Multi-Vitamin/Mineral Supplements

MULTI-VITAMIN/MINERAL SUPPLEMENTS MONOGRAPH Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 604 KB) Date March 31, 2023 Table of Contents 1.0 Proper names, common names and source information 1.1 Vitamin proper names, common names and source information 1.2 Mineral proper names, common names and source information 1.3 Other medicinal ingredient proper names, common names and source information 1.4 Complementary medicinal ingredients proper names, common names and source information 2.0 Route of administration 3.0 Dosage forms 4.0 Uses or purposes 4.1 General use or purpose statements 4.2 Specific use or purpose statements 4.2.1 Specific use or purpose statements for vitamins 4.2.2 Specific use or purpose statements for minerals 4.2.3 Specific use or purpose statements for other medicinal ingredients 5.0 Doses 5.1 Subpopulations 5.2 Background on dose 5.3 Dose information for vitamins 5.4 Dose information for minerals 5.5 Dose information for other medicinal ingredients 5.6 Dose information for complementary medicinal ingredients 5.7 Directions for use 6.0 Durations of use 7.0 Risk information 7.1 Cautions and warnings 7.2 Contraindications 7.3 Known adverse reactions 8.0 Storage conditions 9.0 Non-medicinal ingredients 10.0 Specifications 11.0 References 12.0 Appendices Appendix I Appendix II Appendix III Appendix IV Appendix V Appendix VI Appendix VII Appendix VIII MULTI-VITAMIN/MINERAL SUPPLEMENTS MONOGRAPH This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) forms and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients. This monograph includes specific information for each vitamin and mineral as well as combination rules and may be used to support single ingredient or multi-ingredient products containing any medicinal ingredient from Tables 1, 2 and/or 3. The medicinal ingredients boron, inositol, nickel, PABA, tin and vanadium are complementary ingredients that must be combined with at least one other medicinal ingredient listed in Tables 1, 2 and/or 3. No claim can be supported based on these medicinal ingredients. The product claim(s) must be supported by at least one medicinal ingredient from Tables 1, 2 and/or 3. 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 included as medicinal ingredients on this monograph. The PLA form and label must declare all active components (i.e. vitamin and mineral) of a source ingredient as medicinal ingredients and provide their quantity per dosage unit if the total daily dose of that vitamin or mineral exceeds the monograph's minimum dosage value. For example, if calcium ascorbate is listed as a source ingredient for calcium and also provides vitamin C (ascorbic acid) at medicinal levels (i.e. ≥ 6 mg/day for adults), then the PLA form and label must include vitamin C as a medicinal ingredient and its quantity per dosage unit. See Appendix I for additional information. The dose information for vitamins and minerals outlined in this monograph is the quantity of the medicinal ingredient as opposed to the source material and/or source ingredient, i.e., the amount of the vitamin itself and elemental mineral, respectively. For products containing calcium, iron, magnesium and/or zinc as medicinal ingredient(s), please refer to Appendix VIII for additional guidance on labelling in order to avoid misinterpretation which may lead to serious health consequences. Notes Text in parentheses is additional optional information which can be included on the PLA form and label at the applicant's discretion. The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant. 1.0 Proper names, Common names and Source information Notes The terms chromic, cupric, ferrous, ferric and manganous are not available on the web-based PLA form and will not be added; however, these synonyms may be used on the marketed label for chromium (III), copper (II), iron (II), iron (III) and manganese (II) respectively. Any hydrated form of a source ingredient listed in Tables 1, 2 and 3 would be acceptable on the marketed label as long as it is included in the Natural Health Products Ingredients Database (NHPID). 1.1 Vitamin proper names, common names and source information Table 1. Vitamin proper names, common names and source information Proper name(s) 1 Common name(s) 2 Source information 3 Source ingredient(s) Biotin Biotin Biocytin Biotin Folate Folate Vitamin B 9 Folic acid L-5-Methyltetrahydrofolate

L-5-Methyltetrahydrofolate, calcium salt L-5-Methyltetrahydrofolic acid, glucosamine salt Niacin Niacin Vitamin B 3 Inositol hexanicotinate Niacinamide Nicotinic acid Niacinamide Niacinamide Nicotinamide Vitamin B 3 Niacinamide Niacinamide ascorbate Pantothenic acid Pantothenic acid Vitamin B 5 Calcium D-pantothenate Calcium DL-pantothenate Dexpanthenol DL-Panthenol DL-Pantothenic acid D-Pantethine Panthothenic acid Riboflavin Riboflavin Vitamin B 2 Riboflavin Riboflavin 5'-phosphate Riboflavin 5'-phosphate sodium Thiamine Thiamine Vitamin B 1 Benfotiamine Thiamine Thiamine diphosphate Thiamine hydrochloride Thiamine mononitrate Thiamine monophosphate Vitamin A Vitamin A all-trans -Retinol all-trans -Retinyl acetate all-trans -Retinyl palmitate Vitamin B 6 Vitamin B 6 Pyridoxal Pyridoxal 5'-phosphate Pyridoxal 5'-phosphate, calcium salt Pyridoxal 5'-phosphate monohydrate Pyridoxal hydrochloride Pyridoxamine Pyridoxamine 5'-phosphate Pyridoxine Pyridoxine 5'-phosphate Pyridoxine hydrochloride Vitamin B 12 Vitamin B 12 Cobamamide Cyanocobalamin Hydroxocobalamin Hydroxocobalamin acetate Methylcobalamin Vitamin C Vitamin C Ascorbic acid Ascorbic acid 2-O-glucoside Ascorbyl methylsilanol pectinate Ascorbyl palmitate Calcium ascorbate Calcium ascorbate, dihydrate Magnesium ascorbate Magnesium ascorbyl phosphate Manganese (II) ascorbate Niacinamide ascorbate Potassium ascorbate Sodium ascorbate Zinc ascorbate Vitamin D Vitamin D Vitamin D 2 Ergocalciferol Vitamin D Vitamin D 3 Cholecalciferol Vitamin E Vitamin E d-alpha Tocopherol d-alpha Tocopheryl acetate d-alpha Tocopheryl acid succinate dl-alpha Tocopherol dl-alpha Tocopheryl acetate dl-alpha Tocopheryl acid succinate Vitamin K 1 Vitamin K 1 Phytonadione Vitamin K 2 Vitamin K 2 Menaquinone 4 Menaquinone 6 Menaquinone 7 Menaquinones Menatetrenone 1,2 At least one of the following references was consulted per name: NIH 2015a; Sweetman 2015; USP 38 2015; FCC 9 2014; O'Neil 2013; IOM 2006. 3 At least one of the following references was consulted per source information: NIH 2015a; FAO 2012; Sweetman 2015; USP 38 2015; FCC 9 2014; O'Neil 2013; EFSA 2009a; FSANZ 2008; IOM 2006; Van Der Kuy et al. 2002; Chalmers et al. 2000; EC 2000; Zeitlin et al. 1985. 1.2 Mineral proper names, common names and source information Table 2. Mineral proper names, common names and source information Proper name(s) 1 Common name(s) 2 Source information 3 Source ingredient(s) Organism group(s) Source material(s) Part(s) Calcium 4 Calcium Calcium acetate Calcium amino acid chelate Calcium ascorbate Calcium aspartate Calcium bisglycinate Calcium carbonate Calcium chloride Calcium chloride, dihydrate Calcium chloride, hexahydrate Calcium citrate Calcium citrate malate Calcium citrate, tetrahydrate Calcium diglutamate Calcium D-pantothenate Calcium fumarate Calcium glubionate Calcium glubionate, monohydrate Calcium gluceptate Calcium gluconate Calcium gluconate, monohydrate Calcium glutamate Calcium glutarate Calcium glycerophosphate Calcium hydrolyzed animal protein (HAP) chelate Calcium hydrolyzed vegetable protein (HVP) chelate Calcium hydroxide Calcium hypophosphite Calcium lactate Calcium lactate gluconate Calcium lactate, monohydrate Calcium lactate, pentahydrate Calcium lactate, trihydrate Calcium lactobionate, dihydrate Calcium levulinate Calcium levulinate, dihydrate Calcium lysinate Calcium malate Calcium orotate Calcium oxide Calcium phosphate, dibasic Calcium phosphate, dibasic, dihydrate Calcium phosphate, monobasic Calcium phosphate, tribasic Calcium pidolate Calcium pyrophosphate Calcium pyruvate Calcium saccharate Calcium saccharate, tetrahydrate Calcium silicate Calcium sodium lactate Calcium succinate Calcium sulfate Calcium sulfate, dihydrate Calcium sulfate, hemihydrate Calcium L-threonate Dicalcium malate Dolomite Durapatite N/A N/A N/A N/A Bone meal 4 N/A Bone Coral N/A Calcareous skeleton Oyster N/A Shell Chromium 5 Chromium Chromium amino acid chelate Chromium (III) bisglycinate Chromium (III) chloride Chromium (III) chloride, hexahydrate Chromium (III) citrate Chromium (III) dinicocysteinate Chromium (III) dinicotinate Chromium (III)-enriched yeast Chromium (III) fumarate Chromium (III) glutarate Chromium (III) hydrolyzed animal protein (HAP) chelate Chromium (III) hydrolyzed vegetable protein (HVP) chelate Chromium (III) lactate, trihydrate Chromium (III) malate Chromium (III) nicotinate Chromium (III) nicotinate glycinate Chromium (III) nitrate Chromium (III) picolinate 5 Chromium (III) pidolate Chromium (III) potassium sulfate, dodecahydrate Chromium (III) succinate Chromium (III) sulfate N/A N/A N/A Cobalt Cobalt Cobamamide Cyanocobalamin Hydroxocobalamin Methylcobalamin N/A N/A N/A Copper Copper Calcium copper edetate Copper amino acid chelate Copper (II) acetate Copper (II) aspartate Copper (II) bisglycinate Copper (II) carbonate Copper (II) chloride Copper (II) chloride, dihydrate Copper (II) citrate Copper (II) fumarate Copper (II) gluconate Copper (II) glutarate Copper (II) hydrolyzed animal protein (HAP) chelate Copper (II) hydrolyzed vegetable protein (HVP) chelate Copper (II) malate Copper (II) sebacate Copper (II) succinate Copper (II) sulfate Copper (II) sulfate, monohydrate Copper (II) sulfate, pentahydrate N/A N/A N/A Iodine 6 Iodine Potassium iodate Potassium iodide Sodium iodide N/A N/A N/A N/A N/A Fucus vesiculosus 6 Fucus serratus 6 Ascophyllum nodosum 6 Laminaria digitata 6 Laminaria japonica 6 Macrocystis pyrifera 6 Thallus Whole Iron Iron Dried iron (II) sulfate Ferritin Ferrocholinate Iron, carbonyl Iron, electrolytic Iron, reduced Iron amino acid chelate Iron hydrolyzed animal protein (HAP) chelate Iron hydrolyzed vegetable protein (HVP) chelate Iron (II) ascorbate Iron (II) aspartate Iron (II) aspartate, tetrahydrate Iron (II) bisglycinate Iron (II) carbonate Iron (II) carbonate mass Iron (II) chloride Iron (II) chloride, tetrahydrate Iron (II) citrate Iron (II) citrate, decahydrate Iron (II) citrate, monohydrate Iron (II) fumarate Iron (II) gluceptate Iron (II) gluconate Iron (II) gluconate, dihydrate Iron (II) glutarate Iron (II) glycine sulfate Iron (II) lactate Iron (II) lactate, trihydrate Iron (II) malate Iron (II) oxalate Iron (II) oxalate, dihydrate Iron

(II) phosphate Iron (II) pidolate Iron (II) succinate Iron (II) sulfate Iron (II) sulfate, heptahydrate Iron (II) tartrate Iron (II) taurate Iron (III) ammonium citrate Iron (III) citrate Iron (III) glycerophosphate Iron (III) glycinate Iron (III) phosphate Iron (III) pyrophosphate Polysaccharide-iron complex N/A N/A N/A Magnesium Magnesium Dolomite Magnesium acetate Magnesium acetate, tetrahydrate Magnesium acetyl taurate Magnesium amino acid chelate Magnesium ascorbate Magnesium ascorbate, monohydrate Magnesium aspartate Magnesium aspartate, dihydrate Magnesium aspartate hydrochloride, trihydrate Magnesium aspartate, tetrahydrate Magnesium bisglycinate Magnesium carbonate Magnesium chloride Magnesium chloride, hexahydrate Magnesium citrate Magnesium citrate, tribasic Magnesium citrate malate Magnesium dibutyrate Magnesium fumarate Magnesium gluceptate Magnesium gluconate Magnesium gluconate, dihydrate Magnesium glutarate Magnesium glycerophosphate Magnesium hydrolyzed animal protein (HAP) chelate Magnesium hydrolyzed vegetable protein (HVP) chelate Magnesium hydroxide Magnesium hydroxide carbonate Magnesium lactate Magnesium L-threonate Magnesium lysinate Magnesium lysyl glycinate Magnesium malate Magnesium orotate Magnesium orotate, dihydrate Magnesium oxide Magnesium phosphate, dibasic Magnesium phosphate, dibasic, mixed hydrates Magnesium phosphate, dibasic, trihydrate Magnesium phosphate, monobasic Magnesium phosphate, tribasic Magnesium phosphate, tribasic, octahydrate Magnesium phosphate, tribasic, pentahydrate Magnesium phosphate, tribasic, tetrahydrate Magnesium pidolate Magnesium succinate Magnesium sulfate Magnesium sulfate, heptahydrate Magnesium sulfate, monohydrate Magnesium sulfate, trihydrate Magnesium taurate Magnesium trisilicate N/A N/A N/A Manganese Manganese Manganese amino acid chelate Manganese (II) ascorbate Manganese (II) aspartate Manganese (II) bisglycinate Manganese (II) carbonate Manganese (II) chloride Manganese (II) chloride, tetrahydrate Manganese (II) citrate Manganese (II) fumarate Manganese (II) gluconate Manganese (II) gluconate, dihydrate Manganese (II) glycerophosphate Manganese (II) hydrolyzed animal protein (HAP) chelate Manganese (II) hydrolyzed vegetable protein (HVP) chelate Manganese (II) pidolate Manganese (II) succinate Manganese (II) sulfate Manganese (II) sulfate, monohydrate Manganese (II) sulfate, tetrahydrate Manganese (IV) dioxide N/A N/A N/A Molybdenum Molybdenum Ammonium molybdate (VI) Ammonium molybdate (VI), tetrahydrate Molybdenum amino acid chelate Molybdenum (VI) aspartate Molybdenum (VI) bisglycinate Molybdenum (VI) citrate Molybdenum (VI) fumarate Molybdenum (VI) glutarate Molybdenum (VI) hydrolyzed animal protein (HAP) chelate Molybdenum (VI) hydrolyzed vegetable protein (HVP) chelate Molybdenum (VI) malate Molybdenum (VI) succinate Potassium molybdate (VI) Sodium molybdate (VI) Sodium molybdate (VI), dihydrate N/A N/A N/A Phosphorus 4 Phosphorus Ammonium phosphate, dibasic Ammonium phosphate, monobasic Ammonium polyphosphate Calcium glycerophosphate Calcium phosphate, dibasic Calcium phosphate, dibasic, dihydrate Calcium phosphate, monobasic Calcium phosphate, monobasic, monohydrate Calcium phosphate, tribasic Calcium polyphosphate Calcium pyrophosphate Durapatite Magnesium phosphate, dibasic, mixed hydrates Magnesium phosphate, dibasic, trihydrate Magnesium phosphate, tribasic Potassium phosphate, dibasic Potassium phosphate, monobasic Potassium phosphate, tribasic Potassium polyphosphate Potassium pyrophosphate Sodium glycerophosphate Sodium phosphate, dibasic Sodium phosphate, dibasic, dihydrate Sodium phosphate, dibasic, monohydrate Sodium phosphate, dibasic, dodecahydrate Sodium phosphate, dibasic, heptahydrate Sodium phosphate, monobasic Sodium phosphate, monobasic, dihydrate Sodium phosphate, monobasic, monohydrate Sodium phosphate, tribasic Tetrasodium pyrophosphate Trisodium phosphate, dodecahydrate Zinc phosphate N/A N/A N/A N/A Bone meal 4 N/A Bone Selenium Selenium Methylselenocysteine Selenious acid Selenium amino acid chelate Selenium aspartate Selenium citrate Selenium dioxide, monohydrate Selenium fumarate Selenium glutarate Selenium glycinate Selenium hydrolyzed animal protein (HAP) chelate Selenium hydrolyzed vegetable protein (HVP) chelate Selenium malate Selenium succinate Selenium-enriched yeast Selenocysteine Selenomethionine Sodium hydrogen selenite Sodium selenate Sodium selenite N/A N/A N/A Silicon 7 Silicon Calcium silicate Choline-stabilised orthosilicic acid Methylsilanetriol Orthosilicic acid Silicic acid Silicon dioxide Silicon hydrolyzed animal protein (HAP) chelate Silicon hydrolyzed vegetable protein (HVP) chelate Sodium metasilicate N/A N/A N/A N/A N/A Equisetum arvense 7 Herb top Zinc 8 Zinc Zinc acetate Zinc acetate, dihydrate Zinc amino acid chelate Zinc arginate Zinc ascorbate Zinc aspartate Zinc bisglycinate Zinc carbonate Zinc chloride Zinc citrate Zinc citrate, dihydrate Zinc citrate, trihydrate Zinc fumarate Zinc gluconate Zinc gluconate glycine Zinc glutarate Zinc glycerate Zinc histidinate Zinc hydrolyzed animal protein (HAP) chelate Zinc hydrolyzed vegetable protein (HVP) chelate Zinc lactate Zinc lysinate Zinc malate Zinc methionine Zinc monomethionine Zinc orotate Zinc oxide Zinc phosphate Zinc picolinate 8 Zinc pidolate Zinc propionate Zinc succinate Zinc sulfate Zinc sulfate, heptahydrate Zinc sulfate, monohydrate N/A N/A N/A 1, 2 At least one of the following references was consulted per name: NIH 2015a; Sweetman 2015; USP 38 2015; FCC 9 2014; O'Neil 2013. 3 At least one of the following references was consulted per source information: Albion 2015; BP 2015; NIH 2015a,b; Sweetman 2015; USP 38 2015; FCC 9 2014; O'Neil 2013; Jain et al. 2012; EFSA 2010a; Summers et al. 2010; EC 2009; EFSA 2009b,c,d,e,f,g,h,i,j; EFSA 2008a,b,c,d,e,f; Nowak et al. 2008; Richards 2008; EFSA 2007; Guiry and Guiry 2007; TGA 2007; EFSA 2006; Walsdorf and Alexandrides 2005; Albion 2004a,b; ANZFA 2004;

Gruenwald et al. 2004; Albion 2003a,b; Allen 2002; ANZFA 2002; Ball et al. 2002; EC 2002; Van Der Kuy et al. 2002; Anderson et al. 2001; Hendler and Rorvik 2001; Albion 2000; Chalmers et al. 2000; EC 2000; Tsuboi et al. 2000; Ishitani et al. 1999; Patrick 1999; IPCS 1998; Albion 1997a,b; Grant et al. 1997; Albion 1996a,b; Fujita et al. 1996; Murray 1996; Albion 1995; Henderson 1994; Albion 1993a,b,c,d,e; Evans and Pouchnik 1993; Albion 1992; Zeitlin et al. 1985. 4 Bone meal : When bone meal is used as a source ingredient for calcium or phosphorus, it must be sourced from a non-human animal that is not susceptible to transmissible spongiform encephalopathy diseases, including bovine spongiform encephalopathy (HC 2013). 5 Chromium picolinate : If chromium picolinate is indicated as a source ingredient of chromium, additional restrictions apply (refer to Tables 12, 13 and 14). 6 If iodine is sourced from Fucus vesiculosus, Fucus serratus, Ascophyllum nodosum, Laminaria digitata or Laminaria japonica , it should be isolated and purified. This monograph does not support algal extracts. 7 Silicon from Equisetum arvense : Data (or certification) must be submitted to the Natural and Non-Prescription Health Products Directorate (NNHPD) upon request to show that thiaminase has been inactivated. If silicon is sourced from Equisetum arvense herb top, it should be isolated and purified. This monograph does not support Equisetum arvense extracts. 8 Zinc picolinate : If zinc picolinate is indicated as a source ingredient of zinc, the product must be for Adults only and the maximum daily dose is restricted to 25 mg (refer to Table 9). In addition, additional restrictions apply (refer to Tables 12 and 14). 1.3 Other medicinal ingredient proper names, common names and source information Table 3. Other medicinal ingredient proper names, common names and source information Proper name(s) 1 Common name(s) 2 Source information 3 Source ingredient(s) Source material(s) Part(s) all-trans -beta-Carotene beta-Carotene all-trans -beta-Carotene beta-Carotene beta-Carotene N/A N/A (beta-Hydroxyethyl)trimethylammonium 2-Hydroxy-N,N,N-trimethylethanaminium Choline Choline Choline Choline alfoscerate Choline bitartrate Choline chloride Choline citrate Choline dihydrogen citrate Choline orotate N/A N/A (3R,3'R,6'R)-beta,epsilon-Carotene-3,3'-diol 4 Lutein N/A Tagetes erecta 4 Herb flowering oleoresin all-trans -Lycopene 5 Lycopene Lycopene N/A N/A N/A Solanum lycopersicum 5 Fruit flesh (S)-2-Amino-4-(methylthio)butanoic acid L-Methionine L-Methionine Methionine DL-Methionine L-Methionine N-Acetyl-L-methionine N/A N/A Potassium 6 Potassium Acesulfate potassium Potassium acetate Potassium ascorbate Potassium aspartate Potassium bicarbonate Potassium carbonate Potassium chloride Potassium citrate Potassium citrate, monohydrate Potassium gluconate Potassium glutarate Potassium glycerophosphate Potassium glycerophosphate, trihydrate Potassium glycinate Potassium hydroxide Potassium lactate Potassium malate Potassium phosphate, dibasic Potassium phosphate, monobasic Potassium phosphate, tribasic Potassium pidolate Potassium sorbate Potassium succinate Potassium sulfate Potassium tartrate Potassium tartrate, hemihydrate N/A N/A 1,2 At least one of the following references was consulted per name: NIH 2015a; Sweetman 2015; USP 38 2015; FCC 9 2014; O'Neil 2013. 3 At least one of the following references was consulted per source information: NIH 2015a; Sweetman 2015; USP 38 2015; FCC 9 2014; O'Neil 2013; EFSA 2009e; EFSA 2008d; EFSA 2007; FAO 2006. 4 If lutein is sourced from Tagetes erecta herb flowering oleoresin, it should be isolated and purified. This monograph does not support Tagetes erecta extracts. 5 If lycopene is sourced from Solanum lycopersicum fruit flesh, it should be isolated and purified. This monograph does not support Solanum lycopersicum extracts. 6 Potassium : At least 100 mg of potassium per day is required to support the uses or purposes listed in Section 4.2.3. Only general uses or purposes are permitted at daily doses below 100 mg of potassium. 1.4 Complementary medicinal ingredients proper names, common names and source information The medicinal ingredients boron, inositol, nickel, PABA, tin and vanadium are complementary ingredients that must be combined with at least one medicinal ingredient listed in Tables 1, 2 and/or 3. No claim can be supported based on these medicinal ingredients. The product claim(s) must be supported by at least a medicinal ingredient from Tables 1, 2 and/or 3. Table 4. Complementary medicinal ingredients proper names, common names and source information. Proper name(s) 1 Common name(s) 2 Source information 3 Source ingredient(s) Source material(s) Part(s) Boron Boron Borax Boric acid Boron aspartate Boron citrate Boron glycinate Boron hydrolyzed animal protein (HAP) chelate Boron hydrolyzed vegetable protein (HVP) chelate Calcium borate Calcium borogluconate Calcium fructoborate Magnesium borate Sodium borate N/A N/A myo -Inositol Inositol Inositol Inositol, dihydrate Inositol hexanicotinate Inositol monophosphate N/A N/A Nickel Nickel Nickel (II) sulfate Nickel (II) sulfate, heptahydrate Nickel (II) sulfate, hexahydrate N/A N/A 4-Aminobenzoic acid 4 para-Aminobenzoic acid 4 PABA para-Aminobenzoic acid para-Aminobenzoic acid N/A N/A N/A Saccharomyces cerevisiae 4 Whole Tin Tin Stannous chloride N/A N/A Vanadium Vanadium Sodium metavanadate Vanadium amino acid chelate Vanadium aspartate Vanadium citrate Vanadium fumarate Vanadium glutarate Vanadium hydrolyzed animal protein (HAP) chelate Vanadium hydrolyzed vegetable protein (HVP) chelate Vanadium malate Vanadium metavanadate Vanadium succinate Vanadyl sulfate Vanadyl sulfate, dihydrate N/A N/A 1,2 At least one of the following references was consulted per name: NIH 2015a; Sweetman 2015; USP 38 2015; FCC 9 2014; O'Neil 2013. 3 At least one of the following references was consulted per source information: NIH 2015a; Sweetman 2015; USP 38 2015; FCC 9 2014; O'Neil 2013; EFSA 2009a,e; EFSA 2008d,g; EFSA 2007; O'Neil et al 2006, EFSA 2004. 4 If PABA is sourced

from Saccharomyces cerevisiae whole, it should be isolated and purified. This monograph does not support Saccharomyces cerevisiae extracts. 2.0 Route of administration Oral 3.0 Dosage forms This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document. Acceptable dosage forms by age group: Infants 0-12 months, Children 1-2 years: The acceptable dosage forms are limited to emulsion/suspension and solution/ liquid preparations (Giacoia et al. 2008; EMEA/CHMP 2006). Children 3-5 years: The acceptable dosage forms are limited to chewables, emulsion/ suspension, powders and solution/liquid preparations (Giacoia et al. 2008; EMEA/CHMP 2006). Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. 4.0 Uses or Purposes It is mandatory for all natural health products to indicate at least one use or purpose statement. The use or purpose statements can be combined on the product label as appropriate (e.g. Helps to form red blood cells; Helps in energy metabolism/(and) tissue formation = Helps to form red blood cells and in energy metabolism and tissue formation). In addition, claims such as 'Helps in energy metabolism/(and) tissue formation' could be listed on the label as 'Helps in energy metabolism' or 'Helps in tissue formation' or 'Helps in energy metabolism and tissue formation'. 4.1 General use or purpose statements Products containing any vitamin and/or mineral from Tables 1 and/or 2 and/or beta-carotene and potassium from Table 3 (not acceptable for other medicinal ingredients from Table 3 or medicinal ingredients listed in Table 4). Source of vitamin(s)/mineral(s)/vitamin(s) and mineral(s), a factor/factors in the maintenance of good health. Source of vitamin(s)/mineral(s)/vitamin(s) and mineral(s), a factor/factors in normal growth and development. Source of vitamin(s)/mineral(s)/vitamin(s) and mineral(s) to support biological functions which play a key role in the maintenance of good health. Maintains/supports good health. Contributes to maintaining general health. For maintaining general health. A factor in the maintenance of good health. A factor in normal growth and development Products containing at least one vitamin or mineral from Tables 1 and/or 2 (all vitamins and minerals in the product must be at minimum therapeutic dose as listed in Tables 8 and 9) Vitamin supplement. Mineral supplement. Vitamin and mineral supplement. Products containing at least two vitamins and/or minerals from Tables 1 and/or 2 (all vitamins and minerals in the product must be at minimum therapeutic dose as listed in Tables 8 and 9) Multi-vitamin supplement Multi-mineral supplement Multi-vitamin and multi-mineral supplement. 4.2 Specific use or purpose statements Notes Refer to Appendix II for guidelines on using the specific uses or purposes outlined in this section. Since several medicinal ingredients are associated with a source of antioxidant or electrolyte claim, there is an option to use these statements in plural. The singular should be used when the product only contains one medicinal ingredient associated with these claims; the plural form should be used when more than one medicinal ingredient with such properties are included in the product formulation at therapeutic dose. 4.2.1 Specific use or purpose statements for vitamins Table 5. Specific uses or purposes statements for vitamins Vitamin Specific uses or purposes 1 Biotin Helps to maintain/support healthy hair/nail/mucous membranes/(and) skin. Helps to prevent biotin deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 Folate 4 Helps to form red blood cells. Helps to prevent folate deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 Products providing 400 μg or more of folate per day: Helps to reduce the risk of neural tube defects when taken daily at least three months prior to becoming pregnant and during early pregnancy. Helps to support normal early fetal development (brain and spinal cord). Niacin/ Niacinamide 5 Helps normal growth and development. Helps in energy metabolism/(and) tissue formation. Helps to prevent niacin/niacinamide/vitamin B 3 deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 Pantothenic acid Helps in energy metabolism/(and) in tissue formation. Helps to prevent pantothenic acid deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 Riboflavin Helps in energy metabolism/(and) in tissue formation. Helps to maintain/support healthy mucous membranes. Helps to maintain/support normal red blood cells. Helps to maintain/support normal metabolism of iron. Helps to prevent riboflavin deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 Thiamine Helps in energy production. Supports energy production. Helps normal growth. Helps to prevent thiamine deficiency. 2 Helps to prevent thiamine deficiency 2 which helps supports normal growth. Helps to maintain/support the body's ability to metabolize nutrients. 3 Vitamin A Helps to maintain/support normal vision/eyesight/eye health/(and) night vision. Maintains/supports normal vision/eyesight/eye health/(and) night vision. Helps to maintain/support skin health/(and) mucous membranes health. Maintains/supports skin health/(and) mucous membranes health. Healthy skin/(and) mucous membranes support. Helps to maintain/support immune function/the immune system. Helps with immune function/the immune system. Helps to provide eyesight/skin/mucous membranes/(and) immune function support. Helps in the development and maintenance of night vision. Helps in the development and maintenance of bones/(and) teeth. Helps to build strong bones/(and) teeth. Helps to maintain/support normal metabolism of iron. Helps to prevent vitamin A deficiency. 2 Vitamin B 6 Helps in energy metabolism/(and) in tissue formation. Helps to form red blood cells. Helps to prevent vitamin B 6 deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 Vitamin B 12 Helps in energy metabolism. Helps to form red blood cells. Helps

to maintain/support immune function/the immune system. Helps with immune function/the immune system. Helps to maintain/support healthy metabolism. Helps to prevent vitamin B 12 deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 Vitamin C Helps in the development and maintenance of bones/cartilage/teeth/(and) gums. Helps in wound healing/(and) connective tissue formation. Source of/Provides (an) antioxidant(s) for the maintenance of good health. Source of/Provides (an) antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals. Helps in collagen formation (to maintain/support healthy bones/cartilage/teeth/(and) gums). Helps to maintain/support immune function/the immune system. Helps with immune function/the immune system. Helps to prevent vitamin C deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 Vitamin D Helps in the development and maintenance of bones/(and) teeth. Helps to build strong bones/(and) teeth. Helps in the absorption (and use) of calcium and phosphorus. Vitamin D intake, when combined with sufficient calcium, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis. Helps to maintain/support immune function/the immune system. Helps with immune function/the immune system. Helps to prevent vitamin D deficiency. 2 Vitamin E Source of/Provides (an) antioxidant(s) for the maintenance of good health. Source of/Provides an antioxidant that protects the fat in body tissues from oxidation. Source of/Provides (an) antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals. Helps to prevent vitamin E deficiency. 2 Vitamin K 1 and K 2 Helps in the maintenance of bones. Helps to prevent vitamin K deficiency. 2 1 At least two of the following references were consulted per use or purpose statement: CFIA 2015; EC 2015; IOM 2011; NIH 2011; HC 2009a,b; de Benoist 2008; IOM 2006; Shils et al. 2006; Bjørke Monsen and Ueland 2003; MacKay and Miller 2003; IOM 2001; Groff and Gropper 2000; IOM 2000; NIH 2000; IOM 1998; IOM 1997; Colombo et al. 1990. 2 For deficiency claims : This use or purpose statement is only acceptable if the vitamin is present at dosages at or above the recommended dietary allowance (RDA) or adequate intake (AI). See Appendix III for RDA and AI definitions and Appendix IV for detailed values according to life stage group. Note that most vitamin deficiencies are rare in North America. 3 These vitamins are cofactors in specific biochemical reactions (e.g. inter-conversion of amino acids). This claim is not intended to convey that taking these vitamins helps to boost metabolism, upregulate a bodily system and/or directly convert food to energy. Inferring such claims would be misleading and is not permitted. In order to avoid any misinterpretation of this claim, the terms 'carbohydrates, fats, proteins, etc.' must not be used to further specify the term 'nutrients'. 4 Folate : If a product is marketed specifically as a prenatal supplement (for pregnant women), it must have at least 400 μg of folate per day. Health Canada (HC 2009a,b) recommends that all women who could become pregnant take a daily multivitamin/mineral supplement containing 400 μg of folic acid per day. At a minimum, women who are planning to become pregnant should start taking this supplement 3 months before the pregnancy. 5 Niacin/niacinamide : A specific use or purpose statement must be made for products providing > 35 mg niacin, niacinamide or a combination of the two, per day. 4.2.2 Specific use or purpose statements for minerals Table 6. Specific uses or purposes statements for minerals Mineral Specific uses or purposes 1 Calcium Helps in the development and maintenance of bones/(and) teeth. Helps in the development and maintenance of bones/(and) teeth especially in children and young adults. Adequate calcium (and vitamin D) (throughout life) as part of a healthy diet, (along with physical activity) may reduce the risk of developing osteoporosis (in peri- and postmenopausal women) (in later life). Adequate calcium (and vitamin D) (throughout life) as part of a healthy diet, (along with physical activity) may help prevent bone loss/osteoporosis (in peri- and postmenopausal women) (in later life). As part of a healthy diet (when taken with Vitamin D) may help prevent bone loss/osteoporosis. Source of/Provides (an) electrolyte(s). Source of/Provides (an) electrolyte(s) for the maintenance of good health. Helps to maintain/support normal muscle function. Helps maintain/support bone health. Helps to prevent calcium deficiency. 2 Chromium Provides support for healthy glucose metabolism. Helps to maintain/support normal blood glucose levels. Helps to prevent chromium deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 Cobalt Cobalt is a structural component of vitamin B 12 that helps form red blood cells. Cobalt is a structural component of vitamin B 12 that helps prevent vitamin B 12 deficiency. 2 Cobalt is a structural component of vitamin B 12 that helps to maintain/support the body's ability to metabolize nutrients. 3 Copper Helps to produce and repair connective tissue. Helps to form red blood cells. Helps to maintain/support normal iron transport in the body. Helps to prevent copper deficiency. 2 Iodine Helps in the function of the thyroid gland. Helps to prevent iodine deficiency. 2 Iron 4 Helps to form red blood cells (and helps in their proper function). Helps to prevent iron deficiency. 2 Helps to prevent iron deficiency anaemia. 2 Helps to prevent iron deficiency anemia and associated tiredness and fatigue. 2 Products providing 16 mg or more of iron, per day: Helps pregnant women meet (the) (Health Canada's) recommended intake for iron, when taken in conjunction with a healthy diet. Magnesium 5 Helps in the development and maintenance of bones/(and) teeth. Helps in bone development. Helps in energy metabolism/(and) tissue formation. Helps to maintain/support normal muscle function. Helps to maintain/support normal muscle function, including the heart muscle. Helps to maintain/support heart muscle

function. Source of/Provides (an) electrolyte(s). Source of/Provides (an) electrolyte(s) for the maintenance of good health. Helps to maintain/support normal electrolyte balance. Helps to prevent magnesium deficiency. 2,6 Helps to maintain/support the body's ability to metabolize nutrients. 3 Manganese Helps in the development and maintenance of bones. Helps to prevent manganese deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 Molybdenum Helps to prevent molybdenum deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 Phosphorus Helps in the development and maintenance of bones/(and) teeth. Source of/Provides (an) electrolyte(s) Source of/Provides (an) electrolyte(s) for the maintenance of good health. Helps to prevent phosphorus deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 Selenium Helps normal growth and development. Source of/Provides (an) antioxidant(s) for the maintenance of good health. Source of/Provides an antioxidant that helps protect against oxidative stress. Source of/Provides (an) antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals. Helps to maintain/support normal function of the thyroid gland Helps to prevent selenium deficiency. 2 Zinc 7 Helps in connective tissue formation. Helps in energy metabolism/(and) tissue formation. Helps to maintain/support healthy skin. Helps to maintain/support immune function/the immune system. Helps with immune function/the immune system. Helps to maintain/support healthy bones/hair/nail/(and) skin. Maintains/supports healthy bones/hair/nail/(and) skin. Helps to prevent zinc deficiency. 2 Helps to maintain/support the body's ability to metabolize nutrients. 3 1 At least two of the following references were consulted per use or purpose statement: CFIA 2015; EC 2015; IOM 2011; FDA 2008; Tang et al 2007; IOM 2006; Jackson et al 2006; NAMS 2006; Shils et al. 2006; Meisel et al. 2005; Schwartz et al. 2005; Brown and Josse 2002; IOM 2001; Groff and Gropper 2000; IOM 2000; NIH 2000; IOM 1997; Klimis-Tavantis 1994. 2 For deficiency claims : This use or purpose statement is only acceptable if the mineral is present at dosages at or above the RDA or AI. See Appendix III for RDA and AI definitions and Appendix IV for detailed values according to life stage group. Note that most mineral deficiencies are rare in North America. 3 These minerals are involved as cofactors in specific biochemical reactions (e.g. inter-conversion of amino acids). This claim is not intended to convey that taking these minerals helps to boost metabolism, upregulate a bodily system and/or directly convert food to energy. Inferring such claims would be misleading and is not permitted. In order to avoid any misinterpretation of this claim, the terms 'carbohydrates, fats, proteins, etc.' must not be used to further specify 'nutrients'. 4 Iron : A specific use or purpose statement must be made for products providing > 35 mg iron per day. 5 Magnesium : A specific use or purpose statement must be made for products providing > 350 mg magnesium per day. 6 Magnesium deficiency claim : As the RDA for magnesium for children 1-3 years, children 4-8 years and adolescents 14-18 years exceeds the maximum dose, this claim is not permitted for these subpopulations. 7 Zinc : A specific use or purpose statement must be made for products providing > 40 mg zinc per day. 4.2.3 Specific use or purpose statements for other medicinal ingredients Table 7. Specific uses or purposes statements for other medicinal ingredients Medicinal ingredient Specific uses or purposes 1 beta-Carotene Provitamin A/Source of vitamin A for the maintenance of good health. Source of vitamin A. Provitamin A/Source of vitamin A to help maintain/support eyesight/skin/mucous membranes/(and) immune function/the immune system Helps maintain/support eyesight/skin/mucous membranes/(and) immune function/the immune system. Provitamin A/Source of vitamin A to help with immune function/the immune system Helps with immune function/the immune system. Provitamin A/Source of vitamin A to help in the development and maintenance of night vision. Helps in the development and maintenance of night vision. Provitamin A/Source of vitamin A to help in the development and maintenance of bones/(and) teeth. Helps in the development and maintenance of bones/(and) teeth. Helps to prevent vitamin A deficiency. 2 Choline 3 Helps to support liver function. L-Methionine 3 Helps to support liver function. Source of/Provides an essential amino acid for the maintenance of good health. Source of/Provides an essential amino acid involved in protein synthesis. Lutein Source of/Provides (an) antioxidant(s). Source of/Provides (an) antioxidant(s) for the maintenance of good health. Source of/Provides an antioxidant for the maintenance of eye health. Source of/Provides (an) antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals. Products providing 6 mg or more of lutein per day: Helps to maintain/support eyesight in conditions (associated with sunlight damage), such as cataracts and age-related macular degeneration. Helps to reduce the risk of developing cataracts. Helps to improve macular pigment optical density. Lycopene Source of/Provides (an) antioxidant(s). Source of/Provides (an) antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals. Products providing 6.5 mg or more of lycopene per day: Helps to support prostate health. Potassium Products providing 100 mg or more of potassium per day: Source of/Provides (an) electrolyte(s). Source of/Provides (an) electrolyte(s) for the maintenance of good health. Silicon Products providing 10 mg or more of silicon per day: Helps to maintain/support healthy hair/nail/(and) skin. 1 At least two of the following references were consulted per use or purpose statement: CNF 2015; EC 2015; Erdman et al. 2009; Christen et al. 2008; Fletcher et al. 2008; Johnson et al. 2008; Kristal et al. 2008; Moeller et al. 2008; Schwarz et al. 2008; Silaste et al. 2007;

Wickett et al. 2007; IOM 2006; Miranda et al. 2006; Shao and Hathcock 2006; Shils et al. 2006; Zeisel 2006; Barel et al. 2005; IOM 2005a,b; Mohanty et al. 2005; Porrini et al. 2005; Alves-Rodrigues and Shao 2004; Richer et al. 2004; Blakely et al. 2003; Olmedilla et al. 2003; Giovannucci et al. 2002; IOM 2002; Kucuk et al. 2002; Dwyer et al. 2001; IOM 2001; Kucuk et al. 2001; Matos et al. 2001; Groff and Gropper 2000; Brown et al 1999; Gann et al. 1999; IOM 1998; Seyoum and Persaud 1991; Benevenga 1984. 2 beta-Carotene: Vitamin A deficiency claim : See Appendix V for guidance on the appropriate use of this claim. 3 The term "lipotropic factor" is not permitted to describe choline, methionine or inositol. This term may mislead consumers to perceive that the product is intended for the purpose of weight loss. 5.0 Doses 5.1 Subpopulations Adults 19 and older is the only acceptable subpopulation for the source ingredients HAP or HVP as well as for the following medicinal ingredients: Boron Chromium Lutein Lycopene Manganese Molybdenum Nickel PABA Potassium Selenium Silicon Tin Vanadium Zinc sourced from zinc picolinate 5.2 Background on dose Notes The daily dose of each vitamin and/or mineral, listed in Tables 8, 9 and 10, must meet the minimum dosage value if a general or specific claim is being attributed to them. In addition, the minimum daily dose must be met for all vitamins and minerals in a product making a (multi-)vitamin and/or mineral supplement claim in the brand name or as part of the recommended uses or purposes. The daily dose of each medicinal ingredient must not exceed the maximum dosage value. Refer to Appendix III for definitions and derivations of dosage values. Refer to Appendix VI for conversion factors for pantothenic acid, vitamin A, beta-carotene, vitamin B 12 , vitamin D and vitamin E. Dose information for adults includes pregnant and breastfeeding women. However, products containing PABA, vanadium, chromium sourced from chromium picolinate and/or zinc sourced from zinc picolinate require a mandatory risk statement for these subpopulations. See Section 7.0 for additional details. 5.3 Dose information for vitamins Table 8. Daily doses for vitamins (Min = minimum; Max = maximum) Life Stage Group Biotin (µg/day) Folate 1 (µg/day) Niacin/niacinamide 2 (mg/day) Min Max Min Max Min Max Infants 0-12 months - - - - - - Children 1-3 years 1.0 500 15 300 0.6 10 4-8 years 1.0 500 15 400 0.6 15 Adolescents 9-13 years 1.0 500 15 600 0.6 20 14-18 years 1.8 500 30 800 1.0 30 Adults 19 years and older 1.8 500 30 1,000 1.0 500 Life Stage Group Pantothenic acid (mg/day) Riboflavin (mg/day) Thiamine (mg/day) Min Max Min Max Min Max Infants 0-12 months - - - - - - Children 1-3 years 0.2 500 0.04 100 0.04 100 4-8 years 0.2 500 0.04 100 0.04 100 Adolescents 9-13 years 0.2 500 0.04 100 0.04 100 14-18 years 0.4 500 0.08 100 0.07 100 Adults 19 years and older 0.4 500 0.08 100 0.07 100 Life Stage Group Vitamin A 3 (µg RAE/day) Min all-trans -Retinol - Max all-trans -Retinyl acetate - Max all-trans -Retinyl palmitate - Max Infants 0-12 months 30 600 600 600 Children 1-3 years 30 600 600 600 4-8 years 30 900 900 900 Adolescents 9-13 years 30 1,700 1,700 1,700 14-18 years 65 2,800 2,800 2,800 Adults 19 years and older 65 3,003 3,000 3,022 Life Stage Group Vitamin B 6 (mg/day) Vitamin B 12 4 (µg/day) Vitamin C (mg/day) Min Max Min Max Min Max Infants 0-12 months - - - - - Children 1-3 years 0.05 30 0.09 1,000 2.2 400 4-8 years 0.05 40 0.09 1,000 2.2 650 Adolescents 9-13 years 0.05 60 0.09 1,000 2.2 1,200 14-18 years 0.10 80 0.14 1,000 6.0 1,800 Adults 19 years and older 0.10 100 0.14 1,000 6.0 2,000 Life Stage Group Vitamin D (µg/day) Vitamin E 5 (mg AT/day) Min Max Min dl-alpha-Tocopherol - Max d-alpha-Tocopherol - Max Infants 0-12 months 0.5 25 - - - Children 1-3 years 0.8 25 0.6 100 200 4-8 years 0.8 25 0.6 150 300 Adolescents 9-13 years 0.8 25 0.6 300 600 14-18 years 1.0 25 1.0 400 800 Adults 19 years and older 1.0 25 1.0 500 1,000 Life Stage Group Vitamin K 1 , vitamin K 2 and total vitamin K 1 + K 2 (µg/day) Min Max Infants 0-12 months - - Children 1-3 years 3 30 4-8 years 3 55 Adolescents 9-13 years 3 60 14-18 years 6 75 Adults 19 years and older 6 120 1 Folate : If a product is marketed specifically as a prenatal supplement (for pregnant women), it must have at least 400 µg of folate per day. Health Canada (HC 2009a,b) recommends that all women who could become pregnant take a daily multivitamin/mineral supplement containing 400 µg of folic acid per day. At a minimum, women who are planning to become pregnant should start taking this supplement 3 months before the pregnancy. 2 Niacin/niacinamide: A specific use or purpose statement must be made for products providing > 35 mg niacin, niacinamide, or a combination of the two per day. 3 Vitamin A: There is a potential risk of hypervitaminosis A resulting from the use of products which combine high doses of vitamin A and beta-carotene. See Appendix V ("Mitigating the Risk of Hypervitaminosis A") for information on how to determine acceptable daily doses of each of these medicinal ingredients when used in combination. 4 Vitamin B 12 + Cobalt : As vitamin B 12 is the source ingredient for cobalt, the maximum dose for vitamin B 12 and cobalt combined must not exceed 1000 µg vitamin B 12 per day. Refer to Appendix VI for conversion from vitamin B 12 to cobalt . 5 Vitamin E : A combination of dl-alpha-tocopherol (synthetic form) and d-alpha-tocopherol (natural form) must not exceed the maximum daily dose of 1000 mg of alpha-tocopherol from all sources (IOM 2006) with a maximum of 1500 IU/day of d-alpha-tocopherol and 1100 IU/day of dl-alpha-tocopherol. 1 IU = 0.67 mg for d-alpha-tocopherol 1 IU = 0.90 mg for dl-alpha-tocopherol which is equivalent to 0.45 mg of the biologically active alpha-tocopherol equivalent. The total amount of vitamin E should be used to determine if additional risk statements are required (refer to Table 13). 5.4 Dose information for minerals Table 9. Daily doses for minerals (Min = minimum; Max = maximum) Life Stage Group Calcium 1 (mg/day) Chromium (µg/day) Cobalt 2 (µg/day) Min Max Min Max Min Max Infants 0-12 months - - - - - - Children 1-3 years 65 1,500 - - 0.004 44 4-8 years 65 1,500 - - 0.004 44

Adolescents 9-13 years 65 1,500 - - 0.004 44 14-18 years 65 1,500 - - 0.006 44 Adults 19 years and older 65 1,500 2.2 500 0.006 44 Life Stage Group Copper (µg/day) Iodine (µg/day) Iron 1,3 (mg/day) Min Max Min Max Min Max Infants 0-12 months - - - - 0.6 40 Children 1-3 years 35 700 6 133 0.6 40 4-8 years 35 2,500 6 200 0.6 40 Adolescents 9-13 years 35 4,000 6 400 0.6 40 14-18 years 65 6,500 14 800 1.4 45 Adults 19 years and older 65 8,000 14 800 1.4 45 Life Stage Group Magnesium 1,4 (mg/day) Manganese (mg/day) Molybdenum (µg/day) Min Max Min Max Min Max Infants 0-12 months - - - - - - Children 1-3 years 12 65 - - - - 4-8 years 12 110 - - - - Adolescents 9-13 years 12 350 - - - - 14-18 years 20 350 - - - - Adults 19 years and older 20 500 0.13 9 2.5 2,000 Life Stage Group Phosphorus (mg/day) Selenium (µg/day) Silicon (mg/day) Min Max Min Max Min Max Infants 0-12 months - - - - - - Children 1-3 years 62 2,000 - - - - 4-8 years 62 2,000 - - - - Adolescents 9-13 years 62 2,000 - - - - 14-18 years 62 2,000 - - - - Adults 19 years and older 62 2,000 3.5 200 >0 84 Life Stage Group Zinc (from non-picolinate sources) 1,5,6 (mg/day) Zinc (from zinc picolinate) 1,5,6 (mg/day) Min Max Min Max Infants 0-12 months 0.2 4 - - Children 1-3 years 0.4 7 - - 4-8 years 0.4 12 - - Adolescents 9-13 years 0.4 23 - - 14-18 years 0.7 34 - - Adults 19 years and older 0.7 50 0.7 25 1 Refer to Appendix VIII for additional wording on the label to clarify that the quantity of the medicinal ingredient is the amount of elemental mineral in order to avoid misinterpretation that may lead to serious health consequences. 2 Cobalt + Vitamin B 12 : As vitamin B 12 is the source ingredient for cobalt, the maximum dose for cobalt and vitamin B 12 combined must not exceed 1000 µg of vitamin B 12 per day. Refer to Appendix VI for conversion from cobalt to vitamin B 12. 3 Iron: A specific use or purpose statement must be made for products providing > 35 mg iron per day. 4 Magnesium: A specific use or purpose statement must be made for products providing > 350 mg magnesium per day. 5 Zinc : A specific use or purpose statement must be made for products providing > 40 mg zinc per day. 6 Zinc : As zinc supplementation can cause a copper deficiency, manufacturers of products providing high doses of zinc are encouraged to supplement with sufficient quantities of copper. Refer to Appendix VII to determine how much copper is sufficient to mitigate this risk and for information on how to determine if a risk statement is necessary. 5.5 Dose information for other medicinal ingredients Table 10. Daily doses for other medicinal ingredients (Min = minimum; Max = maximum) Life Stage Group beta-Carotene 1 (µg/day) Choline 2 (mg/day) L-Methionine 2 (mg/day) Min Max Min Max Min Max Infants 0-12 months 180 3,600 - - - - Children 1-3 years 180 3,600 19 1,000 40 1,000 4-8 years 180 5,400 19 1,000 40 1,000 Adolescents 9-13 years 180 10,200 19 1,000 40 1,000 14-18 years 390 16,800 27 1,000 66.5 1,000 Adults 19 years and older 390 18,000 27 1,000 66.5 1,000 Life Stage Group Lutein 2 (mg/day) Lycopene 2 (mg/day) Potassium 3 (mg/day) Min Max Min Max Min Max Infants 0-12 months - - - - - - Children 1-3 years - - - - - - 4-8 years - - - - - - Adolescents 9-13 years - - - - - - 14-18 years - - - - - - Adults 19 years and older >0 20 >0 30 >0 200 1 beta-Carotene : There is a potential risk of hypervitaminosis A resulting from the use of products which combine high doses of vitamin A and beta-carotene. See Appendix V for information on how to determine acceptable daily doses of each of these medicinal ingredients when used in combination. 2 At least two of the following references were consulted: Christen et al. 2008; Fletcher et al. 2008; Johnson et al. 2008; Kristal et al. 2008; Moeller et al. 2008; Silaste et al. 2007; IOM 2006; Shao and Hathcock 2006; Shils et al. 2006; Porrini et al. 2005; WHO 2005; Alves-Rodrigues and Shao 2004; Richer et al. 2004; Olmedilla et al . 2003; Giovannucci et al. 2002; IOM 2002; Kucuk et al. 2002; Brown et al . 1999; Gann et al. 1999; IOM 1998; Giovannucci et al. 1995. 3 Potassium : At least 100 mg of potassium per day is required to support the uses or purposes listed in Section 4.2.3. Only general uses or purposes are permitted at daily doses below 100 mg of potassium. 5.6 Dose information for complementary medicinal ingredients Table 11. Daily doses for complementary medicinal ingredients (Min = minimum; Max = maximum) Life Stage Group Boron (µg/day) Inositol (mg/day) Nickel (µg/day) Min Max Min Max Min Max Infants 0-12 months - - - - - - Children 1-3 years - - >0 650 - - 4-8 years - - >0 650 - - Adolescents 9-13 years - - >0 650 - - 14-18 years - - >0 650 - - Adults 19 years and older >0 700 >0 650 >0 350 Life Stage Group PABA 1 (mg/day) Tin (mg/day) Vanadium (µg/day) Min Max Min Max Min Max Infants 0-12 months - - - - - - Children 1-3 years - - - - - - 4-8 years - - - - - - Adolescents 9-13 years - - - - - - 14-18 years - - - - - - Adults 19 years and older >0 1,200 >0 2 >0 182 1 The following references were consulted: Weidner et al. 2005, Bardhan et al. 2000, Tisdale et al. 1995, Clegg et al. 1994. 5.7 Directions for use Products providing 500 mg of nicotinic acid , per day Do not exceed the recommended dose except on the advice of a physician. Products providing 10 mg or more of nicotinic acid , per day Take with food (IOM 2011; Sweetman 2015). Products providing calcium, iron or zinc Take with food, a few hours before or after taking other medications or natural health products (Sweetman 2015; IOM 2011; ASHP 2005). In all other cases, optional statement(s), as appropriate Take with food, or Take on an empty stomach. Products providing 400 mcg or more of folate, per day (e.g. as a prenatal supplement) (optional statement) 400 mcg of folate per day is adequate for most women (to reduce the risk of neural tube defects). Consult a health care practitioner/health care provider/health care professional/doctor/physician to determine if you would benefit from additional folate before taking this product. 6.0 Durations of use Table 12. Durations of use for specific medicinal ingredients and associated daily doses Medicinal ingredient Daily dose Contraindication(s) Chromium sourced from chromium picolinate All doses Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond

6 months (Anton et al. 2008; Campbell et al. 2002; Campbell et al. 1999; Cefalu et al. 1999; Kato et al. 1998; Anderson et al. 1997; Pasman et al. 1997; Lee et al. 1994). Zinc sourced from zinc picolinate All doses Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 3 months (Sakai et al. 2002) 7.0 Risk information 7.1 Cautions and warnings Table 13. Cautions and warnings for specific medicinal ingredients and associated daily doses Medicinal ingredient Daily dose Caution(s) and warning(s) beta-Carotene > 6,000 μg Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are a tobacco smoker (Touvier et al. 2005; Omenn et al. 1996; ATBC 1994). Chromium sourced from chromium picolinate ≥ 200 μg Consult a health care practitioner/health care provider/health care professional/doctor/physician if you have a kidney disorder and/or diabetes (Wani et al. 2006; Cupp et al. 2003; Bunner and McGinnis 1998; Cerulli et al. 1998; McCarty et al. 1997; Wasser et al. 1997). Iron Where the package contains more than the equivalent of 250 mg of elemental iron Keep out of reach of children. There is enough iron 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 (JC 2011, 2008)]. Manganese > 5 mg Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a liver disorder (IOM 2006; IOM 2001; Krieger et al. 1995). PABA All doses Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding or if you are taking sulfonamides (Maren 1976). Selenium > 70 μg Consult a health care practitioner/health care provider/health care professional/doctor/physician 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/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding (IOM 2006; IOM 2001). Vitamin E ≥ 180 mg AT Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have cancer (Meyer et al. 2008; Bairati et al. 2006; Bairati et al. 2005). ≥ 268 mg AT Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have cardiovascular disease or diabetes (Ward et al. 2007; Winterbone et al. 2007; Lonn et al. 2005). ≥ 360 mg AT Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking blood thinners (CPS 2012; IOM 2006; Booth et al. 2004; Corrigan and Marcus 1974). Vitamin K 1 and/or K 2 All doses Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking blood thinners (ASHP 2005; Franco et al. 2004; IOM 2001; Hansten et al. 1997). 7.2 Contraindications Table 14. Contraindications for specific medicinal ingredients and associated daily doses Medicinal ingredient Daily dose Contraindication(s) Chromium sourced from chromium picolinate All doses Do not use this product if you are pregnant or breastfeeding (EFSA 2009k; IOM 2001). Potassium ≥ 100 mg Do not use this product with other potassium-containing supplements or with potassium-containing salt-substitutes (Sweetman 2015). Zinc sourced from zinc picolinate All doses Do not use this product if you are pregnant or breastfeeding (EFSA 2009k; IOM 2001). 7.3 Known adverse reactions Table 15. Known adverse reactions for specific medicinal ingredients and associated daily doses Medicinal ingredient Daily dose Known adverse reaction(s) Iron > 35 mg Some people may experience constipation, diarrhoea and/or vomiting (IOM 2006; IOM 2001). All doses Stop use if hypersensitivity occurs (de Barrio et al. 2008). Magnesium > 350 mg Some people may experience diarrhoea (IOM 2006; IOM 1997). Nicotinic acid ≥ 10 mg People sensitive to nicotinic acid may experience flushing of the skin that is generally mild and transient (IOM 2006; IOM 1998). PABA All doses Stop use if hypersensitivity occurs (Maren 1976). Zinc 1 Infants 0-12 months ≤ 2 mg Zinc supplementation can cause a copper deficiency (IOM 2006; IOM 2001). If you are unsure whether you are taking enough copper, consult a health care practitioner prior to use. Children 1-3 years 5-7 mg Children 4-8 years 8-12 mg Adolescents 9-13 years 16-23 mg Adolescents 14-18 years 25-34 mg Adults 19 years and older 31-50 mg 1 Zinc : Statement required if the product does not meet the minimum copper requirements outlined in Appendix VII, Table 24. 8.0 Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations (NHPR). 9.0 Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. 10.0 Specifications The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient(s) must comply with the requirements outlined in the NHPID. 11.0 References Albion 2015: Albion Advanced Nutrition. 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For example, a product formulated to provide the maximum dosage value of calcium for adults (i.e. 1500 mg) from the source ingredient, calcium ascorbate, would provide 13.2 g of vitamin C. This exceeds vitamin C's adult maximum dosage value of 2000 mg; and therefore, such a product would not be supported for safety. Based on the calculation described below, the maximum dosage value of calcium from calcium ascorbate would be 228 mg as this dose provides 2000 mg of vitamin C. The following table outlines dose restriction information for calcium ascorbate. It provides the maximum dosage values for calcium and its corresponding source ingredient. Below this table is a sample calculation which demonstrates how these values were derived. Table 16. Dose restrictions for calcium from the source ingredient calcium ascorbate Life Stage Group Maximum dosage value of calcium from calcium ascorbate (mg Ca/day) (mg/day calcium ascorbate) Infants 0-12 months - Children 1-3 years 46 (443) 4-8 years 74 (720) Adolescents 9-13 years 137 (1,330) 14-18 years 205 (1,995) Adults 19 years and older 228 (2,216) Sample Calculation Question: What is the maximum quantity of calcium (maximum dosage value for adults ≥19 y) from the source ingredient calcium ascorbate that can be used in a formulation? Solution: In order to make this determination, the quantity of calcium from calcium ascorbate that provides the maximum dosage value for adults ≥19 y of ascorbic acid (vitamin C) must be calculated. Source ingredient: calcium ascorbate (calcium di-ascorbate): Ca (C 6 H 7 O 6) 2 There are 2 molecules of ascorbate (C 6 H 7 O 6) for every one of calcium (Ca) Molecular weight = MW Maximum dosage value (for adults, ≥19 y) = M Number of molecules = N Calcium = Ca PM Ca = 40,1 g/mol M Ca = ? Ascorbic acid = Aa PM Aa = 176,1 g/mol M Aa = 2 g [M Ca]/[PM Ca x n] = [M Aa]/[PM Aa x n] [M Ca]/[40,1 g/mol x 1] = [2 g]/[176,1 g/mol x 2] M Ca = [g x 40.1 g/mol x 1]/[176,1 g/mol x 2] M Ca = [80,2 g 2 /mol]/[352,2 g/mol] M Ca = 0,228 g ou 228 mg Appendix II Guidelines for use or purpose statements It is mandatory for all natural health products to indicate at least one use or purpose statement. 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 statements). 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. Appendix III Definitions and dosage value 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 a RDA cannot be determined (IOM 2006). Maximum dosage value: The highest medicinal ingredient quantity which a product can supply in a daily dose to support its safe use. Minimum dosage value: The lowest medicinal ingredient quantity which a product can supply in a daily dose to support recommended claims. 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. Maximum dosage values for vitamins and minerals with established physiological functions were developed based on the following criteria: 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?)? What is the average dietary intake? What doses have previously been marketed in Canada? What do other regulatory agencies and expert groups recommend as their maximum daily dose? 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 the Prescription Drug List at 1,000 IU or 25 µg/day (HC 2015)]; Vitamin K 1 and K 2 [adult dose was set as per the listing on the Prescription Drug List at 120 µg/day (HC 2015) and children's doses were set at the AI level (IOM 2006)]. Maximum dosage values for minerals with unestablished physiological functions (i.e. 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 and potassium, 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 (applying the following conversion factor: 6 µg beta-carotene = 1 µg RAE) (HC 1990; FAO/WHO 1967). For potassium, the maximum dosage value was set as per Schedule II of the National Association of Pharmacy Regulatory Authorities (NAPRA 1999). Minimum dosage value: For medicinal ingredients which did not have an RDA or AI, the minimum dose was set at >0. For the remaining medicinal ingredients (with the exception of potassium), 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 vitamin and mineral minimum dose requirements of the Food and Drug Regulations, Sections D.01.004 and D.02.002 (JC 2011)]. The highest value derived for children (1-13 years) was applied to all children within this age category; the highest value derived for adolescents (≥ 14 years) and adults (including pregnant and breastfeeding women) was applied; The highest value derived for infants (0-12 months) was applied (if applicable). For potassium, the AI was inappropriate for setting a minimum dosage value; therefore, the minimum was set at >0. Appendix IV Recommended dietary allowance (RDA) and adequate intake (AI) 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 or purpose statement: "Helps to prevent (appropriate vitamin or mineral) deficiency"; and 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, a RDA or AI value has not been established. For the prevention of deficiency claims, the daily dose of the medicinal ingredient must meet the highest AI or RDA amount for the given subpopulation. For example, for vitamin A, if the subpopulation is "Adults" and if the product is not contraindicated for pregnant or breastfeeding women, the RDA value to be met would be 1,300 µg RAE/day. Life Stage Group Vitamin A (µg RAE/day) Adult males 19-30 years 900 31-50 years 900 51-70 years 900 More than 70 years 900 Adult females 19-30 years 700 31-50 years 700 51-70 years 700 More than 70 years 700 Pregnancy 14-18 years 750 19-50 years 770 Breastfeeding 14-18 years 1,200 19-50 years 1,300 Table 17. Recommended dietary allowance (RDA) and adequate intake* (AI) for vitamins (IOM 2011; IOM 2006) Life Stage Group Biotin (µg/day) Folate (µg/day) Niacin/ niacinamide (mg/day) Panto-thenic acid (mg/day) Riboflavin (mg/day) Infants 0-6 months - - - - - 7-12 months - - - - - Children 1-3 years 8* 150 6 2* 0.5 4-8 years 12* 200 8 3* 0.6 Adolescent males 9-13 years 20* 300 12 4* 0.9 14-18 years 25* 400 16 5* 1.3 Adult males 19-30 years 30* 400 16 5* 1.3 31-50 years 30* 400 16 5* 1.3 51-70 years 30* 400 16 5* 1.3 More than 70 years 30* 400 16 5* 1.3 Adolescent females 9-13 years 20* 300 12 4* 0.9 14-18 years 25* 400 14 5* 1.0 Adult females 19-30 years 30* 400 14 5* 1.1 31-50 years 30* 400 14 5* 1.1 51-70 years 30* 400 14 5* 1.1 More than 70 years 30* 400 14 5* 1.1 Pregnancy 14-18 years 30* 600 18 6* 1.4 19-50 years 30* 600 18 6* 1.4 Breastfeeding 14-18 years 35* 500 17 7* 1.6 19-50 years 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 months - 400* - - - 7-12 months - 500* - - - Children 1-3 years 0.5 300 0.5 0.9 15 4-8 years 0.6 400 0.6 1.2 25 Adolescent males 9-13 years 0.9 600 1.0 1.8 45 14-18 years 1.2 900 1.3 2.4 75 Adult males 19-30 years 1.2 900 1.3 2.4 90 31-50 years 1.2 900 1.3 2.4 90 51-70 years 1.2 900 1.7 2.4 90 More than 70 years 1.2 900 1.7 2.4 90 Adolescent females 9-13 years 0.9 600 1.0 1.8 45 14-18 years 1.0 700 1.2 2.4 65 Adult females 19-30 years 1.1 700 1.3 2.4 75 31-50 years 1.1 700 1.3 2.4 75 51-70 years 1.1 700 1.5 2.4 75 More than 70 years 1.1 700 1.5 2.4 75 Pregnancy 14-18 years 1.4 750 1.9 2.6 80 19-50 years 1.4 770 1.9 2.6 85 Breastfeeding 14-18 years 1.4 1,200 2.0 2.8 115 19-50 years 1.4 1,300 2.0 2.8 120 Life Stage Group Vitamin D (µg/day) Vitamin E (mg AT/day) Vitamin K 1 (µg/day) Infants 0-6 months 10* - - 7-12 months 10* - - Children 1-3 years 15 6 30* 4-8 years 15 7 55* Adolescent males 9-13 years 15 11 60* 14-18 years 15 15 75* Adult males 19-30 years 15 15 120* 31-50 years 15 15 120* 51-70 years 15 15 120* More than 70 years 20 15 120* Adolescent females 9-13 years 15 11 60* 14-18 years 15 15 75* Adult females 19-30 years 15 15 90* 31-50 years 15 15 90* 51-70 years 15 15 90* More than 70 years 20 15 90* Pregnancy 14-18 years 15 15 75* 19-50 years 15 15 90* Breastfeeding 14-18 years 15 19 75* 19-50 years 15 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); however this AI applies to vitamin K 1 , vitamin K 2 and total vitamin K 1 + K 2 . Table 18. Recommended dietary allowance (RDA) and adequate intake* (AI) for minerals (IOM 2011; IOM 2006) Life

Stage Group Boron (mg/day) Calcium (mg/day) Chromium (µg/day) Cobalt 1 (µg/day) Copper (µg/day) Infants 0-6 months - 200* - - - 7-12 months - 260* - - - Children 1-3 years - 700 - 0.04 340 4-8 years - 1000 - 0.05 440 Adolescent males 9-13 years - 1,300 - 0.08 700 14-18 years - 1,300 - 0.10 890 Adult males 19-30 years - 1,000 35* 0.10 900 31-50 years - 1,000 35* 0.10 900 51-70 years - 1,000 30* 0.10 900 More than 70 years - 1,200 30* 0.10 900 Adolescent females 9-13 years - 1,300 - 0.08 700 14-18 years - 1,300 - 0.10 890 Adult females 19-30 years - 1,000 25* 0.10 900 31-50 years - 1,000 25* 0.10 900 51-70 years - 1,200 20* 0.10 900 More than 70 years - 1,200 20* 0.10 900 Pregnancy 14-18 years - 1,300 - 0.11 1,000 19-50 years - 1,000 30* 0.11 1,000 Breastfeeding 14-18 years - 1,300 - 0.12 1,300 19-50 years - 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 months - 0.27* - - - 7-12 months - 11 - - - Children 1-3 years 90 7 80 - - 4-8 years 90 10 130 - - Adolescent males 9-13 years 120 8 240 - - 14-18 years 150 11 410 - - Adult males 19-30 years 150 8 400 2.3* 45 31-50 years 150 8 420 2.3* 45 51-70 years 150 8 420 2.3* 45 More than 70 years 150 8 420 2.3* 45 Adolescent females 9-13 years 120 8 240 - - 14-18 years 150 15 360 - - Adult females 19-30 years 150 18 310 1.8* 45 31-50 years 150 18 320 1.8* 45 51-70 years 150 8 320 1.8* 45 More than 70 years 150 8 320 1.8* 45 Pregnancy 14-18 years 220 27 400 - - 19-50 years 220 27 355 2.0* 50 Breastfeeding 14-18 years 290 10 360 - - 19-50 years 290 9 315 2.6* 50 Life Stage Group Nickel (mg/day) Phosphorus (mg/day) Selenium (µg/day) Silicon (mg/day) Tin (mg/day) Infants 0-6 months - - - - - 7-12 months - - - - - Children 1-3 years - 460 - - - 4-8 years - 500 - - - Adolescent males 9-13 years - 1,250 - - - 14-18 years - 1,250 - - - Adult males 19-30 years - 700 55 - - 31-50 years - 700 55 - - 51-70 years - 700 55 - - More than 70 years - 700 55 - - Adolescent females 9-13 years - 1,250 - - - 14-18 years - 1,250 - - - Adult females 19-30 years - 700 55 - - 31-50 years - 700 55 - - 51-70 years - 700 55 - - More than 70 years - 700 55 - - Pregnancy 14-18 years - 1,250 - - - 19-50 years - 700 60 - - Breastfeeding 14-18 years - 1,250 - - - 19-50 years - 700 70 - - Life Stage Group Vanadium (mg/day) Zinc (mg/day) Infants 0-6 months - 2* 7-12 months - 3 Children 1-3 years - 3 4-8 years - 5 Adolescent males 9-13 years - 8 14-18 years - 11 Adult males 19-30 years - 11 31-50 years - 11 51-70 years - 11 More than 70 years - 11 Adolescent females 9-13 years - 8 14-18 years - 9 Adult females 19-30 years - 8 31-50 years - 8 51-70 years - 8 More than 70 years - 8 Pregnancy 14-18 years - 12 19-50 years - 11 Breastfeeding 14-18 years - 13 19-50 years - 12 1 Calculated from the vitamin B 12 RDA (IOM 2006). Appendix V Guidance for products containing beta-carotene Background: Although all of the claims for beta-carotene are associated with its vitamin A activity, it is not acceptable to list beta-carotene as a source ingredient for vitamin A. This is because the rate of conversion of beta-carotene to vitamin A in the human body depends on numerous factors (e.g. vitamin A status, dietary factors such as vegetable consumption and fat intake, genetic factors, etc.). In other words, the consumption of supplemental beta-carotene does not always result in a consistent rate of conversion to vitamin A. Nevertheless, products providing beta-carotene do contribute to vitamin A requirements; therefore, all of the health claims associated with beta-carotene are linked to its vitamin A activity. Furthermore, there is a potential risk of hypervitaminosis A associated with the consumption of combinations including both beta-carotene and vitamin A. Determining dosage requirements for the claim "Helps to prevent vitamin A deficiency": In order to make any prevention of deficiency health claims, a nutrient must be included in a product at a dose at or above its recommended dietary allowance (RDA) or adequate intake (AI). There are three potential scenarios in which a product would qualify for the claim: "Helps to prevent vitamin A deficiency": The product could provide vitamin A on its own: See Appendix IV to determine vitamin A minimum dosage requirements; The product could provide beta-carotene on its own: See Table 19 below for minimum dosage requirements; or The product could provide both beta-carotene and vitamin A: See Appendix IV to determine vitamin A minimum dosage requirements and apply the conversion factor of 6 µg of beta-carotene = 1 µg all-trans -retinol (HC 1990; FAO/WHO 1967). Table 19. Daily dose in microgram (µg) of beta-carotene Life Stage Group Minimum dose of beta-carotene 1 (µg/day) Infants 0-6 months 2,400* 7-12 months 3,000* Children 1-3 years 1,800 4-8 years 2,400 Adolescent males 9-13 years 3,600 14-18 years 5,400 Adult males 19 years and older 5,400 Adolescent females 9-13 years 3,600 14-18 years 4,200 Adult females 19 years and older 4,200 Pregnancy 14-18 years 4,500 19-50 years 4,620 Breastfeeding 14-18 years 7,200 19-50 years 7,800 1 These values are based on the RDA and AI values for vitamin A based on life stage group (IOM 2006) and were derived from the conversion factor of 6 µg of beta-carotene = 1 µg all - trans -retinol; hence, a ratio of 6:1 beta-carotene:vitamin A, on a weight to weight basis (HC 1990; FAO/WHO 1967). Example: As per Appendix IV, the minimum dose for the vitamin A deficiency claim for adults (excluding breastfeeding women) is 900 µg per day. This is based on the highest RDA for all adult subpopulations (i.e. 900 µg for adult males). There are three potential ways this dose can be achieved: Vitamin A alone (900 µg RAE (from vitamin A) per day); beta-Carotene alone (5400 µg beta-carotene per day); or Combinations of vitamin A plus beta-carotene (e.g. 500 µg RAE (from vitamin A) + 2400 µg beta carotene = 900 µg RAE per day). Note: The depiction of beta-carotene in RAE is to demonstrate the efficacy of the combination of vitamin A and beta-carotene only and must not appear on the PLA form or label. Mitigating the risk of hypervitaminosis A: In products containing both vitamin A and beta-carotene, the risk of hypervitaminosis A is to be mitigated by ensuring that the combined doses of these two medicinal ingredients

is not excessively high. Therefore, the combined dose of vitamin A plus beta-carotene must not exceed the maximum dosage value for vitamin A, measured in μg RAE (See Table 8). The conversion factor of 6 μg beta-carotene = 1 μg RAE (HC 1990; FAO/WHO 1967) can be applied for the specific purpose of ensuring safety of the combined dose. The example below illustrates how the 6:1 conversion factor can be used to determine the safety of combinations including beta-carotene and vitamin A: Example: The maximum dosage value of vitamin A for adults is 3000 μg RAE per day. If a product contained 2800 μg vitamin A (i.e. all-trans -retinol, vitamin A acetate, vitamin A palmitate), then it could contain no more than 1200 μg beta-carotene. See calculation below: 2800 μg vitamin A + 1200 μg beta-carotene (200 μg RAE) = 3000 μg RAE. Note: The value of 3000 μg RAE is to demonstrate the safety of the combination of vitamin A and beta-carotene only and must not appear on the PLA form or label. Appendix VI Conversion factors 1. Pantothenic acid (USP 38) : Table 20. Conversion of pantothenic acid source ingredient quantity into pantothenic acid quantity Source ingredient (1 mg) Pantothenic acid quantity (mg) Calcium D-pantothenate 0.92 Calcium DL-pantothenate 0.46 Dexpanthenol 1.07 DL - Panthenol 0.53 DL - Pantothenic acid 0.50 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 ingredient used. International Units (IU) may be provided as optional additional information on the PLA form in the "additional quantity per dosage unit" field and on product labels. Table 21. Conversion of vitamin A source ingredient quantity into vitamin A quantity in terms of retinol activity equivalents (RAE) and vitamin A activity in terms of International Units (IU) Source ingredient (1 μg) Vitamin A quantity (μg RAE) Vitamin A activity (IU) all-trans -Retinol 1.00 3.33 all-trans -Retinyl acetate 0.87 2.91 all-trans -Retinyl palmitate 0.55 1.82 Examples using the vitamin A conversion factors: 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 or = 3000 IU x 0.87 μg RAE/2.91 IU vitamin A = 897 μg RAE 3. beta-Carotene: The quantity of beta-carotene must always be provided in weight amount (i.e. μg). IUs may be provided as optional additional information on the PLA form in the "additional quantity per dosage unit" field and on product labels. 1 IU beta-carotene = 0.6 μg beta-carotene (USP 38) 4. Vitamin B 12 : 1.5 μg of vitamin B 12 = 0.06 μg of cobalt 5. Vitamin D: The quantity of vitamin D must always be provided in weight amount (i.e. μg). IUs may be provided as optional additional information on the PLA form in the "additional quantity per dosage unit" field and on product labels. 1 IU of vitamin D = 0.025 μg cholecalciferol (IOM 2006) = 0.025 μg ergocalciferol 6. Vitamin E (IOM 2006) The quantity of vitamin E must always be provided in terms of alpha-tocopherol (AT) (i.e. mg 2R-alpha-tocopherol), irrespective of the source ingredient used. IUs may be provided as optional additional information on the PLA form in the "additional quantity per dosage unit" field and on product labels. Table 22. Conversion of vitamin E source ingredient quantity into vitamin E quantity in terms of alpha-tocopherol (mg AT) and vitamin E activity in terms of International Units (IU) Source ingredient (1 mg) Vitamin E quantity (mg AT) Vitamin E activity (IU) d-alpha-Tocopherol 1.00 1.49 d-alpha-Tocopheryl acetate 0.91 1.36 d-alpha-Tocopheryl succinate 0.81 1.21 dl-alpha-Tocopherol 0.50 1.10 dl-alpha-Tocopheryl acetate 0.45 1.00 dl-alpha-Tocopheryl succinate 0.40 0.89 Table 23. Conversion of vitamin E source ingredient activity (IU) into vitamin E quantity in terms of alpha-tocopherol (mg AT) Source ingredient (1 IU) Vitamin E quantity (mg AT) d-alpha-Tocopherol 0.67 d-alpha-Tocopheryl acetate 0.67 d-alpha-Tocopheryl succinate 0.67 dl-alpha-Tocopherol 0.45 dl-alpha-Tocopheryl acetate 0.45 dl-alpha-Tocopheryl succinate 0.45 Examples using the vitamin E conversion factors: Converting vitamin E activity into quantity of AT (mg) Convert 400 IU of d-alpha-tocopheryl succinate activity into mg AT: = 400 IU x 0.67 mg AT/IU = 268 mg AT Converting vitamin E source ingredient quantity into quantity of AT (mg) Convert 200 mg of dl-alpha-tocopheryl acetate into mg AT: = 200 mg x 0.45 mg AT/mg = 90 mg AT Appendix VII Zinc and copper interaction Zinc supplements can cause a copper deficiency. In order to mitigate this risk, applicants are encouraged to supplement high dose zinc products with copper. Table 24 below outlines how much copper is sufficient to mitigate this risk based on both life stage group and zinc daily dosage. Products which do not fulfill the zinc and copper quantity guidelines below require an additional risk statement. See Section 7.0 Risk Information. Table 24. Daily dosage of copper required to mitigate the risk of copper deficiency in products containing high doses of zinc Life Stage Group Daily dosage range of zinc which requires added copper or a risk statement (mg/day) Daily dosage range of copper required to avoid a risk statement (μg/day) Infants 0-12 months ≤ 2 0 Children 1-3 years 5-7 280-700 Children 4-8 years 8-12 480-2,500 Adolescents 9-13 years 16-23 920-4,000 Adolescents 14-18 years 25-34 1,360-6,500 Adults 19 years and older 31-50 2,000-8,000 Examples using Table 24: Question: Product A is targeted to adults only. The product provides a daily dose of zinc of 30 mg but does not contain copper. Is a risk statement necessary on this product? Answer: No. According to Table 24, for an adult subpopulation, there is no need for copper supplementation at a dose of 30 mg zinc per day. Therefore, no risk statement is required. Question: Product B is targeted to adults and adolescents ≥ 12 years. The product provides zinc and copper at daily dosages of 20 mg and 500 μg, respectively. Is a risk statement necessary on this product? Answer: Yes. According to Table 24, for an adult subpopulation, there is no need for copper supplementation at a daily dose of 20 mg zinc. However, for adolescents ≥ 12 years, products providing daily doses of zinc between 16-23 mg need at least

920 µg copper per day. As the product in this example provides 500 µg of copper per daily dose, the following risk statement is required: "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". Appendix VIII Guidance on labelling for specific mineral supplements: calcium, iron, magnesium and zinc Health care professionals and consumers have reported confusion in distinguishing between the quantity of the element (i.e., the medicinal ingredient) and the quantity of the salt (i.e., the source information) of the above four mineral supplements when reading the product label, which has led to medication errors in Canada including dosing errors. In the case of these minerals, dosing errors may lead to serious health consequences (ISMP 2021a, b, c). Health care professionals may recommend or prescribe to consumers calcium, iron, magnesium or zinc by either the elemental quantity or the salt quantity. The medicinal ingredient quantity listed on the label should be clearly associated with the elemental mineral. a) Single ingredient mineral supplements The quantity of the element must be clearly associated with the element name, so that it is not confused with the quantity of the salt. In addition, the quantity of the element and the salt may both appear on the label. Anhydrous salts should be clearly identified in order to account for their element-to-salt ratio. Note that the label generated by the web-based PLA form has not been adjusted to represent single ingredient products as recommended above; however, the information on the marketed label should be represented as clearly as possible based on this guideline. Examples Each tablet contains: Calcium.....500 mg (calcium carbonate 1250 mg) Each tablet contains: Calcium.....500 mg derived from calcium carbonate 1250 mg Each tablet contains: Iron.....60 mg (from anhydrous Iron (II) sulfate 190 mg) In cases where a mineral supplement is derived from mixed source ingredients or complexes of the same element, the quantity of the salt(s) does not need to be identified. However, the addition of a note clarifying that the quantity of the mineral represents the amount of the element is recommended. As per the label generated from the web-based PLA form: Medicinal ingredient (Source information) Medicinal ingredient Quantity per 1 tablet* Calcium ..... (Calcium carbonate, Calcium citrate, Calcium fumarate) 500 mg * For minerals, the medicinal ingredient quantity represents the amount of the element per tablet. b) Multi-ingredient mineral supplements The quantity of the element(s) must be clearly associated with the element name, so that it is not confused with the quantity of the salt(s). The quantity of the salt(s) does not need to be identified. However, the addition of a note clarifying that the quantity of the mineral represents the amount of the element would be recommended. As per the label generated from the web-based PLA form: Medicinal ingredient (Source information) Medicinal ingredient Quantity per 1 tablet* Calcium ..... (Calcium carbonate) 500 mg Iron ..... (Iron (II) sulfate) 30 mg * For minerals, the medicinal ingredient quantity represents the amount of the element per tablet. Report a problem on this page Date modified: 2019-03-01

Proper name(s)1	Common name(s)2	Source information3
Source ingredient(s)		
Biotin	Biotin	BiocytinBiotin
Folate	FolateVitamin B9	Folic acidL-5-MethyltetrahydrofolateL-5-Methyltetrahydrof
Niacin	NiacinVitamin B3	Inositol hexanicotinateNiacinamideNicotinic acid
Niacinamide	NiacinamideNicotinamideVitamin B3	NiacinamideNiacinamide ascorbate
Pantothenic acid	Pantothenic acidVitamin B5	Calcium D-pantothenateCalcium DL-pantothenateDexpan
Riboflavin	RiboflavinVitamin B2	RiboflavinRiboflavin 5'-phosphateRiboflavin 5'-phosphate
Thiamine	ThiamineVitamin B1	BenfotiamineThiamineThiamine diphosphateThiamine hy
Vitamin A	Vitamin A	all-trans-Retinolall-trans-Retinyl acetateall-trans-Retinyl p
Vitamin B6	Vitamin B6	PyridoxalPyridoxal 5'-phosphatePyridoxal 5'-phosphate, c
Vitamin B12	Vitamin B12	CobamamideCyanocobalaminHydroxocobalaminHydroxo
Vitamin C	Vitamin C	Ascorbic acidAscorbic acid 2-O-glucosideAscorbyl methyl
Vitamin D	Vitamin DVitamin D2	Ergocalciferol
Vitamin DVitamin D3	Cholecalciferol	

Vitamin E	Vitamin E	d-alpha Tocopherold-alpha Tocopheryl acetated-alpha To
Vitamin K1	Vitamin K1	Phytonadione
Vitamin K2	Vitamin K2	Menaquinone 4Menaquinone 6Menaquinone 7Menaquino

Proper name(s)1	Common name(s)2	Source information3			
Source ingredient(s)	Organism group(s)	Source material(s)	Part(s)		
Calcium4	Calcium	Calcium acetateCalcium amino acid chelateCalcium	N/A	Calcium ascorbateCalcium	N/A Calcium aspartate
N/A	Bone meal4	N/A	Bone		
Coral	N/A	Calcareous skeleton			
Oyster	N/A	Shell			
Chromium5	Chromium	Chromium amino acid chelateChromium (III)	N/A	Chromium (III)	N/A Chromium (III) chlorideC
Cobalt	Cobalt	CobamamideCyanocobalaminHydroxocobalamin	N/A	Methylcobalamin	N/A N/A
Copper	Copper	Calcium copper edetateCopper amino acid chelate	N/A	Copper (II) acetate	N/A Copper (II)
Iodine6	Iodine	Potassium iodatePotassium iodideSodium iodide	N/A		N/A N/A
N/A	N/A	Fucus vesiculosus6Fucus serratus6Ascophyllum nodosum6	N/A	Thallus6	N/A Laminaria digitata6La
Iron	Iron	Dried iron (II) sulfateFerritinFerrocholinate	N/A	Iron, carbonyl	N/A Iron, electrolytic N/A redu
Magnesium	Magnesium	DolomiteMagnesium acetateMagnesium acetate,	N/A	tetrahydrate	Magnesium N/A Acetyl t
Manganese	Manganese	Manganese amino acid chelate	N/A	Manganese (II)	N/A N/A aspartat
Molybdenum	Molybdenum	Ammonium molybdate (VI)	N/A	Ammonium molybdate (VI), tetrahydrate	N/A Molybdenum a
Phosphorus4	Phosphorus	Ammonium phosphate, dibasic	N/A	Ammonium phosphate, monobasic	N/A N/A Ammonium pol
N/A	Bone meal4	N/A	Bone		
Selenium	Selenium	MethylselenocysteineSelenious acid	Selenium	N/A	Amino acid chelate Selenium N/A Aspar
Silicon7	Silicon	Calcium silicateCholine-stabilised orthosilicic acid	N/A	Methylsilanetriol	N/A Orthosilicic acid N/A
N/A	N/A	Equisetum arvense7	Herb top		
Zinc8	Zinc	Zinc acetateZinc acetate, dihydrate	Zinc amino acid chelate	N/A	Zinc arginate N/A Zinc asc

	Common name(s)2	Source information3		
	Source material(s)	Part(s)		
eta-Carotene	all-trans-beta-Carotene	beta-Carotene	N/A	N/A
thylammonium2-Hydroxy-N,N,N-trimethylethanaminium	Choline	CholineCholine alfoscerate	Choline bitartrate	N/A Choline chloride Choline citrate N/A Choline dihyd
n-Carotene-3,3'-dio	4Lutein	N/A	Tagetes erecta4	Herb flowering c
	Lycopene	Lycopene	N/A	N/A
	Solanum lycopersicum5	Fruit flesh		
o)butanoic acid	L-Methionine	DL-MethionineL-Methionine	N-Acetyl-L-methionine	N/A N/A
	Potassium	Acesulfate potassium	Potassium acetate	Potassium ascorbate Potassium aspartate Potass

Proper name(s)1	Common name(s)2	Source information3		
Source ingredient(s)	Source material(s)	Part(s)		
Boron	Boron	BoraxBoric acidBoron aspartateBoron citrateBoron glycina	N/A	N/A
myo-Inositol	Inositol	InositolInositol, dihydrateInositol hexanicotinateInositol mo	N/A	N/A
Nickel	Nickel	Nickel (II) sulfateNickel (II) sulfate, heptahydrateNickel (II)	N/A	N/A
4-Aminobenzoic acid4para-Aminobenzoic acid4	PABApara-Aminobenzoic acid	para-Aminobenzoic acid	N/A	N/A
N/A	Saccharomyces cerevisiae4	Whole		
Tin	Tin	Stannous chloride	N/A	N/A
Vanadium	Vanadium	Sodium metavanadateVanadium amino acid chelate	N/A	N/A

Vitamin	Specific uses or purposes1
Biotin	Helps to maintain/support healthy hair/nail/mucous membranes/(and) skin.Helps
Folate4	Helps to form red blood cells.Helps to prevent folate deficiency.2Helps to mainta
Niacin/ Niacinamide5	Helps normal growth and development.Helps in energy metabolism/(and) tissue
Pantothenic acid	Helps in energy metabolism/(and) in tissue formation.Helps to prevent pantother
Riboflavin	Helps in energy metabolism/(and) in tissue formation.Helps to maintain/support
Thiamine	Helps in energy production.Supports energy production.Helps normal growth.He
Vitamin A	Helps to maintain/support normal vision/eyesight/eye health/(and) night vision.M
Vitamin B6	Helps in energy metabolism/(and) in tissue formation.Helps to form red blood ce
Vitamin B12	Helps in energy metabolism.Helps to form red blood cells.Helps to maintain/supp
Vitamin C	Helps in the development and maintenance of bones/cartilage/teeth/(and) gums
Vitamin D	Helps in the development and maintenance of bones/(and) teeth.Helps to build s
Vitamin E	Source of/Provides (an) antioxidant(s) for the maintenance of good health.Sourc
Vitamin K1and K2	Helps in the maintenance of bones.Helps to prevent vitamin K deficiency.2

Mineral	Specific uses or purposes1
Calcium	Helps in the development and maintenance of bones/(and) teeth.Helps in the developmen
Chromium	Provides support for healthy glucose metabolism.Helps to maintain/support normal blood
Cobalt	Cobalt is a structural component of vitamin B12that helps form red blood cells.Cobalt is a
Copper	Helps to produce and repair connective tissue.Helps to form red blood cells.Helps to mai
Iodine	Helps in the function of the thyroid gland.Helps to prevent iodine deficiency.2
Iron4	Helps to form red blood cells (and helps in their proper function).Helps to prevent iron def
Magnesium5	Helps in the development and maintenance of bones/(and) teeth.Helps in bone developm
Manganese	Helps in the development and maintenance of bones.Helps to prevent manganese deficie
Molybdenum	Helps to prevent molybdenum deficiency.2Helps to maintain/support the body's ability to
Phosphorus	Helps in the development and maintenance of bones/(and) teeth.Source of/Provides (an)
Selenium	Helps normal growth and development.Source of/Provides (an) antioxidant(s) for the mai

Zinc7	Helps in connective tissue formation.Helps in energy metabolism/(and) tissue formation.H

Medicinal ingredient	Specific uses or purposes1
beta-Carotene	Provitamin A/Source of vitamin A for the maintenance of good health.Source of v
Choline3	Helps to support liver function.
L-Methionine3	Helps to support liver function.Source of/Provides an essential amino acid for the
Lutein	Source of/Provides (an) antioxidant(s).Source of/Provides (an) antioxidant(s) for
Lycopene	Source of/Provides (an) antioxidant(s).Source of/Provides (an) antioxidant(s) tha
Potassium	Products providing 100 mg or more of potassium per day:Source of/Provides (an
Silicon	Products providing 10 mg or more of silicon per day:Helps to maintain/support h

day)	Folate1(µg/day)	Niacin/niacinamide2(mg/day)	
	Min	Max	Min
hs	-	-	-
	1.0	500	15
	500	15	400
s	1.0	500	15
	500	30	800
nd older	1.8	500	30
ic acid ay)	Riboflavin (mg/day)	Thiamine (mg/day)	
	Min	Max	Min
hs	-	-	-
	0.2	500	0.04
	500	0.04	100
s	0.2	500	0.04
	500	0.08	100
nd older	0.4	500	0.08
3(µg RAE/day)			
etinol - Max	all-trans-Retinyl acetate - Max	all-trans-Retinyl palmitate - Max	
hs	30	600	600
	30	600	600
	900	900	900
s	30	1,700	1,700
	2,800	2,800	2,800
nd older	65	3,003	3,000

6(mg/day)	Vitamin B124(µg/day)	Vitamin C (mg/day)	
	Min	Max	Min
hs	-	-	-
	0.05	30	0.09
	40	0.09	1,000
s	0.05	60	0.09
	80	0.14	1,000
nd older	0.10	100	0.14
(µg/day)	Vitamin E5(mg AT/day)		
	Min	dl-alpha-Tocopherol - Max	d-alpha-Tocopherol - Max
hs	0.5	25	-
	0.8	25	0.6
	25	0.6	150
s	0.8	25	0.6
	25	1.0	400
nd older	1.0	25	1.0
1, vitamin K2and total vitamin K1+	K2(µg/day)		
hs	-	-	
	3	30	
	55		
s	3	60	
	75		
nd older	6	120	

	Calcium1(mg/day)	Chromium (µg/day)	Cobalt2(µg/day)		
	Max	Min	Max	Min	Ma
	0-12 months	-	-	-	-
	1-3 years	65	1,500	-	-
	65	1,500	-	-	0.0
	9-13 years	65	1,500	-	-
	65	1,500	-	-	0.0
	19 years and older	65	1,500	2.2	500
	Copper (µg/day)	Iodine (µg/day)	Iron1,3(mg/day)		
	Max	Min	Max	Min	Ma
	0-12 months	-	-	-	-
	1-3 years	35	700	6	133

	35	2,500	6	200	0.6
	9-13 years	35	4,000	6	400
	65	6,500	14	800	1.4
	19 years and older	65	8,000	14	800
	Magnesium1,4(mg/day)	Manganese (mg/day)	Molybdenum (µg/day)		
	Max	Min	Max	Min	Ma
	0-12 months	-	-	-	-
	1-3 years	12	65	-	-
	12	110	-	-	-
	9-13 years	12	350	-	-
	20	350	-	-	-
	19 years and older	20	500	0.13	9
	Phosphorus (mg/day)	Selenium (µg/day)	Silicon (mg/day)		
	Max	Min	Max	Min	Ma
	0-12 months	-	-	-	-
	1-3 years	62	2,000	-	-
	62	2,000	-	-	-
	9-13 years	62	2,000	-	-
	62	2,000	-	-	-
	19 years and older	62	2,000	3.5	200
	Zinc (from non-picolinate sources)1,5,6(mg/day)	Zinc (from zinc picolinate)1,5,6(mg/day)			
	Max	Min	Max		
	0-12 months	0.2	4	-	-
	1-3 years	0.4	7	-	-
	0.4	12	-	-	
	9-13 years	0.4	23	-	-
	0.7	34	-	-	
	19 years and older	0.7	50	0.7	25

age Group	beta-Carotene1(µg/day)	Choline2(mg/day)	L-Methionine2(mg/day)			
	Max	Min	Max	Min	Max	
	0-12 months	180	3,600	-	-	-
	1-3 years	180	3,600	19	1,000	40
s	180	5,400	19	1,000	40	1,000
ents	9-13 years	180	10,200	19	1,000	40
ears	390	16,800	27	1,000	66.5	1,000
	19 years and older	390	18,000	27	1,000	66.5

ge Group	Lutein2(mg/day)	Lycopene2(mg/day)	Potassium3(mg/day)			
	Max	Min	Max	Min	Max	
	0-12 months	-	-	-	-	-
	1-3 years	-	-	-	-	-
s	-	-	-	-	-	-
ents	9-13 years	-	-	-	-	-
ears	-	-	-	-	-	-
	19 years and older	>0	20	>0	30	>0

Stage Group	Boron (µg/day)	Inositol (mg/day)	Nickel (µg/day)			
	Max	Min	Max	Min	Max	
s	0-12 months	-	-	-	-	-
ren	1-3 years	-	-	>0	650	-
ears	-	-	>0	650	-	-
scents	9-13 years	-	-	>0	650	-
years	-	-	>0	650	-	-
s	19 years and older	>0	700	>0	650	-
tage Group	PABA1(mg/day)	Tin (mg/day)	Vanadium (µg/day)			
	Max	Min	Max	Min	Max	
s	0-12 months	-	-	-	-	-
ren	1-3 years	-	-	-	-	-
ears	-	-	-	-	-	-
scents	9-13 years	-	-	-	-	-
years	-	-	-	-	-	-
s	19 years and older	>0	1,200	>0	2	-

Medicinal ingredient	Daily dose	Contraindication(s)
Chromium sourced from chromium picolinate	All doses	Consult a health care practitioner/health care provider/health care
Zinc sourced from zinc picolinate	All doses	Consult a health care practitioner/health care provider/health care

Medicinal ingredient	Daily dose	Caution(s) and warning(s)
beta-Carotene	> 6,000 µg	Consult a health care practitioner/health care provide
Chromium sourced from chromium picolinate	≥ 200 µg	Consult a health care practitioner/health care provide
Iron	Where the package contains more than the equivalent of 250 mg of elemental iron	Keep out of reach of children. There is enough iron in [As per Section 97 of theNatural Health Product

Manganese	> 5 mg	Consult a health care practitioner/health care provide
PABA	All doses	Consult a health care practitioner/health care provide
Selenium	> 70 µg	Consult a health care practitioner/health care provide
Vanadium	All doses	Consult a health care practitioner/health care provide
Vitamin E	≥ 180 mg AT	Consult a health care practitioner/health care provide
≥ 268 mg AT	Consult a health care practitioner/health care provider/health care professional/doctor/physician pr	
≥ 360 mg AT	Consult a health care practitioner/health care provider/health care professional/doctor/physician pr	
Vitamin K1and/or K2	All doses	Consult a health care practitioner/health care provide

Medicinal ingredient	Daily dose	Contraindication(s)
Chromium sourced from chromium picolinate	All doses	Do not use this product if you are pregnant or breastfeeding (EFSA
Potassium	≥ 100 mg	Do not use this product with other potassium-containing supplemer
Zinc sourced from zinc picolinate	All doses	Do not use this product if you are pregnant or breastfeeding (EFSA

ingredient	Daily dose	Known adverse reaction(s)	
	> 35 mg	Some people may experience constipation, diarrhoea and/or vomiting (IOM	
	Stop use if hypersensitivity occurs (de Barrio et al. 2008).		
	> 350 mg	Some people may experience diarrhoea (IOM 2006; IOM 1997).	
d	≥ 10 mg	People sensitive to nicotinic acid may experience flushing of the skin that is	
	All doses	Stop use if hypersensitivity occurs (Maren 1976).	
	Infants 0-12 months	≤ 2 mg	Zinc supplementation can cau
3 years	5-7 mg		
3 years	8-12 mg		
s 9-13 years	16-23 mg		
s 14-18 years	25-34 mg		
ears and older	31-50 mg		

Life Stage Group		Maximum dosage value of calcium from calcium ascorbate (mg Ca/day) (mg/day calcium ascorbate)
Infants	0-12 months	-
Children	1-3 years	46 (443)
4-8 years	74 (720)	
Adolescents	9-13 years	137 (1,330)
14-18 years	205 (1,995)	
Adults	19 years and older	228 (2,216)

Life Stage Group	Vitamin A (μg RAE/day)	
Adult males	19-30 years	900
	31-50 years	900
	51-70 years	900
	More than 70 years	900
Adult females	19-30 years	700
	31-50 years	700
	51-70 years	700
	More than 70 years	700
Pregnancy	14-18 years	750
	19-50 years	770
Breastfeeding	14-18 years	1,200
	19-50 years	1,300

in (μg/day)	Folate (μg/day)	Niacin/ niacinamide (mg/day)	Panto-thenic acid (mg/day)
months	-	-	-
	-	-	-
ears	8*	150	6
	200	8	3*
years	20*	300	12
	400	16	5*
0 years	30*	400	16
	400	16	5*
	400	16	5*
	400	16	5*
years	20*	300	12
	400	14	5*
0 years	30*	400	14
	400	14	5*
	400	14	5*
	400	14	5*
8 years	30*	600	18
	600	18	6*
8 years	35*	500	17
	500	17	7*

	Thiamine (mg/day)	Vitamin A (μg RAE/day)	Vitamin B6(mg/day)	Vitamin B12(μg/day)	Vitam
	0-6 months	-	400*	-	-
	-	500*	-	-	-
	1-3 years	0.5	300	0.5	0.9
	0.6	400	0.6	1.2	25
	9-13 years	0.9	600	1.0	1.8
	1.2	900	1.3	2.4	75
	19-30 years	1.2	900	1.3	2.4
	1.2	900	1.3	2.4	90
	1.2	900	1.7	2.4	90
	1.2	900	1.7	2.4	90
	9-13 years	0.9	600	1.0	1.8
	1.0	700	1.2	2.4	65
	19-30 years	1.1	700	1.3	2.4
	1.1	700	1.3	2.4	75
	1.1	700	1.5	2.4	75
	1.1	700	1.5	2.4	75
	14-18 years	1.4	750	1.9	2.6
	1.4	770	1.9	2.6	85
	14-18 years	1.4	1,200	2.0	2.8
	1.4	1,300	2.0	2.8	120
	Vitamin D (μg/day)	Vitamin E (mg AT/day)	Vitamin K1(μg/day)		
	0-6 months	10*	-	-	
	10*	-	-		
	1-3 years	15	6	30*	
	15	7	55*		
	9-13 years	15	11	60*	
	15	15	75*		
	19-30 years	15	15	120*	
	15	15	120*		
	15	15	120*		
	20	15	120*		
	9-13 years	15	11	60*	
	15	15	75*		
	19-30 years	15	15	90*	
	15	15	90*		
	15	15	90*		
	20	15	90*		

	14-18 years	15	15	75*	
	15	15	90*		
	14-18 years	15	19	75*	
	15	19	90*		

day)	Calcium (mg/day)	Chromium (μg/day)	Cobalt1(μg/day)
	-	200*	-
	260*	-	-
	-	700	-
	1000	-	0.05
	-	1,300	-
	1,300	-	0.10
	-	1,000	35*
	1,000	35*	0.10
	1,000	30*	0.10
	1,200	30*	0.10
	-	1,300	-
	1,300	-	0.10
	-	1,000	25*
	1,000	25*	0.10
	1,200	20*	0.10
	1,200	20*	0.10
	-	1,300	-
	1,000	30*	0.11
	-	1,300	-
	1,000	45*	0.12
ay)	Iron (mg/day)	Magnesium (mg/day)	Manganese (mg/day)
	-	0.27*	-
	11	-	-
	90	7	80
	10	130	-
	120	8	240
	11	410	-
	150	8	400
	8	420	2.3*
	8	420	2.3*
	8	420	2.3*

	120	8	240
	15	360	-
	150	18	310
	18	320	1.8*
	8	320	1.8*
	8	320	1.8*
	220	27	400
	27	355	2.0*
	290	10	360
	9	315	2.6*

y)	Phosphorus (mg/day)	Selenium (μg/day)	Silicon (mg/day)
	-	-	-
	-	-	-
	-	460	-
	500	-	-
	-	1,250	-
	1,250	-	-
	-	700	55
	700	55	-
	700	55	-
	700	55	-
	-	1,250	-
	1,250	-	-
	-	700	55
	700	55	-
	700	55	-
	700	55	-
	-	1,250	-
	700	60	-
	-	1,250	-
	700	70	-
	Zinc (mg/day)		
	-	2*	
	3		
	-	3	
	5		

	-	8	
	11		
	-	11	
	11		
	11		
	11		
	-	8	
	9		
	-	8	
	8		
	8		
	8		
	-	12	
	11		
	-	13	
	12		

Life Stage Group	Minimum dose of beta-carotene1(μg/day)	
Infants	0-6 months	2,400*
7-12 months	3,000*	
Children	1-3 years	1,800
4-8 years	2,400	
Adolescent males	9-13 years	3,600
14-18 years	5,400	
Adult males	19 years and older	5,400
Adolescent females	9-13 years	3,600
14-18 years	4,200	
Adult females	19 years and older	4,200
Pregnancy	14-18 years	4,500
19-50 years	4,620	
Breastfeeding	14-18 years	7,200
19-50 years	7,800	

Source ingredient (1 mg)	Pantothenic acid quantity (mg)
Calcium D-pantothenate	0.92
Calcium DL-pantothenate	0.46
Dexpanthenol	1.07

DL-Panthenol	0.53
DL-Pantothenic acid	0.50

Source ingredient (1 μg)	Vitamin A quantity (μg RAE)	Vitamin A activity (IU)
all-trans-Retinol	1.00	3.33
all-trans-Retinyl acetate	0.87	2.91
all-trans-Retinyl palmitate	0.55	1.82

Source ingredient (1 mg)	Vitamin E quantity (mg AT)	Vitamin E activity (IU)
d-alpha-Tocopherol	1.00	1.49
d-alpha-Tocopheryl acetate	0.91	1.36
d-alpha-Tocopheryl succinate	0.81	1.21
dl-alpha-Tocopherol	0.50	1.10
dl-alpha-Tocopheryl acetate	0.45	1.00
dl-alpha-Tocopheryl succinate	0.40	0.89

Source ingredient (1 IU)	Vitamin E quantity (mg AT)
d-alpha-Tocopherol	0.67
d-alpha-Tocopheryl acetate	0.67
d-alpha-Tocopheryl succinate	0.67
dl-alpha-Tocopherol	0.45
dl-alpha-Tocopheryl acetate	0.45
dl-alpha-Tocopheryl succinate	0.45

Life Stage Group	Daily dosage range of zinc which recommended to avoid (mg/day)	Daily dosage range of copper which recommended to avoid (µg/day)
Infants 0-12 months	≤ 2	0
Children 1-3 years	5-7	280-700
Children 4-8 years	8-12	480-2,500
Adolescents 9-13 years	16-23	920-4,000
Adolescents 14-18 years	25-34	1,360-6,500
Adults 19 years and older	31-50	2,000-8,000

Medicinal ingredient(Source information)	Medicinal ingredient Quantity per 1 tablet*
Calcium	500 mg ..... (Calcium carbonate, Calcium citrate, Calcium fumarate)

Medicinal ingredient(Source information)	Medicinal ingredient Quantity per 1 tablet*
Calcium	500 mg ..... (Calcium carbonate)
Iron	30 mg ..... (Iron (II) sulfate)