PRODUCT SPECIFICATION SHEET

Ready-to-Use Therapeutic Food (RUTF) paste: Novel

With legumes, seeds and cereals fortified with amino acids

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1. General Description

Ready-to-Use Therapeutic Food (RUTF) spread– combination of legumes, seeds, or cereals fortified with added amino acids in place of dairy or animal sourced protein, sachet (+/-10%) 92g/CAR-150 is a high-energy fortified food used for the treatment of Severe Acute Malnutrition (SAM.) Each 92g sachet contains approximately 500 calories, vitamins, and minerals.

2. Intended Use

RUTF should have an acceptable taste for infants and young children undergoing SAM treatment as evidenced by an acceptability study. RUTF paste is the sole source of food, except for breast milk in the case of breast-fed infants, during the period of SAM treatment. RUTF paste is ready to eat, directly from the sachet without prior cooking, mixing or dilution. RUTF paste is portion controlled**:** each unit has the same nutritional value for control and monitoring of dietary intake.

3. Target Population

Children identified as having Severe Acute Malnutrition (SAM), for children aged 6 to 59 months with severe wasting without medical complications and with appetite or as advised by a qualified physician.

4. Technical Specification

Texture

Smooth, homogeneous, thick paste, easy to squeeze out of sachet. It should be a uniform paste with no lumps or grittiness, having a small particle size (e.g.: size < 500 microns). The paste should not elicit chewing when consumed by the target population. Attention should be given to the sugar (sucrose) particle size, which if not properly ground, could cause oil separation from the paste and lead to oil leakage when opening the sealed part of the sachet.

Flavour and odour

RUTF paste should have a pleasing sweet, fresh flavour. RUTF paste should be free from foreign odours and flavours such as, (but not limited to) burnt, scorched, rancid, malted, sour, or stale.

Colour

RUTF paste should have cream to light or orangey brown colour. The RUTF paste should not have a dull, grey tinge, or other abnormal cast. It should show no evidence of excessive heating (materially darkened or scorched).

5. Nutritional composition per 100 g of RUTF paste

Moisture content:	2.5% maximum
Water activity:	0.6 maximum
Energy:	2176-2301kJ
	520-550 kcal
Proteins*:	10-12% total energy
	13-17g/100g
	2.5-3g/100kcal
Lipids (total fats):	45-60% total energy
	26g-37g/100g
	5-7 g/100kcal
n-6 fatty acids:	3-7 % total energy
	1.7g -4.3g/100g
	330mg-780mg/100kcal
n-3 fatty acids[1]:	1-2.5% total energy
	580-1530mg/100g
	110-280mg/100kcal
Trans-fatty acids:	<3% total fat
	1.1g/100g
	0.20g/100kcal
Free (added) Sugar:	<20% of total energy
	<28g/100g
	<5g/100kcal
*PDCASS[2]:	90-100.

6. Minerals per 100g Minerals per 100 kcal

Sodium:	290 mg maximum	56 mg
Potassium:	1100-1600 mg	200-308 mg

[1] Composition of n-3 component can optionally Include pre-formed DHA as it is recommended as a preferred source of n-3. Recommended inclusions rates are 72mg/100g RUTF as per Stevenson K etal. 2022. https://academic.oup.com/ajcn/article/115/5/1322/6415893

[2]Protein quality should be determined using PDCAAS, calculated according to the reference amino acid requirement and scoring patterns related to catch up growth of 10 g/kg/day in the target population of children 6 to 59 months for RUTF, as explained in the Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods, 2017

Calcium:	300-785 mg	55-151 mg
Phosphorus*:	300-785 mg	55-151 mg
Magnesium:	80-235 mg	15-45 mg
Iron:	10-14 mg	1.8-2.7 mg
Zinc:	11-14 mg	2.0-2.7 mg
Copper:	1.4-1.8 mg	0.25-0.35 mg
Selenium:	20-40 µg	3.6-8 µg
Iodine:	70-140 µg	13-27µg

*Expressed in terms of non-phytate Phosphorus

7. Vitamins per 100g Vitamins per 100 kcal

Vitamin A (Retinol Equivalent)[2]:	> 0.8-1.6mg	145-308µg
Vitamin B1 (Thiamine):	> 0.5 mg	0.09 mg
Vitamin B2 (Riboflavin):	>1.6 mg	0.29 mg
Vitamin B3 (Niacin):	>5 mg	0.91 mg
Vitamin B5 (Pantothenic acid):	> 3 mg	0.55 mg
Vitamin B6 (Pyridoxine):	>0.6 mg	0.11 mg
Vitamin B7 (Biotin):	>60µg	11µg
Vitamin B9 (Folic acid):	>200 µg	36 µg
Vitamin B12 (Cyanocobalamin):	>1.6 µg	0.29 µg
Vitamin C (Ascorbic acid):	> 50 mg	9 mg
Vitamin D (Cholecalciferol)[3]:	15-22 µg	2.7-4.2 µg
Vitamin E (α-Tocopherol)[4]:	>20 mg	3.6 mg
Vitamin K (Phytonadione):	15-30 µg	2.7-6 µg

Applicable reference

1. CXG 95-2022 Guidelines for Ready-To-Use Therapeutic Foods (RUTF)

8. Directions for Use

Knead the sachet prior to opening, wash the hands of the carer and child open sachet at the tear notch at the side of the sachet, squeeze out the RUTF and feed the child directly from the sachet. Provide clean water to the child as needed. Feeding must always be supervised by a caregiver.
For dosage recommendations see the latest WHO Guidelines

9. Shelf life

24 months. Shelf-life claims should be supported by stability studies, please refer to latest

[2] 1µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.
[3] 1 µg calciferol = 40 IU vitamin D. Two forms of Vitamin D allowed in RUTF formulation are cholecalciferol (D3) and ergocalciferol (D2).
[4] 1 mg α tocopherol = 1 mg RRR α tocopherol (d α tocopherol) 4 1 mg RRR α tocopherol =2.00 mg all rac α tocopherol (d l α tocopherol)

version of the "*Requirements for Stability Studies for Therapeutic Foods*" attachment with the bid document.
Unless specifically authorised in writing by UNICEF, products should be of fresh production having at least 80% of their shelf life.

10. Raw materials and Ingredients

10.1 Cereals, Legumes and Seeds

Mixtures of cereals, legumes, pulses/or oilseed flours can constitute an appropriate source of protein, fat, and carbohydrate.

Cereals

All milled cereals suitable for human consumption may be used, provided that they are processed in such a way as to reduce the fibre content, when necessary, and to decrease and, if possible, to eliminate antinutrients such as phytates, tannins or other phenolic materials, lectins, trypsin, and chymotrypsin inhibitors which can lower the protein quality and digestibility, amino acid bioavailability and mineral absorption.

Legumes

Legumes and seeds such as soybeans, lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and seeds must comply with the relevant Codex Alimentarius texts when used in the manufacturing of RUTF. Sufficient reductions of anti-nutritional factors and undesirable toxic substances such as trypsin and chymotrypsin inhibitors and gossypol must be assured.

Oil Seed Flours and Oil Seed Protein Products

Flours, protein concentrates, and protein isolates of oil seeds are acceptable if manufactured to appropriate specifications, which assure sufficient reduction of anti-nutritional factors and undesirable toxic substances such as trypsin and chymotrypsin inhibitors and gossypol. Such oil seeds may include:

- Soya beans: dehulled flour, (full fat and defatted) protein concentrate, protein isolate
- Groundnuts: paste, protein isolate
- Sesame seed: whole ground and defatted flour
- Cottonseed: defatted flour
- Sunflower seed: defatted flour, full fat
- Low erucic acid rapeseed: full fat flour

Applicable reference

All ingredients must comply with the relevant codex standards.

10.2 Oil (edible refined vegetable oil)

The manufacturer should choose judiciously the type of oil and establish specifications for oil to ensure that finished product specifications are met (with particular attention to requirements for omega 3 and omega 6). Oil ingredients must comply with the relevant codex standards.

Applicable reference

1. CXS 210-1999 (updated 2019) *Codex 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.

11. Carbohydrates

Carbohydrates are used to provide energy and can be used to increase palatability of the RUTF. Lactose, plant starch, maltodextrin and sucrose are the preferred carbohydrates in RUTF. Only precooked and/or gelatinized starches may be added. Carbohydrates must adhere to the relevant Codex Alimentarius texts. Glucose and corn syrup products as ingredients and fructose ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Honey must not be used in RUTF due to the risk of infant botulism from Clostridium botulinum. Free sugars added for sweetness should be used sparingly, not more than 15% of energy.
Attention should be given to the sugar (sucrose) particle size, which if not properly ground, could cause oil separation from the paste and lead to oil leakage when opening the sealed part of the packet. Starch and sugar ingredients must comply with the relevant codex standards.

Applicable reference

1. *CXS 212-1999: Codex Standard for Sugars*

12. Food additives

Only the food additives listed in this Section (Table A: Food Additives in RUTF Formulation) or in the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979) may be present in the foods described in section 4.1 of this Guideline. Other than by direct addition, an additive may be present in RUTF as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to the General Standard for Food Additives (CXS 192-1995)

b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in the General Standard for Food Additives (CXS 192-1995); and
c) The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of the raw materials or ingredients under proper technological conditions or good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CXS 192-1995, 2019).

Table A: Food Additives in RUTF Formulation

Functional Class	Food Additive	International Numbering System (INS)	Maximum Use Level
Emulsifier	Mono- and di-glycerides of fatty acids	471	4000 mg/kg
	Citric and fatty acid esters of glycerol	472c	9000 mg/kg
	Lecithin	322(i)	5000 mg/kg
Antioxidant	Ascorbyl palmitate	304	10 mg/kg
	Tocopherol concentrate, mixed	307b	10 mg/kg
	Ascorbic acid, L	300	GMP
Acidity regulator	Citric acid	330	GMP
Packaging gas	Nitrogen	941	GMP
	Carbon dioxide	290	GMP
Carrier	Silicon dioxide, amorphous	551	10 mg/kg

Applicable reference

1. CXM 239-2003 *General Methods of Analysis for Food Additives* Codex Stan
2. CXS 192-1995 *General Standard for Food Additives*

13. Flavouring

Artificial flavourings are not allowed. Only natural flavours are allowed.

14. Mineral and vitamin premix

Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. Children with SAM have low or absent gastric acid which means that they should not be given inorganic salts of minerals that are insoluble or requiring an acid gastric environment for absorption, in order to avoid metabolic acidosis. It is important that RUTF should have a mineral composition that leads to a moderate excess of non-metabolizable buffer base. The non-metabolizable buffer base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride).

All added vitamins and minerals must be in accordance with examples of mineral forms for RUTF formulation can be found in the *WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999).* The quantity of vitamins and minerals added to achieve the target level must be adjusted based on the chemical form, interaction, and impaired absorption with other nutrients and non-nutrients and scientific evidence showing adequate stability and bioavailability in the finished product. The mineral and vitamin premix(es) must be supplied from suitably qualified premix facilities.
RUTF suppliers must validate their premix supplier to ensure the quality of the premix facility.

Applicable reference

1. CXG 10-1979 *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children.*
2. Appendix 4 of *Management of Severe Malnutrition: a manual for physicians and other senior health workers, WHO,1999*)

15. Coefficient of variation

The coefficient of variation, calculated using the method proposed by WFP, should be as low as possible, and always <5%. http://foodqualityandsafety.wfp.org/coefficient-of-variation-calculator. Indicators for process capability shall be implemented and monitored, with fixed target and corrective actions. Trend analysis shall be in place for continual monitoring.

16. Thermo-treatments

Thermal (heat) treatment processes for microbial log reduction can be applied to RUTF and raw materials contained in RUTF.

Applicable reference

1. *CXG 69-2008: Guidelines for the Validation of Food Safety Control Measures*
2. *CXG 63-2007: Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)*

17. Safety

Manufacturers supplying UNICEF are responsible for assuring that the product does not contain any harmful substance originating from micro-organisms or any other poisonous or deleterious substances, including micro-organisms, heavy metals, pesticides objectional or foreign matter or anti-nutritional factors, in amounts that may represent a hazard to health. Foreign matter detection is expected to be carried out on the filled sachet.

18. Quality Assurance

Products must be manufactured in accordance with Codex Alimentarius applicable references,

Good Manufacturing Practice (GMPs) and Good Hygiene Practices (GHPs). 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. FSSC 22000 certification is highly recommended.

Prerequisite programs

Prerequisite programs including HACCP plan and environmental monitoring programs must be implemented. Environmental monitoring of sampling sites should be prioritized according to the likelihood of contamination of processing lines and the impact on the product and should be conducted under normal operating condition. Manufacturers are expected to implement an environmental monitoring program with a four-sanitary zoning system.

Raw material and starting material control

Legumes and seeds must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutinins), trypsin, chymotrypsin inhibitors and phytoestrogens. Lectins can be reduced by moist heat treatment; Trypsin inhibitor activity may be reduced to acceptable levels by heating to high temperatures or by prolonged boiling. Phytate can be reduced enzymatically or by soaking or fermentation. Phytoestrogens can be reduced by fermentation. Field beans or faba beans (Viciafaba L.) should not be used in the formulation of RUTF because of the danger of favism. Heat treatment does not completely inactivate the toxic components (vicine and co-vicine).

Raw material and starting material testing of all starting materials is recommended at the goods receipt stage. It is recommended to use validated suppliers for raw material who have use sufficient measures (e.g., blanching, roasting, or extrusion technology, GMP) to eliminate the microbiological risk e.g., Salmonella.

Applicable Reference

1. CXC 75 2012, (2016). *Code of Hygienic Practice for Low moisture foods*
2. CXS/RCP 1-1969, Rev. 4-2003*: Recommended International Code of Practice. General Principles of Food Hygiene.*
3. ISO 22000:2005*: Food Safety Management Systems - Requirements for any Organization in the Food Chain.*

19. Microbiological Safety and Testing

The manufacturer establishes safety criteria for production as well as for the finished product based on a risk assessment performed on the raw materials and the processing methods. Raw material testing of high-risk ingredients upon receipt is required. Methods for detection and/or quantification and sampling plan details including the n, c, m, M and p (see annotation section for definitions). The microbiological criteria should follow the principles specified in the

following standards below:

Applicable reference

1. *CAC/GL 21, 1997, the Principles for the Establishment and Application of Microbiological Criteria for Foods (revision scheduled for 2013).*
2. *CAC/GL 63-2007: Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM).*

20. Microbiological tests

The manufacturer is responsible to elaborate an analytical plan for the RUTF paste finished product. All analytical test procedures must be described in sufficient detail, including analysis methods.

ISO 17025 certified laboratories should preferably be used. Analytical control plans should be detailed and include[5]: tests for *Salmonella* & Enterobacteriaceae as a minimum.

Following the sampling plan and recommended method (or alternative validated method) in example (e) in the Appendix 1 of the *Codex of Hygienic Practice for Low moisture foods* CXC 75 2012, (2016) for Salmonella:

a) *Salmonella*:
0cfu per 25g n=30 (× 25 g)
c=0; m=0/25g;2 class plan[1]

Method: ISO 6579; or alternative validated method

b) Enterobacteriaceae (EB):
10cfu per g maximum n=10, (×10grams),
c=2, m=10 cfu/g ; M=100 cfu/g maximum[1].

Method: AOAC 975.55; AOAC 2003.01; ISO 21528-2, or alternative validated method

Applicable reference

1. *CXC 75 2015, (2018): Codex of Hygienic Practice for Low moisture*

21. Pesticides, Heavy metals, and other Contaminants

[1] **Annotations**

n = number of 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

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

P = class plan

Verifying those pesticides, heavy metals and other identified contaminant risks are below accepted limits is the responsibility of the manufacturer. Control of contaminants is best achieved during validation of ingredient suppliers and thru testing of ingredients prior to processing.
Examples of mycotoxins, pesticides and heavy metals that must be controlled:

Mycotoxins: Aflatoxin: 10µg/ kg max
Heavy metals: Arsenic, Cadmium, Lead, Mercury
Pesticides: Carbamates Organochlorine Organophosphorus, pyrethroid

Applicable reference

1. CXS 193-1995 *General Standard for Contaminants and Toxins in Food and Feed* 1995 (2015)
2. *CXC 55-2004: Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts CXS 228 -2001 General Methods of Analysis for Contaminants.*
3. *CXC 49-2001 Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals.*
4. *CXM 2 Maximum residue limits (MRLs) and risk management recommendations (RMRr) for residues of veterinary drugs in foods Codex CX/MRL 2-2018*

22. Radioactivity

Radioactive compound may contaminant foods if grown in soils contaminated from nuclear accidents or if ionizing radiation is used as preservation method. This risk is best managed by using only ingredients certified free of radioactivity. The nuclear radiation level should meet the values valid in the area of consumption.

Applicable reference

1. *CXS 193-1995 General Standard for Contaminants and Toxins in Food and Feed 1995 (2015)*

23. Melamine

The level of melamine must not exceed 1 mg/kg in milk products.

Applicable reference

1. CXS 193-1995 General Standard for Contaminants and Toxins in Food and Feed 1995 (2015)

24. Analytical requirements

The manufacturer should conduct a complete analysis of the finished product in order to verify that the finished product is manufactured in compliance with the applicable references in this specification and that production of RUTF is homogeneous and consistent. ALL parameters included in this specification sheet should be tested at least once a year. The minimum testing frequency per year is dependent on the production volume. Frequency for each parameter can be adapted when trends analysis of 6 consecutive results demonstrate that the standard deviation is under control. Requirements are listed below:

	Minimum Frequency of testing, per year	
Total annual production	**Nutritional properties and micronutrients listed in points 5, 6, 7**	**Food safety parameters, including contaminants listed in points 20, 21, 22, 23**
< 1 000 MT	**1**	**1**
< 2 000 MT	**2**	**1**
< 5 000 MT	**3**	**1**
> 5 000 MT	**4**	**1**

Analytical CoA Requirements per Batch

A Certificate of Analysis (CoA) should be issued and forwarded prior to each shipment or order collection for each batch provided. This certificate must mention the laboratory name, methods of analysis, laboratory variability ranges for each nutrient, specifications, and targets for all the criteria below, to be applied to the finished product after primary packaging or anytime thereafter up to the point when the primary packaging is opened. Tests below are mandatory for each shipment. The batch cannot be released if there is a failure to meet the following criteria:

Nutritional value and nutrients per 100 g.

Moisture content	<2.5%
Energy value	520-550 kcal/100g
Protein content	10-12% total energy
	13-17% by weight
Fat content	45-60% total energy
	26-37% by weight
Vitamin A	0.8-1.6 mg RE

Minimum of one mineral & one vitamin tracer per premix (e.g., vitamin C, and Iron) should be tested per shift.

Microbiological and Chemical criteria

Salmonella: 0cfu per 25g Enterobacteriaceae (EB): 10cfu per gram max total aflatoxin: 10 µg per kg max (see sampling plan and method references listed under '20 Microbiological Tests' section above.)

25. 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, customer's sites delivered, etc.).

26. Batch size

Batches should not exceed either 250 metric tons or one week of production which ever quantity is smaller.

27. Packaging and Labelling

Primary Packaging specifications

The primary packaging must be portion controlled: each unit of 92g net. Weight and quantity tolerance shall meet. The International Organization of Legal Metrology International Recommendation OIML R 87. Packaging material cannot contain any detachable parts that present a choking hazard. Inks used for marking and glue must be contact food grade, water, and lipid resistant. The information printed on sachet must be intact by the end of the shelf life, including pre-printed marking as well as date and batch markings. Reverse printing is mandatory. The pouch material must not transfer any element (particle, flavour, or odour) to the product. Packaging material must ensure to withstand pressure changes associated with air transport. Sachets must be free of damage, such as (but not limited to) tears, cuts, holes, abrasions through one or more layers in the pouch material, leakage through any seal, etc. The primary packaging materials must not transfer particle, flavour, or odour to the product. The closure seal must be free of wrinkles, occluded matter, or evidence of entrapped moisture or grease.

Packaging under nitrogen is recommended as it contributes to lengthening product shelf life, i.e., protecting lipid oxidation and vitamins from oxidizing.

A comprehensive quality assurance system shall be implemented to cover the sachet seal integrity. This shall include regular checks of the filling parameters (e.g., sealing temperature) in combination with a visual inspection of the sealing and a leak test. This shall be complemented by an additional quality control system for microleaks to comply with the UNICEF specification (4) above. During pre-delivery inspection UNICEF will normally apply General Inspection Level I and use an AQL value of 1.0 as a guidance value, where a carton contains 150 sachets. A more

stringent AQL may need to be applied in certain circumstances. Any indication of leakage will be counted as a leakage. The manufacturer should apply stricter in-process controls to avoid rejection.

Applicable reference

1. ISO 2859 Sampling procedures for inspection by attributes — Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection.
2. CAC/GL 50-2004 General Guidelines on Sampling.

Primary Packaging composition preferred

Packaging specification:12micron PET/12micron METPET/40micron NylonPE or 40micron LLDPE, with minimum thickness 60 microns or equivalent.

Example of Applicable standard and test for barrier properties:
WVTR <1.5 g/m^2.day (38°C/90% RH) (ASTM F1249-13 or equivalent)
OTR < 2 cc/m^2.day (23°C/50% RH) (ASTM F1927-14 or equivalent)

English, Spanish, and French languages are preferred. Arabic and English labels may also be requested. Other (local) language labels require additional English language.

Text to include on the label:

FRONT

On the front side of the sachet two zones (Red zone and Pictogram zone) are mandatory.

Red Zone

The red zone should preferably be used for the generic name of the product, the dose (WHO guidelines 150kcal/kg/day to 185kcal /kg/day) and flavour/main ingredient of product (e.g., peanut, soy, chickpea, cereals) indicated as an icon + flavour / main ingredient in words in 3 languages.
-The red zone should be red, PMS 485 (Pantone Matching System) should represent minimum 30-50% of the front surface. No branding should appear in the Red zone and contain the following information:
-Generic name: RUTF with [main ingredient(s)
-The statement "For the dietary management of children aged over 6 months with severe acute malnutrition without medical complications”
-1 sachet=500 kcal.
-Dose recommendation: 150-185 kcal/kg/day per child for 4 to 8 weeks

Pictogram Zone

Pictograms should be of a size that is easy to read by the consumer. It should contain minimum six pictograms:
-Icon for hand washing (with a tap)
-Icon showing kneading of the sachet
-Icon for squeeze and eat
-Icon of the caregiver feeding the child
-Icon for breastfeeding with sachet in caregiver's hand
-Icon for glass of water

Other information that should appear on the sachet

- All the ingredients listed in order of descending quantities. This includes listing vitamin and mineral composition of the premix in parenthesis. When the premix is less than 5% of the total formula, it is enough to state it as "vitamin and mineral premix." Ingredients should be identified using the CXS 1-1985 class names. e.g.: non-hydrogenated palm oil.
-Nutritional information: amounts of nutrients per serving and per 100g and per 92g must be listed. A table format is preferred. The table list of nutrients can be in English only to conserve label space.
- Information on allergens (where relevant) in bold.
- Name and address of manufacturer, packer, distributor, importer, exporter, or vendor including country of origin.
- Net weight.
- Manufactured date & Best Before date (clearly visible throughout the whole shelf life of the product.)
- Batch number (clearly visible throughout the whole shelf life of the product).
- Storage instructions (store below 30°C away from direct sunlight) and "Once opened, discard after 24 hours."
- The statements:
- "**Not for sale**". In Bold
- "Not to be used for Nasogastric Tube (NG tube) administration."
- "Intended as the sole source of nutrition in conjunction with breastfeeding."
- "Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to two years or beyond."
-Statement: "**USE UNDER MEDICAL SUPERVISION"** in bold text.

The artwork of sachet must be approved by UNICEF-or Médecins Sans Frontières (MSF). Any change in the approved artwork must be submitted for further approval. Please see Annex 1 for translated artwork copy for French, Spanish and Arabic.
Suppliers should adapt the translations for their ingredient lists.

Applicable reference

1. *CXS 180-1991 General Standard for Labelling of and claims for Foods for Special Medical Purposes*
2. *CXS 146-1985: General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses*
3. *CXS 1-1985: General Standard for the Labelling of Pre-packaged Foods*

Secondary packaging

Cartons should be strong and sturdy; allowing stacking up to 2.4m high, resistant to puncturing and provide 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.
Cartons should be stacked on pallets and secured in the transportation vessel in a way that prevents movement during transportation. Pallets should be wrapped with plastic wrap to protect goods from contamination and movement of cartons during shipment.

Following requirements apply

ECT (Edge Crush Test) >11kN/m with minimum 60% remaining with 90% humidity at the highest recommended temperature of storage. Manufacturers are required to choose suitable carton strength that is appropriate for domestic or export transportation. Cartons should be protected by isolating sachets inside the carton in a plastic bag to prevent damaging other cartons in case of possible leakage. Cartons should be colour coded, using PMS 485 red colour.

The following information should appear

-Red zone: same requirements as for the red zone of the sachet
-Name and address of manufacturer, packer, distributor, importer, exporter, or vendor, including country of origin
-Storage conditions
-Net weight
-Number of units in the carton
-Lot number, manufactured date
and best before date
Each carton containing a minimum of 150 sachets

Protocol and instructions for use

RUTF paste is suitable for children aged 6 months and above. Children below 6 months should be exclusively breastfed or if necessary, given other therapeutic product(s) prescribed by clinician. RUTF paste must be prescribed and initiated by a trained health and nutrition

professional only. RUTF paste should not be shared with other members of the family. RUTF paste should be used according to the national protocols on the management of SAM. If there is no national protocol, recommended dosage regimen is 150-185kcal/kg/day per child for an average period of 4 to 8 weeks. For more details on dosage and length of treatment refer to existing international and national guidelines.

Applicable reference

1. WHO guideline on the prevention and management of wasting and nutritional oedema (acute malnutrition) in infants and children under 5. WHO Geneva, Switzerland 2023.

MAGICapp - Making GRADE the Irresistible Choice - Guidelines and Evidence summaries

Annexes

Annex 1: Sachet translation text

FRONT English Text	**FRONT** Spanish Text	**FRONT** French Text
RUTF For the dietary management of children > 6 months with Severe Acute Malnutrition without medical complications 1 sachet=500 kcal. Dose recommendation: *150-185* kcal/kg/day per child for 4 to 8 weeks.	ATLU Para el manejo de la desnutrición aguda severa sin complicaciones médicas en niños/as > 6 meses 1 sobre = 500 kcal. Dosis recomendada: 150-185 kcal/kg/día por niño durante 4 a 8 semanas.	ATPE Pour la prise en charge de la malnutrition aiguë sévère sans complications médicales chez les enfants > 6 mois 1 sachet = 500 kcal. Dose recommandée : 150-185 kcal/kg/jour par enfant pendant 4 à 8 semaines.
BACK	**BACK**	**BACK**

Ingredients Supplier to adapt ingredients according to their récipe, for example: sugar, peanuts, vegetable oils (palm, canola, soya), skimmed milk powder, whey powder, vitamin and mineral premix, emulsifier Supplier to adapt ingredients according to their récipe, for example: Allergens: peanuts, soy, dairy products. May contain traces of soy. Manufactured by: Net weight Best Before date Batch number Storage instructions Once opened, discard after 24 hours. **Not for sale**. Not to be used for Nasogastric Tube (NG tube) administration. Intended as the sole source of nutrition in conjunction with breastfeeding. Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to two years or beyond. **USE UNDER MEDICAL SUPERVISION.**	Ingredientes Supplier to adapt ingredients according to their récipe, for example: Azúcar, maní, aceite vegetal (de palma, canola o soya), leche descremada en polvo, lactosuero en polvo, premezcla de vitaminas y minerales, emulsificante. Alérgenos: Supplier to adapt ingredients according to their récipe, for example: Maní, soya, productos lácteos. Puede contener trazas de soya. Fabricado por: Peso Neto Fecha de consumo preferente Número de lote Instrucciones de almacenamiento. Una vez abierto, descarte luego de 24 horas. **No para la venta.** No se debe administrar por vía nasogástrica (sonda NG). Destinado para ser usado como la fuente única de nutrición en conjunto con la lactancia materna. Se recomienda la lactancia materna exclusiva durante los primeros 6 meses de vida. Debe continuarse hasta los 2 años o más allá. **ÚSESE BAJO SUPERVISION MÉDICA**.	Ingrédients Supplier to adapt ingredients according to their récipe, for example: Sucre, arachides, huiles végétales (palme, canola, soja), lait écrémé en poudre, lactosérum en poudre, prémélange de vitamines et minéraux, émulsifiant Allergènes: Supplier to adapt ingredients according to their récipe, for example: arachides, soja, produits laitiers. Peut contenir des traces de soja. Fabriqué par: Poids net: à consommer de préférence avant fin: Numéro de lot: Instructions de stockage: Une fois ouvert, jeter après 24 heures. **Interdit à la vente.** Ne pas utiliser pour l'administration par sonde nasogastrique (sonde NG). Conçu comme la seule source de nutrition en conjonction avec l'allaitement. L'allaitement exclusif est recommandé pendant les 6 premiers mois de la vie, et la poursuite de l'allaitement est recommandée jusqu'à deux ans ou au-delà. **UTILISATION SOUS SURVEILLANCE MÉDICALE.**

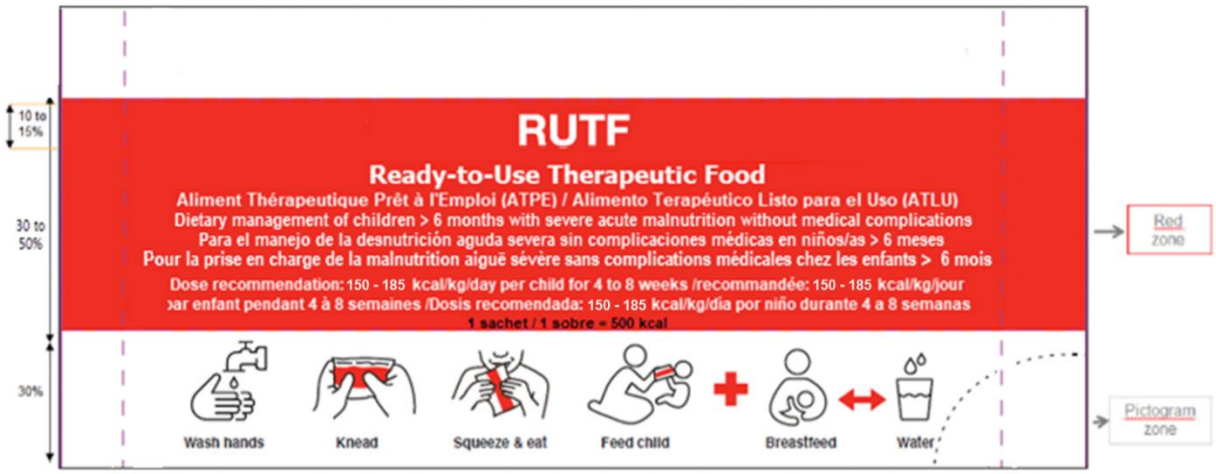
Arabic Translation

FRONT RUTF For the dietary management of children > 6 months with Severe Acute Malnutrition without complications 1 sachet=500 kcal. Dose recommendation: *150-185* kcal/kg/day per child for 4 to 8 weeks.	**FRONT** الأغذية العلاجية الجاهزة للإستخدام لإدارة النظام الغذائي للأطفال أكبر من 6 أشهر المصابين بسوء التغذية الحاد الوخيم دون مضاعفات الظرف الواحد = 500 سعرة حرارية الجرعة العلاجية الموصى بها: 150-185 سعرة حرارية / كجم / يوم - لكل طفل لمدة 4 إلى 8 أسابيع
BACK Ingredients sugar, peanuts, vegetable oils (palm, canola, soya), skimmed milk powder, whey powder, vitamin and mineral premix, emulsifier Allergens: For example: peanuts, soy, dairy products. May contain traces of soy. Manufactured by: Net weight. Best Before date Batch number Storage instructions Once opened, discard after 24 hours. Not for resale. Not to be used for Nasogastric Tube (NG tube) administration. Intended as the sole source of nutrition in conjunction with breastfeeding. Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to two years or beyond. **USE UNDER MEDICAL SUPERVISION.**	**BACK** المكونات: سكر ، فول سوداني ، زيوت نباتية (نخيل ، كانولا ، صويا) ، مسحوق حليب منزوع الدسم ، مسحوق مصل اللبن ، مزيج من الفيتامينات والمعادن ، مستحلب المكونات المسببة للحساسية والمكونات من أصل حيواني: :For example الفول السوداني وفول الصويا ومنتجات الألبان .قد تحتوي على آثار من فول الصويا. صنع من قبل: الوزن الصافي: يفضل استهلاك المنتج قبل تاريخ: رقم الدفعة المنتجة: إرشادات التخزين: في حال فتح المنتج تخلص من المتبقي منه بعد 24 ساعة المنتج ليس لإعادة البيع لا يستخدم المنتج في إدارة الأنبوب الأنفي المعدي (NG Tube) - الغرض منه هو أن يكون المصدر الوحيد للتغذية بالتزامن مع الرضاعة الطبيعية - يوصى بالرضاعة الطبيعية الخالصة خلال الأشهر الستة الأولى من الحياة ، ويوصى باستمرار الرضاعة الطبيعية لمدة تصل إلى عامين أو أكثر

"يستخدم تحت إشراف طبي"	

Annex 2:

Example of Artwork mock-up (not true to scale). Must be modified to accurately reflect the content of the product. Suppliers may be asked to add a pictogram and description of the main ingredient variant and its flavour.



Ingredients: sugar, **peanuts**, vegetable oils (palm, canola, soya), skimmed **milk** powder, **whey** powder, vitamin and mineral premix, emulsifier. **Allergens**: **peanuts**, **soy**, **dairy** products. May contain traces of soy. **USE UNDER MEDICAL SUPERVISION / Ingredientes**: Azúcar, **maní**, aceite vegetal (de palma, canola o soya), **leche** descremada en polvo, ***lactosuero*** en polvo, premezcla de vitaminas y minerales, emulsificante.

Alérgenos: **Maní**, soya, productos **lácteos**. Puede contener trazas de soya. **ÚSESE BAJO SUPERVISION MÉDICA / Ingrédients**: Sucre, **arachides**, huiles végétales (palme, canola, soja), lait écrémé en poudre, ***lactosérum*** en poudre, prémélange de vitamines et minéraux, émulsifiant. **Allergènes**: **arachides**, **soja**, produits **laitiers**. Peut contenir des traces de soja. **UTILISATION SOUS SURVEILLANCE MÉDICALE**.

Best Before date Batch number / Fecha de consumo preferente Número de lote / Date de péremption Numéro de lot:

Nutritional Values (average or minimum) - Nutrients - per 100g - per 92g

Energy (kcal)	x	x	Vitamin B1 (mg)	x	x	Vitamin K (µg)	x	x
Energy (kJ)	x	x	Vitamin B2 (mg)	x	x	Calcium (mg)	x	x
Lipids (g)	x	x	Vitamin B3 (mg)	x	x	Copper (mg)	x	x
n-3 fatty acids (g)	x	x	Vitamin B6 (mg)	x	x	Iron (mg)	x	x
n-6 fatty acids (g)	x	x	Vitamin B8 (mg)	x	x	Iodine (µg)	x	x
Trans fatty acids (g)	x	x	Vitamin B9 (µg)	x	x	Potassium (mg)	x	x
Carbohydrates (g)	x	x	Vitamin B9 (µg)	x	x	Magnesium (mg)	x	x
Sucrose (g)	x	x	Vitamin B12 (µg)	x	x	Sodium (mg)	x	x
Dietary fibers (g)	x	x	Vitamin C (mg)	x	x	Phosphorus (mg)	x	x
Proteins (g)	x	x	Vitamin D (µg)	x	x	Selenium (µg)	x	x
Vitamin A (µg RE)	x	x	Vitamin E (mg α-TE)	x	x	Zinc (mg)	x	x

Not to be used for Nasogastric Tube (NG tube) administration. Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to two years or beyond / No se debe administrar por vía nasogástrica (sonda NG). Se recomienda la lactancia materna exclusiva durante los primeros 6 meses de vida. Debe continuarse hasta los 2 años o más allá / Ne pas utiliser pour l'administra tion par sonde nasogastrique (sonde NG). L'allaitement exclusif est recommandé pendant les 6 premiers mois de la vie, et la poursuite de l'allaitement est recommandée jusqu'à deux ans ou au-delà.

Not for sale /
No para la venta /
Interdit à la vente.

Intended as the sole source of nutrition in conjunction with breastfeeding / Destinado para ser usado como la fuente única de nutrición en conjunto con la lactancia materna / Conçu comme la seule source de nutrition en conjonction avec l'allaitement.

Storage instructions: store below 30°C away from direct sunlight. Once opened, discard after 24 hours / Instrucciones de almacenamiento: almacenar por debajo de 30°C lejos de la luz solar directa. Una vez abierto, descarte luego de 24 horas / Instructions de stockage: stocker en dessous de 30°C à l'abri de la lumière directe du soleil. Une fois ouvert, jeter après 24 heures.

Net weight: x / Peso Neto: x / Poids net: x

Manufactured by / Fabricado por / Fabriqué par: Manufacturer 123, Address 456, Country 789

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 |sd.nutritionsupplies@unicef.org

Technical resources for nutrition products | UNICEF Supply Division