

	<p><b>PRODUCT SPECIFICATIONS SHEET</b></p> <p><b>RUTF Biscuit (BP-100)</b></p>	<p><b>Date of issue:</b></p> <p><b>Author:</b> A Fleet</p> <p><b>Revision:</b> ARF, MEFB</p> <p><b>Version:</b> 2.0</p> <p><b>Date:</b> 23.09.2019</p>
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### 1. General Description:

BP- 100 is a Ready-to-Use Therapeutic Food (RUTF) biscuit, a high-energy fortified food equivalent to that of the WHO-F100 rehabilitation diet but with a higher energy density. RUTF biscuits are compressed bars, manufactured from a mixture of cereal, milk powder, vegetable oil and carbohydrates, with added vitamins and minerals.

See more on: Management of severe malnutrition: a manual for physicians and other senior health workers, WHO 1999:

<http://www.who.int/nutrition/publications/severemalnutrition/9241545119/en/index.html>

and the updated version of the manual:

[http://apps.who.int/iris/bitstream/10665/95584/1/9789241506328\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/95584/1/9789241506328_eng.pdf)

### 2. Intended Use:

BP-100, RUTF biscuit is to be used by humanitarian agencies, governmental and non-governmental organisations for the treatment of Severe Acute Malnutrition (SAM) in any cultural setting. RUTF biscuit may be used in a wide variation of climatic zones and may be the sole source of food, except for water and breast milk, during the period of use.

#### Suggested dosage:

- The average daily dosage of BP 100 equal to 2 sachets of RUTF (92g) is 7 x 28.3g tablets of BP 100.
- Each box of BP-100 contains 510g, enough for 2,6 days for a child using 7 tablets a day.
- 1 carton (12.24 Kg net weight) of BP-100 provides treatment for an average SAM child for 63 days

### 3. Target population: Children with SAM.

### 4. Technical Specification:

Product shall be ready to use and to be eaten directly (no cooking/mixing/dilution required) or crumbled into 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: bars shall have smooth exterior. Interior particle size shall be uniform; and shall easily crumble with gentle finger pressure.

Appearance: 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 max

Energy: 500kcal/100g min

Proteins: 10-12% total energy (12.3-15.5% by weight)

Lipids: 45-60% total Energy or 24.8-33.0% by weight

n-6 fatty acids: 3-10% total energy

n-3 fatty acids: 0.3-2.5% total Energy

Trans fats: <3% total fat

Carbohydrate: 44.5-59.9% by weight

Fibres: 5%

Ash: 5g/100g max

**Mineral content (per 100g):**

Sodium <290mg

Potassium: 1100-1400 mg

Calcium: 300-600 mg

Phosphorous: 300-600 mg expressed in terms of non-phytate phosphorus

Magnesium: 80-140 mg

Iron: 10-14 mg

Zinc: 11-14 mg

Copper: 1.4-1.8 mg

Selenium: 20-40 mcg

Iodine: 70-140 mcg

**Vitamin content (per 100g):**

vitamin A (Retinol Equivalent): 0.8-1.2mg

vitamin B1 (Thiamine): >0.5 mg

vitamin B2 (Riboflavin): >1.6 mg

vitamin B3 (Niacin): >5 mg

vitamin B5 (Pantothenic acid): >3 mg

vitamin B6 (Pyridoxine): >0.6 mg

vitamin B7 (Biotin): >60 mcg

vitamin B9 (Folic acid): >200 mcg

vitamin B12 (Cyanocobalamin): >1.6 mcg

vitamin C (Ascorbic acid): >50 mg

vitamin D (Cholecalciferol): 15-20 mcg

vitamin E (Tocopherol): >20 mg

vitamin K (Phytonadione): 15-30 mcg

**5. Processing:**

**5.1 Requirements for raw materials:**

Milk (milk powder):

At least half of the proteins contained in RUTF biscuit shall come from milk/dairy products. Acceptable sources of dairy protein are:

- Full cream milk powder
- Skimmed milk powder
- Whey powder

Applicable standards reference:

-Codex STAN 207-1999: Codex Standard for Milk Powders and Cream Powder

-Codex STAN 289-1995: Codex Standard for Whey Powders

#### Cereal:

Indigestible fibre from cereals (measured as grams ash/100g finished product) shall be less than 5 g/100 g.

Applicable standards reference:

-Codex STAN 152-1985

#### Oil:

Edible refined vegetable oil:

The manufacturer shall choose judiciously the type of oil and establish specifications for oil to ensure that the specifications in finished product are met (paying special attention to requirements for omega 3 and omega 6).

Applicable standards reference:

-Codex STAN 210-1999: Codex Standard for Named Vegetable Oils

#### Carbohydrates (sweetener):

Lactose and glucose polymers shall be used. Honey shall not be used.

The following carbohydrates are acceptable:

Sucrose, Fructose, Lactose, precooked and/or gelatinised starches, maltodextrin.

Applicable standards reference:

-Codex STAN 212-1999: Codex Standard for Sugars

#### Other agricultural products:

Applicable standards reference:

-CAC/GL 08-1999: Guidelines on Formulated Supplementary Foods for Older Infants and Young Children

-Relevant Codex standards

#### Flavouring:

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

#### Antioxidants:

The following antioxidants are allowed:

- Ascorbyl palmitate
- Mixed tocopherols
- Butylhydroxyanisol (BHA) and Butylated hydroxytoluene (BHT) shall not be added as an antioxidant.

### **5.2 Requirements to the Mineral and vitamin premix:**

The mineral and vitamin premix cannot be produced by RUTF biscuit manufacturer itself and shall be supplied only from a restricted list of suppliers of premix. Manufacturers are responsible for their own quality assurance of premix supplies and should conduct their own quality assessments. Some examples of suppliers of premixes are found here:

[http://documents.wfp.org/stellent/groups/public/documents/manual\\_guide\\_proced/wfp251174.pdf](http://documents.wfp.org/stellent/groups/public/documents/manual_guide_proced/wfp251174.pdf)

A detailed Certificate of Analysis of the premix with all mineral and vitamin components shall be available from the supplier of premix for every batch of premix delivered.

To verify adequate mixing, the manufacturer must identify at least 1 tracer element per premix whose concentration is measured prior to batch release. The tracer shall be representative of the only addition of the premix. The manufacturer is free to determine which vitamin/mineral should be measured, in accordance with available laboratory capacity. E.g.: potassium (1100-1400mg/100g), vitamin C (> 50 mg/100g. Vitamin A must also be tested, additionally to the tracer.

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.

Vitamin and mineral forms used shall be soluble and easily absorbed by patients with Severe Acute Malnutrition (SAM). The added minerals shall be water-soluble and shall not form insoluble components when mixed together. RUTF biscuit shall have a mineral composition that will not alter the acid-base metabolism of patients with SAM. It shall have a moderate positive non-metabolisable base enough to eliminate the risk of metabolic acidosis. The non-metabolisable base can be approximated by the formula:

*Estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (minus) phosphorous + chloride*

An example of a mineral mix with a suitable positive non-metabolizable base can be found in the Appendix 4 of *Management of Severe Malnutrition: a manual for physicians and other senior health workers*, WHO 1999.

*Potassium chloride, Pripotassium citrate, Magnesium chloride (MgCl<sub>2</sub> - 6H<sub>2</sub>O), Zinc acetate, Copper Sulphate, Sodium selenite, Potassium iodide*

Another potentially useful source of acceptable mineral and vitamin compounds can be found in Annex 3 of the COMMISSION DIRECTIVE 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC. Vitamin and mineral compounds approved for use in infant formulae are listed on pages 22 and 23; in general, these same compounds shall be acceptable for RUTF biscuit.

## **6. Requirements for Food Safety: Hygiene, Microbiology and control of contamination.**

RUTF biscuit does not contain any substance originating from micro-organisms or any other poisonous or deleterious substances, including anti-nutritional factors, heavy metals or pesticides in amounts that may represent a hazard to health.

### **6.1 Microbiological and toxicological safety:**

The manufacturer establishes microbiological criteria for production as well as for the finished product, by following the definitions and include the components specified in the following standards: Applicable standards reference:

-CAC/GL 21, 1997, *the Principles for the Establishment and Application of Microbiological Criteria for Foods* (revision scheduled for 2013).

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

*Salmonella* is the highest priority infectious foodborne hazard and its control in RUTF biscuit is the most important microbiological food safety program goal ("*Microbial safety of Ready-to-Use Lipid based Therapeutic and Supplementary Foods - Technical meeting*", summary report released on the 6<sup>th</sup> March 2013, FAO and WHO). The manufacturer shall have an adequate environmental monitoring program in place, including product contact surface, in-line product surveillance, with investigation to assure adequate process control and hygiene. The manufacturer undertakes ingredient, environment, in-line, and end-product surveillance for salmonella and Enterobacteriaceae (EB), initially to establish baseline statistics (the first 12 months of data collection) and then, in conjunction with other indicators

(attention to *Listeria monocytogenes*, *Clostridium botulinum* and *mesophilic aerobic bacteria* shall be considered) to monitor process control by reviewing trends.

Analytical control plans shall be detailed, and include:

analytical methods for detection and/or quantification

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

## **6.2 Microbiological Certificate of Analysis (CoA) per batch:**

The manufacturer shall conduct a complete analysis of the finished product to verify that the finished product is manufactured in a homogeneous and consistent content. All parameters included in this specification sheet shall be tested at least once a year.

A Certificate of Analysis (CoA) shall 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, 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:

Microbiology parameters to be included on the CoA for every batch delivered:

Microorganism content: <10,000cfu in 1g max.

Coliform test: negative in 1g

Yeast: Maximum 10cfu in 1g

Moulds: Maximum 50cfu in 1g

Cronobacter sakazakii: Maximum 10cfu in 1g

Clostridium perfringens: negative in 1g

Pathogenic Staphylococci: negative in 1g

Salmonella: negative in 25g

Listeria: negative in 25g

### **6.2.1 Note on Sampling:**

#### Salmonella:

Sampling for Salmonella detection:

Salmonella: negative in 25g. Testing method: ISO 6579

*No composite sample. Maximum pooling authorized is 375g, only if the laboratory method has been validated and accredited.*

The testing method ISO 6579 requires that salmonella is found negative in 25 grams from taking 25 samples. Many laboratories cannot composite large sample weights, so the 25 samples can be analysed in two composites no greater than 375 grams, for example 15 samples of 25 grams (375 grams) and then 10 samples of 25 grams making up 250 grams. This gives a total of 25 samples taken and each of these samples should be negative for salmonella. (0 cfu in 25 grams).

n (number of samples with conformance criteria) = 25.

c (the maximum allowable number of defective sample units in a 2-class plan or marginally acceptable sample units in a 3-class plan) = 0

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) = 0

p (class plan) = 2

#### Enterobacteriaceae:

Enterobacteriaceae (EB at 30°C): 10 cfu in 1 g. Testing method: ISO 21528-2 (no pooling).

Sampling for Enterobacteraceae (EB):

For sampling for EB, UNICEF currently takes 10 separate samples of 10 grams. EB should be below 10 cfu per gram in 8 of the samples. 2 samples may have EB between 10 and 100 cfu. Any result above this will lead to rejection of the batch. The samples should be incubated at 37°C.

Pooling of the 10 samples is only allowed, if you test for absence of EB. If detected, then 10 individual samples must be tested, so with the prior history of EB in the PPB product we suggest you stick to the individual testing of samples.

n = 10

c = 2

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) = 10

M (microbiological limit, which, in a 3-class plan, separates marginally acceptable quality from defective quality) = 100/g

p (class plan) = 3

#### *Cronobacter sakazakii*:

*Cronobacter sakazakii*: maximum 10cfu in 1 g. Testing method: ISO 22964

n=10

c=0

Sampling for *C.sakazakii*.

At present UNICEF has no defined sampling plan specified for *C. sakazakii*. Tests for *C. sakazakii*, are carried out, when the EB results are higher than the specification allows (10 cfu per gram) and require the results to be within the specified limits.

### **6.3 Control of contaminants:**

#### **Mycotoxins**

Total Aflatoxins: 10 ppb max.

If any organization (NGO, UN, etc.) decides to test the product in an accredited laboratory at its own initiative, and obtains results that do not meet those criteria, the supplier must recall the product, determine and correct the root cause of the failure.

*Aflatoxins are not the only mycotoxin associated with acute & chronic toxicity.*

#### **Chemical safety**

Applicable standard reference:

-CAC/RCP 49-2001: *Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals.*

#### **Pesticides and heavy metals**

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

**Pesticides:**

Carbamates: <10ppb

Organochlorine: < 10 ppb

Organophosphorous: < 10 ppb

Pyrethroid: < 10 ppb

**Heavy metals:**

Arsenic: < 0.06 mg/kg

Cadmium: < 0.03 mg/kg

Lead: < 0.1 mg/kg

Mercury: < 0.02 mg/kg

Applicable standards reference:

*CODEX STAN 228-2001: General Methods of Analysis for Contaminants.*

*CODEX STAN 193-1995: Codex General Standard for Contaminants and Toxins in Food and Feed.*

*CODEX STAN 229-1993, REV.1-2003: Analysis of Pesticide Residues: Recommended Methods.*

**Radioactivity**

This risk is managed by using only ingredients certified free of radioactivity. The nuclear radiation level shall meet the values valid for consumption. If limits are not defined, the value must not exceed 370Bq/kg (Cs 134&Cs137).

**Melamine**

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

Applicable standards reference:

*COMMISSION REGULATION (EU) No 594/2012 of 5 July 2012 amending Regulation (EC) 1881/2006 as regards the maximum levels of the contaminants ochratoxin A, non-dioxin-like PCBs and melamine in foodstuffs.*

**6.4 Production process specifications and Quality Assurance:**

Products shall be manufactured in accordance with Codex Alimentarius applicable references, Good Manufacturing Practice (GMPs) and Good Hygiene Practices (GHPs). All producers shall 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. Prerequisite programs including environmental monitoring programs shall be implemented.

Applicable standards reference:

*-CAC/RCP 1-1969, Rev. 4-2003: Recommended International Code of Practice. General Principles of Food Hygiene*

*-ISO 22000:2005: Food Safety Management Systems - Requirements for any Organization in the Food Chain.*

The manufacturer is responsible to elaborate an analytical plan for the finished product. All analytical test procedures shall be described in enough detail, including analysis methods. ISO 17025 certified laboratories shall preferably be used.

Validation of the process and coefficient of variation

The coefficient of variation, calculated using the method proposed by WFP, shall be as low as possible, and always <10.

**6.4.1 Traceability**

A complete traceability system shall be in place. For every batch number, the manufacturer shall be able to find all the history of the finished products (composition, raw materials used, processing parameters, analytical results, quantity produced and dispatched, customers sites delivered, etc.).

#### **6.4.2 Batch size**

The batch size shall not exceed 200 MT and one week of production.

#### **6.5 Stability Study and Shelf-life:**

Stability study shall be conducted on the final product in primary packaging, to confirm shelf life and storage conditions.

The stability study shall be conducted in accordance to the Interagency Requirements for stability Study, attached to the bid document.

Shelf life: 4 years

### **7. Certificate of Analysis of final product:**

A Certificate of Analysis is required for every batch supplied against UNICEF Supply Division Purchase Orders. The principal tests listed below must be performed to check if the quality of the finished product meets above requirements. Additional analyses shall be defined in case of further quality assessment.

#### **7.1 List of compulsory tests for Certificate of Analysis and reference methods:**

Moisture: 4.0 % maximum

Energy: 500 Kcal/100g

Protein: 10 - 12 % total energy

Ash max.: 5g/100g

Lipids: 45 - 60 % total energy

\*Vitamin A: 0.8-1.2mg/100g

\*Vitamin C: min. 50mg/100g

\*Iron: 10-14mg/100g

Total viable count: <10000cfu/g

Salmonella: neg/ 25g

Enterobacteracea: <10cfu/g

Aflatoxin: <5ppb

\* One vitamin and one mineral are expected to be analysed and included in the CoA.

### **8. Storage:**

Storage conditions: as defined by the manufacturer, no refrigeration required.

### **9. Specifications for labelling and packaging:**

#### **9.1 Labelling:**

Label shall be colour coded: red, PMS 485 (Pantone Matching System) and shall include the following information clearly printed out in English, French and Spanish:

- The generic name: Ready to Use Therapeutic Food, Biscuit
- The statement: "To be prescribed and initiated by a trained health and nutrition professional only"
- Raw materials listed in order of descending quantities. A detailed list of the active ingredients (vitamin and mineral premix) showing the amount of each present in a dosage unit can be provided in a leaflet and not on the product label;



- Net content
- Best Before date
- Lot number
- Clear pictorial instructions for use

Applicable standards reference:

*-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*

## **9.2 Primary and secondary packaging**

The finished product should be packed in cartons of 24 packs where each pack contains 9 bars.

Each bar is 2 biscuits of 28.4 g.

- Packaging material shall be child appropriate and cannot contain any detachable parts that present a choking hazard.
- Packaging materials, inks used for marking and glue shall be contact food grade, and water resistant.
- Packaging material shall not transfer any element (particle, flavour or odour) to the product.
- Packaging material shall be able to withstand pressure changes associated with air transport.
- Primary packaging shall be free of damage, such as (but not limited to) tears, cuts, holes, etc.
- Individual bar: shall be wrapped in a thin monolayer, grease-proof wrap, to provide low level protection, this shall be applied to each individual bar. The shrink film shall be determined by the manufacturer.
- 1 unit (box) = 9 bars

9 bars shall be packed into a vacuum-packed brick style and water repellent cardboard box. Packaging materials, inks and glue shall be food-contact approved;

- Carton: 24 boxes shall be packed in a strong corrugated board carton.

The cartons shall be of a sturdy quality, and provide protection of the goods for carriage by air, sea and/or road to final destination worldwide, including remote locations under adverse climatic and storage conditions, and high humidity - i.e. ECT (Edge Crush test) > 11kN/m with minimum 60% remaining with 90% humidity at temperature of 40°C (tropical conditions) or similar

The carton shall be strong, able to be stacked to a height of 2.4 m, and resistant to puncturing.

The following information shall appear on the carton: name and address of the manufacturer, packer, distributor, importer, exporter or vendor, country of origin, storage condition, weight, volume, numbers of units in a carton, storage conditions, batch number, best before date.

- Leaflet: Each carton shall contain a leaflet with the following information:
  - Name and address of manufacturer including country of origin
  - Composition: all ingredients shall be listed in order of descending quantities
  - Information of allergens and ingredients of animal origin
  - Nutritional values in 100g: energy content, proteins, lipids, and detailed content of each vitamin and mineral
  - Storage instructions
  - Net weight
  - Protocol and instructions for use:

RUTF biscuit is designed for children from 6 months of age and above - children below 6 months must be exclusively breastfed or if necessary with a specific regimen with therapeutic product prescribed by a 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 shall be used according to the national protocols on the management of SAM. For more details on dosage and length of treatment refer to existing international and national guidelines.