PRODUCT SPECIFICATION SHEET

92g/CAR-150 Ready-to-Use Therapeutic Food (RUTF) paste

Version no: 1.0
Material No: S0000264
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Revised by: AF
Date: 03.12.2020

1. General Description

Powdered infant formula is a breast milk substitute, with added vegetable fat, carbohydrates, vitamins and minerals. It comes as powder packed in a canister to prepare a liquid infant formula. Each canister contains 400g of powdered infant formula in cartons of 24 canisters and comes with a scoop.
The formulation is according to the Codex standard CXS 72-1981 Standard for infant formula and formulas for special medical purposes intended for infants.

2. Intended Use

For use in infants who cannot be breastfed or are partially breastfed in situations of orphans, humanitarian contexts or medical conditions that make it not possible for a mother to breastfeed.
The specified quantity of powdered infant formula is mixed with the specified quantity of water, which has been boiled and cooled down to not below 70˚C to obtain a defined quantity of liquid infant formula.
Powdered infant formula must be administered under the supervision of a health professional.

3. Target Population

Infants up to the age of 6 months.

4. Technical Specifications

4.1 General quality
Milk based white or pale yellowish fine powder; free from impurities, coloured particles, caking or lumps.

4.2 Ingredients: milk powder, refined vegetable oil, sugar, maltodextrin, milk derivate, emulsifier (lecithin) vitamin and mineral (optionally premix can be used).

5. Nutritional composition

As per the Codex standard, Standard for Infant formula and Formulas for Special Medicinal Purposes intended for Infants. Codex standard CXS 72 – 1981.
https://www.fao.org/fao-who-codexalimentarius/sh-

proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B72-1981%252FCXS_072e.pdf

6.0 Formulation and Starting materials

The product must provide at least 50% of protein in the form of dairy protein.
After reconstitution according to the manufacturer´s preparation instruction 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. Frothing of the milk after preparation should be minimal to enable accurate dosage measurements of the milk to each individual recipient. The product should have a characteristic milk taste and smell. It shall be white as cream, shall not have rancid, pungent or unpleasant taste or smell.
All ingredients, including optional ingredients, shall be clean, of good quality, safe and with minimal fibre removed when necessary. All ingredients and food additives shall be gluten free.
Applicable codex references for ingredients can be found in this link: Standards | CODEXALIMENTARIUS FAO-WHO

6.1 Milk

Full cream milk powder
Skimmed milk powder and/or
Whey powder (NB: may produce bitter taste)
Applicable standards reference:
Codex standard CXS 207-1999 Codex standard for Milk Powders and Cream Powder.
Codex standard CXS 289-1995: Codex standard for Whey Powders

6.2 Carbohydrates

Carbohydrates used shall be gluten free and readily soluble in water.
Fructose shall not be added.
Glucose or lactose polymers are the preferred sources of carbohydrate and should be pre-gelatinized (e.g. maltodextrin).
Applicable standards reference:
Codex standard CXS 212 – 1999: Codex standard for Sugars

6.3 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 standards reference:
Codex standard CXS 210 -1999: Codex standard for Named Vegetable Oils.

6.4 Vitamins and minerals

The used nutrient compounds shall comply with the criteria established in CXG 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. ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN (fao.org)
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. EUR-Lex - 32006L0141 - EN - EUR-Lex (europa.eu)
If the manufacturer uses a mineral and vitamin premix (es), they must source it from a specialized premix manufacturers.

6.5 Flavouring
The use of artificial flavourings is not permitted.
Applicable standard:
Codex standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants. Codex standard CXS 72-1981.
https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B72-1981%252FCXS_072e.pdf

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

6.7 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.

7.0 Shelf-life

The product shall retain the above-mentioned specifications for unopened canisters for at least 18-24 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 *Interagency Requirements for stability study for Therapeutic Food*.
Supplier should indicate shelf life of opened canister; e.g. Use within 4 weeks after opening, keep in original container, do not store above 30°C; protect from direct sunlight, protect from moisture.
Supplier should indicate instruction for use for reconstituted milk: Use within 2hrs if at room temperature or 24 hours if stored in the refrigerator.

8.0. Packaging

8.1 Primary packaging (canister)
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 as per Codex standard CXS 72-1981.
Product shall be packed in airtight canisters. Packaging under inert gas (nitrogen or carbon

dioxide) prolongs products shelf-life and is recommended.
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 reference:
https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B72-1981%252FCXS_072e.pdf

8.1.1. Canister seal
Canisters should be hermetically sealed and resistant to humid and hot climates. Seal and canister integrity shall be adequate to withstand pressure changes associated with international distribution channels such as air transport. The canister shall be capped with a reusable lid to adequately close the canister and protect its content form external contamination and humidity during storage. The period when opened canister can be used shall be minimum 4 weeks.

8.1.2 Primary label (Canister)
Labels must have adequate information to permit identification, safe transport, storage and use of the product throughout its shelf life. Labels must be self-adhesive and made from paper, e.g. pharmaceutical defiberised paper (80gsm), that is film or UV coated for protection against humidity and firmly affixed to be tamper proof and to prevent detachment in tropical climates. Type preferably by lithography directly on container/packaging.
Ink/colour: The writing on primary and secondary packs must be in indelible ink.. The labelling shall be in English, Arabic and/or French, one of these languages may be replaced by a local language as requested by UNICEF.

The label shall follow CODEX STANDARD CXS 72-1981 and contain the following information:
-Generic name, unbranded plain labels are preferred.
-Clear statement: Use under medical supervision.
- Applicable warnings (such as handling product leftovers, how long reconstituted diet can be kept at room temperature and in the refrigerator, use by date after opening, scoop hygiene. 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

Additional to this information, the canister label shall also contain a table representing the number of scoops and water needed to make up the formula.
Labelling must comply with the WHO International Code of Marketing for Breastmilk Substitutes.
Applicable reference:
International Code of Marketing of Breast-Milk Substitutes (who.int)

8.1.3 Model instruction for preparation

A pictogram schema for preparation instructions shall be included on the canister label OR as a package leaflet. The preparation instructions shall be based on the World Health Organization 2007. How to Prepare Powdered Infant Formula in Care Settings.
Safe preparation, storage and handling of powdered infant formula: guidelines (who.int)

8.1.4 Scoop (canister)

A scoop must be included with each canister. Scoops should be made of a food contact material and a design that is easily kept clean.

8.2 Secondary packaging

Canisters 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 Powdered Infant Milk is prepared and 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.”

8.2.1 Secondary packaging Label

Carton label shall contain this information:
-Generic name
- 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 canisters 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

8.2.2 Palletisation

Cartons shall be securely closed, stacked (cross stacked if possible, to maximize stacking strength) on one-way pallets and wrapped with stretch/shrink wrap. Please see UNICEF supply division Packing Specifications (non-CPH destinations)
Updated specifications for packing, packaging and labelling (to be enforced from 2 October 2023) | UNICEF Supply Division

9. Processing requirements

9.1 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 and CAC/RCP 1-1969, Rev. 4-2003: Recommended International Code of Practice. General Principles of Food Hygiene.
http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/
and 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:
ISO 22000:2005 - Food Safety Management Systems – Requirements for any Organization in the Food Chain.
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 details, 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.

9.2 Process validation

The coefficient of variation shall be as low as possible, and always <5%. For a calculator refer to the WFP method:
https://docs.wfp.org/api/documents/WFP-0000145318/download/

9.3 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).

9.4 Batch Size

The batch size shall be defined as one bulk mix.

10. Product Safety

Powdered Infant formula 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.

10.1 Microbiological criteria

Manufacturers are responsible for ensuring the compliance of finished products with the microbiological criteria as specified. Regarding limitations of the end-product testing, 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 and deviations, and assuring that critical control points (CCPs) are kept under control and that 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 the points considered as most likely to cause product contamination.
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.

10.1.2 Food Safety Criteria

The criteria set out in Annex 1 Code of Hygienic Practice for powdered formulae for Infants and Young Children CAC/RCP 66-20083 using ISO 6579 and ISO 22964 or other validated methods applied to the finished product (powder form) after primary packing is 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.

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.

10.1.3 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 66-20083 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.

10.2. Chemical and other Safety Considerations

The products covered by this Standard shall comply with the Maximum Levels of the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995).
The products covered by this Standard shall comply with the maximum residues limits for pesticides established by the Codex Alimentarius Commission.
Applicable standards reference:
CAC/RCP 49-2001 Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals.
CODEX STANDARD CXS 228-2001: General Methods of Analysis for Contaminants.
CODEX STANDARD CXS 193-1995: Codex General Standard for Contaminants and Toxins in Food.

10.2.1 Pesticides

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

Applicable standards reference: CODEX STANDARD CXS 229-1993, REV.1-2003: Analysis of Pesticide Residues: Recommended Methods

Applicable reference:
Codex standard CXS 193- 1995 General Standard for Contaminants and Toxins in Food and feed.

10.2.3 Hydrocarbons

Benzo[a]pyrene <1ppb

10.2.4 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.

10.2.5 GMO (Genetically Modified Organisms)

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

10.2.6 Other contaminants

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

11.0 Minimum requirement for release of Infant Formula

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 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 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 infant 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 10.1.2 and food hygiene criteria set in 10.1.3.

12.0 Nutrient values

Energy: 60 kcal (250kJ) to 70 kcal (295 kJ)
Protein: 1.8 to 3.0g / 100 kcal or 0.45 to 0.7 g/100 kJ
Fat: 4.4 to 6.0 g / 100 kcal or 1.05 to 1.14 g / 100 kJ
Vitamin C: 10 to 70 mg / 100 kcal or 2.5 to 17 mg / 100 kJ
Vitamin A: 60 to 180 mcg RE /100 kcal or 14 to 43 mcg RE/100 kJ
Thiamine: 60 to 300 mcg /100 kcal or 14 to 72 mcg / 100 kJ
Riboflavin: 80 to 400† mcg /100 kcal or 19 to 95 mcg /100 kJ
Iron*: 0.3 to 1.3† / 100 kcal or 0.07 to 0.3 mg / 100 kJ
* Iron can be substituted for another mineral - at least one mineral must be tested per batch.
† Maximum values have been taken from section 11, EU 2016/127, 2015 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0127&from=en

Actual value of the powder´s bulk density in ml/100g

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.

Certificates required:

Certificate of analysis
Certificate of conformity
Health Certificate
Certificate of non-radioactivity
Non-GMO certificate

Items to be supplied with:
Supplier shall provide one scoop inside each canister.
Supplier should indicate items required, but not supplied: thermometer, measuring jug, feeding cup, feeding spoon in their leaflet or label.

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: XXX kg/ carton
Supplier shall provide gross volume of carton, around: XXX m3 / carton
Supplier must include other important instructions e.g Protect from direct sunlight

Material safety data sheet information (MSDS): N/A
Packaging and labelling: preparation instructions included on the label or in a leaflet

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. Requirements “Nutritional Products”

FOR MORE INFORMATION

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

Technical resources for nutrition products | UNICEF Supply Division