World Food Programme

# Technical Specifications for

# MICRONUTRIENT POWDER (MNP) – CHILDREN 6-59 MONTHS (COLOMBIA)

Commodity codes: **MIXMNP040**
Version: **1, adopted 2020**
Replacing: **First Version – MNP 1-gram sachet**
Date of **OSCQ** issue: **31.01.2020**

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## 1. SCOPE

This specification applies to micronutrient powder (MNP) single-use 1-gram sachet to be added once a day or less frequently (depending on programme's instructions for use) in the normal meal of children between 6-59 months of age. MNPs are designed for point of use fortification of complementary foods for children to improve their intake of micronutrients and prevent anaemia and vitamin and mineral deficiencies.

## 2. REFERENCES AND STANDARDS

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

- WHO guideline: use of multiple micronutrient powders for point-of-use fortification of foods consumed by infants and young children aged 6–23 months and children aged 2–12 years[1]
- Ministry of Health- Govt of Colombia Resolution No. 3280 of 20183280[2]
- HF-TAG programmatic guidance brief on use of micronutrients powders (MNP) for home fortification
- HF-TAG Quality Manual on Micronutrient Powders — A Guiding Document[3]
- HF-TAG Manual on Micronutrient Powder (MNP) Composition, July 2013
- Codex Guidelines for Vitamin and Mineral Food Supplements CAC/GL 5
- Code of Practice for Food Premix Operations' (Pan American health Organisation (FCH/NU/66)
- Recommended International Code of Practice: General Principles of Food Hygiene", CAC/RCP 1-1969 Rev 3 1997 Amended (1999) including Annex "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its application".

## 3. PRODUCT SPECIFICATION

### 3.1 Raw Material

All materials used shall be of food or pharmaceutical grade and their selection and approval shall take into consideration origin, transport, storage, processing, handling and the intended use of the finished product.

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[1] https://apps.who.int/iris/bitstream/handle/10665/252540/9789241549943-eng.pdf;jsessionid=04627F286E77381A5FAE9C4A93A3CE90?sequence=1
[2] https://www.minsalud.gov.co/Normatividad_Nuevo/Forms/DispForm.aspx?ID=5333
[3] Home Fortification Technical Advisory Group (HF-TAG). See http://www.hftag.org

### 3.2 Vitamins and Minerals

Vitamins and minerals used in the premix shall correspond to the monographs of the latest additions of official pharmacopoeias: BP, Ph.Eur, Ph.Int, USP. MNPs shall meet food chemical codex (FCC) for identity and Purity criteria and in case countries require that they meet Halal requirements, WFP may request that certification is provided for these countries.

### 3.3 Excipients – Carrier and anticaking agent

The formulation shall be in the base of dextrose anhydrous maltodextrin (DE 11-14) or another suitable carrier, with the addition of silica dioxide, tricalcium phosphate or other suitable flow agents. Excipients shall meet the requirements of not more than 5% moisture (loss-on-drying) and shall comply with FCC Standard and the International Pharmacopeia monograph for Oral powders.

**3.4 Nutritional value:** MNP shall retain characteristics shown in table 1 during whole shelf life. Consideration of addition rates (overage) to account for shelf life degradation.

*Table 1: nutritional value:*

| **Nutrients** | **Composition per one-gram sachet** | | **Nutrient source – chemical form** |
|---|---|---|---|
| Vitamin A | µg RE | 300 | As dry CWS Vitamin A acetate or palmitate beadlets |
| Vitamin C | mg | 30 | Ascorbic acid fine powder |
| Vitamin D | µg | 5 | As dry CWS Cholecalciferol |
| Vitamin E | mg TE | 6 | As CWS d or dl-alpha tocopheryl acetate |
| Vitamin B1 | mg | 0.5 | Thiamine mononitrate |
| Vitamin B2 | mg | 0.5 | Riboflavin fine powder or Riboflavin 5 Phosphate |
| Vitamin B6 | mg | 0.5 | Pyridoxine hydrochloride |
| Vitamin B12 | µg | 0.9 | Cyanocobalamin (1% or 0.1%) |
| Folic acid | µg | 160 | Folic acid |
| Niacin | mg | 6 | Niacinamide |
| Iron | mg | 12.5 | NaFe EDTA (2.5mg) + 10mg from other iron source (micronized ferric pyrophosphate / encapsulated ferrous fumarate / bisglycinate), alternatively it can be 12.5 from ferrous bisglycinate or encapsulated ferrous fumarate |
| Zinc | mg | 5 | Zinc gluconate or Zinc aminoqulated |
| Copper | mg | 0.3 | Copper gluconate or copper sulphate |
| Iodine | µg | 90 | Potassium iodide* |
| Selenium | µg | 17 | Sodium selenite |

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

### 3.5 Physical and organoleptic characteristics

- Product should be a fine, off white (slightly yellow), odourless powder without segregation.
- Taste shall be bland and addition of the MNP shall not significantly change the taste, colour or texture of the food.
- Powder shall be homogeneous, stable and dry.
- Powder shall be easy to mix uniformly with any semi-solid or solid food the child is eating.

### 3.6 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.
- For all nutrients of the formulation, mixing and particle size shall ensure that from one sachet to another, the maximum coefficient of variation is 10%.

- To minimize water content of the formulation anhydrous forms of vitamins and minerals are preferable. The product should be manufactured in a humidity-controlled environment and the sachet filling done under nitrogen or with limited exposure to air. Some nutrients may require microencapsulation to ensure shelf life, to help prevent oxidation through nutrient-nutrient or nutrient-food interactions and to minimise bitter and metallic tastes within the formulation. This is particularly relevant for iron and Vitamin C.
- As the powder could be heterogenous in its particle size, segregation of the powder needs to be carefully monitored during production. The beadlet ingredients (vitamin A) and encapsulated ingredients have a high propensity to segregate within the powder mixture.

### 3.7 Food Safety and risk assessment at manufacturing premises

The product shall be manufactured within a quality and food safety management environment in accordance with 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), and the 'Code of Practice for Food Premix Operations' (PanAmerican health Organization (FCH/NU/66).
Other standards and food safety approaches such as ISO, GMP and HACCP (Annex 5 of the U.S. Department of Health and Human Services, and FDA 199 Food Code) are highly recommended. Pharmaceutical companies manufacturing this product shall comply with a Quality Management System commensurate with Good Manufacturing Practice (GMP) according to WHO (Technical Report Series 986, 2014).
The manufacturer shall respect the national and international code practice for processing of this commodity. The producer shall be registered under national food law as a processor of foods for human consumption.
For compliance with Codex standards the processor shall be able to demonstrate by principle and practice the adoption, implementation and recording of:

- Good Manufacturing Practice
- Hazard Analysis Critical Control Point program

In this context an appointed WFP staff/ WFP appointed Inspector / Quality Surveyor is entitled to visit the factory without prior notice during any period when WFP product is being manufactured to check that the production is done as per contract specification. The Inspector / Quality Surveyor may request to see:

- **Records** (i.e. names of people in charge of the process and quality control, temperatures of the process, mixing times / net contents, cleaning schedules, CCP monitoring, traceability etc.).
- **Procedures** (e.g. cleaning, personnel hygiene, risk assessment and HACCP, environmental monitoring programme, sampling & analysis, product release and control of non-conformance etc.).
- **Instructions** (e.g. process instructions, cleaning instructions, zoning instructions etc.).
- The **quality manual** for the process or factory.
- Conditions in the factory (process rooms, warehouses, laboratories, cloakrooms, factory grounds, utility rooms, etc.)

### 3.8 Statement of quality

WFP enforces strict quality standards starting from raw materials to movement of the finished product throughout the supply chain. Quality refers to the bioavailability, chemical, microbiological, physical and stability attributes that a product should maintain if it is to be deemed suitable for intended use. The manufacturer shall present a CoA of the final product to be delivered for each shipment

### 3.9 Safety and contaminants

MNPs shall be free from objectionable matter. It shall not contain any poisonous or deleterious substances, including microbial contaminants, anti-nutritional factors, heavy metals or pesticides in amounts that may represent a hazard to health, and with microbiological limits. Heavy metals, residual solvents and other contaminant levels need to meet the limits as set out by the current USP, BP, Ph. Eu or Pharmacopeia Int.

***Reference Standards***

- USP 2021, Microbial Enumeration Tests - Nutritional and Dietary Supplements USP http://www.usp.org/dietary-supplements/reference-standards & (http://www.pharmacopeia.cn/v29240/usp29nf24s0_c2021.html)
- USP, Elemental Impurities - Limits http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/keyissues/232_ElementalImpuritiesLimits.pdf
- USP, General Chapter on Inorganic Impurities: Heavy metals http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/2008-04-10InorganicImpuritiesStim.pdf
- Elemental Contaminants in Dietary Supplements: http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/keyissues/2232_elemental_contaminants_in_dietary_supplements.pdf

### 3.10 Uniformity of Content and Mass

WFP requires suppliers to adhere to the standards for uniformity of content and mass as set out in the WHO monograph for oral powders: http://apps.who.int/phint/en/p/docf/

## 4. OTHER REQUIREMENTS

***Halal and Kosher Vitamins***

Sources of vitamins and minerals can contain animal products. Certain countries may request halal or Kosher certificates for products, WFP may request that certification is provided for these countries. Specific attention shall be paid to vitamin A and D as these are often manufactured using animal products as excipients.

***GMO free requirements***

Many countries request that imported products are GMO free. Naturally derived vitamin E and corn derived maltodextrin may be manufactured from GMO soy or corn and thus could lead to custom delays without adequate certification. WFP may request GMO free certification if required by the recipient country office.

***Additional requirements***

WFP may request additional information when required.

- Specifications and CoA's for all raw materials used in production.
- Last date of audit performed on each raw material supplier, information on who performed the audit.
- Mixing records (amount of raw material added in the mix, confirmation that mixing is performed as per recipe).
- Mixing validation documents (Coefficient of Variation).
- CoA's for final product (internal and external laboratory, all parameters of specification analysed at least in external laboratory)
- ISO 17025 certificate with full scope of accreditation for external laboratory used for analysis (for both raw materials and final product).

## 5. PACKAGING AND MARKING

### 5.1 Primary packaging

MNP powder shall be packaged in food-grade flexible sachets, hermetically sealed and robust enough to withstand multiple handling & transport and protect the product throughout its shelf life. Sachet material shall not represent a hazard for children when sachets is opened and put in contact with the mouth.

Each package shall contain 1 gram of MNP. Weight and quantity tolerance shall meet The International Organization of Legal Metrology International Recommendation OIML R 87[4].

It is the responsibility of the manufacturers to select a packaging material that will protect the MNP powder from moisture as well as from vitamin and fat degradation during the required 24-months of shelf life.

Sachets shall be:

- Food grade materials compliant with the last amendments of national regulations in the country of production (if not existing: compliance with EU or FDA legislations requested).
- Properly sealed (test example: ASTM F2338 – 09, ASTM D3078 – 02 or equivalent)
- The sachets shall be placed in an appropriate way in the carton box during the packing process to avoid packaging & product damage
- The laminate shall include a high barrier layer to highly reduce permeability of oxygen and water vapour

Typically, a laminate composed of PET/ Al 8 / PE (total typical thickness 65) or equivalent can be used.

### 5.2 Secondary packaging

30 Sachets shall be firstly packed inside a cardboard case. Secondly the cases shall be packaged inside a corrugated box: Corrugated box shall be:

- New, manufactured from well-constructed double walled corrugated board
- With an edge crush resistance of 45ECT = 45 lbs/in eq 8 kN/m (ISO 3037) and a specific weight of 700 to 1000 grams per square meter
- Fully filled for maximum strength
- The fluting shall be vertical, supporting the load
- The carton should be plain brown
- Dimensions adjusted to the load
- No stapling will be accepted

Unless otherwise specified in the contract, two percent empty, marked cartons (included in the price) shall be sent with the lot.

### 5.3 Tertiary packaging

If pallets are used inside containers: it is highly recommended to have 3 first bottom layers placed as column stacking, the rest can be interlocked (cross-stacking) for load stability. Pallet shall be wrapped in a suitable manner (locked to the pallet, enough containment force) and the cartons should be banded when necessary. The cartons shall be secured to pallets in order to prevent any damage to the contents or packaging during shipment. Pallet used should be strong enough to support the charge during transportation. Pallets shall be stackable (minimum double stock) without damage to the cartons during shipment.

If no pallets are used inside container: dunnage (of strong sheets such as carton, plywood) should be placed inside each container at every three layers of cartons to provide the required stacking strength. In addition,

[4] OIML R 78 Quantity of commodity in prepackages https://www.oiml.org/en/files/pdf_r/r087-e04.pdf, latest edition to be followed

protecting material like air bag, carton, polystyrene, can be used. Also, kraft paper shall be adhered to all internal sides, door, and floor of container. Kraft paper also need to be placed on the top of packaging.

For shipping containers, unless fully shrink-wrapped pallets are used, and unless otherwise specified in the contract, it is highly recommended to place desiccant in container at appropriate location in order to absorb moisture. Supplier needs to use high quality desiccant and calculate the quantity of desiccant based on:

- Efficiency of desiccant
- Length of time in transit in container
- Container capacity

Supplier needs to provide in the offer the type of desiccant and quantity to be used for the consignment.

*Table 2: Guideline on the quantity to be used for calcium chloride-based desiccants:*

| Estimated days in container | 20 ft container | 40 ft container |
|---|---|---|
| 15-59 days | 9.00 kg | 17.50 kg |
| 60-89 days | 11.25 kg | 22.50 kg |
| 90-120 days | 13.50 kg | 25.00 kg |

*Better alternative material can be used upon agreement with WFP.*

Empty containers/vehicles shall be clean, pest free and free of damage, odours and previous cargo remains.

### 5.4 Marking

Finished products shall be marked in accordance with local design developed by WFP, if any, and with generic label requirement in an appropriate language (table 3 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 3: Generic marking requirement:*

| | sachet | inside case | outside box |
|---|---|---|---|
| Product name | "Micronutrient powder – Children 6-59 months" or local appropriate name as per contractual agreement | | |
| Net weight | 1g | 30 x 1g | 200 x 30 x 1g (6kg) |
| Ingredient list | NA | XX[5] | |
| Nutrients content | NA | As per table 1 and contractual requirement (i.e. nutrient + content per portion or per sachet) | |
| 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 *(Follow storage instructions from the producer, clearly marked on cartons)* | NA | "Best stored below 30 C, in dry and hygienic conditions", [6] "Store away from children" | |
| Manufacturer name | XX | | |
| Manufacturer address | NA | XX | |
| Production date | Date/month/year | | |
| Best Before End | Best Before end: month/year | | |
| Manufacturer batch/lot number | XX | | |
| Other | NA | "not for sale" or as per contractual agreement | |
| Donor and WFP logo | As per contractual agreement | | |

[5] All XX shall be provided by the manufacturer.

[6] Follow storage conditions as specified by the manufacturer.

## 6. SHELF LIFE

Minimum durability: Unless stated otherwise in the contractual agreement, MNP sachets shall have minimum 24 months shelf life when stored up to 30°C and 65% Relative Humidity. Shelf life studies shall demonstrate the product has levels of all nutrients within specification at minimum 24 months at those conditions as the product will be delivered to countries with hot and humid climates.

Please refer to the WHO guidelines for Stability testing: Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. World Health Organization WHO Technical Report Series, No. 953, 2009 http://apps.who.int/medicinedocs/en/d/Js5517e/12.html

## 7. ANALYTICAL REQUIREMENTS

Analytical requirements shown in table 4 are defined, at the point of procurement, on a composite sample made from 20 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 4: analytical requirement at the point of purchase*

| No | Test | Unit | Minimum per g | Maximum[7] per g | Reference method* |
|---|---|---|---|---|---|
| ***Micronutrients*** | | | | | |
| 1 | Vitamin A | RE µg | 270.00 | 495.00 | HPLC |
| 2 | Vitamin C | mg | 27.00 | 45.00 | HPLC/Titration |
| 3 | Vitamin D | µg | 4.50 | 7.50 | HPLC |
| 4 | Vitamin E | TE mg | 5.40 | 9.00 | HPLC |
| 5 | Vitamin B1 | mg | 0.45 | 0.75 | HPLC/Microbiology |
| 6 | Vitamin B2 | mg | 0.45 | 0.75 | HPLC/ Microbiology |
| 7 | Vitamin B6 | mg | 0.45 | 0.75 | HPLC |
| 8 | Vitamin B12 | µg | 0.81 | 1.35 | HPLC/Microbiology |
| 9 | Folic acid | µg | 144.00 | 208.00 | HPLC |
| 10 | Niacin | mg | 5.40 | 7.50 | HPLC |
| 11 | Iron | mg | 11.25 | 15.63 | ICP-MS |
| 12 | Zinc | mg | 4.50 | 6.25 | ICP-MS |
| 13 | Copper | mg | 0.27 | 0.38 | ICP-MS |
| 14 | Iodine | µg | 81.00 | 144.00 | ICP-MS/HPLC |
| 15 | Selenium | µg | 15.30 | 27.20 | ICP-MS/HPLC |
| ***Microbiology*** | | | | | |
| **No** | **Test** | | **Limit** | | **Reference method** |
| 16 | Total Aerobic Count | | Max. 1000/ g | | USP 2021/2022, Microbial Enumeration Tests - Nutritional and Dietary Supplements |
| 17 | Yeast and moulds | | Max. 100/ g | | |
| 18 | Escherichia Coli | | Negative in 10g | | |
| 19 | Salmonella spp. | | Negative in 50g | | |
| 20 | Staphylococcus aureus | | Negative in 10g | | |

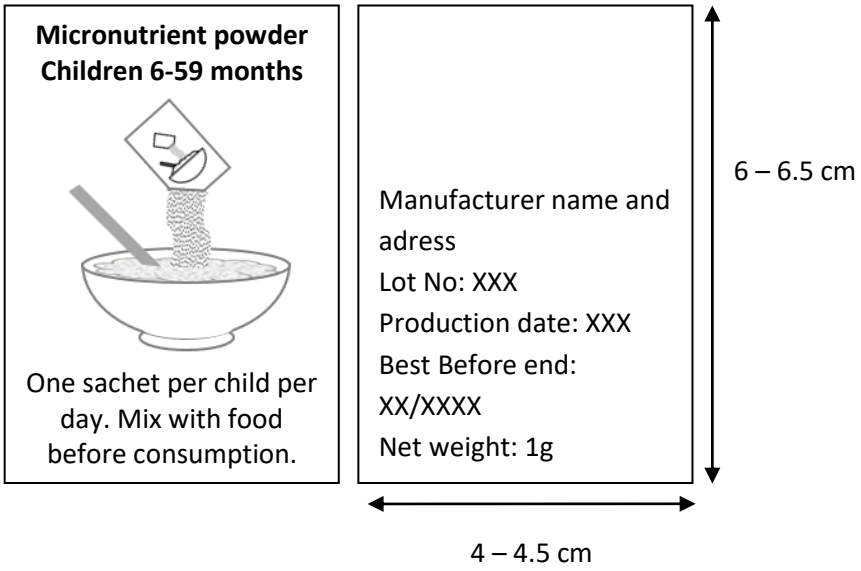
**or equivalent validated method*

Note: Minimum and maximum values include consideration of uncertainty limits and variation in the mixing blend.

[7] MNP shall 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 case design, including pictogram[8]

**Sachet generic design:**
*Dimensions are recommended only*




**Cardboard case**

One sachet per child per day. Mix with food before consumption.

| Nutrient content per portion of 1g | | | |
|---|---|---|---|
| Vitamin A RE µg | 300 | Folic acid µg | 160 |
| Vitamin C mg | 30 | Niacin mg | 6 |
| Vitamin D µg | 5 | Iron mg | 12.5 |
| Vitamin E TE mg | 6 | | |
| Vitamin B1 mg | 0.5 | Zinc mg | 5 |
| Vitamin B2 mg | 0.5 | Copper mg | 0.3 |
| Vitamin B6 mg | 0.5 | Iodine µg | 90 |
| Vitamin B12 µg | 0.9 | Selenium µg | 17 |

Ingredient list: XXX

Best stored below 30 C, in dry and hygienic conditions. Store away from children

**NOT FOR SALE**

# Micronutrient powder Children 6-59 months

Net weight: 30x1 g

LOGO if required

Manufacturer name and adress
Lot No:
Production date:
Best Before end : XX/XXXX
Best stored below 30 C, in dry and hygienic conditions Store away from children

[8] 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.