(1) General Description

Ready-to-use Supplementary Food (RUSF) is a food supplement for the dietary management of children 6 months and older with moderate acute malnutrition.

RUSF is intended to be eaten directly from the package with no dilution, mixing or cooking. One 100 g sachet per day, which provides 535 kcal, is the recommended dose of RUSF. This product cannot be used as a replacement of breast milk.

(2) Intended Use

Supplementary spread, sachet 100 g (RUSF) is a supplement to treat moderate acute malnutrition (MAM), for children aged 6 months or older.

Target Population

Children aged 6 months and older

(3) Technical Specifications

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., < 500 microns). The paste should not elicit chewing when consumed by the target population. Attention should be given to the sugar (sucrose) and minerals particle size, which if not properly ground, could contribute to oil separation from the paste and lead to oil leakage when opening the sealed part of the sachet. RUSF is generally produced with heat treated oil seeds, pulses, or cereals, together with sugar, milk powder, vegetable oils, vitamins, and minerals.

Flavour and odour

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

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

**Moisture content:** 2.5% maximum  
**Water activity:** 0.6 maximum

**Nutritional composition of RUSF per 100 g**

Energy: 510 - 560 kcal  
Protein*: 11 – 16 g  
Lipids: 26 – 36 g  
Omega-6 fatty acids: 2.6 - 6.10 g  
Omega-3 fatty acids: 0.3 - 1.8 g  
Trans fats: <3% of total fat  
PDCAAS** >70

**Vitamins**

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>vitamin A (Retinol Equivalent)</td>
<td>700 mcg</td>
<td>1600 mcg</td>
</tr>
<tr>
<td>vitamin B1 (Thiamine)</td>
<td>&gt;1.0 mg</td>
<td></td>
</tr>
<tr>
<td>vitamin B2 (Riboflavin)</td>
<td>&gt;2.1 mg</td>
<td></td>
</tr>
<tr>
<td>vitamin B3 (Niacin)</td>
<td>&gt;13 mg</td>
<td></td>
</tr>
<tr>
<td>vitamin B5 (Pantothenic acid)</td>
<td>&gt;4.0 mg</td>
<td></td>
</tr>
<tr>
<td>vitamin B6 (Pyridoxine)</td>
<td>&gt;1.8 mg</td>
<td></td>
</tr>
<tr>
<td>Biotin</td>
<td>&gt;60 mcg</td>
<td></td>
</tr>
<tr>
<td>folates (DFE)</td>
<td>&gt;330 mcg</td>
<td></td>
</tr>
<tr>
<td>vitamin B12(Cyanocobalamin)</td>
<td>&gt;2.7 mcg</td>
<td></td>
</tr>
<tr>
<td>vitamin C (Ascorbic acid)</td>
<td></td>
<td>80- 220 mg</td>
</tr>
<tr>
<td>vitamin D (Cholecalciferol)</td>
<td>15mcg - 20mcg</td>
<td></td>
</tr>
<tr>
<td>vitamin E (Tocopherol)</td>
<td>&gt;16 mg</td>
<td></td>
</tr>
<tr>
<td>vitamin K (Phytonadione)</td>
<td>&gt;27 mcg</td>
<td></td>
</tr>
</tbody>
</table>

**Minerals**

<table>
<thead>
<tr>
<th>Mineral</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium</td>
<td>535</td>
<td>750 mg</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>450</td>
<td>750 mg</td>
</tr>
<tr>
<td>Potassium</td>
<td>800</td>
<td>1400 mg</td>
</tr>
<tr>
<td>Magnesium</td>
<td>150</td>
<td>225 mg</td>
</tr>
<tr>
<td>Manganese</td>
<td>1.2</td>
<td>2.4 mg</td>
</tr>
<tr>
<td>Zinc</td>
<td>11</td>
<td>14 mg</td>
</tr>
</tbody>
</table>
Copper: 1.4 - 1.9 mg
Iron: 10 - 14 mg
Iodine: 100 - 190 mcg
Selenium: 20 - 45 mcg
Sodium: <270 mg

*Preferable source of protein: dry skinned milk protein 5.5-8 g/100 g
**PDCAAS should not be less than 70 per cent of that of the WHO amino acid reference pattern for children from 2 – 5 years, where PDCAAS (%) = 100 X (mg of limiting amino acid in 1 g test protein)/ (mg of same amino acid in reference pattern) X true faecal digestibility of test protein (Reference: CA2487EN.pdf (fao.org) p. 17)

(4) Directions for Use

Handwashing is recommended before use. Knead the sachet prior to opening, open sachet at the tear notch at the side or top of the sachet, squeeze out the RUSF and feed the child directly. Provide clean water to the child as needed. Feeding must always be supervised by a caregiver.

Dose recommendation

1 sachet (100 g) per day per child

(5) Shelf life

24 months. Shelf-life claims should be supported by stability studies, please refer to the "Interagency Requirements for Stability Studies for Specialised Food" 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. The nutritional composition of RUSF remains within the minimum and maximum limits as mentioned in nutritional composition required above. There shall be no oil separation throughout the shelf life of the product.

(6) Raw materials and Ingredients

RUSF shall be manufactured from ingredients that are fresh, of good quality, free from foreign material and substances hazardous to health, that comply with Codex Alimentarius and relevant regulations. The quality of raw materials should be adequate so that the final product will meet all requirements specified in this specification.

6.1 Milk and dairy ingredients

Milk and dairy ingredients such as milk powder, whey powder or dairy permeate powder can be included in RUSF.

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

6.2 Peanuts

Peanuts and peanut paste. Ingredients must comply with the latest version of the relevant codex standards.

Applicable reference


6.3 Legumes

Soy based ingredients, chickpeas, lentils, and other legume products (e.g., flour and isolates) must comply with the latest version of the relevant codex standards.

Applicable reference

1. CXS 175-1989 General Standard for Soy Protein Products
2. CXS 171-1989 Standard for Certain Pulses

6.4 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), providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour, and shelf life. Partially hydrogenated fats and oils should not be used. Trans fats must be kept to a minimum. Oil ingredients must comply with the most recent version of the relevant codex standards.

Applicable reference

2. Code of Practice for the reduction of 3-Monochloropropane-1-2- DIOL Esters (3-MCPDEs) and GLYCICYIDL Esters (GEs) in Refined Oils and Food Products made with refined oils.

(7) Carbohydrates

Carbohydrates are used to provide energy and can be used to increase palatability of the RUSF. Lactose, plant starch, maltodextrin and sucrose are the preferred carbohydrates in
RUSF. 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 RUSF, because of potential adverse effects. Free sugars added for sweetness should be used sparingly and should not be more than 20% 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 sachet. Starch and sugar ingredients must comply with the relevant codex standards.

Applicable reference

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

**(8) Food additives**

Only natural flavours are allowed. The following antioxidants may be included: Ascorbyl palmitate
Mixed tocopherols
Not permitted as an antioxidant: Butylhydroxyanisol (BHA) and Butylated hydroxytoluene (BHT)

Applicable reference

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

**(9) Mineral and vitamin premix**

The mineral and vitamin premix(es) cannot be produced by the RUSF paste manufacturer itself and must be supplied only from suitably qualified premix facilities.
A list of suppliers of sources of premix is available at: [https://gpf.gainhealth.org/suppliers/current-suppliers](https://gpf.gainhealth.org/suppliers/current-suppliers), However, not all these suppliers are approved by UNICEF. RUSF suppliers must validate their premix supplier to ensure the quality of the premix facility on its own merit.

Vitamin and mineral forms used must be soluble and easily absorbed by children with nutrients deficiency. The added minerals should be water-soluble and should not form insoluble components when mixed. The RUSF paste should have a mineral composition complying with the *Applicable reference* listed below.

Please find an example of the nutritional premix composition* listed at table 1. This premix is a guide to manufacturers only, and it will require adaption to your process and facility. Inclusion of the premix example below is at the manufacturer's own discretion, as compliance to the composition of RUSF at the end of shelf life is the responsibility of the supplier.
Table 1. Example of Premix Contribution and Premix Nutrient Sources

<table>
<thead>
<tr>
<th>Micronutrients</th>
<th>Unit</th>
<th>Recommended Nutrient Sources (alternative options)</th>
<th>Nutrients addition of 100 g LNS-MQ (+/-10%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retinol (Vit A)</td>
<td>mcg</td>
<td>Dry Vitamin A Palmitate/ Dry Vitamin A Acetate</td>
<td>1400</td>
</tr>
<tr>
<td>Thiamine (Vit B1)</td>
<td>mg</td>
<td>Thiamine hydrochloride/Thiamine mononitrate</td>
<td>1.5</td>
</tr>
<tr>
<td>Riboflavin (Vit B2)</td>
<td>mg</td>
<td>Riboflavin</td>
<td>2.6</td>
</tr>
<tr>
<td>Niacin (Vit B3)</td>
<td>mg</td>
<td>Niacinamide</td>
<td>16</td>
</tr>
<tr>
<td>Pantothenic acid (Vit B5)</td>
<td>mg</td>
<td>Calcium d-Pantothenate</td>
<td>4.9</td>
</tr>
<tr>
<td>Pyridoxine</td>
<td>mg</td>
<td>Pyridoxine hydrochloride</td>
<td>2.2</td>
</tr>
<tr>
<td>Biotin (Vit B7)</td>
<td>mcg</td>
<td>Biotin</td>
<td>65</td>
</tr>
<tr>
<td>Folic acid (DFE)</td>
<td>mcg</td>
<td>Folic acid food grade</td>
<td>500</td>
</tr>
<tr>
<td>Cobalamin (Vit B12)</td>
<td>mcg</td>
<td>Cyanocobalamin</td>
<td>2.9</td>
</tr>
<tr>
<td>Ascorbate (Vit C)</td>
<td>mg</td>
<td>Ascorbic Acid fine powder</td>
<td>130</td>
</tr>
<tr>
<td>Cholecalciferol (Vit D)</td>
<td>mcg</td>
<td>Cholecalciferol</td>
<td>18</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>mg α-TE</td>
<td>Vitamin E acetate (50% dl-alpha-tocopherol acetate)</td>
<td>20</td>
</tr>
<tr>
<td>Phytomenadione (Vit K)</td>
<td>mcg</td>
<td>Phytomenadione</td>
<td>27</td>
</tr>
<tr>
<td>Calcium (Ca)</td>
<td>mg</td>
<td>Di-Calcium Phosphate anhydrous/tricalcium phosphate</td>
<td>413</td>
</tr>
<tr>
<td>Copper (Cu)</td>
<td>mg</td>
<td>Copper sulfate anhydrous/Copper gluconate</td>
<td>1.2</td>
</tr>
<tr>
<td>Iodine (I)</td>
<td>mcg</td>
<td>Potassium Iodide</td>
<td>110</td>
</tr>
<tr>
<td>Iron (Fe)</td>
<td>mg</td>
<td>2.5 mg from NaFeEDTA + 7.5 mg, which can be from Ferrous sulphate monohydrate, dried/ferrous sulphate/ferrous fumarate, encapsulated or no</td>
<td>10</td>
</tr>
<tr>
<td>Magnesium (Mg)</td>
<td>mg</td>
<td>Magnesium sulphate monohydrate/magnesium citrate or gluconate</td>
<td>100</td>
</tr>
<tr>
<td>Manganese (Mn)</td>
<td>mg</td>
<td>Manganese sulphate monohydrate</td>
<td>1.0</td>
</tr>
<tr>
<td>Phosphorus (P)</td>
<td>mg</td>
<td>Tricalcium phosphate/di-calcium phosphate anhydrous</td>
<td>319</td>
</tr>
<tr>
<td>Potassium (K)</td>
<td>mg</td>
<td>175 mg from potassium chloride + 175 mg from tri potassium citrate</td>
<td>350</td>
</tr>
<tr>
<td>Micronutrient</td>
<td>Unit</td>
<td>Form</td>
<td>Amount</td>
</tr>
<tr>
<td>--------------</td>
<td>------</td>
<td>-----------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Selenium (Se)</td>
<td>mcg</td>
<td>Sodium selenite/Sodium selenate</td>
<td>20</td>
</tr>
<tr>
<td>Zinc (Zn)</td>
<td>mg</td>
<td>Zinc sulfate monohydrate</td>
<td>11</td>
</tr>
</tbody>
</table>

*Levels of micronutrients in the premix are based on GAIN studies on micronutrient retention in lipid-based nutrient supplements, available knowledge on expected nutrient contribution of the various raw ingredients and variability calculation throughout processing and shelf life to allow the different formulas match nutritional targets at time of consumption as recommended by WHO for SAM and MAM.

1. These are preferred chemical forms however other forms may be acceptable after review of their potency and functionality.
2. This is the recommended amount if there is no process loss. If process losses have been demonstrated by a study appropriate overdosage should be applied to ensure that analytical target is reached.
3. Beadlet or spray dried form can be used assuming there is no carryover of antioxidants not approved in codex.
4. This is equivalent to a total of 1.4% Di-calcium phosphate: In final product Ca/P ratio should be 1-1.5, where 30% of P from plant sources and 100% from animal sources can be included in the estimate.
5. This is equivalent to a total of 1.4% Di-calcium phosphate: In final product Ca/P ratio should be 1-1.5, where 30% of P from plant sources and 100% from animal sources can be included in the estimate.

Applicable reference

1. Appendix 4 of Management of Severe Malnutrition: a manual for physicians and other senior health workers, WHO1999

(10) Emulsifying agents

Emulsifiers are potentially of importance for lipid-based paste as this type of food is prone to phase separation. Phase separation may also be minimised by reducing the particle granule size and adjusting the emulsifier level added. Permissible emulsifiers are mono and diglycerides (0.15-2g /100g) or lecithin.

Applicable reference

1. CXS 192-1995 General Standard for Food Additives

(11) Validation of the process and coefficient of variation

The coefficient of variation, calculated using the method proposed by WFP, should be as low as possible, and always <5%. https://docs.wfp.org/api/documents/WFP-0000145318/download/. Indicators for process capability shall be implemented and monitored, with fixed target and corrective actions. Trend analysis shall be in place for continual monitoring.

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

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)

(13) 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.

(14) 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 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 testing of high-risk ingredients is required.

Applicable Reference

1. CXC 75 2012, (2016). Codex of Hygienic Practice for Low moisture foods

(15) 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

2. CAC/GL 63-2007: Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)

15.1 Microbiological tests

The manufacturer is responsible to elaborate an analytical plan for the RUSF paste. 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:\n
a) *Salmonella*:

\[ 0 \text{ cfu per 25g} \]
\[ n=30 \text{ (x 25 g)} \]
\[ c=0; m=0/25g; 2 \text{ class plan}^1 \]

**Method:** ISO 6579; or alternative validated method

b) Enterobacteriaceae (EB):

\[ 10 \text{ cfu per g maximum} \]
\[ n=10, (x10\text{grams}), \]
\[ c=2, m=10 \text{ cfu/g}; \text{M}=100 \text{ cfu/g maximum}^1. \]

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

Applicable reference

1. CXC 75-2015 *Codex of Hygienic Practice for Low Moisture Foods*

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1 Annotated
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
(16) Pesticides, Heavy metals, and other Contaminants

Verifying that pesticide and heavy metals levels are below accepted limits is the responsibility of the manufacturer. Examples of mycotoxins, pesticides and heavy metals that must be controlled, include, but are not limited to:

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

Applicable reference

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

(17) 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


(18) Melamine

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

Applicable reference


(19) Analytical requirements
The manufacturer should conduct a complete analysis of the finished product to verify that the finished product is manufactured in compliance with the applicable references in this specification and that production of RUSF 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**

<table>
<thead>
<tr>
<th>Total annual production</th>
<th>Nutritional properties and micronutrients listed in point (3)</th>
<th>Food safety parameters, including contaminants listed in points (15), (16), (17), (18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1000 MT</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>&lt;2000 MT</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>&lt;5000 MT</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>&gt;5000 MT</td>
<td>4</td>
<td>1</td>
</tr>
</tbody>
</table>

**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. 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: 510-560 kcal
- Protein content: 11.0 -16.0 g
- Fat content: 26-36 g
- Vitamin A: 700-1600 mcg RE

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

**Microbiological and Chemical criteria**

- Salmonella: 0cfu per 25g
- Enterobacteriaceae (EB): 10cfu per g max
Total aflatoxin: 10 µg per kg max
(See sampling plan and method references listed under ‘15.1 Microbiological Tests’ section above.)

(20) 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.).

(21) Batch size

UNICEF does not wish to receive batches that exceed 250 metric tons or one week of production.

(22) Packaging and Labelling

Specifications Primary packaging

The primary packaging must be portion controlled: each unit should have 100 g net. Packaging material can not contain any detachable parts that present a choking hazard. Inks used for marking and glue must be contact food grade, plus 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. Pouches 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 lengthen product shelf life, i.e., protecting lipid oxidation and vitamins from oxidising.

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 predelivery 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 around 150 sachets. A more stringent AQL may need to be applied is certain circumstance. 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.

Primary Packaging composition preferred

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

Example of Applicable standard and test for barrier properties:
WVTR <1.5 g/m².day (38°C/90% RH) (ASTM F1249-13 or equivalent)
OTR < 2 cc/m².day (23°C/50% RH) (ASTM F1927-14 or equivalent)

Text to include on the label

English and French languages are mandatory. Additional language (e.g., Arabic) in addition to English and French may also be requested. Other (local) language labels require additional English language.

FRONT

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

Orange Zone

The orange zone should preferably be used for generic name of the product, the dose and flavour/main ingredient of the product (e.g., peanut, soy, chickpea, lentil) indicated as an icon+ flavour/main ingredients in 2 languages. The colour of orange zone must be Pantone 151 C (Pantone Matching System), and it should represent minimum 30-50% of the front surface. No branding should appear in the orange zone and contain the following information:

- Generic Name: RUSF
- Ready-to-use supplementary food
- Fortified Complementary food
- Complements the treatment of moderate acute malnutrition in children 6 months and older
- **EAT ONE SACHET PER DAY =XXX kcal**

Pictogram zone

Pictograms should be of a size that is easy to read by the consumer. It should contain minimum four pictograms:
- Icon of hand washing before feeding a child,
- Icon showing kneading of the sachet
- Icon showing tear & eat
- Icon showing breastfeeding plus bowl of food

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 100g must be listed. A table format is preferred.

- Information on allergens (where relevant) in bold.
- Name and address of manufacturer, packer, distributor, importer, exporter, or vendor including country of origin.
- Net weight
- Date of manufacture
- 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. After opening, keep sachet tightly closed) and “consume within 24 hours of opening.”
- The statements:
  - “Not for sale or Exchange”. In Bold
  - “Consume in addition to family food”
  - It is strongly recommended to start breastfeeding immediately after birth, exclusively breastfeed during the first 6 months and continue until at least 24 months"
  - “Consultation with a health-worker is recommended for assessing child’s development needs.”

The artwork of sachet must be approved by UNICEF. 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
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 orange, Pantone 151 C (Pantone Matching System).

The following information should appear

- Orange zone: same requirements as for the orange 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, date of manufacture and best before date
- "Not for sale or Exchange". In Bold

Each carton contains a minimum of 150 sachets.

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 for Nutritional Products

FOR MORE INFORMATION

CPHHQ-SD- Nutrition Supplies | sd.nutritioussupplies@unicef.org
Technical resources for nutrition products | UNICEF Supply Division