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DRAFT EAST AFRICAN STANDARD

Vitamin and mineral supplements — Specification

EAST AFRICAN COMMUNITY

Second Edition 2022

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Foreword

Development of the East African Standard 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 which 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 East African Standard, DEAS 797:2022, was prepared by the Technical Committee EASC/TC 018, Nutrition and foods for special dietary uses. The Technical Committee is composed of representatives from National Standards Bodies, regulators, academia, the private sector and consumer organizations in Partner States.

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

This second edition DEAS 797:2022 cancels and replaces the first edition, EAS 797:2013, which has been technically revised.

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.

Vitamin and mineral supplements— Specification

1 Scope

1.1 This Draft East African Standard specifies the requirements, sampling and test methods for vitamin and mineral supplements intended for use in supplementing the daily food/ diet with vitamins and/or minerals for human consumption

1.2 This Draft East African standard covers vitamin and mineral 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements 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*

CODEX STAN 192, *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*

EAS 803, *Nutrition labelling — Requirements*

EAS 804, *Claims on foods — Requirements*

EAS 805, *Use of nutritional and health claims — Requirement*

ISO 11290-1, *Microbiology of the food chain — Horizontal method for the detection and enumeration of Listeria monocytogenes and of Listeria spp. — Part 1: Detection method*

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

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*

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 4833-1, *Microbiology of the food chain — Horizontal method for the enumeration of microorganisms — Part 1: Colony count at 30 °C by the pour plate technique*

ISO 6579-1, *Microbiology of the food chain — Horizontal method for the detection, enumeration and serotyping of Salmonella — Part 1: 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*

3 Terms and definitions

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

3.1
vitamin and mineral 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 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 nutrition labelling and relevant claims. They comprise the following two types of NRVs:Nutrient Reference Values - Requirements (NRVs-R) refer to NRVs that are based on levels of nutrients associated with nutrient requirements; and Nutrient Reference Values - Non-communicable Disease (NRVs-NCD) refer to NRVs that are based on levels of nutrients associated with the reduction in the risk of diet-related non-communicable diseases not including nutrient deficiency diseases or disorders.

3.3
food for special dietary uses
foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.

3.4
Ready to use therapeutic food (RUTF)

food for special medical purposes and are high- energy and contain adequate protein and other essential nutrients for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications with appetite

4 Requirements

4.1 General requirements

4.1.1 The vitamins and minerals 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 Specific requirements

4.2.1 Vitamin and mineral 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 recognized by Food and Agriculture Organization (FAO) and World Health Organization (WHO).

Table 1 provides a list of recognized 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 B 3 (Niacin)	mg NE	Sodium	mg
Pantothenic Acid	mg	Potassium	mg
Vitamin B 6 (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 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 or to pharmacopoeias.

5 Levels of vitamin and mineral supplements

5.1 The minimum level of each vitamin and/or mineral contained in a vitamin and mineral 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 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 supplements

S/N	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 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 supplements

S/N	Microorganisms	Maximum Limits	Test method
i.	Total plate count, cfu/g, max.	10^3	ISO 4833-1
ii.	Total Coliforms cfu/g	absent	ISO 4832
iii.	Salmonella spp,per25g	absent	ISO 6579-1
iv.	*Staphylococcus aureus* cfu/g	absent	ISO 6888-1
v.	Listeria spp per 25 g	absent	ISO 11290-1
vi.	Mould and yeast, cfu/g	10^2	ISO 21527-2

8 Packaging

The vitamin and mineral supplements shall be packaged in food grade, non-absorbent materials which do not have adverse effects on the composition of the product including its nutritional value, properties and appearance.

NOTE 1 Packaging materials may be required to meet different regulations in the different destination Partner States

9 Labelling

9.1 General labelling requirements

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

The amount of vitamins and minerals shall be declared on the label in accordance with EAS 803.

Nutrition and health claims on vitamin and mineral supplements may be made in accordance with EAS 804 and EAS 805.

9.2 Specific labelling requirements

9.2.1 Name of the product

The name of the product shall be “XXX Supplement", where XXX indicates vitamin or mineral or Vitamin and mineral 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 supplement” (where several vitamins are incorporated);

b) “Mineral supplement” (where several minerals are incorporated);

c) “Vitamin and mineral supplement” (where vitamins and minerals are used in combination); and

d) “Vitamin “X” or mineral “Y” supplement”, (where “X” and “Y” represent specific vitamin or mineral used respectively).

Declaration “**food/dietary**” in case where product is intended for general population

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 preparation 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, and physical address of the manufacturer; packer, distributor, importer, exporter or vendor;

b) country of origin;

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.

Annex A
(normative)

Nutrient Reference Value (NRVs)

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

Table A.1 — Nutrient Reference Values

Vitamins (Maximum limits)	
Vitamin A (µg)	800*
Vitamin D (µg)	5-15
Vitamin C (µg)	100
Vitamin K (µg)	60
Vitamin E (mg)	9
Thiamin (mg)	1.2
Riboflavin (mg)	1.2
Niacin (mg NE)	15
Vitamin B6 (mg)	1.3
Folate (µg DFE)	400
Vitamin B12 (µg)	2.4
Pantothenate (mg)	5
Biotin (µg)	30
Minerals	
Calcium (mg)	1,000
Magnesium (mg)	310
Iron (mg)	14 (15% dietary absorption; Diversified diets, rich in meat fish, poultry, and/or rich in fruit and vegetables) 22 (10% dietary absorption; Diets rich in cereals, roots or tubers, with some meat, fish, poultry and/or containing some fruit and vegetables)
Zinc (mg)	11 (30% dietary absorption; Mixed diets, and lacto-ovo vegetarian diets that are not based on unrefined cereal grains or high extraction rate (>90%) flours) 14 (22% dietary absorption; Cereal-based diets, with >50% energy intake from cereal grains or legumes and negligible intake of animal protein)
Iodine (µg)	150
Copper µg	900
Selenium µg	60
Manganese mg	3
Molybdenum µg	45

Phosphorous mg	700
* For the declaration of β-carotene (Provitamin A) the conversion factor should be used: 1 µg retinol = 6 β-carotene	

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 400b	6	26[a] 36c	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 10 -18 yrs	21.8 (11–14 yrs) 20.7 (15–17 yrs)	27.7 (11–14 yrs 25.8 (15–17 yrs)	32.7 (11–14 yrs) 31.0 (15–17 yrs)	65.4 (11–14 yrs) 62.0 (15–17 yrs)	150 (13–18 yrs)
Males 10 – 18 yrs	9.7 (11–14 yrs) 12.5 (15–17 yrs	12.2 (11–14 yrs) 15.7 (15–17 yrs)	14.6 (11–14 yrs) 18.8 (15–17 yrs)	29.2 (11–14 yrs) 37.6 (15–17 yrs)	150 (13–18 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 Pantothaenate)

Group	Vitamin C, mg/day	Thiamine µg/day	Riboflavin mg/day	Niacin**mg NE/day	Vitamin B6 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
Lactatating	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, Folates and Biotin)

Group	Biotin µg/day	Vitamin B12	Folates[a] µg DFE/day	Vitamin Ab,c, µg	Vitamin D, µg/kg	Vitamin E, mg α-	Vitamin K, µg/day

		µg/day		RE/day		TE/kg	
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:

1 µg retinol = 1 RE

1 µg β-caritene = 0.167 µg RE

□ 1 µg other provitamins A carotenoids = 0.084 µg RE