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(57) Abstract: Disclosed are nutritional compositions that include intact pea protein. In some embodiments, the intact pea protein is an intact pea protein concentrate. The nutritional compositions may include the intact pea protein source in combination with one or more additional protein sources, such as milk protein concentrate and/or soy protein isolate. The intact pea protein imparts a number of benefits to the nutritional compositions including improved viscosity and texture.



## PEA PROTEIN CONTAINING NUTRITIONAL COMPOSITIONS

**CROSS-REFERENCE TO RELATED APPLICATION**

[0001] This application claims priority to and any other benefit of U.S. Provisional Patent Application Serial No. 61/615,632, filed March 26, 2012, and entitled “NUTRITIONAL COMPOSITIONS INCLUDING INTACT PEA PROTEIN AND METHODS OF USE,” the entire disclosure of which is incorporated by reference herein.

**FIELD OF THE DISCLOSURE**

[0002] The present disclosure relates to nutritional compositions that include an intact pea protein. More particularly, the present disclosure relates to liquid nutritional compositions that include an intact pea protein concentrate and methods of using the nutritional compositions.

**BACKGROUND OF THE DISCLOSURE**

[0003] Adult, pediatric, and infant manufactured nutritional liquids and powders comprising a targeted selection of nutritional ingredients are well known and widely available, some of which may provide a sole source of nutrition, while others may provide a supplemental source. These nutritionals include powders that can be reconstituted with water or other aqueous liquid, as well as concentrated and ready-to-drink nutritional liquids such as milk or protein based emulsions or non-emulsified or substantially clear liquids. These nutritional liquids are especially useful when formulated with selected nutritional ingredients. For example, some nutritional compositions include proteins for building or maintaining healthy muscle mass and

strength in selected individuals, increasing bone density, preventing protein degradation and the like. These nutritional compositions are also often selected for use by individuals at risk of affliction with a disease or condition associated with the wasting of skeletal muscles.

[0004] Conventional nutritional compositions will generally include a source of fat, a source of carbohydrate, and a source of protein that make up the macronutrients of the composition and provide the majority of the calories. The nutritional compositions will also generally include vitamins, minerals and possibly other optional components as well. Traditionally, protein sources have included cow milk-based proteins (casein and whey proteins), and plant proteins such as soy protein. Elemental proteins and peptides have also been used in certain nutritional compositions. The proteins may be intact, partially hydrolyzed, or substantially hydrolyzed and are typically utilized as concentrates (about 60%-80% by weight protein generally) or isolates (generally greater than 80% by weight protein). The protein source or combination of sources utilized in the nutritional compositions can significantly impact resulting properties of the composition, including, for example, viscosity, taste, texture, and mouthfeel.

[0005] Although conventional protein systems provide desired protein levels in nutritional compositions, there is a need in the art for novel protein systems that not only provide the desired protein levels and are not only well-tolerated and digested by the individual users, but can be economically utilized in nutritional compositions while providing the desired hedonic, product, and processing characteristics.

### **SUMMARY OF THE DISCLOSURE**

[0006] The present disclosure is generally directed to nutritional compositions that include intact pea protein. The nutritional compositions are generally aseptically processed and include an intact pea protein concentrate that provides excellent protein and hedonic characteristics to the nutritional composition. The intact pea protein may be used as a sole protein source in the nutritional composition, or may be used in combination with one or more additional protein sources as described herein to form the protein component of the nutritional

composition. The intact pea protein imparts a number of important benefits to the nutritional compositions including excellent texture, sweetness and a smooth and creamy mouthfeel. The intact pea protein also provides improved viscosity characteristics to the nutritional compositions, and has been found to have beneficial protein and muscle building properties, as well as beneficial effects on glycemic control and response and glucose modulation.

[0007] The present disclosure is directed to a nutritional composition comprising a protein component in an amount of from about 0.5% to about 25% by weight, a carbohydrate component in an amount of from about 0.1% to about 50% by weight, and a fat component in an amount of from about 0.1% to about 25% by weight, wherein the protein component comprises from about 5% to about 95% by weight intact pea protein.

[0008] It has been discovered that intact pea protein, and in particular intact pea protein concentrates, when utilized in nutritional compositions impart a number of surprising benefits and properties to the nutritional compositions. Despite the conventional views and beliefs that many plant-based protein materials, when included in nutritional compositions, result in beany, starchy/pasty tastes and a more viscous, undesirable mouthfeel, the intact pea protein surprisingly imparts beneficial viscosity properties to the nutritional composition in that, even at elevated amounts of the intact pea protein, the viscosity of a liquid nutritional composition remains manageable and processable, which is a significant commercial advantage. Additionally, the intact pea protein provides improved hedonic characteristics as compared to other proteins and protein systems such that the resulting texture and mouthfeel of the intact pea protein-containing nutritional composition is commercially advantageous.

[0009] Additionally, it has been unexpectedly found that intact pea protein may provide significant protein building in the body and a resulting increase in muscle accretion in an individual as compared to other conventional proteins and protein systems. When used in combination with a rapidly digested protein such as whey protein and a slowly digested protein such as casein protein, the intact pea

protein, which is an intermediate rate digested protein, may provide significant muscle accretion benefits as compared to other protein systems such, as for example, whey and casein. The intact pea protein may also result in improved glucose tolerance and bone health in individuals.

### **DETAILED DESCRIPTION OF THE DISCLOSURE**

[0010] The nutritional compositions of the present disclosure comprise a protein system that includes intact pea protein. Intact pea protein, and in particular intact pea protein concentrate, is an economical protein that provides a number of unexpected benefits to the nutritional compositions. Much like traditional proteins used in nutritional compositions, the intact pea protein provides a source of healthy protein and the desired caloric value to the nutritional composition. But unlike other traditional protein sources, the intact pea protein confers a number of additional benefits to the nutritional composition including, for example, an improved viscosity profile, improved texture, and mouthfeel. Additionally, the intact pea protein provides an excellent source of protein for protein synthesis and muscle building in individuals and may be advantageous over traditional whey protein-based muscle building nutritional compositions. In some embodiments, the intact pea protein may be used with beta-hydroxy-beta-methylbutyrate, and/or other additives, to impart additional protein and muscle building attributes.

[0011] These and other features of the nutritional compositions, as well as some of the many optional variations and additions, are described in detail hereafter.

[0012] The terms “nutritional composition” or “nutritional product” as used herein, unless otherwise specified, refer to nutritional liquids and nutritional powders, the latter of which may be reconstituted to form a nutritional liquid, all of which comprise one or more of fat, protein, and carbohydrate and are suitable for oral consumption by a human.

[0013] The terms “liquid nutritional composition” and “nutritional liquid” are used interchangeably herein, and unless otherwise specified, refer to nutritional products in ready-to-drink liquid form and concentrated form.

[0014] The terms “fat” and “oil” as used herein, unless otherwise specified, are used interchangeably to refer to lipid materials derived or processed from plants or animals. These terms also include synthetic lipid materials so long as such synthetic materials are suitable for oral administration to humans.

[0015] The term “shelf stable” as used herein, unless otherwise specified, refers to a liquid nutritional composition that remains commercially stable after being packaged and then stored at 18-24°C for at least 3 months, including from about 6 months to about 24 months, and also including from about 12 months to about 18 months.

[0016] The terms “retort packaging” and “retort sterilizing” are used interchangeably herein, and unless otherwise specified, refer to the common practice of filling a container, most typically a metal can or other similar package, with a liquid nutritional composition and then subjecting the liquid-filled package to the necessary heat sterilization step, to form a sterilized, retort packaged, liquid nutritional product.

[0017] The term “aseptic packaging” as used herein, unless otherwise specified, refers to the manufacture of a packaged product without reliance upon the above-described retort packaging step, wherein the liquid nutritional composition and package are sterilized separately prior to filling, and then are combined under sterilized or aseptic processing conditions to form a sterilized, aseptically packaged, liquid nutritional product.

[0018] All percentages, parts and ratios as used herein, are by weight of the total composition, unless otherwise specified. All such weights as they pertain to listed ingredients are based on the active level and, therefore, do not include solvents or by-products that may be included in commercially available materials, unless otherwise specified.

[0019] All references to singular characteristics or limitations of the present disclosure shall include the corresponding plural characteristic or limitation, and vice

versa, unless otherwise specified or clearly implied to the contrary by the context in which the reference is made.

[0020] All combinations of method or process steps as used herein can be performed in any order, unless otherwise specified or clearly implied to the contrary by the context in which the referenced combination is made.

[0021] The various embodiments of the nutritional compositions of the present disclosure may also be substantially free of any optional or selected ingredient or feature described herein, provided that the remaining nutritional composition still contains all of the required ingredients or features as described herein. In this context, and unless otherwise specified, the term “substantially free” means that the selected nutritional composition contains less than a functional amount of the optional ingredient, typically less than 1%, including less than 0.5%, including less than 0.1%, and also including zero percent, by weight of such optional or selected ingredient.

[0022] The nutritional compositions may comprise, consist of, or consist essentially of the elements of the nutritional compositions as described herein, as well as any additional or optional element described herein or otherwise useful in nutritional composition applications.

### **Product Form**

[0023] The nutritional compositions of the present disclosure include an intact pea protein, and in many embodiments an intact pea protein concentrate, and include ready-to-feed liquids, concentrated liquids, liquids derived from nutritional powders (reconstituted liquids), powders, solids, semi-liquids, and semi-solids. The liquid embodiments may include solutions (including clear solutions), suspensions, and emulsions. The powders that are reconstituted to produce a liquid may include any flowable or scoopable particulate solid that can be diluted with water or other aqueous liquid to form a nutritional liquid prior to use.

[0024] The nutritional compositions may be formulated with sufficient kinds and amounts of nutrients to provide a sole, primary, or supplemental source of

nutrition, or to provide a specialized nutritional product for use in individuals afflicted with specific diseases or conditions or with a targeted nutritional benefit.

### **Nutritional Powders**

[0025] The nutritional powders may be reconstituted by the intended user with a suitable aqueous liquid, typically water or other aqueous liquid, in an amount or volume sufficient to form a nutritional liquid for immediate oral or enteral use. In this context, “immediate” use generally means within about 48 hours, more typically within about 24 hours, most typically right after or within 20 minutes of reconstitution. Further, when reconstituted, the nutritional powders provide the desired ingredient concentrations as described hereinafter for the nutritional liquid embodiments.

[0026] The nutritional powders may include spray dried powders, dry mixed powders, agglomerated powders, combinations thereof, or powders prepared by other suitable methods. In some embodiments, all or a portion of the intact pea protein may be dryblended into the nutritional powder.

### **Nutritional Liquids**

[0027] The nutritional liquids may be formulated in a variety of forms, including emulsions such as oil-in-water, water-in-oil, or complex aqueous emulsions, although such emulsions are most typically in the form of oil-in-water emulsions having a continuous aqueous phase and a discontinuous oil phase, suspensions, or clear or substantially clear liquids.

[0028] The nutritional liquids may be and typically are shelf stable. The nutritional liquids typically contain up to 95% by weight of water, including from about 50% to 95%, also including from about 60% to about 90%, and also including from about 70% to about 85%, of water by weight of the nutritional liquid.

[0029] The nutritional liquids may have a caloric density tailored to the nutritional needs of the ultimate user, although in most instances the liquids comprise generally at least 19 kcal/fl oz (660 kcal/liter), more typically from about 20 kcal/fl oz

(675-680 kcal/liter) to about 25 kcal/fl oz (820 kcal/liter), even more typically from about 20 kcal/fl oz (675-680 kcal/liter) to about 24 kcal/fl oz (800-810 kcal/liter). Generally, the 22-24 kcal/fl oz formulas are more commonly used in preterm or low birth weight infants, and the 20-21 kcal/fl oz (675-680 to 700 kcal/liter) formulas are more often used in term infants. In some embodiments, the liquid may have a caloric density of from about 100 kcal/liter to about 660 kcal/liter, including from about 150 kcal/liter to about 500 kcal/liter.

[0030] The nutritional liquid may have a pH ranging from about 3.5 to about 8, but are most advantageously in a range of from about 4.5 to about 7.5, including from about 4.5 to about 7.0, including from about 4.5 to about 6.7, including from about 4.5 to about 6.5, and including from about 4.5 to about 6.0. In some embodiments, the pH range includes from about 5.5 to about 7.3, including from about 5.5 to about 7.0, including from about 5.5 to about 6.5, and including from about 5.5 to about 6.0. In still other embodiments, the pH range may be from about 6.2 to about 7.2, including from about 6.2 to about 7.0, and including from about 6.2 to about 6.5.

[0031] Although the serving size for the nutritional liquid can vary depending upon a number of variables, a typical serving size is generally at least 2 mL, or even at least 5 mL, or even at least 10 mL, or even at least 25 mL, including ranges from 2 mL to about 300 mL, including from about 4 mL to about 250 mL, and including from about 10 mL to about 240 mL.

### **Intact Pea Protein**

[0032] The nutritional compositions of the present disclosure may comprise intact pea protein as a sole protein component, or may comprise intact pea protein in combination with one or more additional proteins as described herein. In the nutritional compositions, the intact pea protein may be an intact pea protein concentrate, an intact pea protein isolate, or a combination of both. As used herein, the term “intact” means that the protein has not been subjected to a specific process for hydrolyzing the pea protein.

[0033] In some embodiments of the present disclosure, the nutritional composition includes 100% intact pea protein by weight of the protein component. In some other embodiments, the nutritional composition includes the intact pea protein in combination with one, two, three or more sources of additional proteins. These additional proteins may be intact proteins, lightly hydrolyzed proteins, substantially hydrolyzed proteins, and combinations thereof. In one specific embodiment, the intact pea protein provides from about 5% to about 95%, including from about 10% to about 80%, including from about 20% to about 70%, including from about 20% to about 60%, including from about 20% to about 50%, including from about 20% to about 40%, including from about 25% to about 40%, including from about 30% to about 40%, including from about 30% to about 35%, and including from about 32% to about 34% by weight of the total protein component in the nutritional composition. In one specific embodiment, the intact pea protein provides about 34% by weight of the total protein component in the nutritional composition.

[0034] In some embodiments, the intact pea protein provides at least 1% of the total kcal of the protein component in the nutritional composition, including from about 1.5% to about 6% of the total kcal of the protein component, including from about 2% to about 3% of the total kcal of the protein component, and including from about 2.5% to about 2.8% of the total kcal of the protein component. In some embodiments, the intact pea protein provides from about 4% to about 5% of the total kcal of the protein component in the nutritional composition.

[0035] In some embodiments, the protein component of the nutritional composition includes intact pea protein concentrate in combination with milk protein concentrate. In these specific embodiments, the intact pea protein provides from about 20% to about 50% including from about 20% to about 40%, including from about 25% to about 40%, including from about 30% to about 40%, and including from about 30% to about 35% by weight of the protein component and the milk protein provides from about 50% to about 80%, including from about 60% to about 80%, including from about 60% to about 75%, including from about 60% to about 70%, and also including from about 65% to about 70% by weight of the protein component. In one specific embodiment, the intact pea protein provides about 34%

by weight of the protein component and the milk protein provides about 66% by weight of the protein component. In other specific embodiments, when intact pea protein is used in combination with milk protein concentrate, the intact pea protein is from about 50% to about 75%, including from about 50% to about 69% by weight of the protein component.

[0036] In some embodiments, the protein component of the nutritional composition includes intact pea protein in combination with soy protein isolate. In these specific embodiments, the intact pea protein provides from about 20% to about 50% including from about 20% to about 40%, including from about 25% to about 40%, including from about 30% to about 40%, and including from about 30% to about 35% by weight of the protein component and the soy protein provides from about 50% to about 80%, including from about 60% to about 80%, including from about 60% to about 75%, including from about 60% to about 70%, and also including from about 65% to about 70% by weight of the protein component. In one specific embodiment, the intact pea protein provides about 34% by weight of the protein component and the soy protein provides about 66% by weight of the protein component.

[0037] In some embodiments of the present disclosure, it is desirable to have the protein component utilized in the nutritional composition provide a Protein Digestibility Corrected Amino Acid Score (PDCAAS) as close to 1 or more as possible so that the protein can be sufficiently utilized by the body after digestion. A PDCAAS score of 1 indicates that after protein digestion, it provides, per unit of protein, 100% of the indispensable amino acids required. In one specific embodiment, intact pea protein concentrate and milk protein concentrate are used as the protein component in the nutritional composition, wherein the intact pea protein concentrate is about 69% by weight of the protein component and the milk protein concentrate is about 31% by weight of the protein component. In another embodiment, intact pea protein concentrate and milk protein concentrate are used as the protein component in the nutritional composition, wherein the intact pea protein concentrate is about 75% by weight of the protein component and the milk protein concentrate is about 25% by weight of the protein component.

[0038] Particularly suitable intact pea protein for use in the nutritional compositions of the present disclosure includes intact pea proteins derived from *pisum sativum*. Additionally, in some embodiments, the intact pea protein suitably has one or more of the following attributes: (1) poured bulk density, as measured by gravimetry, of about 0.4 Kg/L; (2) a pH in a 10% solution of water of about 7; (3) a residue on a 70 mesh screen as measured by sieving of a maximum of 10% by weight; (4) a carbohydrate concentration of about 3 grams per 100 grams of intact pea protein; (5) a fat concentration of about 6 grams per 100 grams of intact pea protein; and/or (6) an ash concentration of about 4 grams per 100 grams of intact pea protein. In one embodiment, the intact pea protein concentrate is a spray dried intact pea protein. In one desirably embodiment, the intact pea protein in a spray dried intact pea protein that has all attributes 1-6 as noted above.

[0039] One suitable commercially available intact pea protein concentrate for use in the nutritional compositions of the present disclosure is NUTRALYS® F85F pea protein concentrate (about 83% by weight intact pea protein) (Roquette Freres, Lestrem France).

[0040] In addition to the intact pea protein and other protein sources discussed above, the nutritional compositions may further comprise any additional protein or sources thereof that are suitable for use in oral nutritional compositions and are compatible with the elements and features of such compositions. Total protein concentrations in the nutritional compositions may range from about 0.5% to about 50%, including from about 1% to about 45%, and also including from about 2% to about 40%, and including from about 5% to about 35%, including from about 5% to about 30%, including from about 5% to about 25%, including from about 7% to about 25%, including from about 10% to about 25%, including from about 10% to about 20%, by weight of the nutritional composition. In one specific embodiment, the total protein concentration may be from about 1.0% to about 30% by weight, of the nutritional composition. In other specific embodiments, the total protein concentration may be from about 0.5% to about 25%, including from about 1.0% to about 20%, including from about 5% to about 9%, including from about 7% to about

9%, including from about 7.5% to about 8.5%, including from about 7.7% to about 8.2%, including about 8.1% by weight of the nutritional composition.

[0041] Non-limiting examples of additional suitable protein or sources thereof for use in the nutritional compositions described herein include hydrolyzed, partially hydrolyzed or non-hydrolyzed (intact) proteins or protein sources, which may be derived from any known or otherwise suitable source such as milk (e.g., casein, whey), animal (e.g., meat, fish), cereal (e.g., rice, corn), vegetable (e.g., soy), or combinations thereof. Non-limiting examples of such proteins include milk protein isolates, milk protein concentrates as described herein, casein protein isolates, whey protein, whey protein concentrates, whey protein isolates, sodium or calcium caseinates, whole cow's milk, partially or completely defatted milk, soy protein isolates, soy protein concentrates, and so forth. Another example of an additional suitable protein is egg albumin. Both sodium caseinate and calcium caseinate also suitable protein sources for use in combination with the intact pea protein.

### **Carbohydrate**

[0042] In addition to the intact pea protein described above, the nutritional compositions may further comprise any carbohydrates or sources thereof that are suitable for use in an oral nutritional product and are compatible with the elements and features of such compositions. Carbohydrate concentrations in the nutritional compositions, for example, may range from about 0.1% to about 70%, including from about 0.1% to about 50%, including from about 5% to about 70%, including from about 3% to about 65%, including from about 7% to about 30%, and including from about 10% to about 25%, by weight of the nutritional composition. In some embodiments, the carbohydrate is present in an amount of from about 0.1% to about 50%, including from about 0.5% to about 4.0%, including from about 0.5% to about 3.5%, including from about 1.0% to about 3.5%, including from about 1.5% to about 3.5%, including from about 1.5% to about 3.0%, including from about 2.0% to about 2.5%, and including about 2.4%, by weight of the nutritional composition.

[0043] Non-limiting examples of suitable carbohydrates or sources thereof for use in the nutritional products described herein include maltodextrin (and specifically low DE Maltodextrin such as DE10 maltodextrin), corn maltodextrin, sucromalt, maltitol, maltitol powder, glycerine, glucose polymers, corn syrup, corn syrup solids, rice-derived carbohydrates (e.g., tapioca dextrin), isomaltulose, sucrose, extra fine white sugar, glucose, fructose, lactose, high fructose corn syrup, honey, sugar alcohols (e.g., maltitol, erythritol, sorbitol), artificial sweeteners (e.g., sucralose, acesulfame potassium, stevia), fructooligosaccharides, soy fiber, corn fiber, guar gum, konjac flour, polydextrose, Fibersol, and combinations thereof.

### **Fat**

[0044] In addition to the intact pea protein, the nutritional compositions may further comprise fat or sources thereof, most typically as emulsified fat, concentrations of which may range from about 0.1% to about 40%, including from about 1% to about 30%, including from about 1% to about 20%, including from about 2% to about 15%, and also including from about 4% to about 10%, by weight of the nutritional composition. In some embodiments, the fat concentration may be from about 0.1% to about 25%, including from about 0.5% to about 4.0%, including from about 0.5% to about 3.0%, including from about 0.5% to about 2.0%, including from about 0.5% to about 1.5%, including from about 0.5% to about 1.0%, including from about 0.75% to about 1.0%, including from about 0.8% to about 1.0%, including from about 0.85% to about 0.95%, and also including about 0.9% by weight of the nutritional composition.

[0045] Suitable sources of fat for use herein include any fat or fat source that is suitable for use in an oral nutritional product and is compatible with the elements and features of such products. Desirably, a fat source will provide at least one long chain polyunsaturated acid (LC-PUFA) such as DHA, ARA, and/or EPA, although these LC-PUFAs may be optionally added to the nutritional compositions outside of, or in addition to, the fat source.

[0046] Non-limiting examples of suitable fats or sources thereof for use in the nutritional emulsions described herein include coconut oil, fractionated coconut oil, soy oil, corn oil, olive oil, safflower oil, high oleic safflower oil, MCT oil (medium chain triglycerides), sunflower oil, high oleic sunflower oil, palm and palm kernel oils, palm olein, canola oil, marine oils, cottonseed oils, and combinations thereof.

[0047] In addition to the above, in some embodiments of the present disclosure, the amount of carbohydrates, fats, and/or proteins in any of the nutritional compositions described herein may also be characterized in addition to, or in the alternative, as a percentage of total calories in the nutritional product as set forth in the following table. These macronutrients for nutritional compositions of the present disclosure are most typically formulated within any of the caloric ranges (embodiments A-F) described in the following table (each numerical value is preceded by the term “about”).

| <b>Nutrient &amp; Total Cal.</b> | <b>Embodiment A</b> | <b>Embodiment B</b> | <b>Embodiment C</b> |
|----------------------------------|---------------------|---------------------|---------------------|
| <b>Carbohydrate</b>              | 0-98                | 2-96                | 10-75               |
| <b>Protein</b>                   | 0-98                | 2-96                | 5-70                |
| <b>Fat</b>                       | 0-98                | 2-96                | 20-85               |
|                                  | <b>Embodiment D</b> | <b>Embodiment E</b> | <b>Embodiment F</b> |
| <b>Carbohydrate</b>              | 30-50               | 25-50               | 25-50               |
| <b>Protein</b>                   | 15-35               | 10-30               | 5-30                |
| <b>Fat</b>                       | 35-55               | 1-20                | 2-20                |

#### **Beta-Hydroxy-Beta-Methylbutyrate (HMB)**

[0048] In some embodiments of the present disclosure, the nutritional compositions including the intact pea protein additionally comprise HMB, and preferably calcium HMB, which means that the nutritional compositions are either formulated with the addition of calcium HMB, most typically as a monohydrate, or are otherwise prepared so as to contain HMB in the finished composition. Any source of HMB is suitable for use herein provided that the finished product contains HMB,

although such a source is preferably calcium HMB and is most typically added as such to the nutritional compositions during formulation.

[0049] Although calcium HMB monohydrate is the generally preferred source of HMB for use in the nutritional compositions disclosed herein, other suitable sources may include HMB as the free acid, a salt, an anhydrous salt, an ester, a lactone, or other product forms that otherwise provide a bioavailable form of HMB from the nutritional compositions. Non-limiting examples of suitable salts of HMB for use herein include HMB salts, hydrated or anhydrous, of sodium, potassium, magnesium, chromium, calcium, or other non-toxic salt form. Calcium HMB monohydrate is preferred and is commercially available from Technical Sourcing International (TSI) of Salt Lake City, Utah.

[0050] The concentration of HMB in the nutritional compositions may range up to 20%, including from about 0.01% to about 10%, including from about 0.01% to about 8%, and also including from about 0.08% to about 5.0%, and also including from about 0.08% to about 3%, and also including from about 0.1% to about 2.5%, by weight of the nutritional composition. In some specific embodiments, the nutritional compositions include about 0.38% or about 0.71%, by weight HMB.

[0051] The nutritional compositions of the present disclosure desirably include sufficient HMB to provide an individual with from about 0.1 grams to about 10 grams, including from about 0.5 grams to about 10 grams, including from about 1 gram to about 8 grams, including from about 2 grams to about 7 grams, and also including from about 3 grams to about 6 grams, per day of HMB. In one specific embodiment, the daily intake of HMB by the individual is about 3 grams. The total daily HMB may be contained in one, two, three, or more servings of the nutritional composition.

### **Beta-Alanine**

[0052] In some embodiments of the present disclosure, the nutritional compositions including the intact pea protein additionally comprise beta-alanine. Generally, the nutritional compositions will include beta-alanine in concentrations

ranging from about 0.1% to about 3% by weight, including from about 0.1% to about 2% by weight, including from about 0.1% to about 1% by weight, including from about 0.25% to about 0.50% by weight, including from about 0.26% to about 0.47% by weight.

[0053] The nutritional compositions may be formulated with the addition of beta-alanine, or may otherwise be prepared so as to contain beta-alanine in the finished composition. Any source of beta-alanine is suitable for use in the compositions described herein provided that the finished composition contains beta-alanine at the desired level. Such sources may be and typically do include free beta-alanine as well as other sources that provide free beta-alanine in the nutritional composition during or after formulation.

#### **Functional Amino Acids and Branched Chain Amino Acids**

[0054] In some embodiments of the present disclosure, the nutritional compositions including the intact pea protein additionally comprise one or more functional amino acids and/or one or more branched chain amino acids. The term “functional amino acid” as used herein refers to an amino acid that can regulate key metabolic pathways to improve health, growth, development and reproduction of animals and humans. This metabolic regulation involves cell signaling through the functional amino acids and their metabolites. The metabolic pathways may include protein synthesis, hormone secretion (and, in particular, GLP-1 and insulin secretion), antioxidative reactions and oxidation of energy substrates. A functional amino acid can be either a “nonessential” or an “essential” amino acid.

[0055] The functional amino acid may also further promote muscle glycogen synthesis, reduce fat mass, and/or enhance insulin sensitivity. These benefits further provide dietary management of, and thus, delay the progression of type 2 diabetes.

[0056] Functional amino acids for use in the nutritional compositions of the present disclosure include one or more of L-arginine, L-cysteine, L-glutamine, L-leucine, L-proline, valine, isoleucine, and L-tryptophan. Particularly suitable

functional amino acids include L-arginine and L-glutamine. Desirable branched chain amino acids include leucine, isoleucine, and valine.

[0057] The functional amino acids and branched chain amino acids used in combination with the intact pea protein may be in the form of free amino acids, salt form (e.g., L-arginine hydrochloride), peptide-bound form (e.g., L-alanyl-L-glutamine), and protein-bound form (e.g., bovine beta-lactoglobulin, which includes 2/85 wt% arginine, 7.18 wt% glutamine and 15.76 wt% leucine). Although all of these forms are suitable and within the scope of the present disclosure, the free form functional amino acids and free form branched chain amino acids are particularly suitable as the free forms are the most concentrated and their addition rate into the nutritional composition can be easily controlled.

[0058] In some particular embodiments of the present disclosure, the nutritional composition includes the intact pea protein at least one functional amino acid and/or branched chain amino acid and is substantially or completely free of phenylalanine. For example, the nutritional composition may include less than 1%, including less than 0.5%, including less than 0.1%, and also including zero percent, by weight of phenylalanine.

[0059] In some embodiments, the nutritional composition includes a combination of functional amino acids and/or a combination of functional amino acids and branched chain amino acids such that the composition provides sufficient functional amino acid to provide increased insulin secretion to reduce postprandial blood glucose levels and manage type 2 diabetes. For example, in one embodiment, the nutritional composition includes a combination of arginine, glutamine and leucine to increase secretion of insulin.

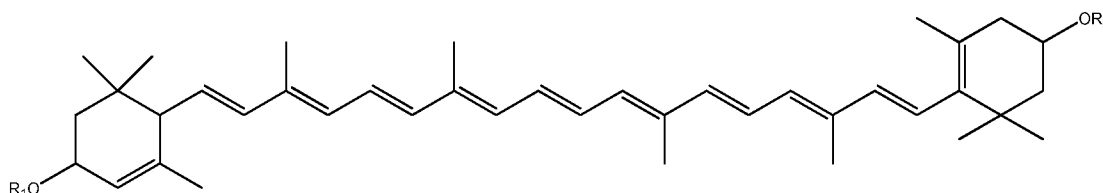
[0060] The nutritional compositions of the present disclosure include the one or more functional amino acids and/or branched chain amino acids in total amounts of from about 1% to about 75% by weight, including from about 10% to about 70% by weight, including from about 15% to about 70% by weight, including from about 20% to about 70% by weight, and including from about 20% to about 50% by weight. In

other embodiments, the nutritional composition may include the functional amino acid and/or branched chain amino acid in an amount of from about 0.1% to about 10%, including 1% to about 10% by weight, including from about 1% to about 5% by weight, including from about 1% to about 3% by weight.

### **Carotenoids**

[0061] In some embodiments of the present disclosure, the nutritional compositions including the intact pea protein additionally comprise one or more carotenoids. Some desirable carotenoids include lutein, lycopene, beta-carotene, and zeaxanthin, with lutein being particularly desirable.

[0062] The term “lutein” as used herein, unless otherwise specified, refers to one or more of free lutein, lutein esters, lutein salts, or other lutein derivatives or related structures as described or otherwise suggested herein. Lutein or lutein sources suitable for use in the nutritional compositions of the present disclosure include free lutein as well as esters, salts or other derivatives or related structures thereof, including those that conform to the formula:



The above formula includes the general structure of lutein and related derivatives or structures. Free lutein, for example, corresponds to the formula wherein  $R_1$  and  $R_2$  are both hydrogen, and includes cis and trans isomers thereof as well as salts thereof, e.g., sodium, potassium.

[0063] Lutein esters suitable for use herein include any lutein ester of the above formula wherein  $R_1$  and  $R_2$  are the same or different, and are nutritionally acceptable monovalent salts, hydrogen or an acyl residue of a carboxylic acid, provided that at least one of  $R_1$  or  $R_2$  is an acyl residue of a carboxylic acid. Suitable lutein esters include, as well, both cis and trans isomers, with trans isomers being

preferred (i.e., trans-lutein). The  $R_1$  and  $R_2$  moieties are residues of a saturated or unsaturated  $C_1$  to  $C_{22}$  fatty carboxylic acids, non-limiting examples of which include formic, acetic, propionic, butyric, valeric, caproic, caprylic, capric, lauric, myristic, palmitic, stearic, and oleic acids.

[0064] Lutein for use herein includes any natural or synthetic source that is known for or is otherwise an acceptable source for use in oral nutritional compositions. Lutein sources can be provided as individual ingredients or in any combination with other materials or sources, including sources such as multivitamin premixes, mixed carotenoid premixes, pure lutein sources, and inherent lutein from other fat or oil components in the nutritional composition. The lutein concentrations and ratios as described herein are calculated based upon added and inherent lutein sources. The nutritional compositions of the present invention preferably comprise at least 25%, more preferably from about 50% to about 95%, by weight of total lutein as added lutein, the remainder being inherent lutein that accompanies added fats and oils.

[0065] It is generally desirable that the nutritional compositions comprise at least one of lutein, lycopene, zeaxanthin, and beta-carotene to provide a total amount of carotenoid of from about 0.001  $\mu\text{g/mL}$  to about 10  $\mu\text{g/mL}$ . More particularly, the nutritional compositions comprise lutein in an amount of from about 0.001  $\mu\text{g/mL}$  to about 10  $\mu\text{g/mL}$ , including from about 0.01  $\mu\text{g/mL}$  to about 10  $\mu\text{g/mL}$ , including from about 0.01  $\mu\text{g/mL}$  to about 1.5  $\mu\text{g/mL}$ , including from about 4  $\mu\text{g/mL}$  to about 6  $\mu\text{g/mL}$ , including from about 0.001  $\mu\text{g/mL}$  to about 5  $\mu\text{g/mL}$ , including from about 0.001  $\mu\text{g/mL}$  to about 0.0190  $\mu\text{g/mL}$ , including from about 0.001  $\mu\text{g/mL}$  to about 0.0140  $\mu\text{g/L}$ , and also including from about 0.044  $\mu\text{g/mL}$  to about 5  $\mu\text{g/mL}$  of lutein. It is also generally preferable that the nutritional compositions comprise from about 0.001  $\mu\text{g/mL}$  to about 10  $\mu\text{g/mL}$ , including from about 0.01  $\mu\text{g/mL}$  to about 10  $\mu\text{g/mL}$ , including from about 0.01  $\mu\text{g/mL}$  to about 1.5  $\mu\text{g/mL}$ , including from about 4  $\mu\text{g/mL}$  to about 6  $\mu\text{g/mL}$ , including from about 0.001  $\mu\text{g/mL}$  to about 5  $\mu\text{g/mL}$ , from about 0.001  $\mu\text{g/mL}$  to about 0.0130  $\mu\text{g/mL}$ , including from about 0.001  $\mu\text{g/mL}$  to about 0.0075  $\mu\text{g/mL}$ , and also including from about 0.0185  $\mu\text{g/mL}$  to about 5  $\mu\text{g/mL}$  of lycopene. It is also generally preferable that the nutritional compositions comprise from about 0.001  $\mu\text{g/mL}$  to about 10  $\mu\text{g/mL}$ , including from about 0.01  $\mu\text{g/mL}$  to

about 10 µg/mL, including from about 0.01 µg/mL to about 1.5 µg/mL, including from about 4 µg/mL to about 6 µg/mL, including from about 1 µg/mL to about 10 µg/mL, including from about 1 µg/mL to about 5 µg/mL, including from about 0.001 µg/mL to about 0.025 µg/mL, including from about 0.001 µg/mL to about 0.011 µg/mL, and also including from about 0.034 µg/mL to about 5 µg/mL of beta-carotene. It should be understood that any combination of these amounts of beta-carotene, lutein, zeaxanthin, and lycopene can be included in the nutritional compositions of the present disclosure. Other carotenoids may optionally be included in the nutritional compositions as described herein. Any one or all of the carotenoids included in the nutritional compositions described herein may be from a natural source, or artificially synthesized.

[0066] Non-limiting examples of some suitable lutein sources for use herein include FloraGLO® Crystalline Lutein, available from Kemin Foods, Des Moines, Iowa, USA; and Xangold® Lutein Esters provided by Cognis, Cincinnati, Ohio, USA.

### **Prune Extract**

[0067] In addition to the intact pea protein, the nutritional compositions of the present disclosure may additionally include a dried fruit solid extract. In some specific embodiments, in addition to the intact pea protein, the nutritional compositions additionally include a prune extract. The term “prune extract” as used herein refers to the extracted concentrate including polyphenolic compounds from prunes, plums, dates, grapes, figs, and combinations thereof and is in a concentrated form. In one specific embodiment, a suitable prune extract is derived from the species *Prunus domestica*.

[0068] Prune extracts suitable for use in the nutritional compositions of the present disclosure desirably include a combination of flavonoids (e.g., quercetin, rutin, daidzin, genistin, epicatechin, 7-methoxycoumarin), procyanadins (or proanthocyanidins), and hydroxycinnamic acids (e.g., p-coumaric acid, caffeic, ferulic, chlorogenic, neochlorogenic).

[0069] The prune extract comprises at least 5%, or at least 10%, or at least 15%, or at least 25%, or at least 30%, or at least 40%, or at least 50%, or at least 60%, or at least 70%, or at least 80%, or at least 90% or even 100%, including from 5% to 100%, including from about 10% to 100%, including from about 25% to 100%, including from about 50% to 100% and further including from about 75% to 100% by weight polyphenolic compounds.

[0070] When a prune extract is utilized in the nutritional compositions of the present disclosure, the compositions desirably include sufficient prune extract to provide an individual with from about 0.1 grams to about 10 grams, including from about 0.5 grams to about 10 grams, including from about 1 gram to about 8 grams, including from about 2 grams to about 7 grams, and also including from about 3 grams to about 6 grams, per day of prune extract. The total daily amount of prune extract may be administered to an individual in a single undivided dose, or may be split into one, two, three, four or more doses per day.

[0071] The prune extract concentration in the nutritional compositions may range up to 15%, including up to 10%, including from about 0.1% to about 10%, and also including from about 0.1% to about 8.0%, and also including from about 0.5% to about 5.0%, and also including from about 1.0% to about 4.5%, and also including from about 2.0% to about 4.0%, and also including about 3.0%, by weight of the nutritional composition. One suitable commercially available prune extract is PE60 (60% polyphenols) (PL Thomas, Morristown, New Jersey).

### **Catechins and Epicatechin Gallate (EGCG)**

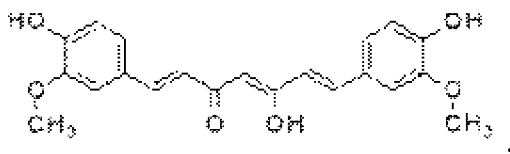
[0072] In addition to the intact pea protein, the nutritional compositions of the present disclosure may additionally include one or more catechins. As used herein, "catechin" is meant to refer to flavonoid phytochemical compounds that appear predominantly in green tea and, to a lesser extent, in black tea, grapes, wine, and chocolate. Examples of catechins that can be used in the practice of the present disclosure include gallocatechin ("GC"), epigallocatechin ("EGC"), epicatechin ("EC"), epicatechin gallate ("ECG"), and epigallocatechin gallate ("EGCG"), as well

as mixtures of these and other catechins. The catechins used in the nutritional compositions of the present disclosure can be prepared from lipid extracts from green tea leaves. The catechins can be purified to any suitable level, such as about 50%, about 60%, about 70%, about 80%, about 85%, about 90%, and/or about 95%. One example of a suitable catechin is an extract (e.g., an 80% catechin extract) of *Camellia sinensis*.

[0073] Generally, the catechins may be present in the nutritional compositions in an amount of from about 0.1% to about 10%, including from about 0.1% to about 5%, including from about 0.1% to about 3%, including from about 0.1% to about 2% by weight of the nutritional composition.

### **Curcumin and Bioavailable Curcumin**

[0074] In some embodiments of the present disclosure the nutritional compositions including the intact pea protein may additionally include curcumin and/or bioavailable curcumin. Curcumin, 1,7-bis (4-hydroxyphenyl)-1,6-heptadiene-3,5-dione, has the formula



Curcumin is the principal Curcuminoid of turmeric. Conventionally, some Curcumin products has suffered lower bioavailability when taken orally, and thus when formulated at higher concentrations to counter its inherent poor bioavailability to achieve the desired systemic delivery, the products often take on an intense undesirable yellow color. In some embodiments, the present nutritional compositions use “bioavailable Curcumin”, which has an improved bioavailability as compared to conventionally used Curcumin. As such, the bioavailable Curcumin can be utilized in lower concentrations in the nutritional compositions and methods of the present disclosure, while still maintaining its anti-inflammatory, antioxidative, and anti-amyloidogenic activity.

[0075] The term “bioavailable Curcumin” refers to Curcumin and derivatives and analogs thereof, including natural and synthetic derivatives of Curcumin, as well as any combination of one or more of Curcumin and a derivative and/or analog. In particular, the term “bioavailable Curcumin” should be understood to encompass compounds having a 1,7-bis (4-hydroxyphenyl)-1,6-heptadiene-3,5-dione or 1,7-bis(4-hydroxyphenyl) hept-4-en-3-one skeleton wherein the phenyl groups independently may bear one or more alkoxy residues, especially one methoxy residue in the 3-position. In some embodiments, additional Curcuminoids, such as demethoxyCurcumin and bisdemethoxyCurcumin, may also be present in the nutritional compositions. When present, demethoxyCurcumin and bisdemethoxyCurcumin may be present as part of a complex with Curcumin.

[0076] The “bioavailable Curcumin” used in the nutritional compositions of the present disclosure shows improved oral bioavailability as compared to Curcumins that are not substantially “bioavailable.” The oral bioavailability can be determined in experiments involving oral administration of the bioavailable Curcumin composition of the present disclosure (and/or a corresponding amount of non-bioavailable Curcumin) to a subject and measuring the level of the Curcumin in a biological sample obtained from the subject over time, wherein the biological sample may be derived from a body fluid, for example serum, plasma, whole blood, or cerebrospinal fluid, and/or a tissue, e.g. from brain, liver, kidney, or heart. For analysis, the Curcumin level in the examined body fluid or tissue may be plotted against time, and the area under the curve (AUC), for example the total area under the curve from  $t = 0$  (time of administration) to  $t = \text{infinity}$  ( $= \text{AUC}_{0-\text{infinity}}$ ), or the area under the curve within a defined period, e.g. from  $t = 0$  to  $t = 6$  hours ( $\text{AUC}_{0-6\text{H}}$ ), may be calculated. In general, a higher AUC relative to the AUC obtained by administration of non-bioavailable Curcumin indicates an improved bioavailability. The absolute bioavailability may be calculated from the resulting AUC data as a percentage based on the corresponding AUC data obtained from intravenous administration of Curcumin.

[0077] In some embodiments, the bioavailable Curcumin amount in the blood, determined as  $\text{AUC}_{0-6\text{H}}$  after a single oral administration of a dose of the

bioavailable Curcumin-containing nutritional composition of the present disclosure corresponding to 20 mg of total Curcumin to a human subject or an animal subject, preferably a rat, is significantly higher than after oral administration of the same amount of non-bioavailable Curcumin in the composition, preferably at least 2 times, at least 3 times, at least 4 times, at least 6 times, at least 8 times, at least 10 times, or at least 15 times, and, for example, up to 30 times higher.

[0078] As used herein, the amount of Curcumin in the blood being “significantly higher” means a statistically significant increase of this parameter in subjects after oral administration of 20 mg of bioavailable Curcumin in the nutritional composition of the present disclosure as compared to the control 20 mg of Curcumin that is not bioavailable. A statistical test known in the art, such as ANOVA or Student’s t-test, may be used to determine the significance of this difference, wherein the p-value is at least  $<0.1$ ,  $<0.5$ ,  $<0.01$ ,  $<0.005$ ,  $<0.001$  or  $<0.0001$ .

[0079] Bioavailable Curcumin can be prepared in a number of ways including, for example, using Meltrex® or similar melt-extrusion technology to prepare extruded solids and improve the bioavailability of the Curcumin as compared to Curcumin not produced by melt extrusion. Meltrex® or similar melt-extrusion technology methods are known in the art and can be applied to produce bioavailable Curcumin by one skilled in the art based on the disclosure herein.

[0080] In another embodiment, Curcumin or bioavailable Curcumin can be co-supplemented with piperine (generally extracted from black pepper) to increase the bioavailability and hence the absorbability of Curcumin. In one embodiment, the piperine is co-supplemented in an amount of about 20 mg to increase the bioavailability of the Curcumin.

[0081] In another embodiment, the Curcumin or bioavailable Curcumin may be solubilized in an oil having an HLB of from about 0.7 to about 14 (polar oils) such that the resulting oil mixture provides increased bioavailability of Curcumin. One suitable polar oil for dissolving the Curcumin is a medium chain triglyceride oil (MCT oil).

[0082] In one embodiment of the present disclosure, the bioavailable Curcumin is a mixture of Curcuminoids (i.e., Curcumin, demethoxyCurcumin and bisdemethoxyCurcumin) obtained from the rhizomes of *Curcuma Longa*. In another embodiment, the bioavailable Curcumin is obtained using Meltrex® technology (Abbott Nutrition, Columbus, Ohio). In yet another embodiment, the bioavailable Curcumin is Meriva Bioavailable Curcumin, commercially available from Idena SPA (Milan, Italy).

[0083] The Curcumin or bioavailable Curcumin concentration in the nutritional compositions may range from at least 0.001%, including from about 0.002% to about 3.36%, including from about 0.005% to about 1.87%, also including from about 0.03% to about 0.935%, also including from about 0.1% to about 0.467%, and also including from about 0.234% to about 0.3%, by weight of the nutritional composition. Exemplary embodiments of the present disclosure include nutritional compositions having Curcumin or bioavailable Curcumin in amounts ranging from about 0.002% to about 0.25%, from 0.002% to about 0.234%, from about 0.005% to about 0.467%, from about 0.03% to about 0.935%, from about 0.1% to about 1.9%, from about 0.1% to about 1.87%, and from about 0.3% to about 3.36%, by weight of the nutritional composition.

[0084] When utilized, the nutritional compositions of the present disclosure desirably include sufficient Curcumin or bioavailable Curcumin to provide an individual with at least 1 milligram, including at least 3 milligrams, including from about 10 milligrams to about 10,000 milligrams, including from about 100 milligrams to about 4000 milligrams, including from about 400 milligrams to about 2000 milligrams, including from about 1200 milligrams to about 1800 milligrams, per day of Curcumin or bioavailable Curcumin. The total daily amount of Curcumin or bioavailable Curcumin may be administered to an individual in a single undivided dose, or may be split into one, two, three, four or more doses per day.

### **Monoglycerides**

[0085] In some embodiments, the fat component of the nutritional compositions including the intact pea protein may include monoglycerides. Monoglycerides are normal metabolites in the body formed during the breakdown of triglycerides and diglycerides.

[0086] Typically the monoglycerides are included in combination with a low DE glucose polymer or an induced viscosity fiber (IVF) system. It has been found that by replacing a portion of the fat component with monoglycerides, and additionally including the monoglycerides with the low DE glucose polymer (e.g., low DE maltodextrin) and/or IVF system as part of the carbohydrate component, a nutritional composition can impart a thick, smooth and creamy mouthfeel upon retort processing and subsequent refrigeration.

[0087] Particularly, when used in combination with the low DE glucose polymer, when the composition is cooled after retorting, the hydrophobic tail of the monoglycerides becomes trapped in the helical core of the low DE glucose polymer, forming a lipid-amylose complex. The lipid amylose complex is in the form of small insoluble particles, which can impart body and creamy mouthfeel. Further, the use of a low DE glucose polymer reduces the Maillard reaction, improving composition color.

[0088] The lipid amylose complex additionally provides an improved satiety benefit, as the lipid amylose complex is a slow digesting carbohydrate/lipid complex. Additionally, monoglycerides, as they include free fatty acids, have been shown to stimulate the release of CCK, which further contributes to an improved satiety feel and a greater reduction in food intake.

[0089] The amount of monoglycerides in the nutritional composition will depend on the other components of the composition as well as the intended end product. Typically, the monoglycerides are present in the nutritional compositions in amounts of from about 0.0001% to no more than 95%, including from about 0.001% to about 50%, including from about 0.0072% to about 25%, including from about 0.0072% to about 2.60%, including from about 0.01% to about 10%, including from

about 0.1% to about 7.5%, and also including from about 0.50% to about 5%, by weight of total fat in the nutritional composition. In one embodiment, the nutritional composition includes from about 0.01% to no more than 10% of monoglycerides by weight of total fat in the nutritional composition.

### **Induced Viscosity Fiber System**

[0090] As noted above, the nutritional compositions may additionally include an induced viscosity fiber (IVF) system formed from a soluble viscous fiber, sometimes referred to as a water-soluble viscous fiber.

[0091] Exemplary soluble viscous fiber sources include gum arabic, sodium carboxymethylcellulose, methylcellulose, guar gum, gellan gum, locust bean gum, konjac flour, hydroxypropyl methylcellulose, tragacanth gum, karaya gum, gum acacia, chitosan, arabinogalactins, glucomannan, xanthan gum, alginate, pectin, low and high methoxy pectin, cereal beta-glucans (i.e., oat beta-glucan, barley beta-glucan), carrageenan and psyllium.

[0092] Preferably, the soluble viscous fibers are neutral in charge. Charged polymers are typically more soluble than neutral polymers, thus, neutral polymers are more preferred for use in the nutritional compositions of the present disclosure. Representative of neutral soluble viscous fiber sources are guar gum, pectin, locust bean gum, methylcellulose, cereal beta-glucans (i.e., oat beta-glucan, barley beta-glucan), glucomannan, and konjac flour.

[0093] One particularly preferred neutral soluble viscous fiber for use in the nutritional compositions is guar gum. Guar gum is a neutral polysaccharide derived from a leguminous plant, in which alpha-D-galactose is linked, as a side chain, by a 1,6 linkage to the main chain backbone of beta-1,4-D-mannan. The ratio of mannose and galactose in guar gum is about 2:1. The side chain content of guar gum is higher than those of other industrially produced galactomannans (tara gum and locust bean gum). Any source of the guar gum that is known or otherwise suitable for use in an oral nutritional composition is also suitable for use herein, provided that such a source is also compatible with, or is otherwise rendered to be compatible with, the other

selected ingredients in the composition. Examples of commercially available guar gum products include Sunfibre® manufactured by Taiyo Kagaku Co. (Yokkaichi, Japan), and VIS-TOP™ D-20 and VIS-TOP™ D-2029 manufactured by San-Ei Gen F.F.I., Inc. (New York, New York). Additional commercially available guar gum products are available from TIC Gums, Inc. (Belcamp, Maryland).

[0094] Another particularly suitable soluble viscous fiber for use in the nutritional compositions is cereal beta-glucan, including oat beta-glucan and barley beta-glucan. Any source of the cereal beta-glucan that is known or otherwise suitable for use in an oral nutritional composition is also suitable for use herein, provided that such a source is also compatible with, or is otherwise rendered to be compatible with, the other selected ingredients in the composition.

[0095] The cereal beta-glucan suitable for use herein is sourced from grains as opposed to and as distinguished from yeast and mushroom-derived beta-glucan. Cereal beta-glucans are linear chains of  $\beta$ -D-glycopyranosyl units (1-3, 1-4- $\beta$ -D-linked as compared to yeast-based beta-glucans that are 1-3, 1-6- $\beta$ -D-linked) in which 70% of the units are typically linked, but which also consist of  $\beta$ -D-cellobiosyl and  $\beta$ -D-cellobiosyl residues separated by linkages arranged in a random manner. The soluble nature of beta-glucans, in conjunction with their chemical structure, helps to increase the viscosity of foods that contain them.

[0096] Suitable cereal-based beta-glucans for use in the nutritional compositions of the present disclosure include oat-derived beta-glucans, barley-derived beta-glucans, and combinations thereof, with barley-derived beta-glucans being especially suitable.

[0097] The beta-glucan source for use in the nutritional composition may comprise up to 100% by weight of a beta-glucan, including from about 30% to 100%, and also including from about 50% to 100%, and also including from about 50% to about 95%, and also including from about 60% to about 85%, beta glucan by weight of the beta-glucan source.

[0098] The cereal beta-glucan selected for use herein may have any weight average molecular weight suitable for the selected use and formulation, but will most typically range from about 50 kDa to about 1000 kDa, including less than 750 kDa, including from about 100 kDa to about 250 kDa.

[0099] One suitable commercially available source of a barley beta-glucan for inclusion in the nutritional composition is Barliv<sup>™</sup> (70% barley beta-glucan), commercially available from Cargill (Panora, Iowa).

[00100] The soluble viscous fiber is generally present in the nutritional compositions in an amount of from about 5% to about 90%, including from about 10% to about 50%, also including from about 11% to about 46%, and also including from about 11% to about 25% soluble viscous fiber by weight of the nutritional composition.

[0101] In some embodiments, the soluble viscous fiber can be used in combination with a soluble carbohydrate. For example, in a specific embodiment, the nutritional composition includes guar gum and DE-1 maltodextrin. The DE-1 maltodextrin prevents the dissolution of guar gum, allowing a composition with a low viscosity. When the composition is ingested, the enzymes in the mouth and stomach begin to digest the DE-1 maltodextrin, allowing the guar gum to dissolve, which creates a viscous solution in the stomach. The high viscosity digesta slows stomach emptying, resulting in increased satiety. Additionally, the slow digestion of the IVF system decreases rate of glucose uptake.

### **Optional Ingredients**

[0102] The nutritional compositions described herein may further comprise other optional ingredients that may modify the physical, chemical, hedonic or processing characteristics of the products or serve as pharmaceutical or additional nutritional components when used in the targeted population. Many such optional ingredients are known or otherwise suitable for use in other nutritional compositions and may also be used in the nutritional compositions described herein, provided that

such optional ingredients are safe and effective for oral administration and are compatible with the essential and other ingredients in the selected product form.

[0103] Non-limiting examples of such optional ingredients include preservatives, antioxidants, emulsifying agents, buffers, pharmaceutical actives, additional nutrients as described herein, colorants, flavors, thickeners (e.g., induced viscosity fibers), additional stabilizers, cereal beta-glucans (barley beta-glucan), probiotics (e.g., *Lactobacillus rhamnosus* HN001 (DR20)), prebiotics (fructooligosaccharides, galactooligosaccharides, inulin, oligofructose), *Salacia* extract, and so forth.

[0104] The products may further comprise vitamins or related nutrients, non-limiting examples of which include vitamin A, vitamin D, vitamin E, vitamin K, thiamine, riboflavin, pyridoxine, vitamin B12, carotenoids, niacin, folic acid, pantothenic acid, biotin, vitamin C, choline, inositol, salts, and derivatives thereof, and combinations thereof.

[0105] The products may further comprise minerals, non-limiting examples of which include phosphorus, magnesium, calcium, iron, zinc, manganese, copper, sodium, potassium, molybdenum, chromium, selenium, chloride, and combinations thereof.

[0106] The products may also include one or more flavoring or masking agents. Suitable flavoring or masking agents include natural and artificial sweeteners, sodium sources such as sodium chloride, and hydrocolloids, and combinations thereof.

[0107] In specific embodiments, the products may include fish oil masking agents to mask “fishy” type flavors/aroma notes that commonly occur with the presence of fish/marine oil. For example, in some embodiments, the nutritional composition may include the lipid-amylose complex described above. Specifically, the combination of monoglycerides and low DE glucose polymers, such as DE-1 maltodextrin, form a lipid-amylose complex that can bind to oxidation products such as the fatty acid chain of aldehydes or ketones formed during oxidation of marine oils.

**Methods of Manufacture**

[0108] The nutritional products for use herein may be manufactured by any known or otherwise suitable method for making the nutritional product form selected. When manufactured as nutritional liquids, the nutritional liquids may either be suitably sterilized by aseptic sterilization or by retort sterilization. Nutritional liquids may be prepared, for example, by any of the well known methods of formulating nutritional liquids by way of retort, aseptic packaging, or hot fill processing methods. Such methods are well known in the nutrition formulation and manufacturing arts.

[0109] In one suitable manufacturing process, for example, at least three separate slurries are prepared, including a protein-in-fat (PIF) slurry, a carbohydrate-mineral (CHO-MIN) slurry, and a protein-in-water (PIW) slurry. The PIF slurry is formed by heating and mixing the oil (e.g., canola oil, corn oil, etc.) and then adding an emulsifier (e.g., lecithin), fat soluble vitamins, and a portion of the total protein (e.g., intact pea protein concentrate, milk protein concentrate, etc.) with continued heat and agitation. The CHO-MIN slurry is formed by adding with heated agitation to water: minerals (e.g., potassium citrate, dipotassium phosphate, sodium citrate, etc.), trace and ultra trace minerals (TM/UTM premix), thickening or suspending agent. The resulting CHO-MIN slurry is held for 10 minutes with continued heat and agitation before adding additional minerals (e.g., potassium chloride, magnesium carbonate, potassium iodide, etc.), and/or carbohydrates (e.g., HMOs, fructooligosaccharide, sucrose, corn syrup, etc.). The PIW slurry is then formed by mixing with heat and agitation the remaining protein, if any.

[0110] The resulting slurries are then blended together with heated agitation and the pH adjusted to 6.6-7.0, after which the composition is subjected to high-temperature short-time (HTST) processing during which the composition is heat treated, emulsified and homogenized, and then allowed to cool. Water soluble vitamins and ascorbic acid are added, the pH is adjusted to the desired range if necessary, flavors are added, and water is added to achieve the desired total solid level. The composition is then aseptically packaged to form an aseptically packaged

nutritional emulsion. This emulsion can then be further diluted, heat-treated, and packaged to form a ready-to-feed or concentrated liquid.

[0111] In another embodiment, the nutritional composition is a solid nutritional composition such as a nutritional powder. Any methods known in the nutritional art for preparing nutritional powders may be used herein. By way of example, the nutritional powders can be prepared by drying the heated, homogenized liquid nutritional composition described above, such as by spray drying.

### **Methods of Use**

[0112] The nutritional compositions as described herein comprise an intact pea protein component. By utilizing an intact pea protein component as the sole protein component in the nutritional composition, or as part of the protein component in the nutritional composition (i.e., the protein component includes intact pea protein plus one, two, three or more additional protein components), the resulting nutritional compositions exhibit one or more beneficial properties. For example, the nutritional compositions exhibit improved rheological and viscosity properties, especially when the nutritional composition are aseptically sterilized. Surprisingly, the nutritional compositions including the intact pea protein also have improved (i.e., smooth creamy mouthfeel) mouthfeel upon ingestion and improved texture as compared to nutritional compositions that do not utilize the intact pea protein.

[0113] The nutritional compositions of the present disclosure including the intact pea protein may be utilized in a number of different methods to produce a desired outcome. For example, the intact pea protein-containing nutritional compositions may be used in methods for stimulating protein synthesis and building muscle in an individual. The intact pea protein, which is an intermediate rate digestion protein, may be particularly beneficial in stimulating protein synthesis and muscle building. Additionally, the pea protein may be particularly beneficial in increasing nitrogen accretion in muscle and preventing protein degradation. These benefits may be useful for adults interested in building and/or maintaining muscle,

older adults (50 years old and older), individuals suffering from (or at risk of or susceptible to) muscle degeneration, and/or wasting disease (cachexia and the like).

[0114] Additionally, in other embodiments of the present disclosure, the intact pea protein-containing nutritional compositions may be used in methods for reducing glucose intolerance, improving glucose metabolism, and/of controlling/reducing/preventing diabetes. These benefits may be useful for adults that have glucose intolerance issues, are prediabetics, or diabetics (or individuals who are at risk of or susceptible to becoming diabetics due to obesity, family history, etc.)

[0115] To obtain any of these above-described benefits, the intact-pea protein-containing nutritional compositions may be utilized on a daily basis for a time period of at least one week, or at least two weeks, or at least three weeks, or at least one month, or at least two months, or at least three months, or at least six months, or at least one year, or continually.

## EXAMPLES

[0116] The following examples illustrate specific embodiments and or features of the nutritional compositions of the present disclosure. The examples are given solely for the purpose of illustration and are not to be construed as limitations of the present disclosure, as many variations thereof are possible without departing from the spirit and scope of the disclosure. All exemplified amounts are weight percentages based upon the total weight of the composition, unless otherwise specified.

[0117] The exemplified compositions are nutritional products prepared in accordance with manufacturing methods well known in the nutrition industry for preparing nutritional compositions.

**Example 1**

[0118] In this Example, nutritional compositions including intact pea protein concentrate and calcium HMB were analyzed for their hedonic properties. Further, the hedonic properties of the nutritional compositions including intact pea protein concentrate and calcium HMB were compared to protein-containing nutritional compositions without intact pea protein concentrate.

[0119] Two nutritional compositions including pea protein concentrate and calcium HMB were prepared according to the present disclosure and evaluated. The nutritional compositions are shown in the tables below:

**Table 1: Vanilla with pea protein concentrate and calcium HMB**

| <b>Ingredient Name</b>         | <b>Amount Kg/1000 Kg Product</b> |
|--------------------------------|----------------------------------|
| Water                          | QS                               |
| Milk Protein Concentrate       | 67.7                             |
| Intact Pea Protein Concentrate | 34.5                             |
| Corn Maltodextrin              | 20.1                             |
| Sunflower Oil                  | 9.6                              |
| Flavor                         | 5.7                              |
| Calcium HMB                    | 3.79                             |
| Potassium Citrate              | 2.5                              |
| Microcrystalline Cellulose     | 1.5                              |

| <b>Ingredient Name</b>  | <b>Amount Kg/1000 Kg Product</b> |
|-------------------------|----------------------------------|
| Monopotassium Phosphate | 1.38                             |
| Sodium Ascorbate        | 1.3                              |
| Potassium Hydroxide     | 1.08                             |
| Sodium Chloride         | 0.7                              |
| Vitamin/Mineral Premix  | 0.56                             |
| Synthetic Sweetener     | 0.5                              |
| Magnesium Carbonate     | 0.24                             |
| Gellan Gum              | 0.13                             |
| Carrageenan             | 0.13                             |

**Table 2: Chocolate with pea protein concentrate and calcium HMB**

| <b>Ingredient Name</b>         | <b>Amount Kg/1000 Kg Product</b> |
|--------------------------------|----------------------------------|
| Water                          | QS                               |
| Milk Protein Concentrate       | 64.00                            |
| Intact Pea Protein Concentrate | 35.00                            |
| Cocoa Powder                   | 15.00                            |
| Corn Maltodextrin              | 12.90                            |
| Sunflower Oil                  | 7.900                            |
| Calcium HMB                    | 3.790                            |
| Potassium Citrate              | 2.500                            |
| Microcrystalline Cellulose     | 1.500                            |
| Flavor                         | 3.250                            |
| Monopotassium Phosphate        | 1.380                            |
| Sodium Ascorbate               | 1.3000                           |
| Potassium Hydroxide            | 1.0800                           |
| Sodium Chloride                | 0.900                            |
| Vitamin/Mineral Premix         | 0.560                            |
| Synthetic Sweetener            | 0.5500                           |
| Gellan Gum                     | 0.1500                           |
| Magnesium Carbonate            | 0.1000                           |
| Carrageenan                    | 0.0800                           |

Two control (vanilla and chocolate) protein-containing nutritional compositions without intact pea protein were also evaluated in this Example.

[0120] A two-day hedonic test was conducted for all of the nutritional compositions. The first day, 103 subjects were asked to independently evaluate approximately four-ounce samples of each of the nutritional compositions, served at refrigerated temperature. The samples were then evaluated (9-point Hedonic scale: 1

= Dislike Extremely; 9 = Like Extremely) for aroma, color, flavor, sweetness, thickness, mouthfeel, aftertaste, and overall liking. The results are shown in the tables below.

**Table 3: Sip Serving Vanilla Hedonic Scoring**

| Diagnostic Mean Scores (N=103) |                               | Metric    | Vanilla Products    |                                        | p-value |
|--------------------------------|-------------------------------|-----------|---------------------|----------------------------------------|---------|
|                                |                               |           | Control Composition | Composition with pea protein and CaHMB |         |
| Attribute                      | Overall Liking                | Mean      | 5.5 b               | 6.5 a                                  | 0.0005  |
|                                | Purchase Intent (5-pt. Scale) | Mean      | 2.9 b               | 3.4 a                                  | 0.0037  |
|                                | Aroma Liking                  | Mean      | 5.4 b               | 6.1 a                                  | 0.0029  |
|                                | Color Liking                  | Mean      | 6.2 b               | 6.7 a                                  | 0.0057  |
|                                | Flavor Liking                 | Mean      | 5.1 b               | 6.4 a                                  | 0.0002  |
|                                | Sweetness Liking              | Mean      | 5.2 b               | 6.2 a                                  | 0.0029  |
|                                | Thickness Liking              | Mean      | 5.0 b               | 6.7 a                                  | 0.0000  |
|                                | Mouthfeel Liking              | Mean      | 5.1 b               | 6.2 a                                  | 0.0014  |
|                                | Aftertaste Liking             | Mean N=60 | 3.7 a               | 4.4 a                                  | 0.1242  |

\* A p-value of < 0.05 indicates that at least one product mean score is significantly different with 95% confidence. Means with the same letter are not significantly different at the 95% confidence level.

**Table 4: Sip Serving Chocolate Hedonic Scoring**

| Diagnostic Mean Scores (N=103) |                               | Metric | Chocolate Products  |                                        | p-value |
|--------------------------------|-------------------------------|--------|---------------------|----------------------------------------|---------|
|                                |                               |        | Control Composition | Composition with pea protein and CaHMB |         |
| Attribute                      | Overall Liking                | Mean   | 4.9 b               | 6.0 a                                  | 0.0001  |
|                                | Purchase Intent (5-pt. Scale) | Mean   | 2.5 b               | 3.3 a                                  | 0.0000  |

| Diagnostic Mean Scores (N=103) | Metric    | Chocolate Products  |                                        | p-value |
|--------------------------------|-----------|---------------------|----------------------------------------|---------|
|                                |           | Control Composition | Composition with pea protein and CaHMB |         |
| Aroma Liking                   | Mean      | 5.1 b               | 5.5 a                                  | 0.042   |
| Color Liking                   | Mean      | 7.0 a               | 7.1 a                                  | 0.2252  |
| Flavor Liking                  | Mean      | 4.3 b               | 6.0 a                                  | 0.0000  |
| Sweetness Liking               | Mean      | 4.6 b               | 5.9 a                                  | 0.0000  |
| Thickness Liking               | Mean      | 5.1 b               | 6.7 a                                  | 0.0000  |
| Mouthfeel Liking               | Mean      | 5.0 b               | 5.9 a                                  | 0.0027  |
| Aftertaste Liking              | Mean N=60 | 3.1 b               | 4.2 a                                  | 0.0297  |

\* A p-value of < 0.05 indicates that at least one product mean score is significantly different with 95% confidence. Means with the same letter are not significantly different at the 95% confidence level.

[0121] As shown in the tables, the Vanilla composition including intact pea protein concentrate out scored the Vanilla control (no intact pea protein concentrate) in all attributes with one exception, aftertaste. Further, while liking scores were only directionally higher for the Vanilla composition including intact pea protein concentrate, two-thirds of the subjects stated that both the control Vanilla and Vanilla composition including intact pea protein concentrate had an undesirable aftertaste. The Chocolate composition including intact pea protein concentrate out scored the Chocolate control in all attributes.

[0122] On the second day, the 103 subjects of the first day were then asked to independently evaluate approximately 17-ounce samples (considered a full serving) of each of the nutritional compositions including intact pea protein concentrate and calcium HMB, served at refrigerated temperature. While only 60% of the subjects consumed the entire 17-ounce serving, 75% of the subjects consumed at least 14 ounces of each sample. The samples were again evaluated (9-point Hedonic scale: 1 = Dislike Extremely; 5 = Neither Like or Dislike; 6 = Like Slightly; 7 = Like Slight to Moderately; 8 = Like Moderately; 9 = Like Extremely), after two-ounces were consumed of each sample and after the full serving for each sample was consumed,

for aroma, color, flavor, sweetness, thickness, mouthfeel, aftertaste, and overall liking. The results are shown in the table below.

**Table 5: Full Serving Vanilla & Chocolate Hedonic Scoring**

| Diagnostic Mean Scores<br>(N=103) |                                  | Metric | Full Drink<br>Compositions with pea protein and CaHMB |                  |
|-----------------------------------|----------------------------------|--------|-------------------------------------------------------|------------------|
|                                   |                                  |        | Vanilla (n=58)                                        | Chocolate (n=45) |
| Attribute                         | 2 oz Overall Liking              | Mean   | 7.2                                                   | 7.2              |
|                                   | Full Serving Overall Liking      | Mean   | 7.2                                                   | 7.2              |
|                                   | Purchase Intent<br>(5-pt. scale) | Mean   | 4.0                                                   | 4.2              |
|                                   | Aroma Liking                     | Mean   | 6.5                                                   | 6.6              |
|                                   | Color Liking                     | Mean   | 7.3                                                   | 7.5              |
|                                   | Flavor Liking                    | Mean   | 7.7                                                   | 7.4              |
|                                   | Sweetness Liking                 | Mean   | 7.2                                                   | 6.8              |
|                                   | Thickness Liking                 | Mean   | 7.1                                                   | 7.0              |
|                                   | Mouthfeel Liking                 | Mean   | 7.1                                                   | 6.8              |
|                                   | Aftertaste Liking                | Mean   | 5.5<br>N=30                                           | 5.6<br>N=26      |

[0123] As shown in the above table, the overall liking scores for both compositions were in the like moderately range. Furthermore, it was found that Vanilla and Chocolate consumption was similar.

### **Example 2**

[0124] Example 2 illustrates an aseptically processed liquid nutritional emulsion of the present disclosure, the ingredients of which are listed in the table below. All ingredient amounts are listed as kg per 1000 kg batch of product, unless otherwise specified.

| <b>Table 6</b>                 |                                               |
|--------------------------------|-----------------------------------------------|
| <u>INGREDIENTS</u>             | <u>APPROXIMATE<br/>AMOUNT PER 1000<br/>KG</u> |
| Ingredient water               | Q.S.                                          |
| Milk protein concentrate       | 67.3                                          |
| Intact Pea protein concentrate | 33.73                                         |
| Corn maltodextrin              | 24.1                                          |
| Potassium hydroxide            | 9.7                                           |
| High oleic sunflower oil       | 9.3                                           |

| <b>Table 6</b>                                                         |                                               |
|------------------------------------------------------------------------|-----------------------------------------------|
| <u>INGREDIENTS</u>                                                     | <u>APPROXIMATE<br/>AMOUNT PER 1000<br/>KG</u> |
| CA-HMB (Calcium $\beta$ -hydroxy- $\beta$ -methylbutyrate monohydrate) | 3.79                                          |
| Flavor                                                                 | 4.994                                         |
| Cocoa powder                                                           | 2.5                                           |
| Potassium citrate                                                      | 2.5                                           |
| Microcrystalline cellulose                                             | 1.5                                           |
| Monopotassium phosphate                                                | 1.38                                          |
| Sodium ascorbate                                                       | 1.3                                           |
| Sodium chloride                                                        | 0.7                                           |
| Vitamin/mineral premix                                                 | 0.56                                          |
| Synthetic Sweetener                                                    | 0.5                                           |
| Gellan gum                                                             | 0.15                                          |
| Magnesium carbonate                                                    | 0.103                                         |
| Carrageenan                                                            | 0.075                                         |

## WHAT IS CLAIMED IS:

1. A nutritional composition comprising a protein component in an amount of from about 0.5% to about 25% by weight, a carbohydrate component in an amount of from about 0.1% to about 50% by weight, and a fat component in an amount of from about 0.1% to about 25% by weight, wherein the protein component comprises from about 20% to about 40% by weight intact pea protein.
2. The nutritional composition of claim 1 wherein the protein component comprises from about 30% to about 40% by weight intact pea protein.
3. The nutritional composition of claim 1 wherein the protein component comprises from about 30% to about 35% by weight intact pea protein.
4. The nutritional composition of claim any one of claims 1-3 wherein the protein is a mixture of milk protein concentrate and intact pea protein.
5. The nutritional compositions of any one of claims 1-4 wherein the protein is a mixture of intact pea protein and soy protein isolate.
6. The nutritional compositions of any one of claims 1-5 wherein the protein is a mixture of intact pea protein and a hydrolyzed protein, wherein the hydrolyzed protein is selected from the group consisting of milk or soy hydrolyzed protein concentrates, milk or soy hydrolyzed protein isolates, and combinations thereof.
7. The nutritional composition of any one of claims 1-6 further comprising beta-hydroxy-beta-methylbutyrate in an amount of 0.38 to 0.71% by weight.
8. The nutritional composition of any one of claims 1-7 further comprising a functional amino acid.
9. The nutritional composition of claim 8 wherein the functional amino acid is selected from the group consisting of leucine, valine, isoleucine, and combinations thereof.

10. The nutritional composition of any one of claims 1-9 wherein the nutritional composition is selected from the group consisting of a powder, a solid, a semi-solid, a liquid, a semi-liquid, and combinations thereof.

11. The nutritional composition of any one of claims 1-10 wherein the nutritional composition is an aseptically manufactured composition.

12. The nutritional composition of any one of claims 1-11, wherein the nutritional composition further comprises at least one of the following:

- a. beta-alanine,
- b. at least one carotenoid,
- c. epigallocatechin gallate,
- d. a dried fruit extract, and
- e. curcumin or bioavailable curcumin.

13. A method for providing a nutritional composition with improved hedonic properties comprising

utilizing pea protein in a nutritional composition comprising from about 0.5% to about 25% by weight, a carbohydrate component in an amount of from about 0.1% to about 50% by weight, and a fat component in an amount of from about 0.1% to about 25% by weight,

wherein the protein component comprises from about 20% to about 40% by weight intact pea protein, and

the resulting nutritional composition has a overall liking of at least 6 on a 9-point hedonic scale.

14. A nutritional composition according to any one of claims 1-12 for use in the treatment of a disease.

15. A nutritional composition according to any one of claims 1-12 for use in the prevention and/or treatment of diabetes.

16. A nutritional composition according to any one of claims 1-12 for use in the prevention and/or treatment of impaired glucose tolerance (IGT).

17. A nutritional composition according to any one of claims 1-12 for use in the treatment of a disease associated with muscle degeneration and/or wasting disease.

18. The nutritional composition of claim 17 for use in the treatment of wasting disease, wherein the wasting disease is cachexia.

19. Non-therapeutical use of a nutritional composition according to any one of claims 1-12 for building and/or maintaining muscle in an individual.

20. The non-therapeutical use of a nutritional composition of claim 19 for building and/or maintaining muscle in an individual, wherein the individual is a human adult.

21. Non-therapeutical use of a nutritional composition according to any one of claims 1-12 for increasing nitrogen accretion in muscle, or for increasing protein synthesis and/or preventing protein degradation.

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2013/033880

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A23L1/305 A23L2/66 A23L1/29 A61K38/01 A61K38/16  
A61K38/17

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A23L A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data, CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                                                                                                                                  | Relevant to claim No.      |
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|           | -/--                                                                                                                                                                                                                                |                            |



Further documents are listed in the continuation of Box C.



See patent family annex.

\* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&amp;" document member of the same patent family

Date of the actual completion of the international search

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Name and mailing address of the ISA/

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Fischer, J

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2013/033880

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                                                      | Relevant to claim No.      |
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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2013/033880

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s)                                                                                                                                                                                                    | Publication<br>date                                                                                                                                                  |
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