

هيئة التقييس لدول مجلس التعاون دول الخليج العربية GCC STANDARDIZATION ORGANIZATION (GSO)

مشروع إعداد
Draft Standard DS

GSO 55/2020

المكملات الغذائية
Food Supplements

ICS: 67.040

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هذه الوثيقة مشروع لمواصفة قياسية خليجية تم توزيعها لإبداء الرأي والملاحظات بشأنها، لذلك فإنها عرضة للتغيير والتبديل، ولا يجوز الرجوع إليها كمواصفة قياسية خليجية إلا بعد اعتمادها من الهيئة.

Foreword

GCC Standardization Organization (GSO) is a regional Organization which consists of the National Standard Bodies of GCC member States. One of GSO main functions is to issue Gulf Standard/ Technical regulation through specialized technical committees (TCs).

GSO through the technical program of committee TC No: (5) "Technical Gulf committee for food and agriculture product standards" has updated the GSO standard No. .../... The draft standard has been prepared by (SAUDI ARABIA).

This standard has been approved as Gulf Technical regulation by GSO Board of Directors in its meeting No...../.....held on / /
H, / /

Food supplements

1 Scope:

This Gulf regulation applies to food supplements products with specific intention to enhance one or several nutritional elements in the normal diet. Food supplements may contain vitamins, minerals, fatty acids, amino acids, enzymes, prebiotics and probiotics, collagen, dietary fibers, melatonin, propolis, pollen, herbs or food herbal extracts...etc.

2 Complementary References:

- 2.1 GSO 9 “Labeling of prepackaged food stuffs”.
- 2.2 GSO 2333 “Health and Nutrition Claims”.
- 2.3 GSO 382 “Maximum Limits of Pesticide Residues in Agricultural and Food Products-Part 1”.
- 2.4 GSO 2500 “Additives Permitted for Use in Food Stuffs”.
- 2.5 GSO 2233 “Requirements of Nutritional Labeling”.
- 2.6 GSO 193 “Contaminants and Toxins in Food and Feed”.
- 2.7 GSO 2055-1 “Halal Food- Part 1: General Requirements”.
- 2.8 GSO 839 “Food Packages- Part 1: General Requirements”.
- 2.9 GSO 1863 “Food packages - Part 2: Plastic package – General requirements”.
- 2.10 GSO 168 “Requirements of Storage Facilities For Dry and Canned Food Stuff”.
- 2.11 GSO 2210 “Ginseng Products”
- 2.12 GSO 2097 “Royal Jelly”.
- 2.13 GSO 147 “Honey”.

3 Definition:

- 3.1 Food supplements food products that used to supplement the normal diet. Which contains ingredients, alone or in combination, may have a nutritional or physiological effect and often it is concentrated and taken in doses. Food supplements consists of one or more of the following components: vitamins, minerals, fatty acids, amino acids, enzymes, prebiotics and probiotics, collagen, dietary fibers, melatonin, propolis, pollen, herbs or food herbal extracts...etc.

4 General requirements:

- 4.1 All components of the product must be in conformity with the requirements of the technical regulations mentioned in Article No. (2.7).
- 4.2 The vitamins and minerals listed in Table No. (1) are permitted, and must be in the formulas listed in Table No. (2).
- 4.3 The quantity of vitamins and minerals in the food supplements are within the limits mentioned in Table No. (3).
- 4.4 If there are health claims on the label, they must comply with the requirements of the technical regulations mentioned in Article No. (2.2).
- 4.5 The additives used in these products must comply with the requirements of the technical regulations mentioned in Article No. (2.4).
- 4.6 The product shall be free of any ingredients with non-food or therapeutic uses.
- 4.7 The pesticide residues in the product shall not exceed the maximum limits mentioned in Article No. (2.3).
- 4.8 The contaminants and toxins in the product shall not exceed the maximum limits mentioned in Article No. (2.6).
- 4.9 The product shall be free from pathogenic microbes and mycotoxins.

- 4.10 The competent authority has the right in to request any additional documents or requirements to demonstrate the safety of the product or its ingredients.
- 4.11 Comply with the variance limits of the product mentioned in Table No. (5).
- 4.12 The ingredients used in the food supplements must be scientifically proven to be safe.
- 4.13 If the product contains high quantities of zinc, it shall be fortified with an adequate amount of copper.
- 4.14 If the product is intended for pregnant women, it must have at least 400 micrograms of folic acid per day.
- 4.15 The maximum dose of cobalt and vitamin B₁₂ together should not exceed 1000 micrograms of vitamin B₁₂ per day.
- 4.16 If the product contains vitamin E a combination of dl-alpha-tocopherol (synthetic form) and d-alpha-tocopherol (natural form) must not exceed the upper limit of 1000 mg of alpha-tocopherol from all sources with a maximum of 1500 IU per day of d-alpha-tocopherol and 1100 IU per day of dl-alpha-tocopherol.

5 Ingredients:

- 5.1 The following ingredients can be added to food supplements:
- 5.1.1 Vitamins.
- 5.1.2 Minerals.
- 5.1.3 Fatty acids.
- 5.1.4 Amino acids.
- 5.1.5 Algae such as Spirulina.

5.1.6 Dietary fibers.

5.1.7 Prebiotics and Probiotics.

5.1.8 Collagen.

5.1.8.1 If the collagen is added to food supplements, the following information must be written on the label:

5.1.8.1.1 The phrases (collagen), (food grade), and determine its source (animal source).

5.1.8.1.2 State the nature of collagen in the list of ingredients as follows (decomposed collagen or collagen peptide).

5.1.8.1.3 Clarify the collagen concentration in the product on its nutritional label.

5.1.9 Plants or herbs and their extracts.

5.1.10 Melatonin.

5.1.11 Coenzyme Q10 (CoQ10).

5.1.12 Enzymes, includes the following:

5.1.12.1 Amylase and protease derived from *Aspergillus flavor oryzae* or *Aspergillus niger*.

5.1.12.2 Bromelin.

5.1.12.3 Ficin.

5.1.12.4 Invertase.

5.1.12.5 Papain.

5.1.12.6 Pectinase.

5.1.12.7 Pepsin.

5.1.12.8 Rennet and Protein- coagulating enzymes.

5.1.12.9 Lactase.

5.1.12.10 Lipase.

5.1.13 (Bovine colostrum).

5.2 Any other permitted ingredients not mentioned in the clause (5.1) above, can be added after evaluating and assessing their safety for human consumption by the competent authority.

5.3 It is permitted to add the following ingredients to the components mentioned above while adhering to their specifications mentioned in the Articles No. (2.11), (2.12,), (2.13):

5.3.1 Ginseng.

5.3.2 Royal jelly, propolis, and pollen, while stating the precautions for special groups, such as infants, pregnant, and lactating women, and those who are allergic to bee products, such as pollen allergy.

6 Packaging:

Without prejudice to what was stipulated in the two Gulf technical regulations mentioned in Articles No. (2.8) and (2.9), the following conditions must be considered:

6.1 Packaging and packing materials shall be made from safe materials.

6.2 It is not permitted for the product to be in pharmaceutical form (capsule, syringe, tablet or pill) or to be filled in packages or strips, which may give the consumer a wrong impression of the product.

6.3 The form of food supplements can be as follows:

- 6.3.1 Chewable tablets (where the base of the product is a food such as chocolate, honey, glucose...etc.).
- 6.3.2 Mouth or throat spray.
- 6.3.3 Liquid.
- 6.3.4 Powder.
- 6.3.5 Lozenges.
- 6.3.6 Ampoule.
- 6.3.7 Drops.
- 6.3.8 Effervescent tablet.

7 Transport and storage:

Without prejudice to what was stipulated in the Gulf technical regulation mentioned in Article No. (2.10).

- 7.1 The product must be transported and stored in an appropriate manner to protect it from contamination and damage at a temperature not exceeding 25 ° C.
- 7.2 In the case of supplements that need to be cooled and to maintain their quality, store at temperatures between -1.5-10 ° C.

8 Labeling:

Without prejudice to the requirements of the Gulf technical regulation mentioned in Article No. (2.1), the following information must be in Arabic language on the product label, and it may also be written in other languages besides Arabic.

- 8.1 Product name.

8.1.1 The name of the product is "Food supplement" followed by the main active ingredient, such as of vitamins/minerals followed by the other optional ingredients it may contains. If the product contains more than three active ingredients (vitamins or minerals and/or with the optional ingredients). Add the following phrase:

8.1.1 “Multivitamin” If the product contains more than three vitamins.

8.1.2 “Multi-mineral” If the product contains more than three minerals.

8.1.3 “Multivitamin & Multi-mineral” If the product contains three elements of vitamins and minerals.

8.2 **Nutritional facts:**

8.2.1 Nutritional facts of the products (carbohydrates, protein, fat, saturated fat, trans fat, and salt or sodium) must be written per 100 grams, or ml, and per serving, and the amount of active ingredients should be clarified according to the units shown in Table No. (1). Specify serving size in grams or ml, and in the case of chewable tablets, ampoules, lozenges, and effervescent tablets, the number must be indicated for each serving.

8.2.2 The amount of energy expressed in calories per 100g/ml, and per serving of product.

8.2.3 Declaration of all the ingredients involved in production.

8.2.4 The information related to the daily need values must be expressed in percentages, and in compliance to regulations mentioned in Article No. (2.5).

- 8.2.5 The nutritional reference value shall be used for the purposes of the label data and in accordance with international standards, and in compliance to regulations mentioned in Article No. (2.5).
- 8.2.6 Conformity to the standard mentioned in item (1.2) regarding allergens, If the product contains an allergen ingredient.
- 8.3 When necessary the target group, and the method of preparation shall be declared.
- 8.4 Clarify the recommended dose for daily use consumption and if needed, it can be declared depending on the target group.
- 8.5 The following phrases must be written:
- 8.5.1 Used under medical supervision.
- 8.5.2 Keep out of reach of children.
- 8.5.3 Do not exceed the recommended daily dose.
- 8.5.4 Food supplements should not be used as a substitute for a varied diet.
- 8.6 The necessary warnings shall be mentioned according to the nature and components of the product as mentioned in Table No. (4).
- 8.7 The net weight shall be stated, and in the case of chewable tablets, ampoules, lozenges, and effervescent tablets, the quantity should be indicated.
- 8.8 Declare production and expiration dates.
- 8.9 Write the conditions of storage and preservation, as well as storing conditions before and after opening the package.
- 8.10. Contrast- A specific contrast must be maintained between the writing and background to ensure legibility on the product label.

- 8.11 A specific use or purpose statement must be made for products providing > 35 mg of niacin, niacinamide or combination of the two, per day.
- 8.12 A specific use or purpose statement must be made for products providing > 35 mg iron per day.
- 8.13 A specific use or purpose statement must be made for products providing > 350 mg magnesium per day.
- 8.14 A specific use or purpose statement must be made for products providing > 40 mg zinc per day.
- 8.15 The following precaution statement must be written if the product contains high doses of vitamin A and beta-carotene. “There is a protentional risk of hypervitaminosis A resulting from the use of product which combine high doses of vitamin A and beta-carotene.”

Table No. (1) Vitamins and minerals that are used in dietary supplements:

1. Vitamins	2. Minerals
Vitamin A (µg RE)	Calcium (mg)
Vitamin D (µg)	Magnesium (mg)
Vitamin E (mg α-TE)	Iron (mg)
Vitamin K (µg)	Copper (µg)
Vitamin B1 (mg)	Iodine (µg)
Vitamin B2 (mg)	Zinc (mg)
Niacin (mg NE)	Manganese (mg)
Pantothenic acid (mg)	Sodium (mg)
Vitamin B6 (mg)	Potassium (mg)
Folic acid (µg)	Selenium (µg)
Vitamin B12 (µg)	Chromium (µg)
Biotin (µg)	Molybdenum (µg)
Vitamin C (mg)	Fluoride (mg)

Table No. (2) Vitamins and minerals forms that are used in dietary supplements:

A. Vitamins

1. Vitamin A

- (a) Retinol
- (b) Retinyl acetate
- (c) Retinyl palmitate
- (d) Beta-carotene

2. Vitamin D

- (a) Cholecalciferol
- (b) Ergocalciferol

3. Vitamin E

- (a) d-alpha-tocopherol
- (b) dl-alpha-tocopherol
- (c) d-alpha-tocopheryl acetate
- (d) dl-alpha-tocopheryl acetate
- (e) d-alpha-tocopheryl acid succinate

4. Vitamin K

- (a) Phylloquinone (phytomenadione)

5. Vitamin B1

- (a) Thiamin hydrochloride
- (b) Thiamin mononitrate

6. Vitamin B2

- (a) Riboflavin
- (b) Riboflavin 5'-phosphate, sodium

7. Niacin

- (a) Nicotinic acid

- (b) Nicotinamide

8. Pantothenic acid

- (a) d-pantothenate, calcium
- (b) d-pantothenate, sodium
- (c) Dexpantenol

9. Vitamin B6

- (a) Pyridoxine hydrochloride
- (b) Pyridoxine 5'-phosphate

10. Folic acid

- (a) Pteroylmonoglutamic acid

11. Vitamin B12

- (a) Cyanocobalamin
- (b) Hydroxocobalamin

12. Biotin

- (a) d-biotin

13. Vitamin C

- (a) l-ascorbic acid
- (b) sodium-l-ascorbate
- (c) calcium-l-ascorbate
- (d) potassium-l-ascorbate
- (e) l-ascorbyl 6-palmitate

B. Minerals

Calcium carbonate

Calcium chloride

Calcium salts of citric acid
Calcium gluconate
Calcium glycerophosphate
Calcium lactate
Calcium salts of orthophosphoric acid
Calcium hydroxide
Calcium oxide
Magnesium acetate
Magnesium carbonate
Magnesium chloride
Magnesium salts of citric acid
Magnesium gluconate
Ferric sodium diphosphate
Ferrous lactate
Ferrous sulphate
Ferric diphosphate (ferric pyrophosphate)
Ferric saccharate
Elemental iron
(carbonyl+electrolytic+hydrogen Reduced)
Cupric carbonate
Cupric citrate
Cupric gluconate
Cupric sulphate
Copper lysine complex
Sodium iodide
Sodium iodate
Potassium iodide
Potassium iodate
Zinc acetate
Zinc chloride
Zinc citrate
Zinc gluconate
Zinc lactate

Magnesium glycerophosphate
Magnesium salts of orthophosphoric acid
Magnesium lactate
Magnesium hydroxide
Magnesium oxide
Magnesium sulphate
Ferrous carbonate
Ferrous citrate
Ferric ammonium citrate
Ferrous gluconate
Ferrous fumarate
Zinc oxide
Zinc carbonate
Zinc sulphate
Manganese carbonate
Manganese chloride
Manganese citrate
Manganese gluconate
Manganese glycerophosphate
Manganese sulphate
Sodium bicarbonate
Sodium carbonate
Sodium chloride
Sodium citrate
Sodium gluconate
Sodium lactate
Sodium hydroxide
Sodium salts of orthophosphoric acid
Potassium bicarbonate
Potassium carbonate
Potassium chloride
Potassium citrate
Potassium gluconate
Potassium glycerophosphate
Potassium lactate

Potassium hydroxide
Potassium salts of orthophosphoric
acid
Sodium selenate
Sodium hydrogen selenite
Sodium selenite
Chromium (iii) chloride
Chromium (iii) sulphate

Ammonium molybdate (molybdenum
(vi))
Sodium molybdate (molybdenum (vi))
Potassium fluoride
Sodium fluoride

Table No. (3) Limits of vitamins and minerals in dietary supplements:

Age categories							
Adults	Adolescence		Children		Infants		
19 years and older	14-18 years	9-13 years	4-8 years	1-3 years	0-12 months		
65	65	65	65	65	-	Min	Calcium (mg/day)
1500	1500	1500	1500	1500	-	Max	
0.006	0.006	0.004	0.004	0.004	-	Min	Cobalt (µg/day)
44	44	44	44	44	-	Max	
2.2	-	-	-	-	-	Min	Chromium (µg/day)
500	-	-	-	-	-	Max	
65	65	35	35	35	-	Min	Copper (µg/day)
8000	6500	4000	2500	700	-	Max	
14	14	6	6	6	-	Min	Iodine (µg/day)
800	800	400	200	133	-	Max	
1.4	1.4	0.6	0.6	0.6	0.6	Min	Iron (mg/day)
45	45	40	40	40	40	Max	
20	20	12	12	12	-	Min	Magnesium (mg/day)
500	350	350	110	65	-	Max	
0.13	-	-	-	-	-	Min	Manganese (mg/day)
9	-	-	-	-	-	Max	
2.5	-	-	-	-	-	Min	Molybdenum (µg/day)
2000	-	-	-	-	-	Max	
>0	-	-	-	-	-	Min	Silicon (mg/day)
84	-	-	-	-	-	Max	
3.5	-	-	-	-	-	Min	Selenium (µg/day)
200	-	-	-	-	-	Max	
62	62	62	62	62	-	Min	Phosphorus

2000	2000	2000	2000	2000	-	Max	(mg /day)
0.7	0.7	0.4	0.4	0.4	0.2	Min	Zinc (From non-source zinc picolinate) (mg /day)
50	34	23	12	7	2	Max	
0.7	-	-	-	-	-	Min	Zinc (From source zinc picolinate) (mg /day)
25	-	-	-	-	-	Max	
>0	-	-	-	-	-	Min	Potassium (mg /day)
200	-	-	-	-	-	Max	
-	-	-	-	-	-	Min	Sodium (mg /day)
-	-	-	-	-	-	Max	
-	-	-	-	-	-	Min	Fluoride (mg /day)
-	-	-	-	-	-	Max	

Age categories							
Adults	Adolescence		Children		Infants		
19 years and older	14-18 years	9-13 years	4-8 years	1-3 years	0-12 months		
1.8	1.8	1	1	1	-	Min	Biotin (µg/day)
500	500	500	500	500	-	Max	
30	30	15	15	15	-	Min	Folic acid (µg/day)
1000	800	600	400	300	-	Max	
1.0	1.0	0.6	0.6	0.6	-	Min	Niacin/niacinamide (mg/day)
500	30	20	15	10	-	Max	
0.4	0.4	0.2	0.2	0.2	-	Min	Pantothenic acid (mg/day)
500	500	500	500	500	-	Max	
0.08	0.08	0.04	0.04	0.04	-	Min	Riboflavin B ₂ (mg/day)
100	100	100	100	100	-	Max	
0.07	0.07	0.04	0.04	0.04	-	Min	Thiamin B ₁ (mg/day)
100	100	100	100	100	-	Max	
0.10	0.10	0.05	0.05	0.05	-	Min	Vitamin B ₆ (mg/day)
100	80	60	40	30	-	Max	
0.14	0.14	0.09	0.09	0.09	-	Min	Vitamin B ₁₂ (µg/day)
1000	1000	1000	1000	1000	-	Max	
6.0	6.0	2.2	2.2	2.2	-	Min	Vitamin C (mg/day)
2000	1800	1200	650	400	-	Max	
1.0	1.0	0.8	0.8	0.8	0.5	Min	Vitamin D (µg/day)
25	25	25	25	25	25	Max	
1.0	1.0	0.6	0.6	0.6	-	Min	Vitamin E (mg AT/day)

500	400	300	150	100	-	Dl-Alpha-Tocopherol Max	
1000	800	600	300	200	-	d-Alpha-Tocopherol Max	
6	6	3	3	3	-	Min	Vitamin K ₁ , Vitamin K ₂ and Vitamin K ₁ + K ₂ (mg/day)
120	75	60	55	30	-	Max	

All trans retinyl palmitate - Max	All trans retinal acetate - Max	All trans retinol - Max	Min	Vitamin A (µg RAE/day)	
600	600	600	30	0-12 months	Infants
600	600	600	30	1-3 years	Children
900	900	900	30	4-8 years	
1700	1700	1700	30	9-13 years	Adolescence
2800	2800	2800	65	14-18 years	
3022	3000	3003	65	19 years and older	Adults

Table (4) Warnings and cautions related to the consumption of types of dietary supplements:

Cautions and warnings for specific medicinal ingredients and associated daily doses:

Caution	Daily dose	The ingredient
Consult a health care provider/ /doctor if you have a kidney disorder and/or diabetes.	$\geq 200 \mu\text{g}$	Chromium Sourced from Chromium Picolinate
Consult a health care provider/ doctor for use beyond 6 months.	All doses	Chromium sourced from chromium Picolinate
Do not use this product if you are pregnant or breastfeeding.	All doses	Chromium sourced from chromium Picolinate
Keep out of reach of children. There is enough iron in this package to harm a child.	When the package contains more than 250 mg of iron.	Iron
Some people may experience constipation, diarrhea and/or vomiting.	$> 35 \text{ mg}$	Iron
Stop use if hypersensitivity occurs.	All doses	
Consult a health care provider /doctor prior to use if you have a liver disorder.	$>5 \text{ mg}$	Manganese
Consult a health care provider/ doctor prior to use if you have a non-melanoma skin cancer.	$>70 \mu\text{g}$	Selenium
Consult a health care provider/ doctor prior to use if you are pregnant or breastfeeding.	All doses	Vanadium
Consult a health care provider/ doctor prior to use if you have cancer.	$\geq 180 \text{ mg AT}$	Vitamin E

Consult a health care provider/ doctor prior to use if you have cardiovascular disease or diabetes.	≥ 268 mg AT	
Consult a health care provider/ doctor prior to use if you are taking blood thinners.	≥ 360 mg AT	
Consult a health care provider/ doctor prior to use if you are taking blood thinners.	All doses	Vitamin K (K1 and/or K2)
Do not use this product if your pregnant or breastfeeding	All doses	Zinc sourced from Zinc Picolinate
Consult a health care provider/ doctor for use beyond 3 months.	All doses	Zinc sourced from Zinc Picolinate
Zinc supplementation can cause a copper deficiency. If you are unsure, whether you are taking enough copper, consult a health care practitioner prior to use.	≤ 2 mg	Infants 0-12 months
	5-7 mg	Toddlers 1-3 years
	8-12 mg	Children 4-8 years
	16-23 mg	Adolescence 9-13 years
	25-34 mg	Adolescence 14-18 years
	31-50 mg	Adults 19 years and older
		Zinc
Do not use this product with other potassium-containing supplements or with potassium-containing salt substitutes.	≥ 100 mg	Potassium
Some people experience diarrhea	> 350 mg	Magnesium

Table No. (5) Variance limit:

The percentage of variance limits for vitamins and minerals added to dietary supplements are as shown in the table:

Percentage of variances allowed for vitamins and minerals in dietary supplements	The nutritional component
% 20- % 50 +	Vitamins
% 20- % 45 +	Minerals

References

- DIRECTIVE 2002/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 10 June 2002 on the approximation of the laws of the Member States relating to food supply.
- GUIDELINES FOR VITAMIN AND MINERAL FOOD SUPPLEMENTS CAC/GL 55 – 2005
- Canada, H. (2019). Consultation - Revised Monograph (Multi-Vitamin/Mineral Supplements).
- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.
- Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling of foodstuffs.
- Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.