

FINAL DRAFT UGANDA STANDARD

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Vitamin and mineral food supplements — Requirements

DRAFT UGANDA STANDARD



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Draft Uganda Standards adopted by the Technical Committee are widely circulated to stakeholders and the general public for comments. The committee reviews the comments before recommending the draft standards for approval and declaration as Uganda Standards by the National Standards Council.

This Final Draft Uganda Standard, FDUS EAS 797: 2013, *Vitamin and mineral food supplements — Requirements*, is identical with and has been reproduced from an East African Standard, EAS 797: 2013, *Vitamin and mineral food supplements — Requirements*, and is being proposed for adoption as a Uganda Standard.

Wherever the words, "East African Standard" appear, they should be replaced by "Uganda Standard."



FDEAS 797 :2013

ICS 67.230

FINAL DRAFT EAST AFRICAN STANDARD

Vitamin and mineral food supplements — Requirements

DRAFT UGANDA STANDARD

EAST AFRICAN COMMUNITY

DRAFT UGANDA STANDARD

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Foreword

Development of the East African Standards has been necessitated by the need for harmonizing requirements governing quality of products and services in the East African Community. It is envisaged that through harmonized standardization, trade barriers that are encountered when goods and services are exchanged within the Community will be removed.

In order to achieve this objective, the Community established an East African Standards Committee mandated to develop and issue East African Standards.

The Committee is composed of representatives of the National Standards Bodies in Partner States, together with the representatives from the private sectors and consumer organizations. Draft East African Standards are circulated to stakeholders through the National Standards Bodies in the Partner States. The comments received are discussed and incorporated before finalization of standards, in accordance with the procedures of the Community.

East African Standards are subject to review, to keep pace with technological advances. Users of the East African Standards are therefore expected to ensure that they always have the latest versions of the standards they are implementing.

This Final Draft East African Standard, FDEAS 797:2013, was prepared by the Technical Committee EASC/TC 018, Nutrition and foods for special dietary uses. The Committee is composed of representatives from National Standards Bodies, regulators, academia, the private sector and consumer organizations in Partner States.

This Final Draft East African Standard is based on CAC/GL 55:2005, *Guidelines for vitamin and mineral food supplements*.

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Introduction

Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet. Because foods contain many substances that promote health, people should therefore be encouraged to select a balanced diet from food before considering any vitamin and mineral supplement. In cases where the intake from the diet is insufficient or where consumers consider their diet requires supplementation, vitamin and mineral food supplements serve to supplement the daily diet.

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Vitamin and mineral food supplements — Requirements

1 Scope

1.1 This Final Draft East African Standard specifies the requirements for vitamin and mineral food supplements intended for use in supplementing the daily diet with vitamins and/or minerals.

1.2 This standard covers vitamin and mineral food supplements in concentrated forms of those nutrients singly or in combinations, marketed in forms such as capsules, tablets, powders, paste and solutions.

1.3 This standard does not cover vitamin and mineral products intended for special dietary uses or medical/therapeutic purposes.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

AOAC 971.21, *Mercury in food — Flameless Atomic Absorption Spectrometric method*

AOAC 973.34, *Cadmium in food — Atomic Absorption Spectrometric method*

CAC/GL 1-1979, *General guidelines on claims*

CAC/GL 2-1985, *Codex guidelines on nutrition labelling*

CAC/GL 23-1997, *Guidelines for use of nutrition and health claims*

CODEX STAN 192-1995, *General standard for food additives*

EAS 38, *Labelling of pre-packaged foods — Specification*

EAS 39, *Hygiene in the food and drink manufacturing industry — Code of practice*

ISO 2590, *General method for the determination of arsenic — Silver diethyldithiocarbamate photometric method*

ISO 4832, *Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of coliforms — Colony-count technique*

ISO 4833, *Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of microorganisms — Colony count technique at 30 °C*

ISO 6579, *Microbiology of food and animal feeding stuffs — Horizontal method for the detection of Salmonella spp.*

ISO 6888-1, *Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) — Part 1: Technique using Baird-Parker agar medium*

ISO 11290-1, *Microbiology of food and animal feeding stuffs — Horizontal method for the detection and enumeration of Listeria monocytogenes — Part 1: Detection method*

ISO 12193, *Animal and vegetable fats and oils — Determination of lead by direct graphite furnace atomic absorption spectroscopy*

ISO 15304, *Animal and vegetable fats and oils — Determination of the content of trans fatty acid isomers of vegetable fats and oils — Gas chromatographic method*

ISO 21527-2, *Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of yeasts and moulds — Part 2: Colony count technique in products with water activity less than or equal to 0.95*

3 Terms and definitions

For the purposes of this standard, the following terms and definitions shall apply.

3.1

vitamin and mineral food supplement

concentrated forms of vitamin and mineral nutrients singly or in combinations, that are designed to be taken in measured small-unit quantities but are not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet

NOTE Small-unit quantities refer to the physical forms of the vitamin and mineral food supplements and not to the potency of the supplements.

3.2

Nutrient Reference Values (NRVs)

set of numerical values that are based on scientific data for purposes of compositional and nutritional labelling and relevant claims. NRVs are based on levels of nutrients associated with nutrient requirements, or with the reduction in the risk of diet-related non-communicable diseases.

4 Requirements

4.1 General requirements

4.1.1 The vitamins and minerals food supplement shall have acceptable flavour and odour and shall be free from rancid, musty or any other foreign odour or flavour characteristic of spoilage.

4.1.2 The product shall be free from dirt; and extraneous and deleterious material.

4.2 Compositional requirements

4.2.1 Vitamin and mineral food supplements shall contain vitamins/pro-vitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins and minerals is recognised by Food and Agriculture Organization (FAO) and World Health Organization (WHO).

Table 1 provides a list of recognised vitamins and minerals and the units of expression to be used for the purposes of labelling.

Table 1 — List of recognised vitamins and minerals for supplements and units for expression

Vitamin	Unit of expression	Mineral	Unit of expression
Fat soluble		Iron	mg
Vitamin A	µg RE		
Vitamin D	µg	Magnesium	mg
Vitamin E	mg α-TE	Calcium	mg
Vitamin K	µg	Copper	µg
Water Soluble		Iodine	µg
Vitamin C	mg	Zinc	mg
Vitamin B1 (Thiamine)	mg	Manganese	mg
Vitamin B2 (Riboflavin)	mg	Phosphorus	mg
Vitamin B3 (Niacin)	mg NE	Sodium	mg
Pantothenic Acid	mg	Potassium	mg
Vitamin B6 (Pyridoxine)	mg	Selenium	µg
Folates	µg	Chromium	µg
Vitamin B12 (Cobalamine)	µg	Molybdenum	µg
Biotin	µg	Fluoride	mg
		Chloride	mg

4.2.2 The sources of vitamins and minerals may be either natural or synthetic and their selection shall be based on considerations such as safety and bioavailability. In addition, purity criteria shall take into account FAO/WHO standards, if FAO/WHO standards are not available, International Pharmacopoeia or recognized international standards. In the absence of international criteria, national legislation of the country of origin or destination shall be used.

4.2.3 Vitamin and mineral food supplements may contain all vitamins and minerals that comply with the criteria in 4.2.1 and 4.2.2 as a single vitamin and/or mineral or an appropriate combination of vitamins and/or minerals.

4.2.4 Other ingredients including vitamins and minerals used as carriers or additives to the food supplements shall conform to CODEX STAN 192:1995 or to pharmacopoeias.

5 Levels of vitamin and mineral food supplements

5.1 The minimum level of each vitamin and/or mineral contained in a vitamin and mineral food supplement, per daily portion of consumption, as suggested by the manufacturer shall provide at least 15 % of the Nutrient Reference Values (NRV) as determined by FAO/WHO. The NRVs for various nutrients for the general population are indicated in Annex A.

5.2 The maximum amount of the vitamin and minerals shall be guided by upper safe level of the vitamins and mineral as set by WHO/FAO taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups and the intake of vitamins and minerals from other dietary sources. The nutrient requirement values for different consumer age groups are indicated in Annex B for minerals and Annex C for vitamins.

5.3 Vitamins and minerals used as carriers shall not be subject to the requirements of 5.1.

6 Heavy metal contaminants

When tested using validated method, the vitamin and mineral food supplements shall not have any heavy metal in amounts that can cause harm to the population and in particular, the product shall comply with the heavy metal limits listed in Table 2.

Table 2 — Limits of heavy metal contaminants in vitamin and mineral food supplements

SL No	Contaminant	Maximum limit, mg/kg	Methods of test
i.	Arsenic	0.1	ISO 2590
ii.	Lead	3	ISO 12193
iii.	Cadmium	3	AOAC 973.34
iv.	Mercury	0.1	AOAC 971.21

7 Hygiene

7.1 The vitamin and mineral food supplements shall be prepared and packaged in the premises built and maintained under hygienic condition in accordance with EAS 39.

7.2 When tested in accordance with relevant test methods, the product shall be free from pathogenic microorganisms and in particular shall conform to the limits in Table 3.

Table 3 — Microbiological limits for vitamin and mineral food supplements

SL No	Characteristic	Limits	Methods of test
i.	Total plate count, cfu/g, max.	10 ³	ISO 4833
ii.	Coliform bacteria count/g	absent	ISO 4832
iii.	<i>Salmonella sp.</i> , cfu /25g	absent	ISO 6579
iv.	<i>Staphylococcus aureus</i> count/g	absent	ISO 6888-1
v.	<i>Listeria</i> count/25 g	absent	ISO 11290-1
vi.	Mould/yeast, cfu/g, max	< 300	ISO 21527-2

8 Packaging

8.1 The vitamin and mineral food supplements shall be packaged in containers of food grade material in such a way as to protect them from deterioration and contamination.

8.2 The fill of the container shall be in accordance to the Weights and Measures legislation of the destination country.

9 Labelling

9.1 General labelling requirements

Vitamin and mineral food supplements shall be labelled in accordance with EAS 38.

The amount of vitamins and minerals shall be declared on the label in accordance with CAC/GL 2 1985.

Nutrition and health claims on vitamin and mineral food supplements may be made in accordance with CAC/GL 1-1979 and CAC/GL 23-1997.

9.2 Specific labelling requirements

9.2.1 Name of the product

The name of the product shall be 'Food Supplement' with an indication of the category(ies) of nutrients or of the individual vitamin(s) and/or mineral(s) contained in the product as the case may be as described in 4.2.1 and as indicated in examples below:

- a) "Vitamin food supplement" (where several vitamins are incorporated);
- b) "Mineral food supplement" (where several minerals are incorporated);
- c) "Vitamin and mineral food supplement" (where vitamins and minerals are used in combination); and
- d) "Vitamin "X" or mineral "Y" food supplement", (where "X" and "Y" represent specific vitamin or mineral used respectively).

9.2.2 Amount of vitamins and minerals

The amount of the vitamins and minerals present in the product shall be declared in the labelling in numerical form. The units shall be those specified in Table 1.

The amount of vitamin and minerals declared shall be average value based on the manufacturers analysis of the product but in either case shall be in compliance with 5.1 and 5.2.

Vitamins and all minerals constituting less than 15 % of NRV per portion, shall not be declared as nutrient supplements on the label.

9.2.3 Instructions for use

The label shall indicate how the product is to be used in relation to target group, quantity, frequency and any special conditions and precautions that need to be observed.

9.3 Specific prohibition and statements

9.3.1 The labelling, presentation and advertising shall not attribute to a food supplements the property of preventing, treating or curing a human disease or refer to such properties.

9.3.2 The label shall contain advice to the consumer not to exceed the maximum one-day amount recommended by the manufacturer as indicated in 9.2.3.

9.3.3 The label shall have a statement to the effect that food supplements should not be used as a substitute for meals or normal diet.

In addition the label, presentation or advertisement shall not include any mention stating or implying that a balanced diet cannot provide appropriate quantities of nutrients in general.

9.3.4 The label shall have a statement to the effect that the product should be stored out of reach of children.

9.4 Other requirements

In addition to the above requirements, the following shall be included on the label:

- a) name, location and address of the manufacturer;
- b) country of origin where applicable;
- c) ingredients in descending order of proportions;
- d) food additives by their specific names;
- e) date of manufacture;
- f) expiry date;
- g) batch/lot number;
- h) condition of storage;
- i) net content; and
- j) allergen(s) if any.

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Annex A (normative)

Nutrient Reference Values (NRVs)

The NRVs for various nutrients for the general population are indicated in Table A.1.

Table A.1 — Nutrient Reference Values

Nutrient	Units	NRV
Vitamin A	(µg)	8008
Vitamin K	(µg)	60
Vitamin D	(µg)	59
Vitamin C	(mg)	60
Thiamin	(mg)	1.2
Riboflavin	(mg)	1.2
Niacin	(mg)	15
Vitamin B6	(mg)	1.3
Folic acid	(µg)	400
Vitamin B12	(µg)	2.4
Pantothenate	(mg)	5
Biotin	(mg)	30
Calcium	(mg)	1000
Magnesium	(mg)	300
Iron	(mg)	14
Zinc	(mg)	15
Iodine	(µg)	150
Copper		Value to be established
Selenium		Value to be established

Annex B (Informative)

Recommended nutrient intakes

The recommended nutrient intakes for minerals for different age groups are indicated in the tables below.

Table B.1 — Recommended nutrient intakes for minerals (Calcium, Selenium, Magnesium and Zinc)

Group	Calcium, mg/day	Selenium, µg/day	Magnesium, mg/day	Zinc, mg/kg		
				High bioavailability	Moderate bioavailability	Low Bioavailability
Infants						
0–6 months	300 400 ^b	6	26 ^a 36 ^c	1.1	2.8	6.6
7–12 months	400	10	54	0.8 2.5	4.1	4.4
Children						
1–3 years	500	17	60	2.4	4.1	8.3
4–6 years	600	22	76	2.9	4.8	9.6
7–9 years	700	21	100	3.3	5.6	11.2
Adolescent						
Females, 10 - 18 years	1300	26	220	4.3	7.2	14.4
Males, 10 – 18 years	1300	32	230	5.1	8.6	17.1
Adults						
Females, 19 - 50 yrs (Premenopausal)	1000	26	220	3.0	4.9	9.8
51 - 65 yrs (Menopausal)	1300	26	220	3.0	4.9	9.8
Males	1300	34	260	4.2	7.0	14.0
Elderly 65 +						
Females	1300	25	190	3.0	4.9	9.8
Males	1300	33	224	4.2	7.0	14.0
Pregnant women						
First trimester	NS	NS	220	3.4	5.5	11.0
Second trimester	Ns	28	220	4.2	7.0	14.0
Third trimester	1200	30	220	6.0	10.0	20.0
Lactating						
0–3 months	1000	35	270	5.8	9.5	19.0
3–6 months	1000	35	270	5.3	8.8	17.5
7–12 months	1000	42	270	4.3	7.2	14.2
^a Breastfed ^b Cow milk-fed ^c Formula fed						

Table B.2 — Recommended nutrient intakes for minerals (Iron and Iodine)

Group	Iron, mg/day				Iodine, µg/day
	15 % Bioavailability	12 % Bioavailability	10 % Bioavailability	5 % Bioavailability	
Infants					
0 – 6 months	-	-	-	-	90
7 – 12 months	6.2	7.7	9.3	18.6	90
Children					
1 – 3 yrs	3.9	4.8	5.8	11.6	90
4 – 6 yrs	4.2	5.3	6.3	12.6	90
7 – 9 yrs	5.9	7.4	8.9	17.8	120 (6 – 12 yrs)
Adolescent					
Females	21.8 (11–14 yrs)	27.7 (11–14 yrs)	32.7 (11–14 yrs)	65.4 (11–14 yrs)	150 (13–18 yrs)
10 -18 yrs	20.7 (15–17 yrs)	25.8 (15–17 yrs)	31.0 (15–17 yrs)	62.0 (15–17 yrs)	
Males	9.7 (11–14 yrs)	12.2 (11–14 yrs)	14.6 (11–14 yrs)	29.2 (11–14 yrs)	150 (13–18 yrs)
10 – 18 yrs	12.5 (15–17 yrs)	15.7 (15–17 yrs)	18.8 (15–17 yrs)	37.6 (15–17 yrs)	
Adults					
Females (19 - 50 yrs) (Premenopausal)	19.6	24.5	29.4	58.8	150
51 - 65 yrs (Menopausal)	7.5	9.4	11.3	22.6	150
Males	9.1	11.4	13.7	27.4	150
Elderly 65 +					
Females	7.5	9.4	11.3	22.6	150
Males	9.1	11.4	13.7	27.4	150
Pregnant women					
First trimester	NS*	NS	NS	NS	200
Second trimester	NS	NS	NS	NS	200
Third trimester	NS	NS	NS	NS	200
Lactating					
0 – 3 months	10.0	12.5	15.0	30.0	200
3 – 6 months	10.0	12.5	15.0	30.0	200
7 – 12 months	10.0	12.5	15.0	30.0	200
* Not specified. It is recommended that iron supplementation be done.					

Annex C (informative)

Recommended nutrient intakes for water and fat soluble vitamins

The recommended nutrient intakes for vitamins for different age groups are indicated in the tables below.

Table C.1 — Recommended nutrient intakes for vitamins (B₆, C, Thiamin, Riboflavin, Niacin and Pantothenate)

Group	Vitamin C, mg/day	Thiamine µg/day	Riboflavin mg/day	Niacin** mg NE/day	Vitamin B ₆ mg/kg	Pantothenate mg/kg
Infants						
0 – 6 months	25	0.2	0.3	2	0.1	1.7
7 – 12 months	30	0.3	0.4	4	0.3	1.8
Children						
1–3 yrs	30	0.5	0.5	6	0.5	2.0
4–6 yrs	30	0.6	0.6	8	0.6	3.0
7–9 yrs	35	0.9	0.9	12	1.0	4.0
Adolescent						
Females 10 -18 ys	40	1.2	1.3	16	1.3	5.0
Males 10 – 18 ys	40	1.2	1.3	16	1.3	5.0
Adults						
Females (19 - 50 yrs) (Premenopausal)	45	1.1	1.1	1.4	1.5	5.0
51 - 65 yrs (Menopausal)	45	1.1	1.1	1.4	1.5	5.0
Males	45	1.2	1.3	16	1.3 (19 – 50 yrs) 1.7 (50+yrs)	5.0
Elderly 65 +						
Females	45	1.1	1.1	1.4	1.5	5.0
Males	45	1.2	1.3	16	1.7	5
Pregnant women	55	1.4	1.4	18	1.9	6.0
Lactating	70	1.5	1.6	17	2.0	7.0
** NE = Niacin Equivalents						

Table C.2 — Recommended nutrient intakes for vitamins (A,B₁₂, D, E, K, Foliates and Biotin)

Group	Biotin µg/day	Vitamin B ₁₂ µg/day	Foliates ^a µg DFE/day	Vitamin A ^{b,c} , µg RE/day	Vitamin D, µg/kg	Vitamin E, mg α- TE/kg	Vitamin K, µg/day
Infants							
0–6 months	5	0.4	80	375	5	2.7	5
7–12 months	6	0.7	80	400	5	2.7	10
Children							
1–3 yrs	8	0.9	150	400	5	5.0	15
4–6 yrs	12	1.2	200	450	5	5.0	20
7–9 yrs	20	1.8	300	500	5	7.0	25
Adolescent							
Females 10 -18 yrs	25	2.4	400	600	5	7.5	35 - 55
Males 10 – 18 yrs	25	2.4	400	600	5	7.5	35 – 55
Adults							
Females (19 - 50 yrs) (Premenopausal)	30	2.4	400	500	5	7.5	55
51 - 65 yrs (Menopausal)	30	2.4	400	500	5	7.5	55
Males	30	2.4	400	600	5 (19–50 yrs) 10 (50+yrs)	10.0	65
Elderly 65 +							
Females	NS	2.4	400	600	15	7.5	55
Males	NS	2.4	400	600	15	10	65
Pregnant Women	30	2.6	600	800	5	NS	55
Lactatating	35	2.8	500	850	5	NS	55
^a DFE = Dietary Folate Equivalents; µg DFE provided = { µg of food folate + (1.7 x µg of synthetic folic acid)} ^b Vitamin A values are 'recommended safe intakes' ^c Recommended safe intakes as µg RE/day; conversion factor are as follows: <ul style="list-style-type: none"> • 1 µg retinol = 1 RE • 1 µg β-caritene = 0.167 µg RE • 1 µg other provitamins A carotenoids = 0.084 µg RE 							

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