Technical Specifications for

Micronutrient powder - children 12-23 months - Cuba

Specification reference: **SNFMNP000**
Version: **1, adopted 2017**
Date of issue: **05/12/2017**
Developed: **OSN - WFP**
Reviewed: **OSPFQ - WFP**

1. SCOPE

This specification applies to micronutrient powder (MNP) in 1 g sachets to be added once a day or less frequently (depending on program's instructions for use) in the normal meal of children between 12-23 months of age (note that programs may define more narrow age ranges).

2. REFERENCE and STANDARD

MNP shall be formulated and manufactured in accordance with latest version of recognized international standards and best practices and/or guidelines, such as:

- HF-TAG programmatic guidance brief on use of micronutrients powders (MNP) for home fortification[1]
- HF-TAG Quality Manual on Micronutrient Powders — A Guiding Document
- Codex Guidelines For Vitamin And Mineral Food Supplements CAC/GL 55
- Code of Practice for Food Premix Operations' (Pan American Health Organisation (FCH/NU/66)

3. PRODUCT SPECIFICATION

Sachets net weight: average sachets weight must be between 0.95 g and 1.05 g with a maximum coefficient of variance of 5%.

Carrier must be Corn maltodextrin with a DE 11-14 and max 5% loss on drying.

Anticaking agent must be Tri-calcium phosphate or Silicon dioxide with adequate particle size.

[1] Home Fortification Technical Advisory Group (HF-TAG). See http://www.hftag.org

Formulation and mixing

- All ingredients in the finished product should be appropriately formulated, and demonstrated to have overcome or significantly minimized any potential problems of bioavailability, stability and acceptability. Indeed, it is well known that interactions between micronutrients can negatively affect stability during storage, and interactions between micronutrients and food can positively or negatively affect bioavailability of one or more micronutrients.
- For all nutrients of the formulation, mixing and particle size must ensure that from one sachet to another, the maximum coefficient of variation is 20%.

Physical/organoleptic characteristics

- Taste must be bland and addition of the MNP must not significantly change the taste, colour or texture of the food.
- Powder must be homogeneous, stable and dry.
- Powder must be easy to mix uniformly with any semi-solid or solid food the child will eat.

Nutritional value: MNP must retain characteristics shown in table 1 during entire shelf life.

Table 1: Nutritional value per g:

Nutrients	**Label declaration per portion of 1 g**	**Nutrient source**
Vitamin A RE µg	400	Vitamin A palmitate 250,000 IU/g (beadlet), or Vitamin A acetate 325,000 IU/g (beadlet)
Folic acid µg	90[2]	Folic acid*
Vitamin C mg	30	Ascorbic acid fine powder
Iron mg	10	NaFeEDTA (2.5 mg) + Ferric pyrophosphate micronized (7.5 mg), or Coated ferrous fumarate (10 mg)
Zinc mg	4.1	Zinc sulphate, or Zinc gluconate

* Dilution must be used prior to blending in order to guarantee homogeneity

[2] Equivalent to 150 µg Dietary Folate Equivalent (DFE).

4. PACKAGING AND MARKING

Packaging material: The package must be leak proof, light enough for easy handling and transportation, and strong enough to withstand a reasonable amount of physical stress during shipment, storage and use, worldwide, at elevated temperatures and humidity. In addition:

- Foil used to produce sachets shall have the following composition PET 12/ Al 8 / PE 45 or equivalent and adequate barrier properties to protect product from moisture, light and Oxygen.
- Inside box shall be made of paperboard.
- Outside box shall be made of corrugated fiberboard.

Labeling

Finished products must be labelled in accordance with local design developed by WFP, if any, and with generic label requirement in an appropriate language (table 2 and annex 1). Production of premix and sachets shall only start when all labels/design of sachet, inside and outside box have been approved by WFP.

Table 2: generic label requirement:

	sachet	**inside box**	**outside box**
Product name	"Micronutrient powder - Children 12-23 months" or local appropriate name as per contractual agreement		
Net weight	1g	30 x 1g	200 x 30 x 1g (6kg)
Ingredient list	NA	XXX	
Nutrients content	NA	First 2 columns of table 1 (i.e. nutrient + amount)	
Preparation instruction	"One sachet per child per day" "Mix with food before consumption", together with a generic pictogram that shows how the powder is sprinkled onto a bowl of food (see annex 1)		NA
Storage instruction	NA	"Best stored below 30 C, in dry and hygienic conditions", "Store away from children"	
Manufacturer name	XXX		
Manufacturer address	NA	XXX	
Manufacturer batch/lot number and production date	XXX		
Best Before Date	Best Before day/month/year or Best Before end month/year		
Other	NA	"Not for sale"	
Donor and WFP logo	As per contractual agreement		

5. SHELF LIFE

Minimum durability: Unless stated otherwise in the contractual agreement, MNP sachets must have minimum 24 months shelf life when stored up to 30°C and 65%RH.

6. ANALYTICAL REQUIREMENTS

Analytical requirements shown in table 3 are defined, at the point of procurement, on a composite sample made from 30 sachets. As per contractual agreement, WFP will appoint an inspection company to perform these analyses and compare results with the minimum and maximum values stated in table 3.

Table 3: Analytical requirements at the point of purchase

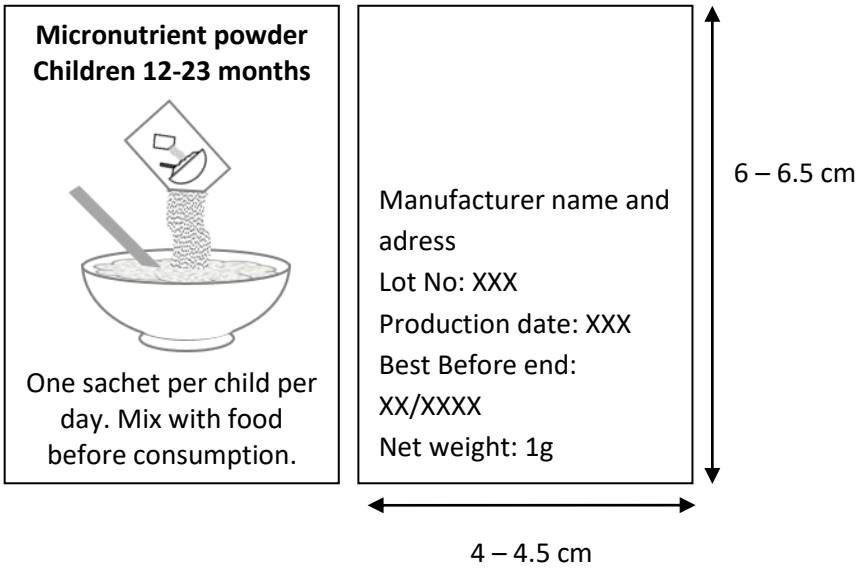
No	Test	Minimum per g	Maximum[3] per g	Reference method*
1	Vitamin A RE µg	400	640	HPLC
2	Folic acid µg	90	140	HPLC
3	Vitamin C mg	30	45	HPLC/Titration
4	Iron mg	10	14	ICP-MS
5	Zinc mg	4.0	5.6	ICP-MS

*or equivalent

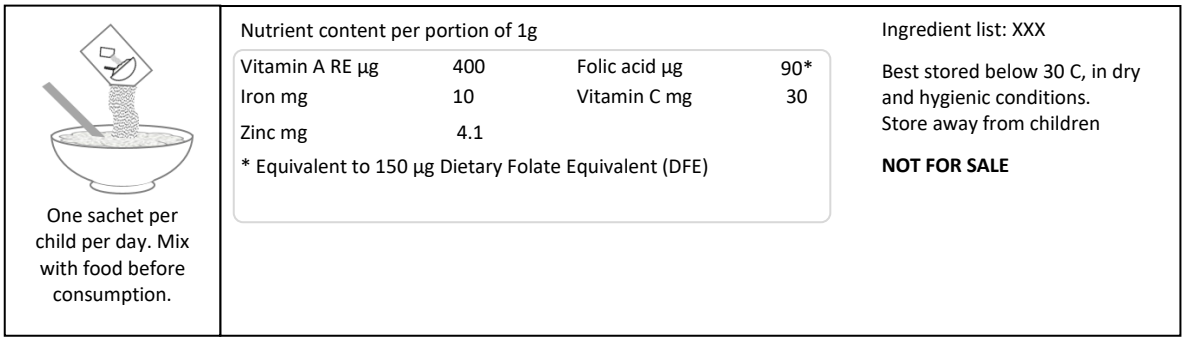
3 MNP must be formulated to guarantee minimum and maximum values all along shelf life. These maximum levels are below the Tolerable Upper Limit (UL) that may be still reached if other fortified foods are used, and MNP is consumed daily (this is often not the case, e.g. 10-15 sachets per month is more common). In that case, as explained in the HF-TAG Programmatic Guidance Brief (See http://www.hftag.org/resource/hf-tag_program-brief-dec-2011-pdf), it is important to keep in mind that: UL includes a safety margin and is conservative; the adverse effects that have been considered for setting the UL are associated with chronic intake, rather than with acute toxicity which occurs at much higher intake levels; where nutrient-nutrient interactions determined the UL (such as a higher zinc intake affecting copper status, or higher folic acid intake affecting vitamin B12 status), a concurrent increase of the intake of both micronutrients involved would allow a higher intake; the UL applies to normal, healthy individuals with adequate stores and no deficits to be corrected; recommended nutrient intakes for treatment of severe and moderate acute malnutrition exceed the UL for 3 nutrients that are also included in MNP (zinc, vitamin A, folic acid), which is considered safe and necessary for treatment.

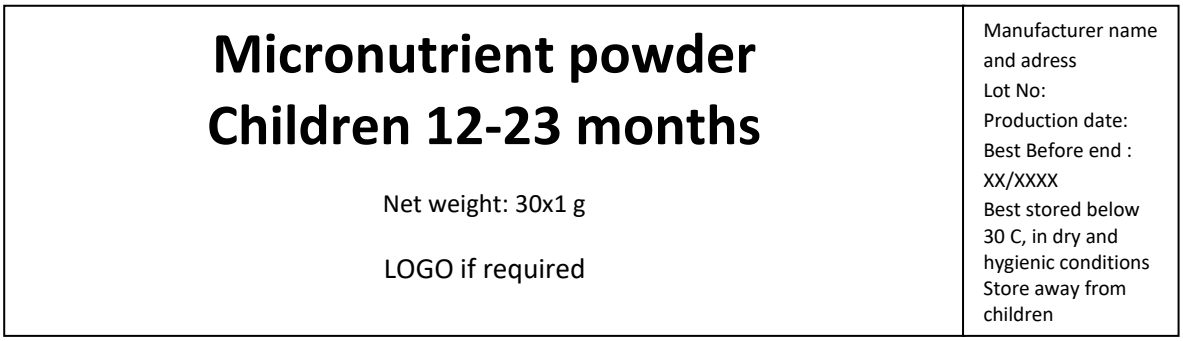
ANNEX 1: sachet and box design, including pictogram[4]

Sachet



Box





[4] Packaging dimensions are provided to harmonize packaging from the different supply sources. If existing production/packaging facility does not allow to follow recommended dimensions, supplier shall inform WFP through their offers during the procurement process.

Box configuration