General Description

LNS-Preg. Breastfeeding WG, 75g/CAR-168 (LNS-PBWG) paste is a high-energy fortified food to address malnutrition during pregnancy and breastfeeding. It is classified as Food for Special Dietary Uses under Codex Alimentarius.

Intended Use

LNS-PBWG is used as a supplement in pregnant and breastfeeding women’s and girls’ diets, in addition to family foods, in undernourished populations. It is ready to eat directly from the sachet; does not require cooking, mixing or dilution. LNS-PBWG paste is portion controlled: each sachet has the same nutritional value to supplement the dietary intake. The recommended period of supplementation is from week 12 until for the remaining duration of pregnancy and one month postpartum during breastfeeding.

Target Population

For pregnant and breastfeeding women and girls with suboptimal nutritional status to reduce the risk of poor birth outcomes where daily diet is low in micronutrients and energy.

Product Description

LNS-PBWG is a smooth, homogeneous, thick paste containing vegetable oils, legumes (e.g., peanuts, soy, chickpeas, lentils), milk powder /whey powder, sugar, maltodextrin, protein isolates, vitamin and mineral premix, fully hydrogenated vegetable oil, emulsifier/stabiliser. It is squeezed out of the sachet and eaten directly.

(1) Technical Specifications

Texture

Smooth, homogeneous, thick paste, easy to squeeze out of sachet. It should be a uniform paste with no lumps or grittiness, having a small particle size (e.g., <500 microns) to minimise phase
separation, granularity, and oil leaking out of the sachet. The paste should not elicit chewing when consumed by the target population. Attention should be given to the sugar (sucrose) particle size, which if not properly ground, could cause oil separation from the paste and lead to oil leakage when opening the sealed part of the sachet.

Flavour and odour

LNS-PBWG paste should have a pleasing sweet, fresh flavour with odour of peanuts, or other legumes such as soy/chickpea/lentils/maize and milk. LNS-PBWG paste should be free from foreign odours and flavours such as, (but not limited to) burnt, scorched, rancid, malted, sour, or stale.

Colour

LNS-PBWG paste should have light brown or orange brown colour. The LNS-PBWG paste should not have a dull, grey tinge, or other abnormal cast. It should show no evidence of excessive heating (materially darkened or scorched).

Nutritional composition per 100 g of LNS-PBWG paste

Moisture content: 2.5% maximum
Water activity: 0.6 maximum
Energy: 2134-2469 kJ
510-590 kcal
Proteins*: 14.7-15.0 % of total energy
18.8-22.2 g
Lipids: 45.9- 60 % of total energy
26-39.3 g
Omega 6: 3.2-8.7 g
Omega 3: 1.7-2.1 g
Lactose <12 g
Free sugar**: <10.0 % of total energy
*PDCASS¹ >90-100 or
*DIAAS² ≥90
** does not include lactose

Minerals per 100g of LNS-PBWG paste

Calcium: 667-1333 mg
Iron: 29-38 mg
Zinc: 20-27 mg
Copper: 1.3-2.2 mg
Selenium: 80-127 µg
Iodine: 279-449 µg
Phosphorus: 400-933 mg
Magnesium*: 193.3-466.7 mg
Manganese*: 2.8-3.4 mg
Potassium*: 2.7-6.8 g
Sodium: <270 mg

*The requirement for these minerals is optional

Vitamins per 100g LNS-PBWG paste

Vitamin A (Retinol Equivalent): 0.733 – 1.339 mg
Vitamin B1 (Thiamine): 1.6 – 3.0 mg
Vitamin B2 (Riboflavin): 1.73 – 2.4 mg
Vitamin B3 (Niacin): 19 – 24 mg
Vitamin B6 (Pyridoxine): 2.3 – 3.2 mg
Vitamin B9 (Folic acid): 533 – 734 µg (DFE)
Vitamin B12 (Cyanocobalamin): 3.2 – 7.3 µg
Vitamin C (Ascorbic acid): 133 – 367 mg
Vitamin D (Cholecalciferol): 13 - 24 µg
Vitamin E (Tocopherol): 29.3 – 53 mg
Vitamin K (phylloquinone): 96-196 µg
Vitamin B5 (Pantothenic Acid)*: 7.5-9.3 mg
Biotin*: 37.3-46.7 µg

*The requirement for these vitamins is optional

1 Protein Digestibility Corrected Amino Acid Score (PDCAAS) or Digestible Indispensable Amino Acid Score (DIAAS) shall be calculated using the method provided in Dietary Protein Quality Evaluation in Human Nutrition (Report of an FAO Expert Consultation, 2011)

2 In formulations with lower PDCAAS scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The addition of limiting amino acids, solely in the L-form, shall be permitted only in amounts necessary to improve the protein quality of the LNS-PBWG.

(2) Directions for Use

Wash hands, knead the sachet prior to opening, open sachet at the tear notch at the side of the sachet, squeeze out the LNS-PBWG and eat directly from the sachet. Drink clean water as needed.

For dosage recommendations see WHO recommendations on antenatal care for a positive pregnancy experience.

https://www.who.int/publications/i/item/9789241549912

(3) Shelf life
24 months when stored at <30 degrees Celsius. Shelf-life claims should be supported by stability studies, please refer to the “Requirements for Stability Studies for Supplementary Foods” attachment with the bid document. Unless specifically authorised in writing by UNICEF, products should be of fresh production having at least 80% of their shelf life.

(4) Raw materials and Ingredients

4.1 Milk and dairy ingredients

Milk and dairy ingredients such as milk powder, whey powder, milk or whey protein isolate, or dairy permeate powder can be included in LNS-PBWG.

Applicable reference

1. CXS 207-1999: Standard for Milk Powders and Cream Powder
2. CXS 281-1971 Standard for evaporated milk
3. CXS 289-1995: Standard for Whey Powders
4. CXS 290-1995: Standard for Edible Casein Products
5. CXS 331-2017 Standard for Dairy Permeate Powders

4.2 Peanuts

Peanuts and peanut paste. Ingredients must comply with the latest version of the relevant codex standards.

Applicable reference


4.3 Legumes

Soy based ingredients, chickpeas, lentils, and other legume products (e.g., flour and isolates) must comply with the latest version of the relevant codex standards.

Applicable reference

1. CXS 175-1989 General Standard for Soy Protein Products
2. CXS 171-1989 Standard for Certain Pulses

4.4 Maize

Pre-gelatinized maize flour (at least 80% of gelatinization) should be used to facilitate starch digestion. Maize (corn) shall be peeled/dehulled to limit the presence of anti-nutritional factors.
Maize flour shall be heat treated e.g., extrusion or drum drying. Maize flour must comply with relevant Codex standard.

Applicable reference

1. CXS 155-1985 Standard for degermed maize (corn) meal and maize (corn) grits.

4.5 Oil (edible refined vegetable oil)

The manufacturer should 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), providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour, and shelf life. Partially hydrogenated fats and oils should not be used. Trans fats must be kept to a minimum. Oil ingredients must comply with the most recent version of the relevant codex standards.

Applicable reference

2. Code of Practice for the reduction of 3-Monochloropropane-1-2- DIOL Esters (3-MCPDEs) and GLYCYCIDL Esters (GEs) in Refined Oils and Food Products made with refined oils.

(5) Carbohydrates

Carbohydrates are used to provide energy and can be used to increase palatability of the LNS-PBWG. Lactose, plant starch, maltodextrin and sucrose are the preferred carbohydrates in LNS-PBWG. Only precooked and/or gelatinized starches may be added. Carbohydrates must adhere to the relevant Codex Alimentarius texts. Glucose and corn syrup products as ingredients and fructose ingredients should be avoided in LNS-PBWG, because of potential adverse effects. Free sugars added for sweetness should be used sparingly, not more than 10% of energy.

Attention should be given to the sugar (sucrose) particle size, which if not properly ground, could cause oil separation from the paste and lead to oil leakage when opening the sealed part of the sachet. Starch and sugar ingredients must comply with the relevant Codex standards.

Applicable reference

2. Food Chemicals Codex Specifications for maltodextrin

(6) Food additives
Only natural flavours are allowed. The following antioxidants may be included: Ascorbyl palmitate, Mixed tocopherols. Not permitted as an antioxidant: Butylhydroxyanisol (BHA) and Butylated hydroxytoluene (BHT).

Applicable reference

1. CXS 239-2003 General Methods of Analysis for Food Additives
2. CXS 192-1995 General Standard for Food Additives

(7) Mineral and vitamin premix

The mineral and vitamin premix(es) cannot be produced by the LNS-PBWG paste manufacturer itself and must be supplied only from suitably qualified premix facilities. A list of suppliers of sources of premix is available at: http://gpf.gainhealth.org/suppliers/current-suppliers, however not all these suppliers are approved by UNICEF. LNS-PBWG suppliers must validate their premix supplier to ensure the quality of the premix facility on its own merit.

Vitamin and mineral forms used must be soluble and easily absorbed. The added minerals should be water-soluble and should not form insoluble components when mixed. The LNS-PBWG paste should have a mineral composition complying with the Applicable reference 1 listed below.

Applicable reference

1. Appendix 4 of Management of Severe Malnutrition: a manual for physicians and other senior health workers, WHO 1999
   http://apps.who.int/iris/bitstream/handle/10665/41999/a57361.pdf;jsessionid=2E0AD90EB73456665DA9D248DDA9EFCD?sequence=1 or

(8) Emulsifying agents

Emulsifiers are potentially of importance for lipid-based pastes as this type of food is prone to phase separation. Phase separation may also be minimised by reducing the particle granule size. Permissible emulsifiers are mono and diglycerides (0.15-2g /100g) or lecithin.

Applicable reference

1. CXS 192-1995 General Standard for Food Additives

(9) Validation of the process and coefficient of variation

The coefficient of variation, calculated using the method proposed by WFP, should be as low as possible, and always <5%. https://docs.wfp.org/api/documents/WFP-0000145318/download/
Indicators for process capability shall be implemented and monitored, with fixed target and corrective actions. Trend analysis shall be in place for continual monitoring.

(10) Thermo-treatments

Thermal (heat) treatment processes for microbial log reduction can be applied to LNS-PBWG and raw materials contained in LNS-PBWG.

Applicable reference

1. CXG 69-2008 Guidelines for the Validation of Food Safety Control Measures
2. CXG 63-2007 Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)

(11) Safety

Manufacturers supplying UNICEF are responsible for assuring that the product does not contain any harmful substance originating from micro-organisms or any other poisonous or deleterious substances, including micro-organisms, heavy metals, pesticides objectional or foreign matter or anti-nutritional factors, in amounts that may represent a hazard to health. Foreign matter detection is expected to be carried out on the filled sachet.

(12) Quality Assurance

Products must be manufactured in accordance with Codex Alimentarius applicable references, Good Manufacturing Practice (GMPs) and Good Hygiene Practices (GHPs). 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. FSSC 22000 certification is highly recommended.

Prerequisite programs including HACCP plan and environmental monitoring programs must be implemented. Environmental monitoring of sampling sites should be prioritized according to the likelihood of contamination of processing lines and the impact on the product and should be conducted under normal operating condition. Manufacturers are expected to implement an environmental monitoring program with a four-sanitary zoning system. Raw material and starting material testing of high-risk ingredients is required.

Applicable reference

1. CXC 75 2012, (2016). Codex of Hygienic Practice for Low moisture foods
2. CXS/RCP 1-1969, Rev. 4-2003: Recommended International Code of Practice. General
Principles of Food Hygiene

(13) Microbiological Safety and Testing

The manufacturer establishes safety criteria for production as well as for the finished product based on a risk assessment performed on the raw materials and the processing methods. Raw material testing of high-risk ingredients is required. Methods for detection and/or quantification and sampling plan details including the n, c, m, M and p (see annotation section for definitions). The microbiological criteria should follow the principles specified in the following standards below:

Applicable reference

2. CAC/GL 63-2007: Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)

13.1 Microbiological tests

The manufacturer is responsible to elaborate an analytical plan for the LNS-PBWG paste finished product. All analytical test procedures must be described in sufficient detail, including analysis methods.

ISO 17025 certified laboratories should preferably be used.
Analytical control plans should be detailed and include¹: tests for Salmonella & Enterobacteriaceae.

Following the sampling plan and recommended method (or alternative validated method) in example (e) in the Appendix 1 of the Codex of Hygienic Practice for Low moisture foods CXC 75 2012, (2016) for Salmonella:

a) Salmonella:
0 cf u per 25g
n=30 ( × 25 g)
c=0; m=0/25g;2 class plan¹
Method: ISO 6579; or alternative validated method

b) Enterobacteriaceae (EB):
10 cf u per g* maximum

¹ Annotations
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
n=10, (×10grams),
c=2, m=10 cfu/g; M=100 cfu/g maximum.
Method: AOAC 975.55; AOAC 2003.01; ISO 21528-2, or alternative validated method

Applicable reference

1. CXC 75-2015 Codex of Hygienic Practice for Low moisture foods

(14) Pesticides, Heavy metals, and other Contaminants

Verifying that pesticide, heavy metals levels and other identified contaminant risks are below accepted limits is the responsibility of the manufacturer. Control of contaminants is best achieved during validation of ingredient suppliers and through testing of ingredients prior to processing. Examples of mycotoxins, pesticides and heavy metals that must be controlled, include, but are not limited to:

Mycotoxins: Aflatoxin: 10µg/ kg max
Heavy metals: Arsenic, Cadmium, Lead, Mercury
Pesticides: Carbamates Organochlorine Organophosphorus, Pyrethroid

Applicable reference

2. CXC 55-2004: Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts
3. CXS 228 -2001 General Methods of Analysis for Contaminants.
4. CXC 49-2001 Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals.
5. CX/MRL 2-2018 Maximum residue limits (MRLs) and risk management recommendations (RMRr) for residues of veterinary drugs in foods Codex

(15) Radioactivity

Radioactive compound may contaminant foods if grown in soils contaminated from nuclear accidents or if ionizing radiation is used as preservation method. This risk is best managed by using only ingredients certified free of radioactivity. The nuclear radiation level should meet the values valid in the area of consumption.

Applicable reference


(16) Melamine
The level of melamine must not exceed 1 mg/kg in milk products.

**Applicable reference**


**(17) Analytical requirements**

The manufacturer should conduct a complete analysis of the finished product in order to verify that the finished product is manufactured in compliance with the applicable references in this specification and that production of LNS-PBWG is homogeneous and consistent. All parameters included in this specification sheet should be tested at least once a year. The minimum testing frequency per year is dependent on the production volume. Frequency for each parameter can be adapted when trends analysis of 6 consecutive results demonstrate that the standard deviation is under control. Requirements are listed below:

<table>
<thead>
<tr>
<th>Total annual production</th>
<th>Nutritional properties and micronutrients listed in point (1)</th>
<th>Food safety parameters, including contaminants listed in points (13), (14), (15), (16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1000 MT</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>&lt;2000 MT</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>&lt;5000 MT</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>&gt;5000 MT</td>
<td>4</td>
<td>1</td>
</tr>
</tbody>
</table>

**Analytical CoA Requirements per Batch**

A Certificate of Analysis (CoA) should be issued and forwarded prior to each shipment or order collection for each batch provided. This certificate must mention the laboratory name, methods of analysis, laboratory variability ranges for each nutrient, 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 batch cannot be released if there is a failure to meet the following criteria:
Nutritional value and nutrients per 100 g.

- **Moisture Content:** <2.5%
- **Energy Value:** 510-590 kcal/100g
- **Protein content:** 18.8-22.2 g
- **Fat content:** 26-39.3 g
- **Vitamin A:** 0.733-1.339 mg RE

Minimum of one mineral & one vitamin tracer per premix (e.g., vitamin C, and Iron) should be tested per shift.

Microbiological and Chemical criteria

- **Salmonella:** 0cfu per 25g
- **Enterobacteriaceae (EB):** 10cfu per g
- **max Total aflatoxin:** 10 µg per kg max
- **Aflatoxin types (e.g., B1 or M1) testing may be requested**
  (See sampling plan and method references listed under ‘13.1 Microbiological Tests’ section above.)

(18) **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, customer’s sites delivered, etc.).

(19) **Batch size**

The batch size should not exceed 250 metric tons and one week of production.

(20) **Packaging and Labelling**

Specifications Primary packaging

The primary packaging must be portion controlled: each unit of 75 g. Packaging material can not contain any detachable parts that present a choking hazard. Inks used for marking and glue must be contact food grade, water, and lipid resistant. The information printed on sachet must be intact by the end of the shelf life, including pre-printed marking as well as date and batch markings. Reverse printing is mandatory. 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 primary packaging materials must not transfer particle, flavour, or odour to the product. The closure seal must be free of wrinkles, occluded matter, or evidence of entrapped
moisture or grease.

Packaging under nitrogen is recommended as it contributes to lengthen product shelf life, i.e., protecting lipid oxidation and vitamins from oxidising.

A comprehensive quality assurance system shall be implemented to cover the sachet seal integrity. This shall include regular checks of the filling parameters (e.g., sealing temperature) in combination with a visual inspection of the sealing and a leak test. This shall be complemented by an additional quality control system for microleaks to comply with the UNICEF specification (4) above. During predelivery inspection UNICEF will normally apply General Inspection Level I and use an AQL value of 1.0 as a guidance value, where a carton contains around 168 sachets. A more stringent AQL may need to be applied is certain circumstance. Any indication of leakage will be counted as a leakage. The manufacturer should apply stricter in-process controls to avoid rejection.

Applicable reference

1. ISO 2859 Sampling procedures for inspection by attributes — Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection.

(21) Primary Packaging composition preferred

Packaging specification:12micron PET/12micron METPET/40micron NylonPE or 40 micron LLDPE, with minimum thickness 60 microns or equivalent.

Example of Applicable standard and test for barrier properties:
WVTR <1.5 g/m².day (38°C/90% RH) (ASTM F1249-13 or equivalent)
OTR < 2 cc/m².day (23°C/50% RH) (ASTM F1927-14 or equivalent)

Text to include on the label

English and French languages are mandatory. English, French, and Arabic labels are preferred. Other (local) languages might be requested.

FRONT

On the front side of the sachet two zones (Dark pink zone and Pictogram zone) are mandatory.

Dark pink Zone

The dark pink zone should preferably be used for the generic name of the product, the dose and flavour/main ingredient of product (e.g., peanut, soy, chickpea, lentils) indicated as an icon + flavour / main ingredient in words in 2 languages.
-The dark pink zone should be dark pink, PMS 246C (Pantone Matching System) should represent minimum 30-50% of the front surface. No branding should appear in the dark pink zone and contain the following information:
-Generic name: LNS-PBWG
-Lipid-based Nutrient Supplement Fortified Food for Pregnant and Breastfeeding Women and Girls
-Eat one sachet per day= XX kcal

Pictogram Zone

Pictograms should be of a size that is easy to read by the consumer. It should contain minimum five pictograms:
-Icon for hand washing (with a tap)
-Icon showing kneading of the sachet
-Icon showing tear & open
-Icon showing breastfeeding
-Icon for woman eating PBWG+Bowl of food and a glass of water

Other information that should appear on the sachet:

- All the ingredients listed in order of descending quantities. This includes listing vitamin and mineral composition of the premix in parenthesis. When the premix is less than 5% of the total formula, it is enough to state it as “vitamin and mineral premix.” Ingredients should be identified using the CXS 1-1985 class names. e.g.: non-hydrogenated palm oil.
-Nutritional information: amounts of nutrients per serving and per 100g and per 75g must be listed. A table format is preferred. The table list of nutrients can be in English only to conserve label space.
- Information on allergens (where relevant) in bold, may content traces of allergens
- Name and address of manufacturer, packer, distributor, importer, exporter, or vendor including country of origin.
- Net weight (can be also in dark pink zone)
- Date of manufacture, Best Before date (clearly visible throughout the whole shelf life of the product.)
- Batch number (clearly visible throughout the whole shelf life of the product).
- Storage instructions (Best stored below 30 C, in a cool dry place and in hygienic conditions and away from direct sunlight. After opening, keep sachet tightly closed) and “consume within 24 hours of opening.”

- The statements:
  - “Not for sale or exchange”. In Bold
  - “Consume in addition to family food”
  - “It is strongly recommended to start breastfeeding immediately after birth, exclusively breastfeed during the first 6 months and continue until at least 24 months.”
Consultation with a health-worker is recommended for assessing the status of the pregnant woman and the fetus.

The artwork of sachet must be approved by UNICEF. Any change in the approved artwork must be submitted for further approval.

Applicable reference

1. CXS 180-1991 General Standard for Labelling of and claims for Foods for Special Medical Purposes
2. CXS 146-1985: General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses
3. CXS 1-1985: General Standard for the Labelling of Pre-packaged Foods

Secondary packaging

Cartons should be strong and sturdy; allowing stacking up to 2.4m high, 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.

Cartons should be stacked on pallets and secured in the transportation vessel in a way that prevents movement during transportation. Pallets should be wrapped with plastic wrap to protect goods from contamination and movement of cartons during shipment.

Following requirements apply

ECT (Edge Crush Test) 11kN/m with minimum 60% remaining with 90% humidity at the highest recommended temperature of storage. Manufacturers are required to choose suitable carton strength that is appropriate for domestic or export transportation. Cartons should be protected by isolating sachets inside the carton in a plastic bag to prevent damaging other cartons in case of possible leakage. Cartons should be colour coded, using PMS246C dark pink colour.

The following information should appear

- dark pink zone: same requirements as for the dark pink zone of the sachet,
- Name and address of manufacturer, packer, distributor, importer, exporter, or vendor, including country of origin
- Storage conditions
- Net weight
- Number of units in the carton
- Lot number, date of manufacture
- Best before date

Not for sale or exchange

Each carton containing a minimum of 168 sachets
Applicable reference

1. *WHO recommendations on antenatal care for a positive pregnancy experience.*

Useful Resources

1. Contaminants Reference Table
2. Stability study template for Nutritional Products
3. Interagency Requirements for stability study
4. Interagency Specialised Food Manufacturer Quality Questionnaire
5. Interagency Specialised food Product Questionnaire
6. Technical Requirements “Nutritional Products”

FOR MORE INFORMATION

CPHHQ-SD- Nutrition Supplies | sd.nutritonsupplies@unicef.org
Technical resources for nutrition products | UNICEF Supply Division