



PRODUCT SPECIFICATION SHEET

RUTF Biscuit, packs, 510 g/CAR-24

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1. General Description

Ready-to-Use Therapeutic Food (RUTF) biscuit is a high-energy fortified food that contains adequate nutrients for dietary management of children aged 6 to 59 months with Severe Acute Malnutrition, without medical complications and have appetite. RUTF biscuits are compressed bars, manufactured from a mixture of pre-cooked cereals, milk powder, vegetable oil and carbohydrates, with added vitamins and minerals.

2. Intended Use

The RUTF biscuit is the sole source of food, except for breast milk in the case of breast-fed infants, and water during the period of Severe Acute Malnutrition (SAM) treatment in any cultural setting and in different climatic zones. RUTF biscuit can also be made into porridge with drinking water.

3. Target population

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

4. Technical Specification

Product shall be ready to use and to be eaten directly (no cooking/mixing/dilution required) or crumbled into hot drinking water and eaten as porridge. The product should also be portion-controlled, and each unit shall have the same nutritional value for control and monitoring of dietary intake.

4.1 Organoleptic properties

Texture

RUTF bar shall have smooth exterior. Interior particle size shall be uniform; and shall easily crumble with gentle finger pressure.

Flavour and odour

RUTF bar should have a pleasing typical flavour. RUTF bar should be free from foreign odours and flavours such as, (but not limited to) burnt, scorched, rancid.

Appearance

RUTF bar shall be compressed rectangular bar, a pale-yellow colour; bars shall not show evidence of excessive heating materially darkened or scorched.

4.2 Nutritional composition

| | |
|--------------------------------|--|
| Moisture content: | < 4% |
| Water activity: | <0.6 |
| Energy: | 500-550 kcal/100g 2092-2301 kJ/100g |
| Protein*: | 10-12 % of total energy 12.3-16.2g/100g 2.4-3.2 g/100 kcal |
| Lipids (total fats): | 45-60% of total energy 24.8-36.3 g/100g 4.5-7.3g/100 kcal |
| n-6 fatty acids: | 3-7% of total energy 1.7-4.2g/100g 300-780mg/100kcal |
| n-3 fatty acids ¹ : | 1-2.5% of total energy 551-1514mg/100g 100-300mg/100kcal |
| Trans fatty acids: | <3% of total fat 1.1g/100g 0.20g/100kcal |
| Free (added) sugar): | <20% of total energy <28g/100 g |

¹ Composition of n-3 component can optionally include pre-formed DHA as it is recommended as a preferred source of n-3. Recommended inclusion rates are 72mg/100g RUTF as per Stevenson K et al. 2022.

<https://academic.oup.com/ajcn/article/115/5/1322/6415893>

**At least half of the protein contained in RUTF products should come from milk/dairy products.²*

² *In formulations with lower PDCAAS scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The addition of limiting amino acids, solely in the L-form, shall be permitted only in amounts necessary to improve the protein quality of the RUTF.*

<5g/100 kcal

*PDCAAS²: 90-100

Mineral content (per 100g)

Sodium: <290mg

Potassium: 1100-1600mg

Calcium: 300-785mg

Phosphorus: 300-785mg expressed in terms of non-phytate phosphorus

Magnesium: 80-235mg

Iron: 10-14mg

Zinc: 11-14mg

Copper: 1.4-1.8mg

Selenium: 20-40 µg

Iodine: 70-140 µg

Vitamin content (per 100g)

Vitamin A (Retinol Equivalent): 0.8-1.6mg

Vitamin B1 (Thiamine): >0.5mg

Vitamin B2 (Riboflavin): >1.6mg

Vitamin B3 (Niacin): >5mg

Vitamin B5 (Pantothenic acid): >3mg

Vitamin B6 (Pyridoxine): >0.6mg

Vitamin B7 (Biotin): >60 µg

Vitamin B9 (Folic acid): >200 µg

Vitamin B12 (Cyanocobalamin): >1.6 µg

Vitamin C (ascorbic acid): >50mg

Vitamin D (Cholecalciferol): 15-22 µg

Vitamin E (Tocopherol): >20mg

Vitamin K (Phytonadione): 15-30 µg

Applicable reference

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

5. Directions of use

Wash the hands of the caregiver and child, open packet, feed the child RUTF bar directly from packet and/or make porridge by crumbling the biscuit and adding hot drinking water. Feed the child. Provide clean water to the child as needed. Feeding must always be supervised by a caregiver.

For dosage recommendations see the latest WHO Guidelines.

6. Shelf-life

Minimum 48 months, when stored at <30 degree Celsius. Shelf-life claims should be supported by stabilities studies, please refer to the latest version of interagency “*Requirements for Stability Studies for Therapeutic Foods*”

Unless specifically authorised in writing by UNICEF, products should be of fresh production having at least 80% of their shelf life when shipped.

7. Raw materials and ingredients

7.1 Milk and dairy ingredients

Milk and dairy ingredients such as milk powder, whey powder or dairy permeate powder must be included in RUTF to make up at least 50% of the protein. Milk ingredients must comply with the latest version of the relevant codex standards.

Applicable reference

1. CXS 207-1999: *Standard for Milk Powders and Cream Powder*
2. CXS 281-1971 *Standard for evaporated milk*
3. CXS 289-1995: *Standard for Whey Powders*
4. CXS 290-1995: *Standard for Edible Casein Products*
5. CXS 331-2017 *Standard for Dairy Permeate Powders*

7.2 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.

7.2 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-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.*

7.3 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 20% of energy.

Starch and sugar ingredients must comply with the relevant codex standards.

Applicable reference

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

7.4 Other agricultural products

Applicable reference

1. *CAC/GL 08-1999: Guidelines on Formulated Supplementary Foods for Older Infants and Young Children*
2. *Relevant Codex standards*

7.5 Flavouring

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

7.6 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).
- c) The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced using 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).

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*
3. *Combined Compendium of Food Additive Specifications. Joint FAO/WHO Expert Committee on Food Additives* <https://www.fao.org/3/a0691e/a0691e00.htm>

7.8 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. The manufacturers 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*

8. 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.

9. Thermo-treatments

Thermal (heat) treatment or equivalent processes for microbial reduction to the safe level can be applied to RUTF biscuit.

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)*

10. Safety

Manufacturers supplying to 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.

11. 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 certified 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 including controls from the 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 testing of high-risk ingredients is required.

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.*

12. 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, as well as methods for detection and/or quantification and sampling plan details including the n, c, m, M and p (see annotations⁶ in Section 13 Microbiological tests for definitions). The microbiological criteria should follow the principles specified in the following standards:

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)*.

13. Microbiological tests

The manufacturer is responsible for elaborating an analytical plan for the RUTF 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 include² tests for *Salmonella* & Enterobacteriaceae.

Suppliers should follow the sampling plan and recommended method (or alternative validated method) in example(s) in the Appendix 1 of the *Codex of Hygienic Practice for Low moisture foods CXC 75 2015, (2018)* for Salmonella:

i. *Salmonella*:

0cfu per 25g

n=30 (× 25 g)

c=0; m=0/25g; 2 class plan⁶

Method: ISO 6579; or alternative validated method

ii. Enterobacteriaceae (EB):

10cfu per g maximum

n=10, (×1grams),

c=2, m=10 cfu/g; M=100 cfu/g maximum⁶

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

⁶Annotations

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

Applicable reference

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

14. Pesticides, Heavy metals, and other Contaminants

Verifying those pesticides, heavy metals and other identified contaminant risks are below maximum limits is the responsibility of the manufacturer. Control of contaminants is best achieved during validation of ingredient suppliers and through 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 49-2001 *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals*.
3. CXM 2 *Maximum residue limits (MRLs) and risk management recommendations (RMRr) for residues of veterinary drugs in foods Codex CX/MRL 2-2018*

15. Radioactivity

Radioactive compound might 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 not exceed the maximum levels as determined in the area of consumption.

Applicable reference

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

16. 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)

17. 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:

| Total annual production | Minimum Frequency of testing, per year | |
|-------------------------|---|--|
| | Nutritional properties and micronutrients listed in points 4. | Food safety parameters, including contaminants listed in points 13, 14, 15, 16 |
| < 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 | <4% |
| Energy value | 500 -550 kcal/100g |
| Protein content | 10-12% total energy 12.3-16.2% by weight 2.4-3.2 g/100 kcal |
| Fat content | 45-60% total energy 24.8-36.3% by weight 4.5-7.3 g/100 kcal |
| 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 (see sampling plan and method references listed under ' 13. Microbiological Tests' section above.)

18. 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 sites delivered, etc.).

19. Batch size

Batches should not exceed either 200 metric tons or one week of production, whichever quantity is smaller.

20. Packaging and labelling

Primary Packaging Specifications

RUTF biscuit pack contains 9 bars, and each bar is 2 biscuits of 56g. 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. The packet 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. Primary packaging must be free of damage, such as (but not limited to) tears, cuts, holes, etc.

1 unit (box) = 9 bars

9 bars shall be packed into a vacuum-packed brick style. A cardboard box can be added. Packaging materials, inks and glue shall be food-contact approved. The information printed on must be intact by the end of the shelf life, including pre-printed marking as well as date and batch markings.

A comprehensive quality assurance system shall be implemented to cover the packet seal integrity. This shall include regular checks of the packing parameters (e.g., sealing temperature, water tightness control) in combination with a visual inspection of the sealing.

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

Example of primary packaging material

a) Individual bar wrap

Monolayer, grease-proof wrap and shall ensure lower-level protection.

b) Shrink film

Shrink film must shrink tightly over RUTF biscuit. Supplier shall choose laminate film composition and thickness suitable for vacuum/shrink pack and has sufficient water vapour and gas barrier properties to achieve the required level of shelf life.

Example of barrier properties

Barrier Water vapour: <0.1 g/m²/24 h (at 23 C, & 85% RH)

Barrier O₂: <0.1 cm³/m²/24 h/atm (at 23 C and 0% RH)

Barrier CO₂: <0.1 cm³/m²/24h/atm (at 23 C and 0% RH)

Labelling primary shrink wrap laminate and/or cardboard box

English, Spanish and French are required. Arabic and English labels may also be requested. Other (local) language labels require additional English language. Following information may require:

The main colour of the packaging should be red, PMS 485 (Pantone Matching System).

The primary packaging must contain the following information:

-Generic name: RUTF (Ready to Use Therapeutic Food) + product name e.g., BP100

-The statement "For the dietary management of children aged over 6 months with severe acute malnutrition without medical complications"

-1 bar/56g /1213.0 kJ/290 kcal

-Dose recommendation: 150-185 kcal/kg/day per child for 4 to 8 weeks

Pictogram

Pictograms should be of a size that is easy to read by the consumer. It should contain minimum eight pictograms:

-Icon for hand washing (with a tap)

-Icon showing open the RUTF biscuit

-Icon for being eaten RUTF biscuit

-Icon for the measurement of drinking water and boil to 100^o C

-Icon for mixing RUTF with hot water

-Icon for feeding RUTF porridge to child

-Icon for breastfeeding plus glass of water

-Icon for bowl with a spoon and clock on background

Other information that should appear on the primary laminate and/or cardboard box

- All the ingredients listed in order of descending quantities. This includes listing vitamin and mineral composition of the premix in parenthesis. 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 bar (56 g) 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 and 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)
- 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.
- Statement to discard left over prepared BP-100 porridge after two hours

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.

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

24 boxes of RUTF biscuits shall be packed in a strong corrugated board carton. Carton 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) >6 KN/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.

The following information should appear

- 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
- Manufacturing date
- Lot number and best before date

Each carton containing a minimum of 24 boxes of RUTF biscuits.

Protocol and instructions for use

RUTF biscuit 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 biscuit must be prescribed and initiated by a trained health and nutrition professional only. RUTF biscuit should not be shared with other members of the family.

RUTF biscuit 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

WHO guideline on the prevention and management of wasting and nutritional oedema (acute malnutrition) in infants and children under 5 years. Geneva: World Health Organisation; 2023.

[MAGICapp - Making GRADE the Irresistible Choice - Guidelines and Evidence summaries](#)

Useful Resources

1. Contaminants Reference
2. Table 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 jsd.nutritionssupplies@unicef.org

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

