tinned TM) Applicable standards reference: · *Codex STAN 207-1999 Codex Standard for milk powders and cream powder* · *Codex STAN 289-1995: Codex Standard for Whey Powders* • **Carbohydrates** - Lactose and glucose polymers shall be used. - Only precooked and/or gelatinised starches gluten-free by nature may be added up to 30% of total carbohydrates. - Carbohydrates used shall be readily soluble in water. - Sucrose, unless needed, and the addition of fructose as an ingredient should be avoided, because of potential life-threatening symptoms in infants with unrecognised hereditary fructose intolerance. Applicable standards reference: · *Codex stan 212 – 1999: Codex standard for sugars* • **Cereal flour** Isotonic versions, which contain malto-dextrine instead of cereal flour and some of the sugar, can be proposed. • **Oil** - Edible refined vegetable oil - The manufacturer shall choose judiciously the type of oil and establish specifications for the oil to ensure that the overall specifications for F-75 are met, with particular attention to the requirements for omega 3, omega 6 and Vitamin A, if fortified. Applicable standards reference: · *Codex STAN 210 -1999: Codex Standard for Named Vegetable Oils* • **Food Additives** - **Complex of minerals and vitamins** The mineral and vitamin premix(es) cannot be produced by the manufacturer itself and must be supplied only from a restricted list of authorised suppliers of premix approved by GAIN and WFP. (http://gpf.gainhealth.org/suppliers/current-suppliers). A detailed

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	Certificate of Analysis of the premix with all mineral and vitamin components must be available from the supplier of premix for every batch of premix delivered. Vitamins and minerals shall be in such forms that they are easily absorbed by patients with SAM. The added minerals shall be water-soluble and shall not form insoluble components when mixed together. Minerals used shall be in forms that are known to be biologically available. Iron salts shall not be added. The 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 sum of strong anions (chloride) should be less than the sum of strong cations (sodium, potassium) when expressed in molar terms. For the purposes of these specifications, magnesium and calcium are to be counted as weak cations and phosphate as a weak anion. The non-metabolisable base can be approximated by the formula: Estimated absorbed millimoles = (Sodium+Potasium+Calcium+Magnesium) – (Phosphorus+Chloride) An example of a mineral mix with a suitable positive non-metabolisable base can be found in the *Appendix 4 of Management of Severe Malnutrition: a Manual for Physisiclas and Other Senior Health Workers, WHO 1999.* Another potentially useful source of acceptable mineral and 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 and in the CAG/GL10 – 1979 Advisory lists of Nutrient Compounds for use in foods for Special Dietary uses for Infants and Young Children*. Vitamin and mineral compounds approved for use in infant formulae are listed on pages 22 and 23; in general, these same compounds shall be acceptable for therapeutic milk. Applicable standards reference: *-Codex Alimentarius guidelines for vitamin and mineral food supplements (CAC/gl 55 - 2005).* - **Flavouring** Artificial Flavourings are not allowed, only natural flavourings. - **Antioxidants** Artificial antioxidants are not permitted, only the following natural antioxidants: · Ascorbyl palmitate · Mixed tocopherols - **Other additives** Nutritional levels of 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 SAM.
6) Packaging and Labelling	• **Primary packaging** ○ 120 sachets of 102.5 g per carton ○ 24 tins of 400g per carton (each with 1 blue measuring scoop)

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	The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. Packaging material must: • be of food-contact grade. • not transfer any element (particle, flavour, or odour) to the product • be able to withstand pressure changes associated with air transport • be free of damage, such as tears, cuts, holes, abrasions through one or more layers, leakage through seals etc. The closure seal must be free of wrinkles and occluded matter. An air and water tightness control must be implemented during the filling process. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply. **Sachets**  Sachet foil to include an aluminium layer to protect against UV light and humidity. **Tins**  Tins are re-sealable. The scoop that is packaged in the tin is the only scoop that should be used with that tin. - **<u>Labelling</u>** <u>The labelling shall be at least bilingual. English is mandatory, the choice of other language(s) is as deemed appropriate.</u> Labels will include: o Generic name: F-75 Therapeutic Milk (or therapeutic formula F-75 or F-75 Therapeutic Milk Powder) o A clear statement: For initial phase (or Phase 1) of treatment of Children with Severe Acute Malnutrition o Any applicable warnings (such as handling product leftovers, how long at room temperature, how long in the fridge) o List of ingredients (raw material specified) in descending order quantity o Nutritional composition per 100 g of powder and 100 ml of reconstituted diet.

	○ A detailed list of the active ingredients (vitamin and mineral premix) showing the amount of each present in a dosage unit, and a statement of the net contents of the container, e.g. number of dosage units, weight or volume should be provided in a leaflet and not on a product label ○ Name and address of the manufacturer, packer, distributor, importer, exporter or vendor and country of origin ○ Net weight ○ Batch number ○ Date of manufacture ○ Best before date ○ Storage conditions Applicable standards reference: *-Codex STAN 146-1985: General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses.* *-Codex STAN 1-1985: General Standard for the Labelling of Pre-packaged Foods* • **Secondary packaging** Packaging for nutrition products must be of a sturdy export quality, of a commercial standard that will provide adequate protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions, and high humidity - i.e. not less than 17kN edge crush resistance with minimum 60% remaining with 90% humidity at a temperature of 40C (tropical conditions). The packaging unit is strong, able to be stacked to a height of 4 pallets as static storage and 2 pallets during transport, and resistant to puncturing. The product is packed under inert gas (nitrogen or carbon dioxide) to prolong in shock resistant, strong export cartons. Each carton securely closed. The cartons are to be securely stacked (cross stacked if possible, to maximize stacking strength) on one-way pallets and stretch/shrink wrapped. The pallet load is to be strapped to the pallet by means of either steel or nylon straps (min. breaking strength 150 kg). - **Carton Label includes:** ○ Generic name: F-75 Therapeutic Milk (or therapeutic formula F-75 or F-75 Therapeutic Milk Powder) ○ 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, packer, distributor, importer, exporter or vendor and country of origin ○ Gross weight ○ Number of sachets per carton ○ Batch number ○ Date of manufacture ○ Best before date ○ Storage conditions ○ Purchase order number: optional for inner boxes

	○ Cubic Measurement ○ IMCO classification (if applicable) No carton may contain items from more than one manufacturing batch. The packing list should indicate the manufacturing batch number (where applicable) and cross-reference to the carton numbers, pallets and containers. One copy of the packing list must be included with the shipment and another copy should accompany the shipping documents.
7) Safety	Therapeutic milk shall be free from objectionable matter. It shall not contain any substances originating from microorganisms, or any other poisonous or deleterious substances like heavy metals or pesticide residues, in amounts which may represent a hazard to health The level of pesticides residues and heavy metals should be checked in the finished product once a year and must be in accordance with the levels allowable by Codex Alimentarius. The product should not contain detectable levels of antibiotics or other drugs used in animal husbandry. • **Microbiology** Manufacturers are responsible for ensuring the compliance of finished products with criteria described below. In regards of limitations of end-product testing, compliance shall be ensured through the design of an appropriate food safety control system and verification of the effectiveness of control measures through appropriate auditing methods, including review of monitoring records, deviations and assuring that CCPs are kept under control and Good Hygienic Practices 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 most likely contaminated. When monitoring of control measures and surveillance or verification results demonstrate deviations, appropriate corrective action shall be taken and the finished product shall not be released until adequate investigation has shown that it complies with appropriate specifications. **Criteria for pathogenic microorganisms** The criteria below are to be applied to the finished product (powder form) after primary packaging or anytime thereafter up to the point when the primary packaging is opened. The batch cannot be released if there is a failure to meet those criteria. **Microorganisms** **n** **c** **m** **p** **Method** Salmonella 60 0 0/25g 2 ISO 6579 *(a)*[2]

[2] (a)No composite sample. Maximum pooling authorized is 4 pooled samples of 375g (25g from 15 sachets), only if the laboratory method has been validated and accredited.

Cronobacter Sakazakii	30	0	0/10g	2	ISO/TS 22964(b)[3]	

With:
n = number of samples units to be taken
c = the maximum allowable number of defective sample units in a 2-class plan or marginally acceptable sample units in a 3-class plan
m = a microbiological limit which, in a 2-class plan, separates good quality from defective quality or, in a 3-class plan, separates good quality from marginally acceptable quality
p = class plan

Criteria for process hygiene

These criteria apply to the finished product (powder form) or at any other previous point that provides the information necessary for the purpose of the verification.
The safe production of these products is dependent on maintaining a high level of hygienic control. The following additional microbiological criteria are intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs. As such these tests are not intended to be used for assessing the safety of a specific lot of product, but instead are intended to be used for verification of the hygiene programs.

Microorganisms	n	c	m	M	p	Method
Mesophilic Aerobic Bacteria	5	2	500/g	5000/g	3	ISO 4833*(c)*[4]
Enterobacteriacea (EB at 30°C)	10	2(d)[5]	0/10g	NA	2	ISO 21528-1/2*(e)*[6]

With:

[3] (b)No composite sample. One pooled sample of 300g (10g from 30 sachets) authorized, only if the laboratory method has been validated and accredited.

[4] (c) No composite sample. No pooled samples

[5] (d) This 2 class plan is proposed because a 3 class plan with equivalent performance would not be practical analytically, given the low levels of EB typically occurring when stringent hygiene conditions are maintained.
It may seem that peak contaminations in up to 2 samples are tolerated in this Microbiological criterion (MC). However, it is assumed that the product is sufficiently homogeneous that high level contaminations will fail the MC. It is further assumed that, in practice, under sufficiently strict hygienic operation, the manufacturer will normally not find positives and that if, occasionally, positives are found the manufacturer will take appropriate actions. Finding 1 or 2 positives should indicates a trend toward potential loss of process control and appropriate actions would include further microbial evaluation of the implicated end product (i.e. re-evaluation of the EB content; when EB MC fails, evaluation of product safety using the proposed MCs for Salmonella and Cronobacter Sakazakii before its release as well as evaluation of the hygiene programme to confirm it is suitable to maintain ongoing hygiene control or to amend the programme in a way that is appropriate to do so). Finding 3 or more positives indicates loss of process control and appropriate actions should be the evaluation of product safety using the proposed MCs for Salmonella and Cronobacter Sakazakii before release of the implicated product as well as evaluation of the hygiene programme to amend the programme such that it is suitable to maintain high hygiene control on an ongoing basis before production is resumed

[6] (e)For ISO 21528-1: One pooled sample of 300g (10g from 30 sachets) 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.

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M = a microbiological limit which, in a 3-class plan, separates marginally acceptable quality from defective quality.

- **Chemical safety**

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

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

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

- **Pesticides**

In general, pesticide levels must be below 10 ppb. Verifying pesticide levels are below accepted limits is the responsibility of the manufacturer. Examples of pesticides that must be controlled are (not necessarily exhaustive):

Carbamates	<10 ppb
Organochlorine	<10 ppb
Organophosphorous	<10 ppb
Pyrethroid	<10 ppb

Applicable standards reference:
-CAC/RCP 49-2001 Code of practice for source directed measures to reduce contamination of food with chemicals.
-CODEX STAN 228-2001: General methods of analysis for contaminants.
-CODEX STAN 193-1995: Codex general standard for contaminants and toxins in food.
-CODEX STAN 229-1993, REV.1-2003 : analysis of pesticide residues: recommended methods

- **Heavy metals**

Arsenic	<0.043 mg/kg
Cadmium	<0.092 mg/kg
Lead	<0.153 mg/kg
Mercury	<0.031 mg/kg
Tin	<85.8 mg/kg

- **Hydrocarbon**

Benzo[a]pyrene	<1 ppb

- **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.

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	The nuclear radiation level shall meet the values valid in the area of consumption. If limits are not defined, the value must not exceed 370 bq/kg (Cs 134 & Cs136). - **GMO (Genetically Modified Organisms)** GMO free is preferred but not required.
8) Stability	Stability study must be conducted on the final product in primary packaging, to confirm shelf life and storage conditions.
9) Quality Assurance	All processing and drying shall be carried out in a manner that minimizes loss of nutritive value, particularly protein quality and vitamin content. The production process shall be in accordance with the Recommended International Code of Hygienic Practice for Foods for Infants of the Codex Alimentarius (Volume 4, Second Edition, FAO Rome 1994) and Good Manufacturing Practice (GMPs) and other Codex Alimentarius applicable references. Except when otherwise specified, the product shall comply with the Standards and Guidelines on Foods for Infants and Children of the Codex Alimentarius (Volume 4, Second Edition, FAO Rome 1994). All producers must have a food safety policy in place and a complete quality management system based on a Hazard Analysis and Critical Control Points (HACCP) approach to food safety. Pre-requisite programs including environmental monitoring programs must be implemented. The variation of the final product with respect to contents of moisture, protein, fat and micronutrients shall not exceed plus or minus 5% of the original value using standard analytical techniques. Products not meeting this requirement are liable for rejection. The manufacturer is responsible to elaborate an analytical plan of finished product. All analytical test procedures must be described in sufficient details, including microbiological methods. ISO 17025 certified laboratories shall be preferably used. Applicable standards reference: · *Recommended International Code of Practice. General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003* · *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. CAC/RCP 66 - 2008* · *ISO 22000:2005 - Food safety management systems – Requirements for any organization in the food chain.* Supplier must have registered the products in its intended countries of supply, in order to facilitate import and use of product The supplier must have registered the products in its intended countries of supply, in order to facilitate import and use of product. Suppliers must ensure that the use of the goods sold under this contract does not infringe any patent, design, trade name or trademark. - **Validation of the process and coefficient of variation**

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	The coefficient of variation, calculated using the method proposed by WFP[7], shall be as low as possible, and always <10. - **Traceability** A complete traceability system must be in place. For every batch number, the manufacturer must be able to find all the history of the finished products (composition, raw materials used, processing parameters, analytical results, quantity produced and dispatched, customers sites delivered, etc). - **Batch size** The batch size shall not exceed 150 Metric tons and one week of production.
10) Documents to provide	• **Commitment of the supplier** The manufacturer must establish its own finished product specification and clearly state the amount and frequency of testing of each ingredient, microbiological contamination, chemical contamination, and other relevant points to be controlled. • **Complete analysis** The manufacturer must conduct a complete analysis of the finished product in order to verify that the finished product is manufactured in a homogeneous and consistent content. All parameters included in this specification sheet shall be tested at least once a year. • **Certificate of analysis** Suppliers will be required to submit a Certificate of Analysis from the manufacturer's own quality control laboratory covering each batch delivered along with shipping documents. A confirmatory certificate of analysis from the supplier should be available at least for the duration of the shelf life of all batches of finished products in which the ingredients and excipients are used. Customer should be notified and approve of any changes in ingredients, excipient sources and finished product specifications. Customer should be notified and approve of any changes in sources, routes of synthesis and/or specifications. The Certificate of Analysis should include: ○ Order number ○ Generic name of product together with pharmaceutical formulation and strength per dosage unit ○ Composition of the product using International Non-proprietary Names (INN) ○ Pharmacopoeia reference (if applicable) ○ Batch number ○ Batch quantity ○ Date of manufacture ○ Expiry date (dd/mm/yyyy) ○ Date of test (dd/mm/yyyy) ○ Contents of dosage form per unit package ○ Description (clarity, colour, etc.) ○ All attributes necessary for the quality control of the type of product, including identity, content (assay), dissolution, sterility, pyrogen and if applicable all other test required by the specified pharmacopoeia. Both the actual results and the limits for the individual tests should be given.

[7] *http://foodqualityandsafety.wfp.org/coefficient-of-variation-calculator*

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	○ The Certificate of Analysis for one batch of product should be submitted for the following microbiological tests every 6 months (Save the Children can require more frequent testing): The batch cannot be released if there is a failure to meet the criteria mentioned in this specification document If any organization (NGO, UN…) decides to perform analyse in an accredited laboratory at its own initiative, and obtain results that do not meet those criteria, the supplier have to recall the product and determine and correct the root cause of the failure. • **Other certificates required (on demand only)** ○ Certificate of Origin ○ Certificate of Conformity ○ Health Certificate (issued by independent regulatory authority) ○ Certificate of non-radioactivity ○ GMO Free Certificate (when applicable) ○ Halal certificate (when applicable) ○ Dioxin free certificate

REFERENCES

(1) UNICEF: https://supply.unicef.org/unicef_b2c/app/displayApp/(layout=7.0-12_1_66_67_115&carea=%24ROOT)/.do?rf=y
(2) WHO: http://www.who.int/nutrition/publications/en/manage_severe_malnutrition_eng.pdf