

Seven Easy Steps To Assess Non-Compliance Of A Food Supplement

Three easy immediate checks of the label

1. If a product is labelled as 'Dietary Supplement', it is non-compliant.
All food supplements must be labelled with 'Food Supplement'.
2. If the product lists the vitamins, minerals and other active substances under 'Supplement Facts' or a similar heading, and follows this by 'Other ingredients' listing the carriers and other additives etc., it is non-compliant.
ALL ingredients (including the active ingredients) must be listed under the heading 'Ingredients' in descending order by weight of input. Active ingredients must be quantified either separately under an appropriate heading or within the ingredients list itself.
3. If the quantity of vitamins A, D or E is given solely or principally as 'IU', it is non-compliant.
The quantity of these vitamins must be stated on food supplement labels using the applicable units: vitamin A 'µg RE'; vitamin D 'µg'; vitamin E 'mg α-TE'.
Although the voluntarily declaration of quantity in IU may sometimes be provided, this must not take priority.

Four easy checks requiring the use of lists

4. The only permitted vitamins and minerals for use in food supplements are listed in Annex I of Directive 2002/46/EC on food supplements, as amended. If the product contains vitamins or minerals other than those listed (e.g. vanadium), it is non-compliant.
The permitted vitamins and minerals, as of November 2016, are listed in Appendix I of this document.
5. The only permitted vitamin and mineral sources for use in food supplements are listed in Annex II of Directive 2002/46/EC on food supplements, as amended. If the product contains vitamin or mineral sources other than those listed (e.g. potassium glycinate complex), it is non-compliant.
The permitted vitamin and mineral sources, as of November 2016, are listed in Appendix II of this document.
6. Certain ingredients have been determined to be novel foods requiring authorisation before they can be permitted for use (e.g. *Acacia rigidula*). These ingredients are listed in the EU novel food catalogue, which also includes the status of a number of other ingredients that may be not novel in food supplements only or not novel in all foods. The catalogue is not exhaustive, but if any of the ingredients stated as novel are present in a product, it is non-compliant, unless proof can be provided by the company that the ingredient falls under one of the few exceptions stated.
 - *EU novel food catalogue*
7. If the product bears health claims, these should relate only to those authorised via Regulation 1924/2006 on nutrition and health claims (including disease risk reduction claims) and present on the EU Register on nutrition and health claims. Certain on-hold claims are also permitted. Claims which refer to preventing, treating or curing a disease / illness are not permitted.
This can be a complicated issue. UK guidance on claims can be found from the Department of Health and Social Care (DHSC), the Committee of Advertising Practice (CAP) and the Medicines and Healthcare products Regulatory Agency (MHRA).
 - *EU Register of nutrition and health claims*
 - *DH Guide to compliance with Regulation (EC) 1924/2006 on nutrition and health claims made on foods*
 - *DHSC guidance relating to 'on hold' health claims*
 - *DHSC 'on hold' claims spreadsheet*
 - *CAP/ASA Advice and Resources*
 - *MHRA Guide to what is a medicinal product*

(The links are current as of November 2018. However, we have no control over other agencies relocating their web pages. Therefore, if any of the links do not work, search in your web browser for the document name)

APPENDIX I

List of permitted vitamins and minerals for use in food supplements and the units by which they should be quantified (as of November 2018)

Taken from Annex I of Directive 2002/46/EC as amended

Vitamins

Vitamin A (μg RE)

Vitamin D (μg)

Vitamin E (mg a-TE)

Vitamin K (μg)

Vitamin B1 (thiamin) (mg)

Vitamin B2 (riboflavin) (mg)

Niacin (mg NE)

Pantothenic acid (mg)

Vitamin B6 (mg)

Folic acid (μg)

Vitamin B12 (μg)

Biotin (μg)

Vitamin C (mg)

Minerals

B

Boron (mg)

C

Calcium (mg)

Chloride (mg)

Chromium (μg)

Copper (μg)

F

Fluoride (mg)

I

Iodine (μg)

Iron (mg)

M

Magnesium (mg)

Manganese (mg)

Molybdenum (μg)

P

Phosphorus (mg)

Potassium (mg)

S

Selenium (μg)

Silicon (mg)

Sodium (mg)

Z

Zinc (mg)

APPENDIX II

List of permitted vitamins and mineral sources for use in food supplements (as of November 2018)

Taken from Annex II of Directive 2002/46/EC as amended

VITAMINS

Vitamin A

Retinol
Retinyl acetate
Retinyl palmitate
Beta-carotene

Vitamin D

Cholecalciferol
Ergocalciferol

Vitamin E

D-alpha-tocopherol
DL-alpha-tocopherol
D-alpha-tocopheryl acetate
DL-alpha-tocopheryl acetate
D-alpha-tocopheryl acid succinate
Mixed tocopherols ⁽¹⁾
Tocotrienol tocopherol ⁽¹⁾

Vitamin K

Phylloquinone (phytomenadione)
Menaquinone ⁽¹⁾

Vitamin B1 (Thiamin)

Thiamin hydrochloride
Thiamin mononitrate
Thiamine monophosphate chloride
Thiamine pyrophosphate chloride

Vitamin B2 (Riboflavin)

Riboflavin
Riboflavin 5'-phosphate, sodium

Niacin

Nicotinic acid
Nicotinamide
Inositol hexanicotinate (inositol
hexaniacinate)

Pantothenic acid

D-pantothenate, calcium
D-pantothenate, sodium
Dexpanthenol
Pantethine

Vitamin B6

Pyridoxine hydrochloride
Pyridoxine 5'-phosphate
Pyridoxal 5'-phosphate

Folate (folic acid)

Pteroylmonoglutamic acid
Calcium-L-methylfolate
(6S)-5-methyltetrahydrofolic acid,
glucosamine salt

Vitamin B12

Cyanocobalamin
Hydroxocobalamin
5'-deoxyadenosylcobalamin
Methylcobalamin

Biotin

D-biotin

Vitamin C

L-ascorbic acid
Sodium-L-ascorbate
Calcium-L-ascorbate (1)
Potassium-L-ascorbate
L-ascorbyl 6-palmitate
Magnesium L-ascorbate
Zinc L-ascorbate

MINERALS

Boron

Boric acid
Sodium borate

Calcium

Calcium acetate
Calcium L-ascorbate
Calcium bisglycinate
Calcium carbonate
Calcium chloride
Calcium citrate malate
Calcium salts of citric acid
Calcium gluconate
Calcium glycerophosphate
Calcium lactate
Calcium pyruvate
Calcium salts of orthophosphoric acid
Calcium succinate
Calcium hydroxide
Calcium L-lysinate
Calcium malate
Calcium oxide
Calcium L-pidolate
Calcium L-threonate
Calcium sulphate
Calcium phosphoryl oligosaccharides

Chloride

Any of the listed chloride salts

Chromium

Chromium (III) chloride
Chromium enriched yeast¹
Chromium (III) lactate trihydrate
Chromium nitrate
Chromium picolinate
Chromium (III) sulphate

Copper

Cupric carbonate
Cupric citrate
Cupric gluconate
Cupric sulphate
Copper L-aspartate
Copper bisglycinate
Copper lysine complex
Copper (ii) oxide

Note: the ingredient may be listed as 'copper...', in which case the company should be able to confirm the source used is cupric (where relevant)

Fluoride

Calcium fluoride
Potassium fluoride
Sodium fluoride
Sodium monofluorophosphate

Iodine

Potassium iodide
Potassium iodate
Sodium iodide
Sodium iodate

Iron

Ferrous carbonate
Ferrous citrate
Ferric ammonium citrate
Ferrous gluconate
Ferrous fumarate
Ferric sodium diphosphate
Ferrous lactate
Ferrous sulphate
Ferric diphosphate (ferric pyrophosphate)
Ferric saccharate
Elemental iron (carbonyl + electrolytic + hydrogen reduced)
Ferrous bisglycinate
Ferrous L-pidolate
Ferrous phosphate
Ferrous ammonium phosphate
Ferric sodium edta
Iron (ii) taurate

Note: the ingredient may be listed as 'iron...', in which case the company should be able to confirm the source used is ferrous or ferric (where relevant)

Magnesium

Magnesium acetate
Magnesium l-ascorbate
Magnesium bisglycinate
Magnesium carbonate
Magnesium chloride
Magnesium salts of citric acid
Magnesium gluconate
Magnesium glycerophosphate
Magnesium salts of
 orthophosphoric acid
Magnesium lactate
Magnesium l-lysinate
Magnesium hydroxide
Magnesium malate
Magnesium oxide
Magnesium l-pidolate
Magnesium potassium citrate
Magnesium pyruvate
Magnesium succinate
Magnesium sulphate
Magnesium taurate
Magnesium acetyl taurate

Manganese

Manganese ascorbate
Manganese l-aspartate
Manganese bisglycinate
Manganese carbonate
Manganese chloride
Manganese citrate
Manganese gluconate
Manganese glycerophosphate
Manganese pidolate
Manganese sulphate

Molybdenum

Ammonium molybdate
 (molybdenum (VI))
Potassium molybdate
 (molybdenum (VI))
Sodium molybdate (molybdenum
 (VI))

Phosphorus

Any of the listed phosphates that
provide a sufficient quantity

Potassium

Potassium bicarbonate
Potassium carbonate
Potassium chloride
Potassium citrate
Potassium gluconate
Potassium glycerophosphate
Potassium lactate
Potassium hydroxide
Potassium l-pidolate
Potassium malate
Potassium salts of orthophosphoric
 acid

Selenium

L-selenomethionine
Selenium enriched yeast¹
Selenious acid
Sodium selenate
Sodium hydrogen selenite
Sodium selenite

Silicon

Choline-stabilised orthosilicic acid
Silicon dioxide
Silicic acid¹
Organic silicon
 (monomethylsilanetriol)

Sodium

Sodium bicarbonate
Sodium carbonate
Sodium chloride
Sodium citrate
Sodium gluconate
Sodium lactate
Sodium hydroxide
Sodium salts of orthophosphoric
 acid
Sodium sulphate

Zinc

zinc acetate
Zinc l-ascorbate
Zinc l-aspartate
Zinc bisglycinate
Zinc chloride
Zinc citrate
Zinc gluconate
Zinc lactate
Zinc l-lysinate
Zinc malate
Zinc mono-l-methionine sulphate
Zinc oxide
Zinc carbonate
Zinc l-pidolate
Zinc picolinate
Zinc sulphate

¹ The ingredient must be in the form specified in Annex II of Directive 2002/46/EC as amended

NOTE: Synonyms might be used in the ingredients list for some of these substances.

APPENDIX I

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Taken from Annex I of Directive 2002/46/EC as amended

Vitamins

Vitamin A ($\mu\text{g RE}$)

Vitamin D (μg)

Vitamin E (mg α -TE)

Vitamin K (μg)

Vitamin B1 (thiamin) (mg)

Vitamin B2 (riboflavin) (mg)

Niacin (mg NE)

Pantothenic acid (mg)

Vitamin B6 (mg)

Folic acid (μg)

Vitamin B12 (μg)

Biotin (μg)

Vitamin C (mg)

Minerals

B

Boron (mg)

C

Calcium (mg)

Chloride (mg)

Chromium (μg)

Copper (μg)

F

Fluoride (mg)

I

Iodine (μg)

Iron (mg)

M

Magnesium (mg)

Manganese (mg)

Molybdenum (μg)

P

Phosphorus (mg)

Potassium (mg)

S

Selenium (μg)

Silicon (mg)

Sodium (mg)

Z

Zinc (mg)

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Taken from Annex II of Directive 2002/46/EC as amended

VITAMINS

Vitamin A

Retinol
Retinyl acetate
Retinyl palmitate
Beta-carotene

Vitamin D

Cholecalciferol
Ergocalciferol

Vitamin E

D-alpha-tocopherol
DL-alpha-tocopherol
D-alpha-tocopheryl acetate
DL-alpha-tocopheryl acetate
D-alpha-tocopheryl acid succinate
Mixed tocopherols ⁽¹⁾
Tocotrienol tocopherol ⁽¹⁾

Vitamin K

Phylloquinone (phytomenadione)
Menaquinone ⁽¹⁾

Vitamin B1 (Thiamin)

Thiamin hydrochloride
Thiamin mononitrate
Thiamine monophosphate chloride
Thiamine pyrophosphate chloride

Vitamin B2 (Riboflavin)

Riboflavin
Riboflavin 5'-phosphate, sodium

Niacin

Nicotinic acid
Nicotinamide
Inositol hexanicotinate (inositol
hexaniacinate)

Pantothenic acid

D-pantothenate, calcium
D-pantothenate, sodium
Dexpanthenol
Pantethine

Vitamin B6

Pyridoxine hydrochloride
Pyridoxine 5'-phosphate
Pyridoxal 5'-phosphate

Folate (folic acid)

Pteroylmonoglutamic acid
Calcium-L-methylfolate
(6S)-5-methyltetrahydrofolic acid,
glucosamine salt

Vitamin B12

Cyanocobalamin
Hydroxocobalamin
5'-deoxyadenosylcobalamin
Methylcobalamin

Biotin

D-biotin

Vitamin C

L-ascorbic acid
Sodium-L-ascorbate
Calcium-L-ascorbate (1)
Potassium-L-ascorbate
L-ascorbyl 6-palmitate
Magnesium L-ascorbate
Zinc L-ascorbate

MINERALS

Boron

Boric acid
Sodium borate

Calcium

Calcium acetate
Calcium L-ascorbate
Calcium bisglycinate
Calcium carbonate
Calcium chloride
Calcium citrate malate
Calcium salts of citric acid
Calcium gluconate
Calcium glycerophosphate
Calcium lactate
Calcium pyruvate
Calcium salts of orthophosphoric acid
Calcium succinate
Calcium hydroxide
Calcium L-lysinate
Calcium malate
Calcium oxide
Calcium L-pidolate
Calcium L-threonate
Calcium sulphate
Calcium phosphoryl oligosaccharides

Chloride

Any of the listed chloride salts

Chromium

Chromium (III) chloride
Chromium enriched yeast¹
Chromium (III) lactate trihydrate
Chromium nitrate
Chromium picolinate
Chromium (III) sulphate

Copper

Cupric carbonate
Cupric citrate
Cupric gluconate
Cupric sulphate
Copper L-aspartate
Copper bisglycinate
Copper lysine complex
Copper (ii) oxide

Note: the ingredient may be listed as 'copper...', in which case the company should be able to confirm the source used is cupric (where relevant)

Fluoride

Calcium fluoride
Potassium fluoride
Sodium fluoride
Sodium monofluorophosphate

Iodine

Potassium iodide
Potassium iodate
Sodium iodide
Sodium iodate

Iron

Ferrous carbonate
Ferrous citrate
Ferric ammonium citrate
Ferrous gluconate
Ferrous fumarate
Ferric sodium diphosphate
Ferrous lactate
Ferrous sulphate
Ferric diphosphate (ferric pyrophosphate)
Ferric saccharate
Elemental iron (carbonyl + electrolytic + hydrogen reduced)
Ferrous bisglycinate
Ferrous L-pidolate
Ferrous phosphate
Ferrous ammonium phosphate
Ferric sodium edta
Iron (ii) taurate

Note: the ingredient may be listed as 'iron...', in which case the company should be able to confirm the source used is ferrous or ferric (where relevant)

Magnesium

Magnesium acetate
Magnesium l-ascorbate
Magnesium bisglycinate
Magnesium carbonate
Magnesium chloride
Magnesium salts of citric acid
Magnesium gluconate
Magnesium glycerophosphate
Magnesium salts of
 orthophosphoric acid
Magnesium lactate
Magnesium l-lysinate
Magnesium hydroxide
Magnesium malate
Magnesium oxide
Magnesium l-pidolate
Magnesium potassium citrate
Magnesium pyruvate
Magnesium succinate
Magnesium sulphate
Magnesium taurate
Magnesium acetyl taurate

Manganese

Manganese ascorbate
Manganese l-aspartate
Manganese bisglycinate
Manganese carbonate
Manganese chloride
Manganese citrate
Manganese gluconate
Manganese glycerophosphate
Manganese pidolate
Manganese sulphate

Molybdenum

Ammonium molybdate
 (molybdenum (VI))
Potassium molybdate
 (molybdenum (VI))
Sodium molybdate (molybdenum
 (VI))

Phosphorus

Any of the listed phosphates that
provide a sufficient quantity

Potassium

Potassium bicarbonate
Potassium carbonate
Potassium chloride
Potassium citrate
Potassium gluconate
Potassium glycerophosphate
Potassium lactate
Potassium hydroxide
Potassium l-pidolate
Potassium malate
Potassium salts of orthophosphoric
 acid

Selenium

L-selenomethionine
Selenium enriched yeast¹
Selenious acid
Sodium selenate
Sodium hydrogen selenite
Sodium selenite

Silicon

Choline-stabilised orthosilicic acid
Silicon dioxide
Silicic acid¹
Organic silicon
 (monomethylsilanetriol)

Sodium

Sodium bicarbonate
Sodium carbonate
Sodium chloride
Sodium citrate
Sodium gluconate
Sodium lactate
Sodium hydroxide
Sodium salts of orthophosphoric
 acid
Sodium sulphate

Zinc

zinc acetate
Zinc l-ascorbate
Zinc l-aspartate
Zinc bisglycinate
Zinc chloride
Zinc citrate
Zinc gluconate
Zinc lactate
Zinc l-lysinate
Zinc malate
Zinc mono-l-methionine sulphate
Zinc oxide
Zinc carbonate
Zinc l-pidolate
Zinc picolinate
Zinc sulphate

¹ The ingredient must be in the form specified in Annex II of Directive 2002/46/EC as amended

NOTE: Synonyms might be used in the ingredients list for some of these substances.