Health Canada Santé Canada

MULTI-VITAMIN/MINERAL SUPPLEMENT MONOGRAPH

October 22, 2007

Canada

TABLE OF CONTENTS

MULTI-VITAMIN/MINERAL SUPPLEMENT MONOGRAPH

- This monograph is intended for multi-vitamin, multi-mineral or multi-vitamin/mineral supplements that contain any two or more of the medicinal ingredients listed in Tables 1, 2 or 3 with the exception of combinations containing only the following medicinal ingredients: boron, choline, inositol, L-methionine, lutein, lycopene, nickel, silicon, tin and vanadium.
- For products containing a single vitamin or mineral as their sole medicinal ingredient, please refer to the appropriate single ingredient monograph.
- Products that are manufactured, sold or represented for use as a food or beverage are excluded.
- Sodium is not permitted as a medicinal ingredient on this monograph due to health concerns associated with chronic supplemental use, namely hypertension, which remains the most common and most important risk factor for cardiovascular disease. However, the use of sodium as a counter-ion in medicinal or non-medicinal ingredients (e.g. sodium salts of minerals) is acceptable where warranted.
- Chlorine, fluorine and sulfur are not permitted as medicinal ingredients on this monograph.

1.0 Proper name(s), Common name(s) and Source material(s)

1.1 Vitamin proper name(s), common name(s) and source material(s)

Table 1: Vitamin proper name(s), common name(s) and source material(s)

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
Biotin	Biotin	Biocytin Biotin
Folate	Folacin; Folate; Folic acid; Vitamin B_9	Folacin/Folate/Folic acid
Niacin; Nicotinic acid	Niacin; Nicotinic acid; Vitamin B_3	Nicotinic acid
Niacinamide; Nicotinamide	Niacinamide; Nicotinamide; Vitamin B_3	Niacinamide/Nicotinamide Niacinamide ascorbate/Nicotinamide ascorbate
Pantothenic acid	Pantothenic acid; Vitamin B_5	Calcium-*d*-pantothenate Calcium-*dl*-pantothenate Pantethine *d*-Panthenol/Dexpanthenol

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
		dl-Panthenol *d*-Pantothenic acid *dl*-Pantothenic acid
Riboflavin	Riboflavin; Vitamin B_2	Riboflavin Riboflavin-5-phosphate (sodium salt)
Thiamine	Thiamine; Vitamin B_1	Thiamine/Thiamine monochloride Thiamine diphosphate Thiamine hydrochloride Thiamine mononitrate Thiamine monophosphate
Vitamin A	Retinol; Vitamin A	Beta-carotene/All-*trans* beta-carotene Vitamin A/All-*trans* retinol Vitamin A acetate/All-*trans* retinyl acetate Vitamin A palmitate/All-*trans* retinyl palmitate
Vitamin B_6	Pyridoxine; Vitamin B_6	Pyridoxal Pyridoxal hydrochloride Pyridoxal-5-phosphate (calcium salt) Pyridoxamine Pyridoxamine-5-phosphate Pyridoxine Pyridoxine hydrochloride Pyridoxine-5-phosphate
Vitamin B_{12}	Cyanocobalamin; Vitamin B_{12}	Cyanocobalamin/Vitamin B_{12} Hydroxocobalamin Methylcobalamin
Vitamin C	Ascorbic acid; Vitamin C	Ascorbic acid/Vitamin C Ascorbyl palmitate Calcium ascorbate

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
		Magnesium ascorbate Niacinamide ascorbate/Nicotinamide ascorbate Potassium ascorbate Sodium ascorbate
Vitamin D	Vitamin D; Vitamin D_2; Vitamin D_3	Vitamin D_2/Ergocalciferol Vitamin D_3/Cholecalciferol
Vitamin E	Alpha (α)-tocopherol; Vitamin E	All *racemic* (all *rac*)-α-tocopherol/ *dl*-α-Tocopherol All *rac*-α-tocopheryl acetate/ *dl*-α-Tocopheryl acetate All *rac*-α-tocopheryl succinate/ *dl*-α-Tocopheryl acid succinate/ *dl*-α-Tocopheryl succinate *RRR*-α-Tocopherol/ *d*-α-Tocopherol *RRR*-α-Tocopheryl acetate/ *d*-α-Tocopheryl acetate *RRR*-α-Tocopheryl succinate/ *d*-α-Tocopheryl acid succinate/ *d*-α-Tocopheryl succinate
Vitamin K_1; Vitamin K_2	Vitamin K_1; Vitamin K_2	Vitamin K_1/Phylloquinone/Phytomenadione/ Phytonadione Vitamin K_2/Menaquinones/Menatetrenone

[1,2] At least one of the following references was consulted per name: NIH 2007; Sweetman 2007; USP 30; IOM 2003; O'Neil et al. 2001.
[3] At least one of the following references was consulted per source material: HC 2007a; NIH 2007; Sweetman 2007; USP 30; IOM 2003; Van Der Kuy et al. 2002; O'Neil et al. 2001; Chalmers et al. 2000; EC 2000; Zeitlin et al. 1985; Yamagata et al. 1966.
Additional note: The slash (/) indicates that the terms are synonyms. Either term may be selected by the applicant.

1.2 Mineral proper name(s), common name(s) and source material(s)

Table 2: Mineral proper name(s), common name(s) and source material(s)

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
Boron	Boron	Boracic acid/Orthoboric acid Borax/Disodium tetraborate/Sodium biborate/Sodium borate/Sodium pyroborate/Sodium tetraborate Boron aspartate Boron citrate Boron glycinate Boron hydrolyzed animal protein (HAP) chelate Boron hydrolyzed vegetable protein (HVP) chelate Calcium borate/Calcium pyroborate/Calcium tetraborate Calcium borogluconate/Calcium diborogluconate Calcium fructoborate Magnesium borate
Calcium	Calcium	Bone meal[4] Calcium acetate Calcium ascorbate Calcium bisglycinate Calcium carbonate Calcium chloride Calcium chloride dihydrate Calcium chloride hexahydrate Calcium citrate Calcium citrate malate Calcium citrate tetrahydrate Calcium fumarate

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
		Calcium glubionate
		Calcium glubionate monohydrate
		Calcium gluceptate
		Calcium gluconate
		Calcium gluconate monohydrate
		Calcium glutarate
		Calcium glycerophosphate
		Calcium HAP chelate
		Calcium HVP chelate
		Calcium hydroxide
		Calcium lactate
		Calcium lactate gluconate
		Calcium lactate pentahydrate
		Calcium lactate trihydrate
		Calcium lactobionate dihydrate
		Calcium levulinate
		Calcium levulinate dihydrate
		Calcium malate
		Calcium oxide
		Calcium phosphate dibasic
		Calcium phosphate monobasic
		Calcium phosphate tribasic
		Calcium pidolate
		Calcium pyrophosphate
		Calcium silicate

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
		Calcium sodium lactate Calcium succinate Calcium sulfate Calcium sulfate dihydrate Coral Dolomite Oyster shell
Chromium	Chromium	Chromium (III) bisglycinate/Chromic bisglycinate Chromium (III) chloride/Chromic chloride Chromium (III) chloride hexahydrate/Chromic chloride hexahydrate Chromium (III) citrate/Chromic citrate Chromium (III) dinicotinate/Chromic dinicotinate Chromium (III)-enriched yeast/Chromic-enriched yeast Chromium (III) fumarate/Chromic fumarate Chromium (III) glutarate/Chromic glutarate Chromium (III) HAP chelate/Chromic HAP chelate Chromium (III) HVP chelate/Chromic HVP chelate Chromium (III) malate/Chromic malate Chromium (III) nicotinate/Chromic nicotinate Chromium (III) pidolate/Chromic pidolate Chromium (III) polynicotinate/Chromic polynicotinate Chromium (III) potassium sulfate dodecahydrate/Chromic potassium sulfate dodecahydrate

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
		Chromium (III) succinate/Chromic succinate Chromium (III) sulfate/Chromic sulfate
Cobalt	Cobalt	Cyanocobalamin/Vitamin B_{12} Hydroxocobalamin Methylcobalamin
Copper	Copper	Calcium copper edetate Copper (II) acetate/Cupric acetate Copper (II) bisglycinate/Cupric bisglycinate Copper (II) carbonate/Cupric carbonate Copper (II) chloride/Cupric chloride Copper (II) chloride dihydrate/Cupric chloride dihydrate Copper (II) citrate/Cupric citrate Copper (II) fumarate/Cupric fumarate Copper (II) gluconate/Cupric gluconate Copper (II) glutarate/Cupric glutarate Copper (II) HAP chelate/Cupric HAP chelate Copper (II) HVP chelate/Cupric HVP chelate Copper (II) malate/Cupric malate Copper (II) succinate/Cupric succinate Copper (II) sulfate/Cupric sulfate Copper (II) sulfate pentahydrate/Cupric sulfate pentahydrate
Iodine	Iodine	Bladderwrack (dried thallus of *Fucus vesiculosus* L., *Fucus serratus* L. (Fucaceae) or *Ascophyllum nodosum* L. Le Jolis (Fucaceae)) Kelp (species from the order Laminariales) Potassium iodate

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
		Potassium iodide Sodium iodide
Iron	Iron	Ferritin Ferrocholinate Iron, carbonyl (not pentacarbonyl) Iron, electrolytic Iron HAP chelate Iron HVP chelate Iron, reduced Iron (II) ascorbate/Ferrous ascorbate Iron (II) aspartate/Ferrous aspartate Iron (II) aspartate tetrahydrate/Ferrous aspartate tetrahydrate Iron (II) bisglycinate/Ferrous bisglycinate Iron (II) carbonate/Ferrous carbonate Iron (II) chloride /Ferrous chloride Iron (II) chloride tetrahydrate/Ferrous chloride tetrahydrate Iron (II) citrate/Ferrous citrate Iron (II) fumarate/Ferrous fumarate Iron (II) gluceptate/Ferrous gluceptate Iron (II) gluconate/Ferrous gluconate Iron (II) gluconate dihydrate/Ferrous gluconate dihydrate Iron (II) glutarate/Ferrous glutarate Iron (II) glycine sulfate/Ferrous glycine sulfate Iron (II) lactate/Ferrous lactate

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
		Iron (II) lactate trihydrate/Ferrous lactate trihydrate Iron (II) malate/Ferrous malate Iron (II) oxalate/Ferrous oxalate Iron (II) oxalate dihydrate/Ferrous oxalate dihydrate Iron (II) succinate/Ferrous succinate Iron (II) sulfate/Ferrous sulfate Iron (II) sulfate dried (monohydrate)/Ferrous sulfate dried (monohydrate) Iron (II) sulfate heptahydrate/Ferrous sulfate heptahydrate Iron (II) tartrate/Ferrous tartrate Iron (III) ammonium citrate/Ferric ammonium citrate Iron (III) citrate/Ferric citrate Iron (III) glycerophosphate/Ferric glycerophosphate Iron (III) phosphate/Ferric phosphate Iron (III) pyrophosphate/Ferric pyrophosphate
Magnesium	Magnesium	Magnesium acetate Magnesium acetate tetrahydrate Magnesium ascorbate Magnesium aspartate Magnesium bisglycinate Magnesium carbonate Magnesium chloride Magnesium chloride hexahydrate Magnesium citrate Magnesium fumarate

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
		Magnesium gluceptate Magnesium gluconate Magnesium gluconate dihydrate Magnesium glutarate Magnesium glycerophosphate Magnesium HAP chelate Magnesium HVP chelate Magnesium hydroxide Magnesium lactate Magnesium malate Magnesium oxide Magnesium phosphate dibasic trihydrate/Magnesium hydrogen phosphate trihydrate/Dimagnesium phosphate trihydrate Magnesium phosphate tribasic tetra-, penta-, or octahydrate/Trimagnesium phosphate tetra-, penta-, or octahydrate Magnesium pidolate Magnesium succinate Magnesium sulfate Magnesium sulfate heptahydrate
Manganese	Manganese	Manganese (II) bisglycinate/Manganous bisglycinate Manganese (II) chloride/Manganous chloride Manganese (II) chloride tetrahydrate/Manganous chloride tetrahydrate Manganese (II) citrate/Manganous citrate Manganese (II) gluconate/Manganous gluconate Manganese (II) glycerophosphate/Manganous

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
		glycerophosphate Manganese (II) HAP chelate/Manganous HAP chelate Manganese (II) HVP chelate/Manganous HVP chelate Manganese (II) sulfate/Manganous sulfate Manganese (II) sulfate monohydrate/Manganous sulfate monohydrate Manganese (II) sulfate tetrahydrate/Manganous sulfate tetrahydrate Manganese (IV) dioxide
Molybdenum	Molybdenum	Ammonium molybdate (VI) Ammonium molybdate (VI) tetrahydrate Molybdenum bisglycinate Molybdenum citrate Molybdenum fumarate Molybdenum glutarate Molybdenum HAP chelate Molybdenum HVP chelate Molybdenum malate Molybdenum succinate Sodium molybdate (VI) Sodium molybdate (VI) dihydrate
Nickel	Nickel	Nickel (II) sulfate Nickel (II) sulfate heptahydrate Nickel (II) sulfate hexahydrate
Phosphorus	Phosphorus	Bone meal[4] Calcium glycerophosphate Calcium phosphate dibasic Calcium phosphate monobasic

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
		Calcium phosphate tribasic Potassium phosphate dibasic Potassium phosphate monobasic Sodium phosphate dibasic Sodium phosphate dibasic dihydrate Sodium phosphate dibasic dodecahydrate Sodium phosphate dibasic heptahydrate Sodium phosphate monobasic Sodium phosphate monobasic dihydrate Sodium phosphate monobasic monohydrate
Selenium	Selenium	Monohydrated selenium dioxide Selenium citrate Selenium HAP chelate Selenium HVP chelate Selenium yeast Selenocysteine Selenomethionine Sodium selenate Sodium selenite
Silicon	Silicon	Horsetail (*Equisetum arvense* L.) aerial parts[5] Silicic acid Silicon dioxide Silicon HAP chelate Silicon HVP chelate Sodium metasilicate
Tin[6]	Tin	Tin (II) chloride/Stannous chloride

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
Vanadium	Vanadium	Sodium metavanadate Vanadium citrate Vanadium HAP chelate Vanadium HVP chelate Vanadyl sulfate (IV)
Zinc	Zinc	Zinc acetate Zinc acetate dihydrate Zinc bisglycinate Zinc chloride Zinc citrate Zinc fumarate Zinc gluconate Zinc glutarate Zinc glycerate Zinc HAP chelate Zinc HVP chelate Zinc malate Zinc monomethionine Zinc oxide Zinc phosphate Zinc succinate Zinc sulfate Zinc sulfate heptahydrate

[1, 2] At least one of the following references was consulted per name: NIH 2007; Sweetman 2007; USP 30; IOM 2003; O'Neil et al. 2001.

[3] At least one of the following references was consulted per source material: Guiry and Guiry 2007; HC 2007a; NIH 2007; Sweetman 2007; USP 30; Albion 2004a; Albion 2004b; Commonwealth of Australia 2004; Gruenwald et al. 2004; Albion 2003a; Albion 2003b; IOM 2003, Allen 2002; Commonwealth of Australia 2002; Van Der Kuy et al. 2002; Anderson et al. 2001; Firoz and Graber 2001; Hendler and Rorvik 2001; O'Neil et al. 2001; Albion 2000; Chalmers et al. 2000; EC 2000; Patrick 1999; Albion 1997a; Albion 1997b; Grant et al. 1997; Albion 1996a; Albion

1996b; Murray 1996; Albion 1995; Albion 1993a; Albion 1993b; Albion 1993c; Albion 1993d; Albion 1993e; Evans and Pouchnik 1993; Albion 1992; Zeitlin et al. 1985; Abbott and Hollenberg 1976; Yamagata et al. 1966.
[4] When bone meal is used as a source material for calcium or phosphorus, it must be sourced from a non-human animal that is not susceptible to Transmissible Spongiform Encephalopathy (TSE) diseases, including Bovine Spongiform Encephalopathy (BSE) (HC 2006).
[5] Data (or certification) must be submitted to show that thiaminase has been inactivated.
[6] There is no evidence to support tin as a factor in the maintenance of good health (FSA 2003; FSA 2002).
Additional note: the slash (/) indicates that the terms are synonyms. Either term may be selected by the applicant.

1.3 Other medicinal ingredient proper name(s), common name(s) and source material(s)

Table 3: Other medicinal ingredient proper name(s), common name(s) and source material(s)

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
All-*trans* beta-carotene; Beta-carotene	All-*trans* beta-carotene; Beta-carotene	Beta-carotene/All-*trans* beta-carotene
Choline	Choline	Choline[4] Choline bitartrate[4] Choline chloride[4] Choline dihydrogen citrate[4] Choline orotate[4]
Inositol	Inositol	Inositol[4] Inositol dihydrate[4] Inositol monophosphate[4]
L-Methionine; Methionine	L-Methionine; Methionine	DL-Methionine[4] L-Methionine[4]
Lutein	Lutein	Lutein isolated from marigold flower (oleoresin of *Tagetes erecta* L. (Asteraceae))[4]
Lycopene	Lycopene	Lycopene[4] Lycopene extracted from tomato (pulp of ripe fruit of *Lycopersicon esculentum* Mill. (Solanaceae))[4]
Potassium	Potassium	Potassium acetate Potassium aspartate Potassium bicarbonate Potassium carbonate Potassium chloride

Proper name(s)[1]	Common name(s)[2]	Source material(s)[3]
		Potassium citrate Potassium citrate monohydrate Potassium gluconate Potassium glycerophosphate Potassium glycerophosphate trihydrate Potassium sulfate

[1,2] At least one of the following references was consulted per name: NIH 2007; Sweetman 2007; USP 30; IOM 2003; O'Neil et al. 2001.
[3] At least one of the following references was consulted per source material: HC 2007a; NIH 2007; Sweetman 2007; USP 30; IOM 2003; O'Neil et al. 2001.
[4] Ingredient must be pharmacopoeial grade (for a list of acceptable pharmacopoeial grades, see the *Compendium of Monographs*) or cited in an approved NHP Master File, authorized by a letter of access issued to the applicant by the NHP Master File's registered owner.
Additional note: The slash (/) indicates that the terms are synonyms. Either term may be selected by the applicant.

2.0 Route(s) of administration

Oral

3.0 Dosage form(s)

Those pharmaceutical dosage forms suited to oral administration, including but not limited to chewable tablets, caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons, are acceptable. This monograph is not intended to include food-like dosage forms such as bars, gums or beverages.

4.0 Use(s) or Purpose(s)

Refer to Appendix I for guidelines on using the use(s) or purpose(s) outlined in this section.

4.1 General use or purpose statement(s)

The following use or purpose statement(s) can be used in reference to any combination of vitamins or minerals, as appropriate.

Statement(s) to the effect of:

- Vitamin supplement, mineral supplement, vitamin/mineral supplement, multi-vitamin, multi-mineral or multi-vitamin/mineral

- A factor in the maintenance of good health.

4.1.1 Medicinal ingredients for which only general use or purpose statement(s) are permitted

Table 4: Medicinal ingredients for which only general use or purpose statement(s) are permitted

Medicinal Ingredient	Reference(s)
Boron	IOM 2006; IOM 2001
Choline[1]	IOM 2006; IOM 1998
Inositol[1]	FDA 1975
L-Methionine[1]	IOM 2006; IOM 2005a
Lutein	Shao and Hathcock 2006; Alves-Rodrigues and Shao 2004
Lycopene	Shao and Hathcock 2006
Nickel	IOM 2006; IOM 2001
Potassium	IOM 2006; IOM 2005b; Burgess et al. 1999
Silicon	IOM 2006; IOM 2001
Tin[2]	FSA 2003; FSA 2002
Vanadium	IOM 2006; IOM 2001

[1] The term "lipotropic factor" is not permitted to describe choline, inositol or L-methionine. This term may mislead consumers to perceive the product as fat-burning or for the purpose of weight loss.
[2] There is no evidence to support tin as a factor in the maintenance of good health (FSA 2003; FSA 2002).

4.2 Specific use or purpose statement(s)

Statements(s) to the effect of:

4.2.1 Specific use or purpose statement(s) for vitamins

Table 5: Specific use or purpose statement(s) for vitamins

Vitamin	Specific use(s) or purpose(s)[1]
Biotin	Helps the body to metabolize carbohydrates, fats and proteins. Helps to prevent biotin deficiency.*
Folate	For products providing at least 400 µg per day: Helps to reduce the risk of neural tube defects when taken daily prior to becoming pregnant and during early pregnancy. Helps the body to metabolize proteins. Helps to form red blood cells. Helps to prevent folate deficiency.*
Niacin and Niacinamide[2]	Helps the body to metabolize carbohydrates, fats and proteins. Helps normal growth and development. Helps to prevent niacin deficiency.*
Pantothenic	Helps the body to metabolize carbohydrates, fats and proteins.

Vitamin	Specific use(s) or purpose(s)[1]
acid	Helps in tissue formation. Helps to prevent pantothenic acid deficiency.*
Riboflavin	Helps the body to metabolize carbohydrates, fats and proteins. Helps in tissue formation. Helps to prevent riboflavin deficiency.*
Thiamine	Helps the body to metabolize carbohydrates, fats and proteins. Helps normal growth. Helps to prevent thiamine deficiency.*
Vitamin A	Helps to maintain eyesight, skin, membranes and immune function. Helps in the development and maintenance of night vision. Helps in the development and maintenance of bones and teeth. Helps to prevent vitamin A deficiency.*
Vitamin B_6	Helps the body to metabolize carbohydrates, fats and proteins. Helps in tissue formation. Helps to prevent vitamin B_6 deficiency.*
Vitamin B_{12}	Helps the body to metabolize carbohydrates, fats and proteins. Helps to form red blood cells. Helps to prevent vitamin B_{12} deficiency.*
Vitamin C	Helps the body to metabolize fats and proteins. Helps in the development and maintenance of bones, cartilage, teeth and gums. Helps in connective tissue formation. Helps in wound healing. An antioxidant for the maintenance of good health. Helps to prevent vitamin C deficiency.*
Vitamin D	Helps in the development and maintenance of bones and teeth. Helps in the absorption and use of calcium and phosphorus. For products providing calcium as a medicinal ingredient, if the following statement is used it must be verbatim: “Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis.”

Vitamin	Specific use(s) or purpose(s)[1]
	Helps to prevent vitamin D deficiency.*
Vitamin E	An antioxidant for the maintenance of good health. Helps to prevent vitamin E deficiency.*
Vitamin K_1 and K_2	Helps in the maintenance of bones. Helps to prevent vitamin K deficiency.*

[1] At least two of the following references were consulted per use or purpose statement: IOM 2006; Shils et al. 2006; MacKay and Miller 2003; IOM 2001; Groff and Gropper 2000; IOM 2000; NIH 2000; IOM 1998; IOM 1997.
[2] A specific use or purpose statement **must** be made for products providing > 35 mg niacin or niacinamide per day.
* This use or purpose statement is acceptable only if the vitamin is present at dosages at or above the Recommended Dietary Allowance (RDA) or Adequate Intake (AI). See Appendix II for RDA and AI definitions and Appendix III for detailed values according to life stage group. Note that most vitamin deficiencies are rare in North America.

4.2.2 Specific use or purpose statement(s) for minerals

Table 6: Specific use or purpose statement(s) for minerals

Mineral	Specific use(s) or purpose(s)[1]
Calcium	Helps in the development and maintenance of bones and teeth (optional: "especially in childhood, adolescence and young adulthood"). If the following statement is used, it must be verbatim: "Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis." Helps to prevent calcium deficiency.*
Chromium	Provides support for healthy glucose metabolism. Helps the body to metabolize carbohydrates and fats. Helps to prevent chromium deficiency.*
Cobalt	A structural component of vitamin B_{12} that helps the body metabolize carbohydrates, fats and proteins. A structural component of vitamin B_{12} that helps form red blood cells. A structural component of vitamin B_{12} that helps prevent vitamin B_{12} deficiency.*
Copper	Helps to produce and repair connective tissue. Helps to form red blood cells. Helps to prevent copper deficiency.*
Iodine	Helps in the function of the thyroid gland. Helps to prevent iodine deficiency.*
Iron[2]	Helps to form red blood cells and helps in their proper function.

Mineral	Specific use(s) or purpose(s)[1]
	If one of the following statements is used, it must be verbatim: "Helps to prevent iron deficiency."* "Helps to prevent iron deficiency anaemia."*
Magnesium[3]	Helps the body to metabolize carbohydrates, fats and proteins. Helps in the development and maintenance of bones and teeth. Helps in tissue formation. Helps to maintain proper muscle function. Helps to prevent magnesium deficiency.*
Manganese	Helps the body to metabolize carbohydrates, fats and proteins. Helps in the development and maintenance of bones. Helps to prevent manganese deficiency.*
Molybdenum	Helps the body to metabolize proteins. Helps to prevent molybdenum deficiency.*
Phosphorus	Helps in the development and maintenance of bones and teeth. Helps the body to metabolize carbohydrates, fats and proteins. Helps to prevent phosphorus deficiency.*
Selenium	An antioxidant for the maintenance of good health. Helps to prevent selenium deficiency.*
Zinc[4]	Helps in connective tissue formation. Helps to maintain healthy skin. Helps the body to metabolize carbohydrates, fats and proteins. Helps to maintain immune function. Helps to prevent zinc deficiency.*

[1] At least two of the following references were consulted per use or purpose statement: IOM 2006; Shils et al. 2006; Meisel et al. 2005; Schwartz et al. 2005; IOM 2001; Groff and Gropper 2000; IOM 2000; NIH 2000; IOM 1997; Klimis-Tavantis 1994.

[2] A specific use or purpose statement **must** be made for products providing > 35 mg iron per day.

[3] A specific use or purpose statement **must** be made for products providing > 350 mg magnesium per day.

[4] A specific use or purpose statement **must** be made for products providing > 40 mg zinc per day.

* This use or purpose statement is acceptable only if the mineral is present at dosages at or above the RDA or AI. See Appendix II for RDA and AI definitions and Appendix III for detailed values according to life stage group. Note that most mineral deficiencies are rare in North America.

4.2.3 Specific use or purpose statement(s) for other medicinal ingredients

Table 7: Specific use or purpose statement(s) for other medicinal ingredients

Medicinal ingredient	Specific use(s) or purpose(s)[1]
Beta-carotene	Source of vitamin A for the maintenance of good health. Provitamin A for the maintenance of good health. Source of vitamin A to help maintain eyesight, skin, membranes and immune function. Provitamin A to help maintain eyesight, skin, membranes and immune function. Source of vitamin A to help in the development and maintenance of night vision. Provitamin A to help in the development and maintenance of night vision. Source of vitamin A to help in the development and maintenance of bones and teeth. Provitamin A to help in the development and maintenance of bones and teeth. Helps to prevent vitamin A deficiency.*

[1] At least two of the following references were consulted per use or purpose statement: IOM 2006; Shils et al. 2006; IOM 2001; Groff and Gropper 2000.

* This use or purpose statement is acceptable only if beta-carotene is present at dosages at or above the RDA or AI for vitamin A. See Appendix II for RDA and AI definitions and Appendix III for detailed values according to life stage group. Note that most vitamin deficiencies are rare in North America.

5.0 Dose(s)

5.1 Background on dose

- The daily dose of each medicinal ingredient must be at or above the minimum dosage value and at or below the maximum dosage value. Refer to Appendix II for definitions and derivations of dosage values.
- Vitamin E is expressed as milligrams (mg) of *RRR*-α-tocopherol (AT) and vitamin A as micrograms (µg) of retinol activity equivalents (RAE).
- Refer to Appendix IV for conversion factors (pantothenic acid, vitamin A, beta-carotene, vitamin D, and vitamin E).

5.2 Dose information for vitamins

Table 8: Dose information for vitamins presented as dose per day

Life Stage Group		Biotin (µg/day)		Folate[1] (µg/day)		Niacin or Niacinamide[2] (mg/day)	
		Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Infants	0-12 mo	-	-	-	-	-	-
Children	1-3 y	1.0	500	15	300	0.6	10
	4-8 y	1.0	500	15	400	0.6	15
Adolescents	9-13 y	1.0	500	15	600	0.6	20
	14-18 y	1.8	500	30	800	1.0	30
Adults	≥ 19 y	1.8	500	30	1,000	1.0	500
Life Stage Group		Pantothenic acid (mg/day)		Riboflavin (mg/day)		Thiamine (mg/day)	
		Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Infants	0-12 mo	-	-	-	-	-	-
Children	1-3 y	0.2	500	0.04	100	0.04	100
	4-8 y	0.2	500	0.04	100	0.04	100
Adolescents	9-13 y	0.2	500	0.04	100	0.04	100
	14-18 y	0.4	500	0.08	100	0.07	100
Adults	≥ 19 y	0.4	500	0.08	100	0.07	100
Life Stage Group		Vitamin A[3] (µg RAE/day)		Vitamin B_6 (mg/day)		Vitamin B_{12}[4] (µg/day)	
		Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Infants	0-12 mo	30	600	-	-	-	-
Children	1-3 y	30	600	0.05	30	0.09	1,000
	4-8 y	30	900	0.05	40	0.09	1,000
Adolescents	9-13 y	30	1,700	0.05	60	0.09	1,000
	14-18 y	65	2,800	0.10	80	0.14	1,000
Adults	≥ 19 y	65	3,000	0.10	100	0.14	1,000

Life Stage Group		Vitamin C (mg/day)		Vitamin D (µg/day)		Vitamin E (mg AT/day)	
		Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Infants	0-12 mo	-	-	0.2	25	-	-
Children	1-3 y	2.2	400	0.2	25	0.6	179
	4-8 y	2.2	650	0.2	25	0.6	179
Adolescents	9-13 y	2.2	1,200	0.2	25	0.6	179
	14-18 y	6.0	1,800	0.8	25	1.0	179
Adults	≥ 19 y	6.0	2,000	0.8	25	1.0	179

Life Stage Group		Vitamin K_1 and K_2 (µg/day)	
		Minimum	Maximum
Infants	0-12 mo	-	-
Children	1-3 y	3	30
	4-8 y	3	55
Adolescents	9-13 y	3	60
	14-18 y	6	75
Adults	≥ 19 y	6	120

[1] Products providing folate at doses ≥ 200 µg per day must supplement with vitamin B_{12} at the RDA dosage (HC 2005a). See Appendix II for the RDA definition and Appendix III for a detailed list of RDA values.
[2] A specific use or purpose statement **must** be made for products providing > 35 mg niacin or niacinamide per day.
[3] The maximum daily dose for beta-carotene in combination with other vitamin A source materials must not exceed the Tolerable Upper Intake Level (UL) for vitamin A. (The UL for vitamin A is equivalent to the maximum daily dose outlined in Table 8.)
[4] The maximum dose for cobalt and vitamin B_{12} combined must not exceed 1000 µg vitamin B_{12} per day.

5.3 Dose information for minerals

Table 9: Dose information for minerals presented as dose per day

Life Stage Group		Boron (µg/day)		Calcium (mg/day)		Chromium (µg/day)	
		Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Infants	0-12 mo	-	-	-	-	-	-
Children	1-3 y	-	-	65	1,500	-	-
	4-8 y	-	-	65	1,500	-	-
Adolescents	9-13 y	-	-	65	1,500	-	-
	14-18 y	-	-	65	1,500	-	-
Adults	≥ 19 y	0	700	65	1,500	2.2	500

Life Stage Group		Cobalt[1] (µg/day)		Copper (µg/day)		Iodine (µg/day)	
		Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Infants	0-12 mo	-	-	-	-	-	-
Children	1-3 y	0.004	44	35	700	6	133
	4-8 y	0.004	44	35	2,500	6	200
Adolescents	9-13 y	0.004	44	35	4,000	6	400
	14-18 y	0.006	44	65	6,500	14	800
Adults	≥ 19 y	0.006	44	65	8,000	14	800

Life Stage Group		Iron[2] (mg/day)		Magnesium[3] (mg/day)		Manganese (mg/day)	
		Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Infants	0-12 mo	0.6	40	-	-	-	-
Children	1-3 y	0.6	40	12	65	-	-
	4-8 y	0.6	40	12	110	-	-
Adolescents	9-13 y	0.6	40	12	350	-	-
	14-18 y	1.4	45	20	350	-	-
Adults	≥ 19 y	1.4	45	20	500	0.13	9

Life Stage Group		Molybdenum (µg/day)		Nickel (µg/day)		Phosphorus (mg/day)	
		Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Infants	0-12 mo	-	-	-	-	-	-
Children	1-3 y	-	-	-	-	62	2,000
	4-8 y	-	-	-	-	62	2,000
Adolescents	9-13 y	-	-	-	-	62	2,000
	14-18 y	-	-	-	-	62	2,000
Adults	≥ 19 y	2.5	2,000	0	350	62	2,000

Life Stage Group		Selenium (µg/day)		Silicon (mg/day)		Tin (mg/day)	
		Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Infants	0-12 mo	-	-	-	-	-	-
Children	1-3 y	-	-	-	-	-	-
	4-8 y	-	-	-	-	-	-
Adolescents	9-13 y	-	-	-	-	-	-
	14-18 y	-	-	-	-	-	-
Adults	≥ 19 y	3.5	400	0	84	0	2

Life Stage Group		Vanadium (µg/day)		Zinc[4,5] (mg/day)	
		Minimum	Maximum	Minimum	Maximum
Infants	0-12 mo	-	-	0.2	2
Children	1-3 y	-	-	0.4	7
	4-8 y	-	-	0.4	12
Adolescents	9-13 y	-	-	0.4	23
	14-18 y	-	-	0.7	34
Adults	≥ 19 y	0	182	0.7	50

[1] The maximum dose for cobalt and vitamin B_{12} combined must not exceed 1000 µg of vitamin B_{12} per day.
[2] A specific use or purpose statement **must** be made for products providing > 35 mg iron per day.
[3] A specific use or purpose statement **must** be made for products providing > 350 mg magnesium per day.
[4] A specific use or purpose statement **must** be made for products providing > 40 mg zinc per day.
[5] Products providing zinc without copper or with copper at doses less than those specified below must be labelled with the risk statement set out in 7.3.

Life Stage Group	Zinc (doses exceeding UL – average Intake) (mg/day)	Required Copper (Zn:Cu 25:1) (µg/day)
Infants 0-12 mo	≤ 2	0
Children 1-3 y	5-7	280-700
Children 4-8 y	8-12	480-2,500
Children 9-13 y	16-23	920-4,000
Adolescents 14-18 y	25-34	1,360-6,500
Adults ≥19 y	31-50	2,000-8,000

5.4 Dose information for other medicinal ingredients

Table 10: Dose information for other medicinal ingredients presented as dose per day

Life Stage Group		Beta-carotene[1,2] (µg/day)		Choline (mg/day)		Inositol (mg/day)	
		Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Infants	0-12 mo	60	1,200	-	-	-	-
Children	1-3 y	60	1,200	0	1,000	0	650
	4-8 y	60	1,800	0	1,000	0	650
Adolescents	9-13 y	60	3,400	0	1,000	0	650
	14-18 y	130	5,600	0	1,000	0	650
Adults	≥ 19 y	130	6,000	0	1,000	0	650

Life Stage Group		L-Methionine (mg/day)		Lutein (mg/day)		Lycopene (mg/day)	
		Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Infants	0-12 mo	-	-	-	-	-	-
Children	1-3 y	0	1,000	-	-	-	-
	4-8 y	0	1,000	-	-	-	-
Adolescents	9-13 y	0	1,000	-	-	-	-
	14-18 y	0	1,000	-	-	-	-
Adults	≥ 19 y	0	1,000	0	10	0	5

Life Stage Group		Potassium (mg/day)	
		Minimum	Maximum
Infants	0-12 mo	-	-
Children	1-3 y	-	-
	4-8 y	-	-
Adolescents	9-13 y	-	-
	14-18 y	-	-
Adults	≥ 19 y	0	100

[1]Beta-carotene must be expressed in both micrograms (µg) or milligrams (mg) of beta-carotene **and** micrograms (µg) or milligrams (mg) of RAE. For conversion factors for beta-carotene to RAE, see Appendix IV.
[2] The maximum daily dose for beta-carotene in combination with other vitamin A source materials must not exceed the Tolerable Upper Intake Level (UL) for vitamin A. (The UL for vitamin A is equivalent to the maximum daily dose outlined in Table 8.)

5.5 Directions for use

Statement(s) to the effect of:

For products containing calcium, iron or zinc, the following statement is required:

- Take a few hours before or after taking other medications (Sweetman 2007; ASHP 2005).

For products containing niacin at doses ≥ 30 mg per day or containing iron or zinc, the following statement is required:

- Take with food (Sweetman 2007).

In all other cases, optional statement(s), as appropriate:

- Take with food, or
- Take on an empty stomach.

6.0 Duration of use

No statement required.

7.0 Risk information

Statement(s) to the effect of:

7.1 Caution(s) and warning(s)

Table 11: Caution(s) and warning(s) for all medicinal ingredients with associated daily doses

Medicinal ingredient	Daily dose	Caution(s) and warning(s)
Iron	Where the package contains more than the equivalent of 250 mg of elemental iron	Keep out of reach of children. There is enough drug in this package to seriously harm a child. Note: this must be preceded by a prominently displayed symbol that is octagonal in shape, conspicuous in colour and on a background of a contrasting colour (As per Section 97 of the *Natural Health Products Regulations*, citing Sections C.01.029 and C.01.031 of the *Food and Drug Regulations* (HC 2007b)).
Manganese	> 5 mg	Consult a health care practitioner prior to use if you have a liver disorder (IOM 2006; IOM 2001; Krieger et al. 1995).
Selenium	≥ 200 µg	Consult a health care practitioner prior to use if you have a history of non-melanoma skin cancer (Duffield-Lillico et al. 2003).
Vanadium	All doses	Consult a health care practitioner prior to use if you are pregnant or breastfeeding (IOM 2006; IOM 2001).
Vitamin K_1 and K_2	All doses	Consult a health care practitioner prior to use if you are taking blood thinners (ASHP 2005; Franco et al. 2004; IOM 2001; Hansten et al. 1997).
Additional caution(s) and warning(s)		
When HAP or HVP chelate is used as a source material, the products should be indicated for an adult subpopulation only.		
Products containing one or more of the following medicinal ingredients should be indicated only for an adult subpopulation: Boron, Chromium, Lutein, Lycopene, Manganese, Molybdenum Nickel, Potassium, Selenium, Silicon, Tin[1], Vanadium		

[1] There is no evidence to support tin as a factor in the maintenance of good health (FSA 2003; FSA 2002).

7.2 Contraindication(s)

For products providing niacin at doses of 500 mg per day, the following statement is required.

- Do not exceed the recommended dose except on the advice of a physician.

7.3 Known adverse reaction(s)

Table 12: Known adverse reaction(s) for all medicinal ingredients with associated daily doses

Medicinal ingredient	Daily dose (mg/day)		Known adverse reaction(s)
Iron	> 35		Some people may experience constipation, diarrhoea and/or vomiting (IOM 2006; IOM 2001).
Magnesium	> 350		Some people may experience diarrhoea (IOM 2006; IOM 1997).
Niacin	> 3		Some people may experience a flushing, burning, tingling or itching sensation on the face, arms or chest (IOM 2006; IOM 1998).
Zinc	Infants 0-12 mo	≤ 2	Statement not required if the product meets the minimum copper requirements outlined on Table 9, footnote 5, otherwise: Zinc supplementation can cause a copper deficiency (IOM 2006; IOM 2001).
	Children 1-3 y	5-7	
	Children 4-8 y	8-12	
	Children 9-13 y	16-23	
	Adolescents 14-18 y	25-34	
	Adults ≥ 19 years	31-50	

8.0 Non-medicinal ingredients

Ingredients must be chosen from the current NHPD *List of Acceptable Non-medicinal Ingredients* and must meet the limitations outlined in the list.

9.0 Specifications

Products must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.

10.0 References

Abbott IA, Hollenberg GJ. Marine Algae of California. Stanford (CA): Stanford University Press; 1976. [Accessed 2007-07-30]. Available from: http://www.mbari.org/staff/conn/botany/browns/sarahp/lam.htm

Albion 2004a: Magnesium: A role in the therapy for asthma. Albion Research Notes 2004;13(3) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/newsletter/sept2004.pdf

Albion 2004b: Zinc: A mineral of complex biological activity. Albion Research Notes 2004;13(1) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/newsletter/2004March.pdf

Albion 2003a: The iron conundrum. Albion Research Notes 2003;12(1) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/2003February.pdf

Albion 2003b: Magnesium - clinical and health benefits still without limits. Albion Research Notes 2003;12(3) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/newsletter/2003Oct.pdf

Albion 2000: Implications of the "other half" of a mineral compound. Albion Research Notes 2000;9(3) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/2000October.pdf

Albion 1997a: Is iron getting a bad rap? Albion Research Notes 1997;6(4) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/1997December.pdf

Albion 1997b: Magnesium: mineral link to energy. Albion Research Notes 1997;6(1) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/1997January.pdf

Albion 1996a: Effective calcium supplementation: not as easy as advertised!!! Albion Research Notes 1996;5(3) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/1996june.pdf

Albion 1996b: Iron product safety issue / a non-issue for Albion's ferrochel! Albion Research Notes 1996;5(1) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/1996February.pdf

Albion 1995: Chromium...has the public been mislead? Albion Research Notes 1995;4(3) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/1995june.pdf

Albion 1993a: Calcium absorption conflict. Albion Research Notes 1993;2(2) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/1993Mar.pdf

Albion 1993b: Chromium - an often controversial, but very essential trace mineral. Albion Research Notes 1993;2(5) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/Oct1993.pdf

Albion 1993c: A few words about copper. Albion Research Notes 1993;2(3) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/1993May.pdf

Albion 1993d: Iron treatment failure. Albion Research Notes 1993;2(6) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/1993Dec.pdf

Albion 1993e: Manganese - beware of marginal deficiencies. Albion Research Notes 1993;2(1) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/1993Jan.pdf

Albion 1992: Zinc - the multifaceted trace mineral. Albion Research Notes 1992;1(3) [Accessed 2007-03-21]. Available from: http://www.albion-an.com/human/Newsletter/1992Nov.pdf

Allen LH. Advantages and limitations of iron amino acid chelates as iron fortificants. Nutrition Reviews 2002;60(7):S18-21.

Alves-Rodrigues A, Shao A. The science behind lutein. Toxicology Letters 2004;150(1):57-83.

Anderson RA, Roussel AM, Zouari N, Mahjoub S, Matheau JM, Kerkeni A. Potential antioxidant effects of zinc and chromium supplementation in people with type 2 diabetes mellitus. Journal of the American College of Nutrition 2001;20(3):212-218.

ASHP 2005: American Society of Health-System Pharmacists. American Hospital Formulary Service (AHFS) Drug Information. Philadelphia (PA): Lippincott Williams and Wilkins; 2005.

Burgess E, Lewanczuk R, Bolli P, Chockalingam A, Cutler H, Taylor G, Hamet P. Lifestyle modifications to prevent and control hypertension. 6. Recommendations on potassium, magnesium and calcium. Canadian Hypertension Society, Canadian Coalition for High Blood Pressure Prevention and Control, Laboratory Centre for Disease Control at Health Canada, Heart and Stroke Foundation of Canada. The Canadian Medical Association Journal 1999;160(9):S35-45.

Chalmers RA, Bain MD, Costello I. Oral cobalamin therapy. Lancet 2000;355(9198):148.

Commonwealth of Australia 2004. Australia New Zealand Food Authority: Proposal P242 - Food for Special Medical Purposes: Preliminary Final Assessment Report. Canberra (AU): Department of Health and Ageing, Commonwealth of Australia. 4 August 2004. [Accessed 2007-09-28] Available from: http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp242foodsforspecialmedicalpurposes/index.cfm

Commonwealth of Australia 2002. Australia New Zealand Food Authority: Proposal P93 - Review of Infant Formula. Supplement Final Assessment (Inquiry - s.24) Report. Canberra (AU): Department of Health and Ageing, Commonwealth of Australia. 13 March 2002. [Accessed 2007-09-28] Available from: http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp93reviewofinfantformula/p93finalassessreport1397.cfm

Duffield-Lillico AJ, Slate EH, Reid ME, Turnbull BW, Wilkins PA, Combs GF Jr, Park HK, Gross EG, Graham GF, Stratton MS, Marshall JR, Clark LC; Nutritional Prevention of Cancer Study Group. Selenium supplementation and secondary prevention of nonmelanoma skin cancer in a randomized trial. Journal of the National Cancer Institute 2003;95(19):1477-81.

EC 2000: European Commission. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake level of Vitamin B_{12}. Brussels (BE): European Commission, SCF/CS/NUT/UPPLEV/42 Final 28 November 2000. [Accessed 2007-09-26]. Available from: http://ec.europa.eu/food/fs/sc/scf/out80_en.html

Evans GW, Pouchnik DJ. Composition and biological activity of chromium-pyridine carboxylate complexes. Journal of Inorganic Biochemistry 1993;49(3):177-87.

FDA 1975: Food and Drug Administration. Evaluation of the health aspects of inositol as a food ingredient. Washington (DC): Food and Drug Administration, US Department of Health, Education and Welfare, Contract Number FDA 223-75-2004; 1975.

Firoz M, Graber M. Bioavailability of US commercial magnesium preparations. Magnesium Research 2001;14(4):257-62.

Franco V, Polanczyk CA, Clausell N, Rohde LE. Role of dietary vitamin K intake in chronic oral anticoagulation: prospective evidence from observational and randomized protocols. The American Journal of Medicine 2004;166(10):651-6.

FSA 2003: Food Standards Agency. Expert Group on Vitamins and Minerals: Safe Upper Levels for Vitamins and Minerals. London (UK): Food Standards Agency, Expert Group on Vitamins and Minerals May 2003. [Accessed 2007-03-21]. Available from: http://www.food.gov.uk/multimedia/pdfs/vitmin2003.pdf

FSA 2002: Food Standards Agency. Expert Group on Vitamins and Minerals: Revised Review of Tin. London (UK): Food Standards Agency, EVM/01/10 April 2002. [Accessed 2007-03-21]. Available from: http://www.food.gov.uk/multimedia/pdfs/evm-01-10.pdf

Grant KE, Chandler RM, Castle AL, Ivy JL. Chromium and exercise training: effect on obese women. Medicine and Science in Sports and Exercise 1997;28(8):992-8.

Groff J, Gropper S. Advanced Nutrition and Human Metabolism, 3rd edition. Belmont (CA): Wadsworth/Thomson Learning; 2000.

Gruenwald J, Bendler T, Jaenicke C, editors. Physician's Desk Reference for Herbal Medicines, 3rd edition. Montvale (NJ): Thomson PDR; 2004.

Guiry MD, Guiry GM. AlgaeBase version 4.2. Latin binomial. Galway (IRE): World-wide electronic publication, National University of Ireland; 2007 [Accessed 2007-07-04]. Available from: http://www.algaebase.org

Hansten PD, Horn JR, editors. Drug Interactions Analysis and Management. Vancouver (WA): Applied Therapeutics Inc.; 1997.

HC 2007a: Health Canada. Drug Product Database. Ottawa (ON): Health Canada; 2007. [Accessed 2007-03-21]. Available from: http://search.hc-sc.gc.ca/cgi-bin/query?mss=dpd/english/active/simple

HC 2007b: Health Canada. *Food and Drug Regulations* (F-27 – C.R.C., c.870). Ottawa (ON): Health Canada; 2007. [Accessed 2007-03-21]. Available from: http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/text.html

HC 2006: Health Canada. Evidence for Safety and Efficacy of Finished Natural Health Products. Ottawa (ON): Natural Health Products Directorate, Health Canada; 2006. [Accessed 2007-06-07]. Available from: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/efe-paie_e.html

HC 2005a: Health Canada. Addition of Vitamins and Minerals to Foods: Health Canada's Proposed Policy and Implementation Plans. Ottawa (ON): Health Canada; 2005. [Accessed 2007-03-21]. Available from: http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/nutrition/foritfication_final_doc_e.pdf

HC 2005b: Health Canada. *Food and Drugs Act*: Regulations Amending the *Food and Drug Regulations* (1385 -Vitamin K). Canada Gazette 2005;139(21). [Accessed 2007-03-21]. Available from: http://canadagazette.gc.ca/partII/2005/20051019/html/sor307-e.html

Hendler SS, Rorvik D, editors. Physician's Desk Reference for Nutritional Supplements, 1st edition. Montvale (NJ): Thomson PDR; 2001.

IOM 2006: Institute of Medicine. Otten JJ, Pitzi Hellwig J, Meyers LD, editors. Institute of Medicine. Dietary Reference Intakes: The Essential Guide to Nutrient Requirements. Washington (DC): National Academies Press; 2006.

IOM 2005a: Institute of Medicine. Panel on Macronutrients, Panel on the Definition of Dietary Fiber, Subcommittee on Upper Reference Levels of Nutrients, Subcommittee on Interpretation and Uses of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington (DC): National Academies Press; 2005.

IOM 2005b: Institute of Medicine. Panel on Dietary Reference Intakes for Electrolytes and Water, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Water, Potassium, Sodium, Chloride, and Sulfate. Washington (DC): National Academies Press; 2005.

IOM 2003: Institute of Medicine. Committee on Food Chemicals Codex, Food and Nutrition Board, Institute of Medicine. Food Chemicals Codex, 5th edition. Washington (DC): National Academies Press; 2003.

IOM 2001: Institute of Medicine. Panel on Micronutrients, Subcommittees on Upper Reference Levels of Nutrients and Interpretation and Uses of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc. Washington (DC): National Academies Press; 2001.

IOM 2000: Institute of Medicine. Panel on Dietary Antioxidants and Related Compounds, Subcommittees on Upper Reference Levels of Nutrients and Interpretation and Uses of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Vitamin C, Vitamin E, Selenium and Carotenoids. Washington (DC): National Academies Press; 2000.

IOM 1998: Institute of Medicine. Panel on Folate, other B Vitamins, and Choline and Subcommittee on Upper Reference Levels of Nutrients, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin and Choline. Washington (DC): National Academies Press; 1998.

IOM 1997: Institute of Medicine. Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Food and Nutrition Board, Institute of Medicine. Dietary Reference Intakes for Calcium, Phosphorous, Magnesium, Vitamin D, and Fluoride. Washington (DC): National Academies Press; 1997.

Klimis-Tavantzis DJ, editor. Manganese in Health and Disease. Boca Raton (FL): CRC Press; 1994.

Krieger D, Krieger S, Jansen O, Gass P, Theilmann L, Lichtnecker H. Manganese and chronic hepatic encephalopathy. Lancet 1995;246(8970):270-4.

MacKay D, Miller AL. Nutritional support for wound healing. Alternative Medicine Review 2003;8(4):359-77.

Meisel P, Schwahn C, Luedemann J, John U, Kroemer HK, Kocher T. Magnesium deficiency is associated with periodontal disease. Journal of Dental Research 2005;84(10):937-941.

Murray MT. Encyclopedia of Nutritional Supplements: The Essential Guide for Improving your Health Naturally. Rocklin (CA): Prima Health; 1996.

NIH 2007: National Institutes of Health. ChemIDplus advanced. Bethesda (MD): Specialized Information Services, National Library of Medicine, National Institutes of Health, US Department of Health & Human Services. [Accessed 2007-07-07]. Available from: http://chem.sis.nlm.nih.gov/chemidplus

NIH 2000: National Institutes of Health. Osteoporosis Prevention, Diagnosis, and Therapy. NIH Consensus Statement Online 2000;17(1):1-36. Bethesda (MD): National Institutes of Health; March 27-29, 2000. [Accessed 2007-03-21]. Available from: http://www.consensus.nih.gov/2000/2000Osteoporosis111html.htm

O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals, 13th edition. Whitehouse Station (NJ): Merck & Co., Inc.; 2001.

Patrick L. Comparative absorption of calcium sources and calcium citrate malate for the prevention of osteoporosis. Alternative Medicine Review 1999;4(2):74-85.

Schwartz JR, Marsh RG, Draelos ZD. Zinc and skin health: overview of physiology and pharmacology. Dermatologic Surgery 2005;31(7 Part 2):837-47.

Shao A and Hathcock JN. Risk assessment for the carotenoids lutein and lycopene. Regulatory Toxicology and Pharmacology 2006;45(3):289-98.

Shils ME, Olson JA, Shike M, Ross AC, editors. Modern Nutrition in Health and Disease, 10th edition. Philadelphia (PA): Lippincott Williams and Wilkins; 2006.

Sweetman SC, editor. Martindale: The Complete Drug Reference, 35th edition. London (UK): Pharmaceutical Press; 2007.

USP 30: The United States Pharmacopeia and the National Formulary (USP 30/NF 25). Rockville (MD): United States Pharmacopeial Convention, Inc.; 2007.

Van Der Kuy PH, Merkus FW, Lohman JJ, Ter Berg JW, Hooymans PM. Hydroxocobalamin, a nitric oxide scavenger, in the prophylaxis of migraine: an open, pilot study. Cephalalgia 2002;22(7):513-519.

Yamagata S, Goto Y, Mita M, Kikuchi J, Yamauchi Y. Treatment of diabetic neuropathy with the oral administration of hydroxocobalamin. Vitamins 1966;34(3):349-356.

Zeitlin HC, Sheppard K, Baum JD, Bolton FG, Hall CA. Homozygous transcobalamin II deficiency maintained on oral hydroxocobalamin. Blood 1985;66(5):1022-1027.

11.0 Appendices

Appendix I

Guidelines for use or purpose statements

It is mandatory for all natural health products to cite at least one use or purpose statement.

General use or purpose statements:

1) Permissible use or purpose statements for products containing one or more minerals and one or more vitamins:
   - Vitamin/mineral supplement
   - Multi-vitamin/mineral supplement
   - A factor in the maintenance of good health.

2) Permissible use or purpose statements for products containing two or more minerals:
   - Mineral supplement
   - Multi-mineral supplement
   - A factor in the maintenance of good health.

3) Permissible use or purpose statements for products containing two or more vitamins:
   - Vitamin supplement
   - Multi-vitamin supplement
   - A factor in the maintenance of good health.

Specific use or purpose statements:

Ingredient specific use or purpose statements can be used for **any** or **all** of the medicinal ingredients contained in a multi-ingredient product as applicable (see Section 4.2 - Specific use or purpose statement(s)).

A specific use or purpose statement **must** be made for products providing magnesium (> 350 mg per day), niacin (> 35 mg per day), iron (> 35 mg per day), or zinc (> 40 mg per day).

Inclusion of medicinal ingredient names in a specific use or purpose statement is optional, for example, the specific use or purpose statement can be applied to the whole product. However, if medicinal ingredient names are specified in a use or purpose statement, the statement must be valid for all medicinal ingredients specified. See below for examples on the correct and incorrect use of specific ingredient use or purpose statements:

Correct use:
"Biotin and pantothenic acid to help the body metabolize carbohydrates, fats and proteins."
This is correct because both medicinal ingredients contribute to that use or purpose.

Incorrect use:
"Biotin and folate to help the body metabolize carbohydrates, fats and proteins."
This is incorrect because biotin has that purpose but folate does not.

Appendix II

Dosage value definitions and derivations

1) Definitions:

Adequate Intake (AI): The recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate. An AI is used when an RDA cannot be determined (IOM 2006).

Maximum dosage value: The highest medicinal ingredient quantity which a product can supply in a daily dose.

Minimum dosage value: The lowest medicinal ingredient quantity which a product can supply in a daily dose.

Recommended Dietary Allowance (RDA): The average daily dietary nutrient intake level sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group (IOM 2006).

Tolerable Upper Intake Level (UL): The highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase (IOM 2006).

2) Derivations:

AI, RDA and UL values:

These values were established by the Food and Nutrition Board of the Institute of Medicine in collaboration with Health Canada (IOM 2006).

Maximum dosage value:

The method used to set maximum dosage values varied for each medicinal ingredient depending on numerous factors. The method used to derive maximum dosage levels for vitamins and minerals with established physiological functions was different from the method used for those with unestablished physiological functions.

1. Maximum dosage values for vitamins and minerals with established physiological functions were developed based on the following criteria:
   a) Is there an established UL?
   - If there is an established UL, does it apply to supplements only or to food and supplements?

- If there is an established UL, how was it derived (i.e., what was the critical adverse reaction on which it was based? was it serious or non-serious? if non-serious, could it be mitigated?)?

b) What is the average dietary intake?
c) What doses have previously been marketed in Canada?
d) What do other regulatory agencies and expert groups recommend as their maximum daily dose?
e) What doses have been used in clinical trials and have demonstrated evidence for safety and efficacy?

The only vitamins which were excluded from the method outlined above were:

- Vitamin D (due to its listing on Schedule F of the *Food and Drug Regulations* at 25 µg/ day (HC 2007b))
- Vitamin E (due to the potential health risks of high dose vitamin E in certain subpopulations)
- Vitamin K_1 and K_2 (adult dose was set in Canada Gazette II (HC 2005b) and children's doses were set at the AI level (IOM 2006)).

2. Maximum dosage values for minerals with unestablished physiological functions (boron, nickel, silicon, tin and vanadium) were calculated from the No Observed Adverse Effect Level (NOAEL) divided by an uncertainty factor (UF). The UF chosen was based on the following: 10 for extrapolation of animal data to humans, 10 for intra-species variation, and 10 for chronic use in humans. If applicable, (i.e., NOAEL was based on animal data) the final value was multiplied by an average adult body weight of 70 kg.

With the exception of beta-carotene, the maximum dosage value for non-vitamin and non-mineral ingredients was set based on doses demonstrated to be safe in clinical trials. For beta-carotene the maximum dosage value was set as per the vitamin A UL.

Minimum dosage value:

For medicinal ingredients which did not have an RDA or AI, the minimum dose was set at zero. For the remaining medicinal ingredients (with the exception of potassium and choline), the minimum was set using the following method:

5% of the RDA and/or AI was calculated for each life stage group (This method was modelled after the *Food and Drug Regulation* vitamin and mineral minimum dose requirements as per Sections D.01.004 and D.02.002 (HC 2007b)).

a) The highest value derived for children (1-13 years) was applied to all children within this age category;
b) the highest value derived for adolescents (≥ 14 years) and adults (including pregnant and breastfeeding women) was applied;
c) The highest value derived for infants (0-12 months) was applied (if applicable).

For potassium and choline, the AIs were inappropriate for setting minimum dosage values and therefore, the minimums were set at zero.

Appendix III

Recommended Dietary Allowance (RDA) and Adequate Intake (AI) values

The AI (as indicated by an asterisk) and RDA values are provided below. For the purpose of this monograph, these values are intended to:

- provide targets for setting appropriate supplement dosage levels;
- provide the minimum dose for the use of the dose specific use or purpose statement: "Helps to prevent (appropriate vitamin or mineral) deficiency";
- facilitate the optional labelling of % RDA and AI values.

Notes:

- RDA and AI values have not been provided for those Life Stage Groups where the vitamin or mineral dosage is outside the scope of this Monograph.
- For certain minerals, an RDA or AI value has not been established.

Table 13: Recommended Dietary Allowance and Adequate Intake* values for vitamins (IOM 2006)

Life Stage Group		Biotin (µg/day)	Folate (µg/day)	Niacin (mg/day)	Panto-thenic acid (mg/day)	Riboflavin (mg/day)
Infants	0-6 mo	-	-	-	-	-
	7-12 mo	-	-	-	-	-
Children	1-3 y	8*	150	6	2*	0.5
	4-8 y	12*	200	8	3*	0.6
Adolescent Males	9-13 y	20*	300	12	4*	0.9
	14-18 y	25*	400	16	5*	1.3
Adult Males	19-30 y	30*	400	16	5*	1.3
	31-50 y	30*	400	16	5*	1.3
	51-70 y	30*	400	16	5*	1.3
	> 70 y	30*	400	16	5*	1.3
Adolescent Females	9-13 y	20*	300	12	4*	0.9
	14-18 y	25*	400	14	5*	1.0
Adult Females	19-30 y	30*	400	14	5*	1.1
	31-50 y	30*	400	14	5*	1.1
	51-70 y	30*	400	14	5*	1.1
	> 70 y	30*	400	14	5*	1.1
Pregnancy	14-18 y	30*	600	18	6*	1.4
	19-50 y	30*	600	18	6*	1.4
Breastfeeding	14-18 y	35*	500	17	7*	1.6
	19-50 y	35*	500	17	7*	1.6

Life Stage Group		Thiamine (mg/day)	Vitamin A (µg RAE/day)	Vitamin B_6 (mg/day)	Vitamin B_{12} (µg/day)	Vitamin C (mg/day)
Infants	0-6 mo	-	400*	-	-	-
	7-12 mo	-	500*	-	-	-
Children	1-3 y	0.5	300	0.5	0.9	15
	4-8 y	0.6	400	0.6	1.2	25
Adolescent Males	9-13 y	0.9	600	1.0	1.8	45
	14-18 y	1.2	900	1.3	2.4	75
Adult Males	19-30 y	1.2	900	1.3	2.4	90
	31-50 y	1.2	900	1.3	2.4	90
	51-70 y	1.2	900	1.7	2.4	90
	> 70 y	1.2	900	1.7	2.4	90
Adolescent Females	9-13 y	0.9	600	1.0	1.8	45
	14-18 y	1.0	700	1.2	2.4	65
Adult Females	19-30 y	1.1	700	1.3	2.4	75
	31-50 y	1.1	700	1.3	2.4	75
	51-70 y	1.1	700	1.5	2.4	75
	> 70 y	1.1	700	1.5	2.4	75
Pregnancy	14-18 y	1.4	750	1.9	2.6	80
	19-50 y	1.4	770	1.9	2.6	85
Breastfeeding	14-18 y	1.4	1,200	2.0	2.8	115
	19-50 y	1.4	1,300	2.0	2.8	120

Life Stage Group		Vitamin D (µg/day)	Vitamin E (mg AT/day)	Vitamin K_1[1] (µg/day)
Infants	0-6 mo	5*	-	-
	7-12 mo	5*	-	-
Children	1-3 y	5*	6	30*
	4-8 y	5*	7	55*
Adolescent Males	9-13 y	5*	11	60*
	14-18 y	5*	15	75*
Adult Males	19-30 y	5*	15	120*
	31-50 y	5*	15	120*
	51-70 y	10*	15	120*
	> 70 y	15*	15	120*
Adolescent Females	9-13 y	5*	11	60*
	14-18 y	5*	15	75*
Adult Females	19-30 y	5*	15	90*
	31-50 y	5*	15	90*
	51-70 y	10*	15	90*
	> 70 y	15*	15	90*
Pregnancy	14-18 y	5*	15	75*
	19-50 y	5*	15	90*
Breastfeeding	14-18 y	5*	19	75*
	19-50 y	5*	19	90*

[1]The AI for vitamin K is based on median dietary intakes. Vitamin K_1 is the predominant form of vitamin K in the diet (IOM 2006; IOM 2001).

Table 14: Recommended Dietary Allowance and Adequate Intake* values for minerals (IOM 2006)

Life Stage Group		Boron (mg/day)	Calcium (mg/day)	Chromium (µg/day)	Cobalt[1] (µg/day)	Copper (µg/day)
Infants	0-6 mo	-	-	-	-	-
	7-12 mo	-	-	-	-	-
Children	1-3 y	-	500*	-	0.04	340
	4-8 y	-	800*	-	0.05	440
Adolescent Males	9-13 y	-	1,300*	-	0.08	700
	14-18 y	-	1,300*	-	0.10	890
Adult Males	19-30 y	-	1,000*	35*	0.10	900
	31-50 y	-	1,000*	35*	0.10	900
	51-70 y	-	1,200*	30*	0.10	900
	> 70 y	-	1,200*	30*	0.10	900
Adolescent Females	9-13 y	-	1,300*	-	0.08	700
	14-18 y	-	1,300*	-	0.10	890
Adult Females	19-30 y	-	1,000*	25*	0.10	900
	31-50 y	-	1,000*	25*	0.10	900
	51-70 y	-	1,200*	20*	0.10	900
	> 70 y	-	1,200*	20*	0.10	900
Pregnancy	14-18 y	-	1,300*	-	0.11	1,000
	19-50 y	-	1,000*	30*	0.11	1,000
Breastfeeding	14-18 y	-	1,300*	-	0.12	1,300
	19-50 y	-	1,000*	45*	0.12	1,300

Life Stage Group		Iodine (µg/day)	Iron (mg/day)	Magnesium (mg/day)	Manganese (mg/day)	Molyb-denum (µg/day)
Infants	0-6 mo	-	0.27*	-	-	-
	7-12 mo	-	11	-	-	-
Children	1-3 y	90	7	80	-	-
	4-8 y	90	10	130	-	-
Adolescent Males	9-13 y	120	8	240	-	-
	14-18 y	150	11	410	-	-
Adult Males	19-30 y	150	8	400	2.3*	45
	31-50 y	150	8	420	2.3*	45
	51-70 y	150	8	420	2.3*	45
	> 70 y	150	8	420	2.3*	45
Adolescent Females	9-13 y	120	8	240	-	-
	14-18 y	150	15	360	-	-
Adult Females	19-30 y	150	18	310	1.8*	45
	31-50 y	150	18	320	1.8*	45
	51-70 y	150	8	320	1.8*	45
	> 70 y	150	8	320	1.8*	45
Pregnancy	14-18 y	220	27	400	-	-
	19-50 y	220	27	355	2.0*	50
Breastfeeding	14-18 y	290	10	360	-	-
	19-50 y	290	9	315	2.6*	50

[1] Calculated from the vitamin B_{12} RDA (IOM 2006)

Life Stage Group		Nickel (mg/day)	Phosphorus (mg/day)	Selenium (µg/day)	Silicon (mg/day)	Tin (mg/day)
Infants	0-6 mo	-	-	-	-	-
	7-12 mo	-	-	-	-	-
Children	1-3 y	-	460	-	-	-
	4-8 y	-	500	-	-	-
Adolescent Males	9-13 y	-	1,250	-	-	-
	14-18 y	-	1,250	-	-	-
Adult Males	19-30 y	-	700	55	-	-
	31-50 y	-	700	55	-	-
	51-70 y	-	700	55	-	-
	> 70 y	-	700	55	-	-
Adolescent Females	9-13 y	-	1,250	-	-	-
	14-18 y	-	1,250	-	-	-
Adult Females	19-30 y	-	700	55	-	-
	31-50 y	-	700	55	-	-
	51-70 y	-	700	55	-	-
	> 70 y	-	700	55	-	-
Pregnancy	14-18 y	-	1,250	-	-	-
	19-50 y	-	700	60	-	-
Breastfeeding	14-18 y	-	1,250	-	-	-
	19-50 y	-	700	70	-	-

Life Stage Group		Vanadium (mg/day)	Zinc (mg/day)
Infants	0-6 mo	-	2*
	7-12 mo	-	3
Children	1-3 y	-	3
	4-8 y	-	5
Adolescent Males	9-13 y	-	8
	14-18 y	-	11
Adult Males	19-30 y	-	11
	31-50 y	-	11
	51-70 y	-	11
	> 70 y	-	11
Adolescent Females	9-13 y	-	8
	14-18 y	-	9
Adult Females	19-30 y	-	8
	31-50 y	-	8
	51-70 y	-	8
	> 70 y	-	8
Pregnancy	14-18 y	-	12
	19-50 y	-	11
Breastfeeding	14-18 y	-	13
	19-50 y	-	12

Appendix IV

Conversion factors

1. **Pantothenic Acid** (USP 30)**:**

Table 15: Conversion of pantothenic acid source material quantity into pantothenic acid quantity

Source material (1 mg)	Pantothenic acid quantity (mg)
d-Pantothenic acid	1.00
d-Panthenol	1.07
Calcium-*d*-pantothenate	0.92
dl-Pantothenic acid	0.50
dl-Panthenol	0.54
Calcium-*dl*-pantothenate	0.46

2. **Vitamin A** (IOM 2006)**:**

The quantity of vitamin A must always be provided in terms of retinol activity equivalents (RAE) (i.e. µg all-*trans* retinol), irrespective of the source material used.

International Units (IU) may be provided as optional additional information on the Product Licence Application (PLA) form in the "potency" field and on product labels.

1 IU Vitamin A = 2 IU beta-carotene

Table 16: Conversion of vitamin A source material quantity into vitamin A quantity in terms of retinol activity equivalents (RAE) and vitamin A activity in terms of International Units (IU)

Source material (1 µg)	Vitamin A quantity (µg RAE)	Vitamin A activity (IU)
All-*trans* beta-carotene	0.50	1.67
All-*trans* retinol	1.00	3.33
All-*trans* retinyl acetate	0.87	2.94
All-*trans* retinyl palmitate	0.55	1.82

Examples using the vitamin A conversion factors:

a) Converting vitamin A activity into quantity of RAE (µg)

Convert 500 IU of vitamin A activity from all-*trans* retinol into µg RAE:
= 500 IU x 1 µg RAE/3.33 IU vitamin A
= 150 µg RAE

Convert 3000 IU of vitamin A activity from all-*trans* retinyl acetate into µg RAE:
= 3000 IU x 1 µg RAE/3.33 IU vitamin A
= 900 µg RAE

or

= 3000 IU x 0.87 µg RAE/2.94 IU vitamin A
= 900 µg RAE

b) Converting vitamin A source material quantity into quantity of RAE (µg)

Convert 2000 µg of all-*trans* retinyl palmitate into µg RAE:
= 2000 µg x 0.55 µg RAE/µg all-*trans* retinyl palmitate
= 1100 µg RAE

c) Converting beta-carotene activity into quantity of RAE (µg)

Convert 500 IU of beta-carotene activity into µg RAE:
= 500 IU beta-carotene x 1 IU vitamin A/2 IU beta-carotene x 1 µg RAE/3.33 IU vitamin A
= 75 µg RAE

or

= 500 IU beta-carotene x 1 IU vitamin A/2 IU beta-carotene x 0.5 µg RAE/1.67 IU vitamin A
= 75 µg RAE

or

see beta-carotene conversion factors below.

3. Beta-carotene (IOM 2006)**:**

1 IU beta-carotene = 0.15 µg RAE
1 µg beta-carotene = 0.50 µg RAE

Examples using the beta-carotene conversion factors:

a) Converting beta-carotene activity into quantity of RAE (µg)

Convert 500 IU of beta-carotene activity into µg RAE:
= 500 IU beta-carotene x 0.15 µg RAE/IU beta-carotene
= 75 µg RAE

b) Converting beta-carotene quantity into quantity of RAE (µg)

Convert 2000 µg of beta-carotene into µg RAE:
= 2000 µg beta-carotene x 0.5 µg RAE/µg beta-carotene
= 1000 µg RAE

4. Vitamin D:

1 IU of vitamin D = 0.025 µg cholecalciferol (IOM 2006)
= 0.025 µg ergocalciferol

5. Vitamin E (IOM 2006)**:**

The quantity of vitamin E must always be provided in terms of α-tocopherol (AT) (i.e. mg *RRR*-α-tocopherol), irrespective of the source material used.

IUs may be provided as optional additional information on the PLA form in the "potency" field and on product labels.

Table 17: Conversion of vitamin E source material quantity into vitamin E quantity in terms of alpha-(α)-tocopherol (AT) and vitamin E activity in terms of International Units (IU)

Source material (1 mg)	Vitamin E quantity (mg AT)	Vitamin E activity (IU)
RRR-α-Tocopherol	1.00	1.49
RRR-α-Tocopheryl acetate	0.91	1.36
RRR-α-Tocopheryl succinate	0.81	1.21
All *rac*-α-tocopherol	0.50	1.10
All *rac*-α-tocopheryl acetate	0.46	1.00
All *rac*-α-tocopheryl succinate	0.41	0.89

Table 18: Conversion of vitamin E source material activity into vitamin E quantity in terms of alpha-(α)-tocopherol (AT)

Source material (1 IU)	Vitamin E quantity (mg AT)
RRR-α-Tocopherol	0.67
RRR-α-Tocopheryl acetate	0.67
RRR-α-Tocopheryl succinate	0.67
All *rac*-α-tocopherol	0.45
All *rac*-α-tocopheryl acetate	0.45
All *rac*-α-tocopheryl succinate	0.45

Examples using the vitamin E conversion factors:

a) Converting vitamin E activity into quantity of AT (mg)

Convert 400 IU of *RRR*-α-tocopheryl succinate activity into mg AT:
= 400 IU x 0.67 mg AT/IU
= 268 mg AT

b) Converting vitamin E source material quantity into quantity of AT (mg)

Convert 200 mg of all *rac*-α-tocopheryl acetate into mg AT:
= 200 mg x 0.46 mg AT/mg
= 92 mg AT