

Technical Specifications for

Lipid-based Nutrient Supplement - Small Quantity LNS-SQ

Version: **2.0 adopted 2020** Replacing: **1.1 adopted 2019** Date of issue: **26.10.2020** Replacing Ver.1.1, the main adjustments are:

Set max requirements for tropane alkaloids
 Update Omega 6 and labelling (storage conditions) requirements

1. INTRODUCTION

1.1 Product purpose

LNS-SQ is a food supplement that is intended to complement the diet of children aged 6 months and older with essential nutrients. As such, it contributes to preventing undernutrition, in particular micronutrient deficiencies and stunting. It is to be consumed directly from the package or by mixing with other foods. One package contains one daily dose of **20g**. This product is NOT a breast-milk replacer.

1.2 Product type

LNS-SQ is a fortified lipid-based paste/spread that is stabilized and individually packaged in robust sachets that are packed in sturdy cartons. **LNS-SQ** is generally made with heat treated peanut/pulses/cereals, milk powder, vegetable oils, sugar, maltodextrin, vitamins and minerals.

1.3. Quality and safety

LNS-SQ shall be manufactured within a quality and food safety management environment in accordance with latest versions of 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, of the Codex Alimentarius
- Codex Code of Hygienic Practice for Low-moisture Foods: CAC/RCP 75-2015
- General Principles for Addition of Essential Nutrients to Foods: CAC/GL 09-1987, of the Codex Alimentarius
- ISO 22000:2005: Food Safety Management Systems
- ISO/TS 22004 Guidance on the Application of ISO 22000:2005

2. INGREDIENTS

2.1 Generic requirement

LNS-SQ shall be manufactured from ingredients that are fresh, of good quality, free from foreign materials and substances hazardous to health, that comply with Codex Alimentarius and relevant regulations. The quality of raw materials should be adequate so that the final product will meet all requirements specified in

this document. In particular, the latest versions of the following Codex standards and guidelines shall apply as applicable, depending on the raw ingredients that are used:

- Codex Guidelines CAC/GL 08-1991 on formulated supplementary foods for older infants and young children
- Codex Stan 200-1995 for peanuts and peanuts used to produce peanut paste
- Codex Stan 171-1989 for chick peas and soybeans
- Codex Stan 155-1985 for degermed maize (corn) meal and maize (corn) grits, pre-gelatinized maize flour (at least 80% of gelatinisation) should be used to facilitate starch digestion. In addition, maize (corn) is peeled/dehulled to limit the presence of anti-nutritional factors. Heat treatment of maize flour shall include extrusion or drum drying process.
- Codex Stan 175-1989 for soy protein
- Codex Stan 210-1999 for oil and for oil used to produce shortening
- Codex Stan 212-1999 for sugar
- Codex Stan 207-1999 for sources of dairy protein
- Codex Guidelines CAC/GL 55 for vitamin and mineral premix
- Codex Stan 193-1995 for all ingredients. In particular melamine shall remain below 2.5 mg/Kg in dairy source used
- Codex Stan 192-1995 for flavoring and antioxidants, including carry over from ingredients. Artificial flavoring and synthetic antioxidant such as Butylhydroxyanisol (BHA), Butylated hydroxytoluene (BHT), and tertiary butylhydroquinone (TBHQ) are not authorized.
- Food Chemicals Codex Specifications for maltodextrin

Additionally:

- Honey is prohibited due to a safety hazard.
- LNS-SQ suppliers shall test melamine at least once a year for each individual source of dairy protein used.

2.2 Vitamin and mineral premix

LNS-SQ shall include a premix consisting of the vitamins and minerals described in Table 1. Suppliers should implement an effective food safety and quality management system for the premix, including supplier approval and premix quality control.

Additionally, the premix shall:

- Be purchased from any of the GAIN approved suppliers, as per the list available at the following link: <u>http://gpf.gainhealth.org/suppliers/current-suppliers</u>.
- Be delivered to the processor of **LNS-SQ** with a complete Certificate of Analysis. This document shall be presented to WFP with other documents for payment.
- Be stored as recommended by premix manufacturers.

If the manufacturer would like to adapt the premix, this will have to be discussed and agreed with WFP, and will have to be based on supporting data that show that the combination of raw materials, prescribed premix and specific processing steps results in a product of which the specific nutrient content is consistently outside the range of label values and maximum content (see Table 2). An example of an adaptation that can be considered is higher inclusion of Vitamins A and C to compensate for greater losses due to a specific heat processing step.

Micronutrients	Unit	Recommended nutrient sources (/alternative options)	Nutrient added per 100g LNS +/-10%	
Retinol (Vit A) ¹	mcg RE	Dry Vitamin A Palmitate / Dry Vitamin A Acetate	2927	
Thiamine (Vit B1)	mg	thiamine hydrochloride /Thiamine mononitrate	3.4	
Riboflavin (Vit B2)	mg	Riboflavin	2.7	
Niacin (Vit B3)	mg	Niacinamide	26	
Pantothenic acid (Vit B5)	mg	Calcium d-Pantothenate	12	
Pyridoxine (Vit B6)	mg	Pyridoxine hydrochloride	2	
Biotin (Vit B7)	mcg	Biotin	56	
Folic Acid(Vit B9)	DFE mcg	Folic acid food grade	939	
Cobalamine (Vit B12)	mcg	Cyanocobalamin	3.7	
Ascorbate (Vit C)	mg	Calcium ascorbate dihydrate; Ascorbic acid fine powder	152	
Cholecalciferol (Vit D)	mcg	Cholecalciferol	45	
Vitamin E	aTE mg	Vitamin E acetate (50% dl-alpha-tocopherol acetate)	28	
Phytomenadione (Vit K)	mcg	Phytomenadione	203	
Calcium (Ca)	mg	98.5% Ca from tricalcium phosphate and 1.4% Ca from calcium ascorbate and 0.1% Ca from d- calcium pantothenate	1251	
Copper (Cu)	mg	Copper sulfate anhydrous / copper gluconate	1.8	
lodine (l)	mcg	Potassium iodide	539	
Iron (Fe)	mg	60% Fe from ferrous sulfate monohydrate and 40% Fe from NaFeEDTA	34	
Magnesium (Mg)	mg	Magnesium sulphate monohydrate / magnesium citrate or gluconate	162	
Manganese (Mn)	mg	Manganese sulfate monohydrate	6.5	
Phosphorus (P)	mg	81% from tricalcium phosphate and 19% from dipotassium phosphate	785	
Potassium (K)	mg	61% from Dipotassium phosphate and 39% from potassium chloride	612	
Selenium (Se)	mcg	Sodium selenite /sodium selenate	119	
Zinc (Zn)	mg	Zinc sulfate monohydrate	44	

Table 1: Premix contribution and premix nutrient sources (approximate incorporation rate: 6.87%)

¹ Beadlet or spray dried form can be used assuming there is no carryover of antioxidants not approved in Codex.

3. PRODUCT SPECIFICATION

3.1 Generic requirements

LNS-SQ shall comply with the latest versions of the following guidelines or standards. Additionally, the supplier shall comply with relevant local regulations/standards.

- Guideline on formulated complementary foods for older infants and young children, CAC/GL 08-1991 of the Codex Alimentarius
- FAO/WHO microbiological risk assessment series 28: microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition:
- Codex Stan 193-1995 general standard for contaminants and toxins in food and feed
- Guidelines from Codex Committee on Pesticide Residues (CCPR)
- Recommendations from joint FAO/WHO expert meeting on tropane alkaloids, 2020

In addition:

- **LNS-SQ** shall be safe and suitable for human consumption.
- **LNS-SQ** shall be microbiologically stable with a water activity lower than 0.6
- LNS-SQ shall be free from objectionable matter; free from micro-organisms in amounts which may
 represent a hazard to health; not contain any substances originating from micro-organisms or any
 other poisonous or deleterious substances such as residues of hormones, antibiotics, pharmacologically
 active substances, anti-nutritional factors, heavy metals, toxic or noxious seeds², or pesticide residues, in
 amounts which may represent a hazard to health of the specific population group for which they are
 intended (children 6 months of age and older)
- **LNS-SQ** shall be homogeneous, uniform, with small particle size which does not require and does not encourage chewing before being swallowed. The product shall be free of lumps and of large coarse particles and suitable for consumption by children 6 months and older
- Blend of oils shall be judiciously chosen in order to meet omega 3 and omega 6 requirements in the finished product and to minimize oil separation.
- **LNS-SQ** shall comply with requirements stated in Table 5 list of compulsory tests. Additionally, it shall contain a combined hyoscyamine/scopolamine (tropane alkaloids) concentration in dry food of less than 10ppb.
- **LNS-SQ** destined for Syria should comply fully with relevant Syrian food standards. For example, Aflatoxin B1 in the final product should be less of 0.1 ppb.

3.2 Nutritional value

LNS-SQ shall have a composition that is in line with Table 2 and Table 5.

² Crotolaria (Crotalaria spp.), Corn cockle (Agrostemma githago L.), Castor bean (Ricinus communis L.), Jimson weed (Datura spp.), Mexican Prickly Poppy (Argemone mexicana) and other seeds that are commonly recognized as harmful to health.

Nutrients and nutritional values per 100g finished product	Unit	Minimum	Label ³	Maximum
Energy	Kcal	550	х	620
Added sugar	g			8
Protein ⁴	g	12	х	16
Dry skimmed milk protein ⁵	g	8	х	13
Fat	g	40	х	53
ω-3 fatty acids	g	2.5	х	4
ω-6 fatty acids ⁶	g	4	х	15
Retinol (Vit A)	mcg	2000	2000	3390
Thiamin (Vit B1)	mg	1.5	1.5	3.8
Riboflavin (Vit B2)	mg	2	2	3
Niacin (Vit B3)	mg	20	20	28.8
Pantothenic Acid (Vit B5)	mg	9	9	14
Pyridoxine (Vit B6)	mg	1.5	1.5	2.3
Biotin (Vit B7)	mcg	45	45	65
Folates (Vit B9) DFE	mcg DFE	667	667	1044
Cobalamine (Vit B12)	mcg	2.5	2.5	4.2
Ascorbate (Vit C)	mg	75	75	169
Cholecalciferiol (Vit D)	mcg	25	25	52
Vitamin E	mg aTE	20	20	47
Phytomenadione (Vit K)	mcg	150	150	323
Calcium (Ca)	mg	1400	1400	1960
Copper (Cu)	mg	1.7	1.7	2.2
lodine (I)	mcg	450	450	742
lron (Fe)	mg	30	30	42
Magnesium (Mg)	mg	200	200	280
Manganese (Mn)	mg	6	6	9
Phosphorus (P)	mg	982	982	1375
Potassium (K)	mg	1000	1000	1400
Selenium (Se)	mcg	100	100	160
Sodium (Na)	mg		х	270
Zinc (Zn)	mg	40	40	56

³ All X have to be filled by manufacturer, according to the specific formulation used. Please refer to codex standard in section 5.1 below for the full list of nutrients to be declared.

⁴ Sources of protein in addition to dry skimmed milk shall be selected to maintain a PDCAAS (Protein Digestibility-Corrected Amino Acid Score) of 70% minimum, calculated using the method provided in 2017 FAO protein quality assessment for ready to use therapeutic foods.

⁵ If the dry skimmed milk (DSM) used has 36% protein, this is equivalent to min 25% DSM in the formulation.

 $^{^6}$ The required ω -6/ ω -3 ratio is maximum 5. Oils rich in Omega 3 and low in Omega 6 such as rapeseed oil can be used for reaching a good balance.

3.3 Shelf life

Unless stated otherwise in the contractual agreement, **LNS-SQ** shall have minimum 24 months shelf life when stored up to 30°C. At least one shelf life study per recipe should be initiated in line with WFP requirements⁷ to confirm that:

- Food remains within maximum and minimum defined in Table 2
- There shall be no more than slight oil separation throughout the shelf life of the product

4. PACKAGING AND MARKING

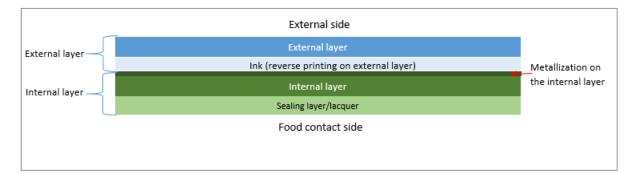
4.1 Packaging

The product covered by the provision of this specification must be packed in appropriate packaging which safeguards the hygienic, nutritional, technological, and organoleptic qualities of the product. The packaging material shall be made of substances which are safe and suitable for their intended use. They should not impart any toxic substance or undesirable odour or flavour to the product.

4.1.1 Primary packaging

LNS-SQ shall be packaged in food-grade flexible sachets, hermetically sealed and robust enough to prevent leakage and protect the product throughout its shelf life. Sachet material shall not represent a hazard for infants and young children when sachets are opened and put in contact with the mouth. 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).
- Weight and quantity tolerance shall meet The International Organization of Legal Metrology International Recommendation OIML R 87.
- Optimized shape to avoid space loss in the sachets and cartons
- Properly sealed with no leakages (test example: ASTM F2338 09, ASTM D3078 02 or equivalent)
- The sachet must have a feature to ease the opening (e.g. a tear notch)
- The sachets must be placed in an appropriate way in the carton box during the packing process to avoid packaging damage and product leakage
- Metalized film is a mandatory barrier, it must be away from the sealing layer and be protected by another layer (see Scheme 1 below)
- Reverse printing is mandatory (see Scheme 1 below)



Scheme 1: Example of film that would fit the required performances

⁷https://foodqualityandsafety.wfp.org

4.1.2 Secondary packaging

LNS-SQ shall be packed in cartons suitable for the humanitarian supply chain, each carton containing either 567 or 602 (or as per contract) individual sachets with a net weight of 20g each. Cartons shall be:

- New, manufactured from well-constructed double walled corrugated board
- With an edge crush resistance of 60ECT = 60 lbs/in eq 11 kN/m (ISO 3037) and a specific weight of 700 to 1000 grams per square meter (or as per contract)
- Fully filled for maximum strength
- The fluting must be vertical, supporting the load
- The carton should be plain brown and paper from sustainably managed forest if possible
- Dimensions adjusted to the load
- No stapling will be accepted

Inside containers: slip sheets or plywood shall be used to provide maximum stacking strength. Pallets with appropriate stacking configuration could also be used. It is highly recommended to have the 3 first bottom layers placed as column stacking the rest can be interlocked (cross stacking) for load stability.

4.1.3 Stuffing of Containers and other transport vehicles

<u>If pallets are used inside containers</u>: 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. The pallets are recommended to be heat treated as per ISPM 15 standards (methyl bromide fumigation is not allowed).

<u>If no pallets are used inside container</u>: 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, 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.

The following table provides a guideline on the quantity to be used.

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. Ventilation holes shall remain clear and unsealed.

4.2 Marking

LNS-SQ shall be labelled in accordance with latest version of recognized international standards and best practices and/or guidelines, such as

- Codex Stan 146-1985 General standard for the labelling of and claims for pre-packaged foods for special dietary uses.
- Codex Stan 1-1985 General standard for the labelling of pre-packaged foods

In addition, **LNS-SQ** shall be labelled in an appropriate language as per contract agreement and artworks available on: https://foodqualityandsafety.wfp.org/ .

Table 4: Generic marking requirement:

	Sachets	Inside leaflet (optional)	Outside box	
Commercial name	Must be kept simple and must not reflect any medical purpose			
Product name	LNS-SQ: Lipid-based Nutrient Supplement – Small Quantity			
Target use	"Intendec	for children aged 6 months		
Net weight	20g	-	567 (or 602)*20g 11.34 kg (or 12.04kg)	
Nutrients content	-	Leaflet or box: in line with target defined		
Ingredient list	XX ⁸ (alle	ergen in bold)	-	
Preparation instruction		day" + Generic pictogram how food is eaten	-	
Storage instruction	"Best stored below 30°C, in a cool, dry place and in hygienic conditions, away from direct sunlight			
Manufactured by: Name & address	XX			
Supplied by: Name & address*	XX			
Country of origin	Pr	roduct of XX/Country of origin	n XX	
Manufacturer batch/lot number**	XX -		XX	
Production date (MM/YYYY)	XX		XX	
Best Before date (MM/YYYY)	XX	-	XX	
Other	"Consume in addition to complementary food and breastmilk" "Immediate breastfeeding after birth, exclusive during the first 6 months and recommended for at least 24 months." Breastfeeding logo No littering logo	"Not for sale or exchange"		

⁸ All XX have to be filled by manufacturer.

Donor and WFP logo	-	as per contractual agreement		
Beneficiary feedback hotline (if required in the	XX	-	xx	
contractual agreement)				

*: if different from the manufacturer

**= supplier need to clearly describe the batch/lot size for the traceability of the product

Templates for artwork available on: <u>https://foodqualityandsafety.wfp.org/specifications</u>

5. SAMPLING AND ANALYTICAL REQUIREMENTS

As per contractual agreement, WFP can appoint an inspection company that will check, based on sampling plan defined below, that the food matches requirements specified in Table 5 and Table 6. Additional tests may be defined in case further quality assessment is required. The following sampling and analytical plans are currently utilized by WFP and shared only for suppliers' information. Suppliers should follow its own food safety and quality management plan. Additionally, WFP reserves the rights to change these plans at any time.

5.1 Sampling plan

Sampling frequency (lot size) will be defined based on the daily production of the producer.

- For producers with daily production equal to or greater than 100MT, the inspection lot size will be one day's production.
- For producers with daily production less than 100MT, the inspection lot size will be one week's production.

The following number of samples representative of the inspection lot will be sent to the laboratory:

- 1. One set of samples for analysis 1-7 in Table 5 and for retention analysis
- 2. Thirty samples for Salmonella analysis
- **3.** Ten samples for Enterobacteriaceae analysis

5.2 List of analyses

No	Parameters	Limit	Method of analysis (or alternative validated method)
1	Protein	12-16 g/100g	AOAC 991.20*
2	Lipid	40 - 53 g/100g	ISO 17189*
3	Vitamin C	75 – 169 mg/100g	EN 14130:2003, AOAC 2012.21, AOAC 985.33*
4	Iron (Fe)	30 – 42 mg/100g	AOAC 990.05* ISO 8294*
5	Total Aflatoxin	Max 10 ppb	ISO 16050*
6	Salmonella	As per table 6	ISO 6579**
7	Enterobacteriaceae	As per table 6	ISO 21528-2***

*Minimum 12 individual sachets from 12 randomly chosen cartons to be mixed into 1 composite test sample by the laboratory

** 25 g analytical unit, samples may be pooled dry, by the laboratory, if lab method has been validated. The total analytical unit should be 750g

*** 10 g analytical unit, no pooling

Table 6: Microbiological criteria

Microorganisms	n	с	m	М	p-class
Salmonella	30	0	Absent in 25 g	n/a	2
Enterobacteriaceae	10	2	≤10 cfu/g	≤100 cfu/g	3

Where

- n: number of sample units in 25g (1 sample unit is taken from 2 sachets of LNS-SQ);

- 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: 2 or 3 class plan