Specification

Ready to use Therapeutic Food paste

Product requirements		
Ingredients	**Specifications**	**Applicable Standards**
Peanut or peanut paste	- select the source of peanut and/or peanut paste to prevent aflatoxin contamination	*Codex STAN 200–1995: Codex Standard for Peanuts*
Dairy powder products	- Minimum 50% proteins are from full cream, skimmed milk, or whey powder	*Codex STAN 207-1999 - Codex Standard for Milk Powders and Cream Powder and/or* - *Codex STAN 289-1995: Codex Standard for Whey Powders*
Oil	- Edible refined vegetable oil - Omega 3 and Omega 6 as stated in the nutritional table available in the Product General Information.	*Codex STAN 210-1999: Codex Standard for Named Vegetable Oils*
Carbohydrates (sweetener)	- Lactose and glucose polymers - Honey is prohibited - The following carbohydrates are acceptable: Lactose, Sucrose, Fructose, Maltodextrin, Precooked and/or gelatinized starches - Attention to the granulometry since it may influence stability of the product and oil separation	- *Codex STAN 212-1999: Codex Standard for Sugars*
Vitamins and Minerals premix	- supplied by a specialized premix supplier with full certificate of analysis - Storage maximum temperature: 20°C - Record frequent measurements of the coefficient of the variation related to the mixing step	- *Codex Standard CAC/GK 09-1987 General principles for the addition of essential nutrients to foods*
Physico-chemical composition of the final product	**Specifications**	**Recommended Method**
Organoleptic	light brown coloration, no off-flavour or odour, smooth and homogeneoux texture (no grittiness, no lumps)	
Protein	- 12.8-16.2% by weight	- AOAC 991.20

Lipid	- 25.8-36.3% by weight	ISO 17189
Vitamin A	- 0.8-1.2 mg RE for 100g of product	EN 12823-1 2014
Vitamin C	- 50 mg minimum for 100g of product	EN 14130:2003 AOAC 2012.21 AOAC 985.33
Iron (Fe)	- 10-14 mg	AOAC 990.05 ISO 8294
Additives		
Emulsifier	- Lecithin: max 0.5g/100g - Mono/Diglycerides: max 0.15g/100g	*CODEX STAN 073-1981 – Acceptable emulsifiers for canned baby foods intended for infants and young children as specified*
Flavouring	- Artificial flavours are prohibited. - Only natural flavours can be added.	
Antioxidants	Butylhydroxyanisol (BHA) and Butylated hydroxytoluene (BHT) are prohibited. Allowed antioxidants are Ascorbyl palmitate and mixed tocopherols	
Shelflife		
shelf life	24 months when stored up to 30 degrees 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 the range defined in the above **Erreur ! Source du renvoi introuvable.** of the final product - There shall be no more than slight oil separation throughout the shelf life of the product.

Microbiology

"Microbiological safety of Ready-to-use Lipid Based therapeutic and supplementary Foods- Technical meeting" summary report released on March 6th 2013, FAO and WHO.

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)

Microbiological criteria

The batch shall not be released if there is a failure to meet the criteria related to Salmonella and Enterobacteriaceae defined below. *In the Microbiological plans defined below*

- n: number of sampling units to be taken
- c: 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 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 in a 3-class plan, separates from marginally acceptable quality to defective quality
- p: define the plan (2 or 3 class plan)

Salmonella	**Max level: 0/25g following a 2-class plan** - n = 30 - p = 2; - c=0; - m = 0/25g (e.g. absent in 25g) maximum allowable number of defective sample: 0 out of the 30 samples tested	ISO 6579 - *Lab sample shall be prepared by pooling with a pool of max 375g* 25g analytical unit, samples may be pooled dry, by the accredited laboratory, if laboratory method has been validated. The total analytical unit should be 750g
Enterobacteriaceae	**Max level :** ≤10cfu/g **following a 3-class plan** - n = 10 - p = 3 - c= 2 - m ≤10cfu/g	ISO 21528-2 - *No composite sample* - 10g analytical unit, no pooling

	- M: ≤100 cfu/g The lot can be released if : - Each of the 10 samples analysed has a level of Enterobacteriaceae which is ≤10 cfu/g - Maximum 2 samples analysed has a level of Enterobacteriaceae which is ≤100 cfu/g. The rest of each sample analysed have a level of Enterobacteriaceae which is ≤10 cfu/g.	

Contaminants		
CAC/RCP 49-2001: Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals. *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.* *COMMISION REGULATION (EU) No 594/2012 of July 2012 amending Regulation (EC) 1881/2006 as regards the maximum levels of the contaminants ochratoxin A, non-dioxin like PCBs and melamine in food stuffs*		
Pesticides	*CODEX STAN 229-1993, REV.1-2003: Analysis of Pesticide Residues: Recommended Methods*	Carbamates < 10ppb Organochlorine < 10 ppb Organophosphorus < 10 ppb Pyrethroid < 10 ppb
Heavy metals	*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.*	Arsenic <0.06 mg/kg Cadmium <0.03 mg/kg Lead <0.1 mg/kg Mercury <0.02 mg/kg
Radioactivity		Only ingredients certified free of radioactivity can be used. If the limits are not defined, the value must not exceed 370bq/kg max (Cs 134&Cs137)
Melamine	*COMMISSION REGULATION (EU) No 594/2012 of 5 July 2012*	must not exceed 1mg/kg

	amending Regulation (EC) 1881/2006 as regards the maximum levels of the contaminants ochratoxin A, non dioxin-like PCBs and melamine in foodstuffs	
Other contaminants		The product should be free from residues of hormones, antibiotics and pharmacologically active substance
Aflatoxin	Total Aflatoxins 5ppb max	ISO 16050

Packaging	
Primary package	Food-grade sachets, hermetically sealed and robust enough to prevent leakage and to 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 mouth. In particular, 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 must be free of wrinkles, occluded matter, or evidence of entrapped moisture or grease.
Secondary package	New double walled corrugated carton of 750g/m² +/-50g, containing 567 sachets of 20g each, with no empty space. Net weight: 11,34kg per carton. Carton edge crush resistance: 11 kN/m. 60% of the edge crush resistance shall remain at 90% relative humidity and 40°C. Stacking resistant to a height of 2.4m.
Inside containers	Slip sheet or plywood shall be used to provide maximum stacking strength. Pallets with appropriate stacking configuration could also be used.
Leaflet	Each carton must contain a leaflet in English (and other language as per contract) including the protocol and instructions for use, and the information as per table below.

Labelling			
Codex STAN 146-1985 : General standards for the labelling of and claims for pre-packaged foods for special dietary uses *Codex STAN 1-1985 : General standard for labelling of pre-packaged foods*			
	Sachets	**Inside leaflet**	**Outside box**
Commercial name	Shall be kept simple		
Product Name	RUTF : Ready-to-use Therapeutic Food		
Target use	For children > 6 months with Severe Acute Malnutrition		
Net Weight	92g	-	150 X 92g (13.8kg)
Nutrients content	-	Nutritional composition	
Ingredient list	filled by manufacturer		-
Storage instruction	" Best stored below 30 degrees, in dry and hygienic conditions"		
Manufacturer name	Produced by: filled by manufacturer		
Manufacturer address	filled by manufacturer, including country of origin		
Manufacturer batch/lot number	filled by manufacturer	-	filled by manufacturer
Production date	filled by manufacturer	-	filled by manufacturer
Best before Date	filled by manufacturer	-	filled by manufacturer
Other	-	"not for sale or exchange" "Contains no ingredients of animal origin besides dairy products"	
Donor and logo	-	as per contractual agreement	
Colour coding	-		
Beneficiary feedback hotline (if required in the contractual agreement)	filled by manufacturer	-	filled by manufacturer


20%
No addition allowed, except HERE in the supplier zone
Supplier zone
10 to 15%
RUTF
PEANUT
ARACHIDE
Ready to Use Therapeutic Food
Aliment Thérapeutique Prêt-à-l'Emploi (ATPE)
For children >6months with Severe Acute Malnutrition
Pour les enfants atteints de Malnutrition Aiguë Sévère
50%
Red zone
1 sachet = 500 kcal
30%
1 Knead
Malaxer
2 Tear & open
Déchirer & ouvrir
3 Squeeze & Eat
Presser & Manger
Pictogram zone