Save the Children

Date of issue: 20th November 2017
Written by: Alice Burrell
Authorized by: Charlotte d'Elloy

PRODUCT SPECIFICATION SHEET
READY-TO USE-THERAPEUTICAL-FOOD

Ready-to-Use Therapeutic Food (RUTF)	
1) General information	Ready-to-use therapeutic food is high energy, fortified food, suitable for the treatment of children with severe acute malnutrition in any cultural setting in accordance with guidelines for the outpatient care and management of SAM.[1] RUTF paste may be used in climatic extremes from the arctic to tropical zones and may be the sole source of food, except for water and breast milk, during the period of use. RUTF paste is ready to eat, can be eaten directly from the sachet without prior cooking, mixing or dilution; it's portion controlled and each unit has the same nutritional value for control and monitoring of dietary intake.
2) Item description	**Taste and smell:** pleasing sweet, clean dairy flavour and odour. The product should be free from foreign odours and flavours such as, but not limited to burnt, scorched, rancid, malted, sour or stale. **Appearance**: yellow, light brown to brown colour. The product should not have a dull, grey tinge, or other abnormal cast. The finished product should show no evidence of excessive heating (materially darkened or scorched). **Texture:** smooth homogeneous texture and should be free of lumps; the oil should not separate and be free of a gritty, grainy, and sandy texture.
3) Nutritional composition[2]	RUTF must be portion controlled: each unit (100 g maximum) must have the same nutritional value for control and monitoring of dietary intake. **Energy:** 520 - 550 kcal/100g **Moisture:** 2.5 % maximum **Water activity** 0.6 maximum **Proteins:** 10 % - 12 % of energy 12.8-16.2% by weight **Lipids:** 45% - 60% of energy 25.8-36.3% by weight N-6 fatty acids: 3% - 10% total energy N-3 fatty acids: 0.3% - 2.5% total energy Trans-fatty acids <3% total fat **Fibres** <5%

[1] Community-Based Management of Severe Acute Malnutrition: A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition, and the United Nations Children's Fund, 2007. http://www.who.int/nutrition/topics/Statement_community_based_man_sev_acute_mal_eng.pdf

[2] MSF Production Specification Sheet: Ready to Use Therapeutic Food Paste (last revision 17/01/2014)

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Vitamins/ 100 gr	Vitamin A: 0.8 -1.1mg Vitamin D: 15 – 20 µg Vitamin E: 20 mg minimum Vitamin C: 50 mg minimum Vitamin B1 (Thiamine): 0.5 mg minimum Vitamin B2 (Riboflavin): 1.6 mg minimum Vitamin B6: 0.6 mg minimum Vitamin B12: 1.6 µg minimum Vitamin K: 15 - 30 µg Biotin: 60 µg minimum Folic acid: 200 µg minimum Pantothenic acid: 3.0 mg minimum Niacin: 5.0 mg minimum
Minerals/ 100 gr	Calcium: 300 - 600 mg Phosphorus: 300 - 600 mg[3] Potassium: 1100 - 1400 mg Magnesium: 80 - 140 mg Zinc: 11 - 14 mg Copper: 1.4 - 1.8 mg Iron: 10 - 14 mg Iodine: 70 - 140 µg Selenium: 20 - 40 µg Sodium: 290 mg maximum
4) Shelf life	24 months from manufacturing date, when stored in a dry place below 30°C. Unless specifically authorized in writing, products must be of fresh production e.g. less than 4 months old at the time of dispatch. Storage conditions: No refrigeration required.
5) Raw material	• **Milk (milk powder)** At least half of the proteins contained in RUTF paste 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* • **Peanuts/peanut paste** Apart from peanut, other ingredients such as soy protein concentrate, sesame, sun

[3] Expressed in terms of non-phytate phosphorus

flower seeds, lentils, chickpeas, rice, sorghum or other cereals can be used but supplier must provide an evidence of suitability of such formulations for the treatment of SAM by submitting efficacy and acceptability studies.

Applicable standards reference:
-Codex STAN 200–1995: Codex Standard for Peanuts
-CAC/RCP 55-2004: Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts.

- **Oil (edible refined vegetable oil)**

The manufacturer shall 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).

Applicable standards reference:
-Codex STAN 210-1999: Codex Standard for Named Vegetable Oils

- **Carbohydrates**

Lactose and glucose polymers shall be used. Honey shall not be used.
The following carbohydrates are acceptable:

- Sucrose
- Lactose
- Precooked and/or gelatinised starch
- Fructose
- Maltodextrin

Particular attention should be given to the sugar particle size, which if not properly ground, can cause oil separation from the paste and lead to leakage when opening the sealed part of the sachet.

Applicable standards reference:
-Codex STAN 212-1999: Codex Standard for Sugars

- **Food additives**

Mineral and vitamin premix
The mineral and vitamin premix(es) cannot be produced by the RUTF paste manufacturer itself and must be supplied only from a restricted list of authorised suppliers of premix (http://gpf.gainhealth.org/suppliers/current-suppliers). A detailed Certificate of Analysis of the premix with all mineral and vitamin components must be available from the supplier of premix for every batch of premix delivered.

Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM.

Carbohydrates used shall be readily soluble in water. The added minerals shall be water-

soluble and shall not form insoluble components when mixed together. Minerals used shall be in forms that are known to be biologically available. Iron salts should not be added.

The RUTF paste shall have a mineral composition that will not alter the acid-base metabolism of patients with SAM. In particular, it shall have a moderate positive non-metabolisable base sufficient to eliminate the risk of metabolic acidosis. The sum of strong anions (chloride) should be less than the sum of strong cations (sodium, potassium) when expressed in molar terms. For the purposes of these specifications, magnesium and calcium are to be counted as weak cations and phosphate as a weak anion. The non-metabolisable base can be approximated by the formula:

estimated absorbed millimoles (Sodium+Potassium+Calcium+Magnesium) - Phosphorus+Chloride (minus)

An example of a mineral mix with a suitable positive non-metabolisable base can be found in the *Appendix 4 of Management of Severe Malnutrition: a Manual for Physicians and Other Senior Health Workers, WHO 1999.:*

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* and in the *CAG/GL10 – 1979 Advisory lists of Nutrient Compounds for use in foods for Special Dietary uses for Infants and Young Children..* 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 paste.

Emulsifying agents

Emulsifiers are potentially of importance for lipid-based pastes as this type of food is prone to phase separation. Phase separation is minimised by reducing the particle size.

Applicable standards reference:
-Acceptable emulsifiers for canned baby foods intended for infants and young children as specified by Codex Standard 073-1981.

Lecithin	Max 0.5g/ 100g
Mono and diglycerides	Max 0.15g/ 100g[4]

Flavouring

[4] A level between 1.5 and 2.0 g/100g can be accepted (no adverse effect - diglycerides are decomposed to monoglycerides in the digestion system prior to absorption).

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	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. **Other ingredients** Lactoferrin is allowed. Nutritional levels of essential L-amino acids, choline, taurine, carnitine, inositol carotene and other semi-essential or biologically useful nutrients may be added to levels which current scientific opinion considers to be within a desirable and safe range for the nutrition of severely malnourished children.
6) Packaging and Labelling	The finished product should be packed in 92g sachets placed in a carton containing 150 sachets. Each carton should contain a detailed leaflet specifying nutritional composition of the product including composition of the mineral and vitamin premix. • **Primary packaging (sachet)**  Primary packaging should be generally recognised as safe for food packaging and should protect the product adequately during the assigned shelf life and the sachet seal should prevent any leakage. ○ The primary packaging must be portion controlled: each unit of 92 g (maximum 100g) net ○ Packaging material can not contain any detachable parts that present a choking hazard. ○ Packaging materials, inks used for marking and glue must be contact food grade, water and lipid resistant. ○ 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 closure seal must be free of wrinkles, occluded matter, or evidence

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	of entrapped moisture or grease. o An air and water tightness control must be implemented during the filling process. o Packaging under nitrogen contributes to lengthening of product shelf life, i.e. protecting lipid and vitamin oxidation - **Primary Labelling** RUTF labelling must include generic name of product in English "Ready to Use Therapeutic Food" and in French "Aliment Thérapeutique Prêts à l'Emploi". It must also include a clear statement in English "RUTF for children with Severe Acute Malnutrition" and in French "RUTF pour les enfants atteints de malnutrition aiguë sévère", as well as the type of formula used (e.g. "Peanut paste"). FRONT Front side of the sachet is divided into three zones. The space limit set for each zone shall be respected. The red zone shall represent at least 50% of the front surface and contain the following information: - Generic name: RUTF - Ready to use Therapeutic Food for children > 6 months with Severe Acute Malnutrition - 1 sachet=500 kcal The colour shall be red, PMS 485 (Pantone Matching System). The supplier's zone shall represent a maximum of 20% of the surface and contain the following information: - Product name (if applicable) - Manufacturer's name and logo The pictogram zone shall represent 30% of the surface and contain three pictograms: knead, tear & open, squeeze & eat. BACK: - All the ingredients listed in order of descending quantities. Types of ingredients shall be specified, e.g.: non-hydrogenated palm oil - Information on allergens (where relevant) and ingredients of animal origin - Name and address of manufacturer, packer, distributor, importer, exporter or vendor including country of origin. - Net weight - Best Before date (clearly visible throughout the whole shelf life of the product) - Lot number (clearly visible throughout the whole shelf life of the product) - Storage instructions - The statement "Not for resale" - Breastfeeding message: Breastfeeding is recommended until 24 months (exclusive until 6 months) and logo - Statement: "RUTF has to be prescribed and initiated by a trained health and nutrition professional only" Applicable standards reference: *-Codex STAN 146-1985: General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses.*

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	-Codex STAN 1-1985: General Standard for the Labelling of Pre-packaged Foods • **Secondary packaging** Cartons shall be strong and sturdy; allowing stacking up to 2.4 m. high, shall be 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. - ECT (Edge Crush Test) > 11kN/m with minimum 60% remaining with 90% humidity at the highest recommended temperature of storage. - Cartons shall be protected by isolating sachets inside the carton in a plastic bag to prevent damaging other cartons in case of possible leakage. Cartons shall be colour coded, using PMS 485 red colour The packaging unit is strong, able to be stacked to a height of 4 pallets astatic storage and 2 pallets during transport, and resistant to puncturing. The following information must appear: • All information appearing on the red zone on the primary packaging must appear also on a red zone on the carton, with the same colour • Name and address of manufacturer, packer, distributor, importer, exporter or vendor including country of origin; • Storage conditions: product to be stored below X degrees Celsius; • Numbers of units in the carton • Lot number and best before date • Purchase Order Number (optional for inner boxes); • Description of contents; • Quantity per carton; • Gross Weight; • Cubic Measurement; • Batch Number Reference (if applicable); • IMCO classification (if applicable); • Manufacturing Date (if applicable); • Expiry Date (if applicable). No carton may contain items from more than one manufacturing batch. The packing list should indicate the manufacturing batch number (where applicable) and cross-reference to the carton numbers, pallets and containers. One copy of the packing list must be included with the shipment and another copy should accompany the shipping documents" - **Leaflet** • Each carton must contain a leaflet. English language is mandatory, selection of other language(s): French and/or local languages as deemed appropriate. • The following information must appear on the leaflet: - All information on the red zone on primary packaging shall also preferably appear on a red zone on the leaflet. - Name and address of manufacturer including country of origin. - Composition: all ingredients must be listed in order of descending quantities. - Information of allergens and ingredients of animal origin.

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	- Nutritional values in 100g: energy content, proteins, lipids, and detailed content of each vitamin and mineral. - Storage instructions - Reference to the joint statement on management of SAM and other references if applicable. - Protocol and instructions for use: - RUTF is designed for children from 6 months of age and above - children below 6 months have to be exclusively breastfeed or if necessary with a specific regimen with therapeutic product prescribed by a clinician. - RUTF has to be prescribed and initiated by a trained health and nutrition professional only. - RUTF should not be shared with other members of the family. - RUTF shall be used according to the national protocols on the management of SAM. - If there is no national protocol, standard regimen is 2 sachets per day for a child between 5.0 and 6.9 kg and 3 sachets for a child between 7.0 and 9.9kg and 4 sachets per day for a child more than 10kg for an average period of 6-8 weeks, for an average period of 6 to 8 weeks. For more details on dosage and length of treatment refer to existing international and national guidelines.
7) Safety	RUTF should be free from objectionable matter. It must not contain any substance originating from microorganisms or any other poisonous or deleterious substances, including anti nutritional factors, heavy metals or pesticides in amounts that may represent a hazard to health. • **<u>Microbiological and mycotoxines safety</u>** 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: *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).* Manufacturers are responsible for ensuring the compliance of finished products to the established criteria. In view of the limitations of end product testing, compliance should be ensured through the design of an appropriate food safety control system and verification of the effectiveness of control measures through appropriate auditing methods, including review of monitoring records and of deviations and confirmation that CCPs are kept under control and GHPs are adhered to. These activities shall be supplemented by appropriately documented microbiological sampling and analysis plans. The microbiological testing should include, as appropriate, analysis of samples taken from raw materials, environment and production line, ingredients and finished products. When monitoring of control measures and surveillance or verification results demonstrates deviations, appropriate corrective action should be taken and the finished product should not be released until adequate investigation has

shown that it complies with appropriate specifications.

Salmonella is the highest priority infectious foodborne hazard and its control in RUTF paste is the most important microbiological food safety programme goal. Particular attention to *Listeria monocytogenes*, *Clostridium botulinum* and *mesophilic aerobic bacteria* shall also be considered ("Microbial safety of Ready-to-Use Lipid based Therapeutic and Supplementary Foods - Technical meeting", summary report released on the 6th March 2013, FAO and WHO).

The manufacturer undertakes ingredient, environment, in-line, and end-product surveillance for *salmonella* and *enterobacteriacea* (EB) initially, to establish baseline statistics (12 months of data collection) and then to monitor process control by reviewing trends.

The manufacturer shall have an adequate environmental monitoring programme in place, including product contact surface, in-line product surveillance, with investigation to assure adequate process control and hygiene

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

- **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	<10 ppb
Organochlorine	<10 ppb
Organophosphorus	<10 ppb
Pyrethroid	<10 ppb

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	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.* **Heavy metals** Arsenic <0.06 mg/kg Cadmium <0.03 mg/kg Lead <0.1 mg/kg Mercury <0.02 mg/kg - **Radioactivity** This risk is managed by using only ingredients certified free of radioactivity. The nuclear radiation level shall meet the values valid in the area of 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* **Pesticides, radioactivity and heavy metal contamination should be checked in the finished product once a year.** **Other contaminants** The product shall be free from residues of hormones, antibiotics and pharmacologically active substances.
8) Stability	There shall be no more than slight oil separation throughout the shelf life of the product. Stability studies must verify every 6 months (Save the Children can require more frequent testing): • Organoleptic stability – in terms of taste, odour, product consistency and behaviour. • Nutrient stability – maintenance of a level of vitamins and minerals over or within specified levels for at least one water soluble and one fat soluble micronutrient every 6 months. • Demonstrate absence of microbiological growth. • Stability of oils and fatty acids – verify absence of oxidation. • Integrity of packing materials. • For details on how to conduct stability study refer to WHO guidelines on Stability testing of active pharmaceutical ingredients and finished pharmaceutical products (Annex 2).

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9) Quality Assurance	All processing and drying shall be carried out in a manner that minimizes loss of nutritive value, particularly protein quality and vitamin content. The variation of the final product with respect to contents of moisture, protein, fat and micronutrients shall not exceed plus or minus 5% of the original value using standard analytical techniques. Products not meeting this requirement are liable for rejection Supplier must have registered the products in its intended countries of supply, in order to facilitate import and use of product. Suppliers must ensure that the use of the goods sold under this contract does not infringe any patent, design, trade name or trademark. Products must be manufactured in accordance with the Codex Alimentarius applicable references and GMPs (Good manufacturing practices). 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. Prerequite programs including environmental monitoring programs must be implemented. Applicable standards reference: · *Recommended International Code of Practice. General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003* · *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. CAC/RCP 66 - 2008* · *ISO 22000:2005 - Food safety management systems – Requirements for any organization in the food chain.* The manufacturer is responsible to elaborate an analytical plan of finished product. All analytical test procedures must be described in sufficient details, including microbiological methods. ISO 17025 certified laboratories shall be preferably used. Suppliers must ensure that the use of the goods sold under this contract does not infringe any patent, design, trade name or trademark - **Validation of the process and coefficient of variation** The coefficient of variation, calculated using the method proposed by WFP[5], shall be as low as possible, and always <10. - **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, customers sites delivered).

[5] For calculator refer to: http://foodqualityandsafety.wfp.org/coefficient-of-variation-calculator.

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	- **Batch size** The batch size shall not exceed 200 Mtons and one week of production. - **Specific prohibition** The product and its components shall not have been treated by ionizing radiation.
10) Documents to provide	• **Complete analysis** The manufacturer must conduct a complete analysis of the finished product in order 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. • **Certificate of Analysis** A confirmatory Certificate of Analysis from the supplier should be available at least for the duration of the shelf life of all batches of finished products in which the ingredients and excipients are used. Customer should be notified and approve of any changes in ingredient and excipient sources and finished product specifications. Customer should be notified and approve of any changes in all sources, routes of synthesis and/or specifications. 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 manufacturer must establish its own finished product specification and clearly state the amount and frequency of testing of each ingredient, microbiological contamination, chemical contamination, and other relevant points to be controlled. Suppliers will be required to submit a Certificate of Analysis from the manufacturer's own quality control laboratory covering each batch delivered along with shipping documents. Supplier should have done an acceptability study with favourable outcome in at least 1 country, preferably in multiple countries in various parts of the world. Suppliers will be required to submit a Certificate of Analysis from the manufacturer's own quality control laboratory covering each batch delivered along with shipping documents. The Certificate of Analysis should include: • Order number • Batch number • Batch quantity • Date of manufacture • Expiry date (dd/mm/yyyy) • Date of test (dd/mm/yyyy) • Contents of dosage form per unit package • Description (clarity, colour, etc.)

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- All attributes necessary for the quality control of the type of product, including identity, content (assay), dissolution, sterility, pyrogenic and if applicable all other test required by the specified pharmacopoeia.
- Both the actual results and the limits for the individual tests should be given.

The batch cannot be released if there is a failure to meet the following criteria:

Nutritional value and nutrients

Moisture content <2.5%
Energy value 520-550 kcal/100g (on the certificate of conformity)
Proteins: 10 % - 12 % of energy
12.8-16.2% by weight
Lipids: 45% - 60% of energy
25.8-36.3% by weight
Ash content 3-4% by weight
Vitamin A 1.2 mg RE[6]
At least one tracer per premix[7]

Microorganisms	n	c	m	M	p	Method
Salmonella	25	0	0/25g	N/A	2	ISO 6579
Enterobacteriacea(EB at 30°C)	10	2	10/g	100/g	3	ISO 21528-2

with n,c, m, M and p as defined above

Mycotoxins (g)
Total Aflatoxins <5 ppb max.

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

Other certificates required (on demand only)
• Certificate of Origin
• Certificate of Conformity
• Health Certificate (issued by independent regulatory authority)
• Certificate of non-radioactivity
• GMO Free Certificate (when applicable

REFERENCES:

- MSF Specs
- UNICEF: http://www.supply.unicef.dk/catalogue
  WHO: http://www.who.int/nutrition/publications/en/manage_severe_malnutrition_eng.pdf

[6] The vitamin A has been found as the best tracer for lipid based vitamin. Vitamin A content must be checked as WHO recommends not supplementing vitamin A anymore for children suffering from SAM because it is already in the RUTF.

[7] The Certificate of Analysis for each batch of product should provide test results of representative tracer in the finished product for at least one vitamin and one mineral from the following list: Calcium (300-600 mg), Copper (1.4-1.8mg), Iron (10-14 g /100 g), Magnesium (80-140 mg), Potassium (850-1200 mg/100 g), Phosphorus (300-600 mg), Zinc (11 to 14 mg/100g), Vitamin A (0.8-1.1mg /100 g), Vitamin C (50 mg minimum) and Vitamin D (15-20 micrograms).

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