unicef	**PRODUCT SPECIFICATIONS SHEET** **Multiple Micronutrient Powder (MNP) 15 component**

General Description:

UNICEF stock number: S1580201 Multiple micronutrient pdr,sach./PAC-30
UNICEF stock number: S0000225 Multiple micrn. pdr,custom sach./PAC-30

Multiple Micronutrient Powder (MNP), 15 components, single-use 1 gram sachet, pack of 30 sachets. MNPs are designed for point of use fortification of complementary foods for children and vulnerable populations to address anaemia and vitamin and mineral deficiencies.

Indications:
Micronutrient supplementation/food fortification in emergencies;
Micronutrient supplementation/food fortification in complementary foods for breast-fed infants.
Micronutrient supplementation/food fortification for young children where dietary micronutrient intakes are insufficient.

Target Group
Multiple micronutrient powder is used for children aged 6 - 59 months.
Primary target: children aged 6 -24 months.

Technical Specifications

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

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 may need to meet Halal and Kosher requirements (See appendix 1).

Excipients:
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 6% moisture (loss-on-drying) and shall comply with FCC Standard for food additives (1.3.4) and the latest International Pharmacopeial monograph for Oral powders. Single nutrients contained within the MNP formulation that require antioxidants as excipients to prevent oxidation, shall be approved for use in young children.

Composition per one gram sachet

Vitamin A 400 µg (as dry CWS vitamin A acetate or palmitate beadlets)
Vitamin C 30 mg (as sodium or calcium ascorbate)
Vitamin D 5 µg (200IU) (as dry CWS Cholecalciferol)
Vitamin E 5 mg TE (as CWS d or dl-alpha tocopheryl acetate)
Vitamin B1 0.5 mg (as Thiamine mononitrate)
Vitamin B2 0.5. mg (Riboflavin or riboflavin -5-phosphate)
Vitamin B3 6 mg (as Nicotinamide)
Vitamin B6 0.5. mg (as Pyridoxine hydrochloride)
Vitamin B12 0.9 µg (1% or 0.1% Cyanocobalamin on a carrier)
Folic acid 90 µg (anhydrous)
Iron 10 mg (as coated Ferrous fumerate, NaFe EDTA*or Ferrous bisglycinate)
Zinc 4.1. mg (as Zinc sulphate, or gluconate)
Copper 0.56 mg (as Copper gluconate or sulphate)
Selenium 17 µg (as Sodium selenate or selenite or selenomethionine)
Iodine 90 µg (as Potassium iodide, or potassium iodate)
Maltodextrin q.s.

(See Appendix 2 for guidance on addition rates)

*Max 2.5mg of elemental iron from NaFeEDTA, the remaining 7.5mg of iron shall be added from another approved form

Physical and organoleptic characteristics
Fine, granular, segregation free, off white, slightly yellow, odorless powder with tiny speckles; having a bland taste which has minimal impact on the taste, smell or color of the food when mixed. The formulation shall be a stable, dry preparation that can be uniformly blended with the food the child is eating.

Formulation Notes:
To minimize water content of the formulation anhydrous forms of vitamins and minerals are preferable. The product shall be manufactured in a humidity controlled environment and the sachet filling shall be done under nitrogen or with limited exposure to air.
Some nutrients may require microencapsulation to ensure shelf life, help to prevent oxidation through nutrient-nutrient or nutrient-food interactions and to minimise bitter and metallic tastes within the formulation. This may be particularly relevant for vitamin C, iron and copper. However, the encapsulated ingredients should be a small particle size to minimise their visibility. For further guidance on the forms of vitamins and minerals used, please consult Home Fortification Technical Advisory Group's manual on micronutrient powder composition, July 2013, available at: http://hftag.gainhealth.org/sites/hftag.gainhealth.org/files/HF-TAG%20MNP%20Composition% 20Manual.pdf

Product Segregation:
As the powder could be heterogeneous in its particle size, segregation of the powder needs to be carefully monitored. The beadlet (vitamin A, D, E) and encapsulated ingredients have a high propensity to segregate within the powder mixture.

Safety:
Reference Standards:

- USP 2021, Microbial Enumeration Tests - Nutritional and Dietary Supplements
- USP 232 Elemental Impurities - Limits
- USP, General Chapter on Inorganic Impurities: Heavy metals

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 as detailed below:

Microbiological criteria:
Total CFU - max 10^3/g.
Yeast/molds - max 10^2/g.
Escherichia coli - negative in 10 g.
Salmonella sp - negative in 50 g.
Staphylococcus aureus - negative in 10 g.

Contaminants

Heavy metals, residual solvents and other contaminant levels need to meet the limits as set out by the current USP, BP Ph. Eu or Ph.Int.

USP <2232> Elemental Contaminants in Dietary Supplements:

Elements	**PDE* (µg/day)**
Arsenic (inorganic)	15 µg/day = 0.015mg/day/1g sachet
Cadmium	5 µg/day = 0.005mg/day/1g sachet
Lead	10 µg/day = 0.01mg/day/1g sachet
Mercury (total)	15 µg/day = 0.015mg/day/1g sachet
Methylmercury (as Hg)	2 µg/day = 0.002mg/day/1g sachet

*Permitted daily exposure.

Standard shelf life
Shelf life studies shall demonstrate the product has levels of all nutrients within specification at 24 months, preferably 36 months, in Zone IV B climatic conditions (temperatures of 30 degrees Celsius and 75% RH) as the product destinations 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

Uniformity of Content and Mass
UNICEF 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/

Analytical Requirements
Certificate of Analyse shall include tests of the following:
All the active components listed on the label
Microbiological criteria
Moisture (LOD) < 4.5%

Manufacturing Standard
Overall food safety management environment.
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 Codex Alimentarius 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 must comply with a Quality Management System commensurate with Good Manufacturing Practice (GMP) according to WHO (Technical Report Series 961).

Packaging
Primary packaging:
Packaging material shall guarantee proper hygiene and stability of the vitamin and mineral powder, following Codex Alimentarius Standards when applicable, and be made of material that is safe (at least food grade; e.g., complying with FDA/CFSAN, white list or with regulations from national health authorities).
Packaging material shall provide a barrier to light, air (oxygen) and moisture to ensure the product is stable for 24 months. Packaging to be made of aluminum-laminate: polyethylene-aluminum – printed polyethylene or PET or another suitable material.

Secondary packaging
Sachets shall be packed inside a cardboard box or a sealed bag made of aluminum laminate, polyethylene or a film coated bag. The secondary packaging material shall be suitable to be fitted in a cardboard box for storage and bulk shipment.

Labeling:
UNICEF shall provide layouts for primary and secondary packaging of standard MNPs. For custom layouts, the supplier shall develop the packaging artwork as per the customer's request.
Labeling shall be appropriate for the consumer, taking into consideration nutritional habits, type of food consumed, as well as other culturally sensitive aspects, e.g. images of children or food appearing on the label.

Primary Labeling
Sachet label shall contain:
- Name of the product: Vitamin and Mineral Powder
- Net weight
- Pictogram with instructions for preparation

- Name and address of the manufacturer
- Expiry date

Secondary labeling
Cardboard box or package label shall include:

- Product name (as above)
- Number of sachets and net weight: e.g.: *Contents: 30 sachets of 1g.*
- Full composition: list of 15 vitamins and minerals and excipients
- Batch number assigned by the manufacturer
- Manufacturing date
- Expiry date
- Storage conditions
- Name and address of the manufacturer, co-packet, distributor
- Written and pictogram instructions for preparation and use, specifying that the product shall be added to the child's usual meal and that the entire sachet is to be added to the child's serving prior to eating
- Age of children: 6-59 months
- Serving: 1 sachet per child per day
- Consumer Guidance Messages:

Breastfeeding is recommended for 24 months and exclusively for 6 months.
Do not use if the sachet or package is torn or damaged.

Storage conditions:
Do not store above 30 °C
Store in tightly closed original packaging, protect from moisture.
Keep out of reach and sight of children

Instruction for use:
Mix the sachet contents with a small portion of solid or semi-solid food just before serving.

Pictogram Guide:
Show a small spoon in the pictorial description demonstrating the powder should be mixed with food.
Do not use images that could be interpreted unfavourably; include a picture of an infant older than 6 months that is ethnically specific for the region

Cautionary Programme Note:
This is not a replacement for any additional nutritional interventions, which shall continue alongside use of this product. Breastfeeding should be encouraged to be continued if MNPs are part of a complimentary diet for the infant (see label requirements for mandatory message).

Dosage:
Children aged 6 - 59 months shall be given one dose (i.e. one sachet) a day for a period of 30 days, or as prescribed by the health professional.

Adverse Effects
No adverse events have been reported during the use of MNPs. However, supplemental iron and zinc have been reported to cause mild gastrointestinal upset in sensitive individuals, particularly if consumed on an empty stomach.

Appendix 1
Halal and Kosher Vitamins
Sources of vitamins and minerals can often contain animal products. Certain countries may request halal or kosher certificates for the MNPs. In this cases UNICEF may request to provide these certificates. 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 can often be manufactured from GMO soy or corn and thus could lead to customs delays without adequate certification. UNICEF may request GMO free certification if required by the importing country office.

Appendix 2
Suggested addition rates to account for shelf life degradation.

1. Vitamin A 400 µg RE (130-150%)
2. Vitamin C 30 mg (120-150%)
3. Vitamin D3 5 µg (130-165%)
4. Vitamin E 5 mg TE (110-165%)
5. Vitamin B1 0.5 mg (125-150%)
6. Vitamin B2 0.5. mg (125-150%)
7. Vitamin B3 6 mg (110-150%)
8. Vitamin B6 0.5. mg (125-150%)
9. Vitamin B12 0.9 µg (125-150%)
10. Folic Acid 90 µg (125-150%)
11. Iodine 90 µg (120%)

Relevant standard and References

- The latest available International Pharmacopeial standard for Oral powders:
- The latest available USP Monograph for Oil and water soluble Vitamins with Minerals Tablets
- USP 2021, Microbial Enumeration Tests - Nutritional and Dietary Supplements
- USP 232, Elemental Impurities - Limits
- USP, General Chapter on Inorganic Impurities: Heavy metals

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

- Codex Alimentaris : GUIDELINES FOR VITAMIN AND MINERAL FOOD SUPPLEMENTS CAC/GL 55 – 2005

- Codex Alimentaris GENERAL GUIDELINES ON SAMPLING CAC/GL 50-2004

- Codex Alimentaris: ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN CAC/GL 10 – 1979

- Food Chemical Codex STANDARD 1.3.4 IDENTITY AND PURITYwww.comlaw.gov.au

- Home Fortification Technical Advisory Group's manual on micronutrient powder composition, July 2013, available at: http://hftag.gainhealth.org/sites/hftag.gainhealth.org/files/HF-TAG%20MNP%20Composition%20Manual.pdf

- WHO good manufacturing practices for pharmaceutical products: main principles. World Health Organization WHO Technical Report Series, No. 961, 2011

- Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. World Health Organization WHO Technical Report Series, No. 953, 2009
- Lindsay Allen.et al. Guidelines on food fortification with micronutrients. World Health Organization and Food and Agriculture Organization of the United Nations, 2006