



Technical Specifications for
-
Ready-to-Use Supplementary Food
-
RUSF

Specification reference: **MIXRSF000**

Version: **16.0**

Date of issue: **28 January, 2016**

Developed: **Charles JELENSPERGER, OSPFQ-WFP;**

Reviewed: **Saskia DE PEE, OSN-WFP; Lynnda KIESS, OSN-WFP**

Approved: **Shane PRIGGE, OSPFQ-WFP**

1. INTRODUCTION

1.1 Product purpose

RUSF is a food supplement that is intended to be eaten during two to three months, as part of a nutritional program, to treat moderate acute malnutrition for children 6 months and older. Product is intended to be eaten directly from the package with no necessary dilution, mixing or cooking. One package contains one daily dose of **100g**. This product is NOT a breast-milk replacer.

1.2 Product type

RUSF is a fortified lipid-based paste/spread that is stabilized and individually packaged in robust sachets that are packed in sturdy cartons. **RUSF** is generally made with heat treated oil seeds/pulses/cereals, sugar, milk powder, vegetable oils, vitamins and minerals.

*Products such as Plumpy'Sup™, eeZeeRUSf and Achamum belong to the **RUSF** group of products. This list is not an exhaustive list and additional product(s) may be included after validation by WFP.*

1.3. Quality and safety

RUSF shall be manufactured within a quality and food safety management environment in accordance with latest version of recognized international standards and best practices and/or guidelines, such as:

- Recommended International Code of Practice. General Principles of Food Hygiene CAC/RCP 1-1969, of the Codex Alimentarius
- General principles for addition of essential nutrients to foods: CAC/GL 09-1987, of the Codex Alimentarius
- ISO 22000:2005: Food safety management systems
- ISO/TS 22004 – Guidance on the application of ISO 22000:2005

2. INGREDIENTS

2.1 Generic requirements

RUSF shall be manufactured from ingredients that are fresh, of good quality, free from foreign materials and substances hazardous to health, that comply with Codex Alimentarius or relevant regulations. In particular, the latest version of the following Codex standards and guidelines shall apply:

- Codex Guideline CAC/GL 08-1991
- Codex Stan 193-1995. In particular melamine shall remain below 2.5 mg/Kg in dairy source used
- Codex Stan 200-1995 for peanut and peanut used to produce peanut paste
- Codex Stan 171-1989 for chick pea and soybean
- Codex Stan 175-1989 for soy protein
- Codex Stan 210-1999 for oil and for oil used to produce shortening
- Codex Stan 212-1999 for sugar
- Codex Stan 207-1999 for sources of dairy protein
- Codex Stan 73-1981 for flavoring and antioxidants, including carry over from ingredients. In particular artificial flavoring and synthetic antioxidant such as Butylhydroxyanisol (BHA), Butylated hydroxytoluene (BHT), and tertiary butylhydroquinone (TBHQ) are not authorized.

Additionally:

- The **RUSF** supplier shall test melamine at least ones a year for each individual source of dairy protein used.
- Honey is prohibited due to a safety hazard.

2.2 Vitamin and mineral premix

RUSF shall include a premix consisting of the vitamins and minerals described in Table 1. Additionally the premix shall:

- Be purchased from GAIN Premix Facility or any of the GAIN approved suppliers, as per the list available at the following link: <http://gpf.gainhealth.org/suppliers/current-suppliers>
- Be delivered to the processor of **RUSF** with a complete Certificate of Analysis. This document shall be presented to WFP with other documents for payment.
- Micronutrient premixes shall be stored as per manufacturer recommendations.

If the manufacturer would like to adapt the premix, this will have to be discussed and agreed with WFP, and will have to be based on supporting data that show that the combination of raw materials, prescribed premix and specific processing steps results in a product of which the specific nutrient content is consistently outside the range of label value and max content (see table 2). An example of an adaptation that can be considered is higher inclusion of vitamins A and C to compensate for greater losses due to a specific heat processing step.

Table 1: Premix contribution and premix nutrient sources (approximate incorporation rate: 3.4%)

Nutrients	Unit	Recommended nutrient sources (/alternative options)	Nutrient added per 100g LNS +/-10%
Retinol (Vit A) ¹	mcg	Dry Vitamin A Palmitate / Dry Vitamin A Acetate	1050
Thiamin (Vit B1)	mg	Thiamine mononitrate / Thiamine hydrochloride	1.5
Riboflavin (Vit B2)	mg	Riboflavin	2.6
Niacin (Vit B3)	mg	Niacinamide	16
Pantothenic Acid (Vit B5)	mg	Calcium d-Pantothenate	4.9
Pyridoxine (Vit B6)	mg	Pyridoxine hydrochloride	2.2
Biotin (Vit B7)	mcg	Biotin (1% trituration)	65
Folic acid (Vit B9)	mcg	Folic acid food grade	300 ²
Cobalamine (Vit B12)	mcg	Vitamin B12 (0.1 sd)	2.9
Ascorbate (Vit C)	mg	Ascorbic acid fine powder	90
Cholecalciferiol (Vit D)	mcg	Dry Vitamin D3 (sd)	18
DL- α tocopherol acetate (Vit E)	mg	Dry Vitamin E acetate (50% dl- α tocopherol acetate))	20
Phytomenadione (Vit K)	mcg	Dry Vitamin K (5%)	27
Calcium (Ca)	mg	Di-Calcium Phosphate anhydrous / tricalcium phosphate	413 ³
Copper (Cu)	mg	Copper sulphate anhydrous / copper gluconate	1.2
Iodine (I)	mcg	Potassium iodide (10% trituration)	110
Iron (Fe)	mg	2.5 mg from NaFeEDTA + 7.5 mg, which can be from Ferrous sulphate monohydrate, dried / ferrous sulphate / ferrous fumarate, encapsulated or not	10
Magnesium (Mg)	mg	Magnesium sulphate monohydrate / magnesium citrate or gluconate	100
Manganese (Mn)	mg	Manganese sulphate monohydrate	1.0
Phosphorus (P)	mg	Di-Calcium Phosphate anhydrous / tricalcium phosphate	319 ⁴
Potassium (K)	mg	175 mg from potassium chloride + 175 mg from tri potassium citrate	350
Selenium (Se)	mcg	Sodium selenite / sodium selenate	15
Zinc (Zn)	mg	Zinc sulphate	11

¹ Beadlet or spray dried form can be used assuming there is no carryover of antioxidants not approved in Codex.

² This is equivalent to 500 mcg Dietary Foliates Equivalent

³ 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

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

3. PRODUCT SPECIFICATION

3.1 Generic requirement

RUSF shall be formulated in accordance with latest version of recognized international standards and best practices and/or guidelines:

- Guideline on formulated complementary foods for older infants and young children, CAC/GL 08-1991 of the Codex Alimentarius,
- WHO. Technical note: supplementary foods for the management of moderate acute malnutrition in infants and children 6–59 months of age. Geneva, World Health Organization, 2012.
- Codex Stan 193-1995
- Codex Committee on Pesticide Residues (CCPR)

In addition:

- **RUSF** shall be microbiologically stable with a water activity between 0.2 and 0.5
- **RUSF** shall be free from objectionable matter; free from micro-organisms in amounts which may represent a hazard to health; not contain any substances originating from micro-organisms or any other poisonous or deleterious substances such as residues of hormones, antibiotics, pharmacologically active substances, anti-nutritional factors, heavy metals or pesticide residues, in amounts which may represent a hazard to health of the specific population group for which they are intended (children 6 months and older with moderate acute malnutrition).
- **RUSF** shall not contain more than 10 ppb total aflatoxins (B1, B2, G1, G2)
- **RUSF** shall be homogeneous, uniform, with small particle size which does not require and does not encourage chewing before being swallowed. The product shall be free of lumps and of large coarse particles and suitable for adequate consumption by children 6 months and older with moderate acute malnutrition
- Blend of oils shall be judiciously chosen in order to meet omega 3 and omega 6 requirements in the finished product and to minimize oil separation.

3.2 Nutritional value

RUSF shall have a composition that is in line with Table 2 and Table 4.

Table 2: Nutritional value at all points of time

Nutrients and nutritional values per 100g finished product	Unit	Minimum	Label	Maximum
Energy	Kcal	510	XX ⁵	560
Protein ⁶	g	11	XX ⁵	16
Dry skimmed milk protein ⁷	g	3.6	-	-
Fat ⁸	g	26	XX ⁵	36
ω-3 fatty acids	g	0.30	-	1.80
ω-6 fatty acids	g	2.6	-	6.10
Retinol (Vit A)	mcg	550	550	1150
Thiamin (Vit B1)	mg	1.0	1.0	-
Riboflavin (Vit B2)	mg	2.1	2.1	-
Niacin (Vit B3)	mg	13	13	-
Pantothenic Acid (Vit B5)	mg	4.0	4.0	-
Pyridoxine (Vit B6)	mg	1.8	1.8	-
Biotin (Vit B7)	mcg	60	60	-
Folates(Vit B9) DFE	mcg DFE	330	330	-
Cobalamine (Vit B12)	mcg	2.7	2.7	-
Ascorbate (Vit C)	mg	60	60	-
Cholecalciferiol (Vit D)	mcg	15	15	20
Tocopherol acetate (Vit E)	mg aTE	16	16	-
Phytomenadione (Vit K)	mcg	27	27	-
Calcium (Ca)	mg	535	535	750
Copper (Cu)	mg	1.4	1.4	1.9
Iodine (I)	mcg	100	100	140
Iron (Fe)	mg	10	10	14
Magnesium (Mg)	mg	150	150	225
Manganese (Mn)	mg	1.2	1.2	2.4
Phosphorus (P)	mg	450	450	750
Potassium (K)	mg	900	900	1400
Selenium (Se)	mcg	20	20	40
Sodium (Na)	mg	-	-	270
Zinc (Zn)	mg	11	11	14.0

3.3 Shelf life

Unless stated otherwise in the contractual agreement, **RUSF** shall have minimum 24 months shelf life when stored up to 30°C at 65% relative humidity. A real time shelf life study at 30°C or an accelerated shelf life study at 40°C shall be initiated on each new formulation to confirm that:

- Food remains within maximum and minimum defined in Table 2
- There shall be no more than slight oil separation throughout the shelf life of the product.

⁵ All XX have to be filled by manufacturer, according to the specific formulation used. Please refer to codex standard in section 5.1 below for the full list of nutrients to be declared.

⁶ As per WHO technical note, source of protein shall be selected to reach a PCDAAS (Protein Digestibility-Corrected Amino Acid Score) of 70% minimum

⁷ If dry skimmed milk with 36% protein is used this is equivalent to 10% dry skimmed milk

⁸ Fat and omega-3 and omega-6 targets are based on WHO technical note requirement for 520 and 550kcal/100g food

4. PACKAGING AND MARKING

4.1 Packaging

RUSF shall be packaged in food-grade sachets, hermetically sealed and robust enough to prevent leakage and protect the product throughout its shelf life. Sachet material shall not represent a hazard for infants and young children when sachets is opened and put in contact with the mouth.

RUSF shall be packed in cartons suitable for the humanitarian supply chain, each carton containing 150 individual sachets with a net weight of 100g each. Cartons shall be:

- New, manufactured from well-constructed double walled corrugated board,
- With an edge crush resistance of 11 kN/m (61 pounds per inch) and a specific weight of 700 to 800 grams per square meter. 60% of the edge crush resistance shall remain at 90% relative humidity and 40°C.
- Fully filled for maximum strength.

Inside containers: slip sheets or plywood shall be used to provide maximum stacking strength. Pallets with appropriate stacking configuration could also be used.

4.2 Labelling

RUSF shall be labelled in accordance with latest version of recognized international standards and best practices and/or guidelines, such as

- Codex Stan 146-1985 - General standard for the labelling of and claims for pre-packaged foods for special dietary uses.
- Codex Stan 1-1985 - General standard for the labelling of pre-packaged foods

In addition **RUSF** shall be labelled in an appropriate language as per Table 3 and Annex 1 requirements.

Table 3: Generic label requirement:

	sachets	inside leaflet (optional)	outside box
Commercial name	Shall be kept simple and shall not reflect any medical purpose		
Product name	RUSF: Ready-to-Use Supplementary Food		
Target use	"To treat moderate acute malnutrition for children 6 months and older"		
Net weight	100g	-	150*100g (15 kg)
Nutrients content	-	Leaflet or box: in line with codex regulation and target defined in table 2	
Ingredient list	XX ⁹		-
Preparation instruction	"Eat one sachet per day" + Generic pictogram that shows how food is eaten + Breastfeeding logo		-
Storage instruction	"Best stored below 30°C, in dry and hygienic conditions"		
Manufacturer name	Produced by: XX		

⁹ All XX have to be filled by manufacturer.

Manufacturer address	XX, including country of origin		
Manufacturer batch/lot number	XX	-	XX
Production date	XX	-	XX
Best Before Date	XX	-	XX
Other	-	"not for sale or exchange" "Contains no ingredients of animal origin besides dairy products"	
Donor and WFP logo	-	as per contractual agreement	
Beneficiary feedback hotline (if required in the contractual agreement)	XX	-	XX

5. SAMPLING AND ANALYTICAL REQUIREMENTS

As per contractual agreement, WFP will appoint an inspection company that will check, based on sampling plan defined below, that the food matches requirements specified in Table 4 and Table 5. Additional tests may be defined in case further quality assessment is required. This will be performed in addition to analysis performed by supplier according to his own sampling plan.

5.1 Sampling plan

Sampling frequency (lot size) will be defined based on the daily production of the producer.

- For producers with daily production equal to or greater than 100MT, the inspection lot size will be one day's production.
- For producers with daily production less than 100MT, the inspection lot size will be one week's production.

The following number of samples representative of the inspection lot will be sent to the laboratory:

1. One set of samples for analysis 1-6 in Table 4 and for retention analysis
2. Twenty five samples for Salmonella analysis
3. Ten samples for Enterobacteriaceae analysis

5.2 List of analyses

Table 4: List of compulsory tests

No	Parameters	Limit	Method of analysis
1	Protein	11-16 g/100g	AOAC 991.20
2	Lipid	26-36 g/100g	ISO 17189
3	Vitamin C	60-120 mg/100g	EN 14130:2003, AOAC 2012.21, AOAC 985.33
4	Iron (Fe)	10-14 mg/100g	AOAC 990.05 ISO 8294
5	Total Aflatoxin	Max 10 ppb	ISO 16050
6	Salmonella	As per table 5	ISO 6579*
7	Enterobacteriaceae	As per table 5	ISO 21528-2**

* 25 g analytical unit, samples may be pooled dry, by the laboratory, if lab method has been validated. The total analytical unit should be 625g

** 10 g analytical unit, no pooling

Table 5: Microbiological criteria

Microorganisms	n	c	m	M	p-class
Salmonella	25	0	Absent in 25 g	n/a	2
Enterobacteriaceae	10	2	≤10 cfu/g	≤100 cfu/g	3

Where

- n: number of sample units;

- 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: 2 or 3 class plan

Annex I. Packaging requirements

Front and Back side of the sachets. Pantone 151 is applicable for both sachets and cartons.

