LOW VISCOSITY, HIGH CALORIC DENSITY ORAL NUTRITIONAL COMPOSITION AND RELATED METHODS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to and any benefit of U.S. Provisional Application No. ~~entirety.~~ 61/738,785, filed December 18, 2012, the ~~entire~~ contents of which ~~are~~ is incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] Disclosed embodiments are in the field of nutritional compositions and more particularly in the field of nutritional compositions displaying high caloric density and low viscosity, and methods for making same.

BACKGROUND

[0003] Organoleptic characteristics such as mouthfeel play an important role in the selection of liquid nutritional compositions by consumers. Nutritional compositions having characteristics such as high protein content, high caloric density, or both may be desirable from a nutritional or medical standpoint, but often display high viscosity. Highly viscous nutritional compositions are often perceived as having an unpleasant mouthfeel and as generally undesirable, making the formulation of high caloric density liquid nutritional compositions in a fashion that is palatable to a wide variety of consumers very difficult.

SUMMARY

[0004] Provided herein are nutritional compositions that have a relatively low viscosity while having a high caloric density. Also provided are related methods for formulating the nutritional compositions. In certain embodiments, the nutritional compositions comprise non-micellar milk protein and lecithin. Additionally, the nutritional compositions provide at least 8 grams of protein per 100 mL of composition while achieving a low viscosity (*i.e.,* 45- 140 cps). In certain embodiments, the nutritional compositions have a high caloric density (*i.e.*, 2-3 kilocalories per mL).

[0005] In a first embodiment, a low viscosity, high caloric density liquid nutritional composition is provided. The nutritional composition comprises protein in amount of between 8 to 27 grams per 100 mL of the nutritional composition, fat in an amount of between 0 and 17 grams per 100 mL of the nutritional composition, and at least one emulsifier selected from the group consisting of: lecithin, monoglycerides, diglycerides, polyglycerol esters, milk phospholipids, citric acid esters, datem and emulsifiers with a ~~hydrophobic~~hydrophilic-lipophilic balance between 5 and 16. The protein comprises non-micellar milk protein isolate or non-micellar milk protein concentrate and a partially hydrolyzed caseinate. Additionally, the nutritional composition has a viscosity of between 45 and 140 cps, a caloric density of 200 to 300 kcal per 100 mL of the nutritional composition, and the total combined amount of fat and protein is 8-27 grams per 100 mL of the nutritional composition.

[0006] In a second embodiment, a low viscosity, high caloric density liquid nutritional composition is provided. The nutritional composition comprises protein in amount of between 8 to 27 grams per 100 mL of the nutritional composition; fat in an amount of between 0 and 17 grams per 100 mL of the nutritional composition; an anti-foaming agent; and a chelating agent selected from the group consisting of divalent citrates, divalent phosphates, and combinations thereof. The chelating agent is present in an amount of 0.3 weight % to 0.5 weight %. The nutritional composition has a viscosity of between 45 and 140 cps. The protein comprises (i) non-micellar milk protein isolate, non-micellar milk protein concentrate, or both and (ii) a

partially hydrolyzed caseinate. In addition, the total combined amount of fat and protein is 8-27 grams per 100 mL of the nutritional composition.

[0007] In a third embodiment, a method for the manufacture of a stable, low viscosity, high caloric density liquid nutritional composition is provided. The steps of this method of manufacture (as described herein) can also be useful for formulating liquid nutritional compositions according to the first and second embodiments disclosed herein. The method according to the third embodiment comprises the steps of combining fat and at least one emulsifier selected from the group consisting of lecithin, monoglycerides, diglycerides, polyglycerol esters, milk phospholipids, citric acid esters, datem and emulsifiers with a ~~hydrophobic~~hydrophilic-lipophilic balance between 5 and 16, to make a first mixture, and wherein the first mixture is free of water. Then, a portion of the first mixture (*i.e.*, 5 -20% by weight) is combined with water in a ratio of 1:110 to 1:20 to make a second mixture. Non-micellar milk protein and partially hydrolyzed caseinate are added to the second mixture to make a third mixture. The non-micellar milk protein is selected from the group consisting of non-micellar milk protein isolate, non-micellar milk protein concentrate, and combinations thereof. The third mixture is combined with the remainder of the first mixture to make a fourth mixture. The fourth mixture is then mixed with one or more of carbohydrates, vitamins and minerals to produce a liquid nutritional composition having a viscosity of 45-140 cps, 8 to 27 grams of protein per 100 mL, 0-17 grams of fat per 100 mL, and a total amount of protein and fat of 8-27 grams per 100 mL, as well as other additional constituents of the liquid nutritional composition, including, but not limited to flavorings, colorants, Ca-HMB, Lutein, EGCG, Plum Extract, Beta Alanine and others.

DETAILED DESCRIPTION

[0008] Provided herein are liquid nutritional compositions that have a relatively low viscosity while having a high caloric density. Also provided are methods for formulating the liquid nutritional compositions. In certain embodiments, the liquid nutritional compositions comprise non-micellar milk protein and lecithin. Additionally, the liquid nutritional compositions provide at least 8g of protein per 100 mL of composition while achieving a low viscosity (*i.e.*, 45-140

cps). In certain embodiments, the liquid nutritional compositions have a high caloric density (*i.e.*, 2-3 kilocalories per mL).

[0009] In a first embodiment, a low viscosity, high caloric density liquid nutritional composition is provided. The nutritional composition comprises protein in amount of between 8 to 27 grams per 100 mL of the nutritional composition, fat in an amount of between 0 and 17 grams per 100 mL of the nutritional composition, and at least one emulsifier selected from the group consisting of lecithin, monoglycerides, diglycerides, polyglycerol esters, milk phospholipids, citric acid esters, datem, emulsifiers with a ~~hydrophobic~~hydrophilic-lipophilic balance between 5 and 16, and combinations thereof. The protein comprises non-micellar milk protein isolate or non-micellar milk protein concentrate and a partially hydrolyzed caseinate. Additionally, the nutritional composition has a viscosity of between 45 and 140 cps, a caloric density of 200 to 300 kcal per 100 mL of the nutritional composition, and the total combined amount of fat and protein is 8-27 grams per 100 mL of the nutritional composition.

[00010] In a second embodiment, a low viscosity, high caloric density liquid nutritional composition is provided. The liquid nutritional composition comprises protein in amount of between 8 to 27 grams per 100 mL of the nutritional supplement; fat in an amount of between 0 and 17 grams per 100 mL of the liquid nutritional supplement; an anti-foaming agent; and a chelating agent selected from the group consisting of divalent citrates, divalent phosphates, and combinations thereof. The chelating agent is present in an amount of 0.3 weight % to 0.5 weight %. The nutritional composition has a viscosity of between 45 and 140 cps. The protein comprises (i) non-micellar milk protein isolate, non-micellar milk protein concentrate, or both, and (ii) a partially hydrolyzed caseinate. In addition, the total combined amount of fat and protein is 8-27 grams per 100 mL of the liquid nutritional composition.

[00011] In a third embodiment, a method for the manufacture of a stable, low viscosity, high caloric density liquid nutritional composition is provided. The steps of this method of manufacture (as described herein) can also be useful for formulating liquid nutritional compositions according to the first and second embodiments disclosed herein. The method according to the third embodiment comprises the steps of combining fat and at least one

emulsifier selected from the group consisting of lecithin, monoglycerides, diglycerides, polyglycerol esters, milk phospholipids, citric acid esters, datem, emulsifiers with a ~~hydrophobic~~hydrophilic-lipophilic balance between 5 and 16, and combinations thereof, to make a first mixture, and wherein the first mixture is free of water. Then, a portion of the first mixture (*i.e.,* 5 -20% by weight) is combined with water in a ratio of 1:20 to 1:110 to make a second mixture. Non-micellar milk protein and partially hydrolyzed caseinate are added to the second mixture to make a third mixture. The non-micellar milk protein is selected from the group consisting of non-micellar milk protein isolate, non-micellar milk protein concentrate, and combinations thereof. The third mixture is combined with the remainder of the first mixture to make a fourth mixture. The fourth mixture is then mixed with one or more of carbohydrates, vitamins and minerals to produce a liquid nutritional composition having a viscosity of 45-140 cps, 8 to 27 grams of protein per 100 mL, 0-17 grams of fat per 100 mL, and a total amount of protein and fat of 8-27 grams per 100 mL, as well as other additional constituents of the liquid nutritional composition, including, but not limited to flavorings, colorants, Ca-HMB, Lutein, EGCG, Plum Extract, Beta Alanine and others.

[00012] Disclosed embodiments provide liquid nutritional compositions with high caloric density and low viscosity. High caloric density as used herein refers to a calorie content that is at a level of 200-300 kcal per 100 mL of the nutritional composition. Low viscosity as used herein refers to a viscosity of 45-140 cps (at 22°C).

[00013] It should be understood that when discussing the liquid nutritional compositions and compositions herein, that the discussion is equally applicable to nutritional compositions that can be made according to the disclosed methods. In other words, in certain embodiments, the disclosed methods can be viewed as methods for preparing a nutritional composition according to the first embodiment disclosed herein or a nutritional composition according to the second embodiment disclosed herein. However, it should also be understood that the disclosed methods of the third embodiment can also be used to prepare nutritional compositions that vary in one or more ways from the nutritional compositions of the first and second embodiments.

cps including a viscosity of between 50 and 70 cps or in other embodiments a viscosity of between 50 and 65 cps. In certain embodiments, according to the first, second and third embodiments, the liquid nutritional compositions have a viscosity of between 90 and 125 cps.

[00017] As previously discussed, the liquid nutritional compositions according to the first, second and third embodiment include between 8 and 27 grams of protein per 100 mL of the liquid nutritional compositions, including between 8 and 12 grams of protein per 100 mL of the liquid nutritional compositions with the protein comprising (i) non-micellar milk protein isolate, non-micellar milk protein concentrate or combinations thereof, and (ii) partially hydrolyzed caseinate. The term non-micellar milk protein refers to milk protein which is no longer native protein; the term likewise refers to milk protein which has been denatured. While in its non-denatured state, proteins in milk naturally form micelles in an aqueous environment. Denaturing results in a breakdown of a portion of these naturally occurring protein micelles present in milk. The denaturing of the milk proteins can be achieved according to one or more treatments such as hydrolysis, heat treatment, reaction with soluble divalent minerals, and combinations thereof. In other embodiments, the denaturing of the milk proteins is achieved through homogenization by pressurization at 4000 psig.

[00018] The term milk protein concentrate is generally used to refer to a milk protein containing product that has had a considerable amount of the inherent water from ordinary milk removed and also has had inherent fat from the ordinary milk removed. The term milk protein isolate is generally used to refer to a type of milk-protein containing product that has not only had a considerable amount of the inherent water and inherent fat from ordinary milk removed ~~and inherent fat~~ but also a certain amount of inherent lactose removed. In most instances, milk protein isolates can be considered to be a type of further purified milk protein concentrate.

[00019] As used herein, the phrase milk protein isolate should be understood to mean a source of milk protein that comprises milk that has been concentrated (*i.e.*, to remove water and fat) and has also had a portion of its lactose content removed. Generally, commercially available milk protein isolates contain about 85-90 weight % protein (or more), about 2-5 weight % lactose, minimal fat (*i.e.*, 1-3%) and about 5-6 weight % water. As used herein, the phrase milk

protein concentrate should be understood to mean a source of milk protein that comprises milk that has had a considerable amount of water and a portion of the inherent fat removed. Generally, commercially available milk protein ~~isolates~~ concentrates contain about 40- to less than 85 weight % protein (sometimes less), minimal fat and about a somewhat higher amount of lactose than milk protein isolates. Certain manufacturers may use the term milk protein concentrate to refer to milk-based protein products even if they contain at least 85 weight % protein and such products should be considered to be within the scope of the term milk protein ~~isolate~~ concentrate as that term is used herein.

[00020] When non-micellar milk protein concentrate is utilized in the liquid nutritional compositions according to the first, second and third embodiments disclosed herein, the non-micellar milk protein concentrate may be provided by one or more sources. In certain embodiments according to the first, second and third embodiments disclosed herein, non-micellar milk protein concentrate comprises 0-90 weight % (*i.e.*, 0 to 90 weight %), including up to 80 weight % (*i.e.*, 0 to 80 weight %) including up to 75 weight % (*i.e.*, 0 to 75 weight %), including up to 50 weight % (*i.e.*, 0 to 50 weight %) of the total protein. Various commercial sources of non-micellar milk protein concentrate suitable for use in the liquid nutritional compositions according to the first, second and third embodiments are available from: Arla Foods Inc., USA 645 Martinsville Road, 3rd floor Basking Ridge, NJ 07920; FrieslandCampina DMV 1285 Rudy Street Onalaska, Wisconsin, 54650; Kerry Ingredients & Flavours 3330 Millington Road Beloit, WI 53511; and Fonterra USA Inc. Columbia Centre III, Ste. 700, 9525 W. Bryn Mawr Ave. Rosemont, IL 60018.

[00021] When non-micellar milk protein isolate is utilized in the liquid nutritional compositions according to the first, second and third embodiments disclosed herein, the non-micellar milk protein isolate may be provided by one or more sources. In certain embodiments according to the first, second and third embodiments disclosed herein, non-micellar milk protein isolate comprises 0-90 weight % (*i.e.*, 0 to 90 weight %), including up to 80 weight % (*i.e.*, 0 to 80 weight %) including up to 75 weight % (*i.e.*, 0 to 75 weight %), including up to 50 weight % (*i.e.*, 0 to 50 weight %) of the total protein. Various commercial sources of non-micellar milk protein isolate suitable for use in the liquid nutritional compositions according to the first, second

and third embodiments are available from, Arla Foods Inc., USA 645 Martinsville Road, 3rd floor Basking Ridge, NJ 07920; FrieslandCampina DMV 1285 Rudy Street Onalaska, Wisconsin, 54650; Kerry Ingredients & Flavours 3330 Millington Road Beloit, WI 53511; and Fonterra USA Inc. Columbia Centre III, Ste. 700, 9525 W. Bryn Mawr Ave. Rosemont, IL 60018.

[00022] In certain embodiments according to the first, second and third embodiments disclosed herein, the non-micellar milk protein component comprises a combination of non-micellar milk protein concentrate and non-micellar milk protein isolate. Various relative amounts of each may be utilized ranging from 0-100% of each, including amounts such as 50/50 isolate/concentrate, 25/75 isolate/concentrate, 75/25 isolate/concentrate, 40/60 isolate/concentrate and 60/40 isolate/concentrate, all based upon the total amount of non-micellar milk protein. Additionally, in certain other embodiments, according to the first, second and third embodiments the protein comprises some amount of micellar milk protein. The micellar milk protein is present in an amount in accordance with the amounts of nonmicellar milk protein and hydrolyzed casein. Further, when present in the disclosed embodiments, micellar milk protein is a minor component (*i.e.*, less than 25% by weight of protein).

[00023] As previously discussed, according to the first, second and third embodiments, the protein of the liquid nutritional compositions includes a partially hydrolyzed caseinate. As used herein, the term "partially hydrolyzed caseinate" refers to a caseinate in which a portion of the protein has been hydrolyzed. (*e.g.*, 0.5 to 10% hydrolyzed, 0.5 to 20%, 0.5 to 30%, 0.5 to 40%, 0.5 to 50%, 0.5 to 60%, 0.5 to 70%, 0.5 to 80%, and 0.5 to 90% hydrolyzed). Another way of referring to the extent of hydrolyzation in a partially hydrolyzed caseinate is by Degree of Hydrolzyzation (DH). A DH value of, for example, 30 refers to casein in which 30% of the total casein is hydrolyzed casein. When used in the disclosed liquid nutritional compositions, the partially hydrolyzed caseinate comprises 10-60 weight % (*i.e.*, 10 to 60 weight %), including 10 to 50 weight %; including 10 to 40 weight %, including 10 to 30 weight %, including 20 to 25 weight % of the total protein. When present in the disclosed embodiments, the partially hydrolyzed caseinate may include sodium caseinate, potassium caseinate, magnesium caseinate, calcium caseinate and combinations thereof. Further, the partially hydrolyzed caseinates useful

and di glycerides, milk phospholipids, polyglycerol esters, citric acid esters and combinations thereof.

[00032] As previously mentioned, according to the first and second and in certain embodiments of the third embodiment, in the liquid nutritional compositions the sum of the total amount of protein added to the total amount of fat equals 8-27 grams per 100 mL. For example, if the amount of protein in the nutritional composition is 16 grams per 100 mL, then the corresponding amount of fat must be no more than 11 grams per 100 mL (*i.e.*, 0-11 g/100mL).

[00033] Lecithin is the popular and commercial name for a naturally occurring mixture of phosphatides (also called phospholipids or phosphoglycerides), which varies in color from light tan to dark reddish brown and in consistency from a fluid to a plastic solid. Lecithin is the gummy material contained in crude vegetable oils and is generally removed from the oils by degumming. Soybeans are currently the most important source of commercial lecithin and lecithin is the most important by-product of the soy oil processing industry because of its many applications in foods and industrial products, but it should be understood that the present disclosure encompasses the use of lecithins other than soy-sourced lecithin. The three main phosphatides in the complex mixture ~~called~~ sold commercially as soy lecithin are phosphatidyl choline, phosphatidyl ethanolamine (popularly called "cephalin"), and phosphatidyl inositols (also called inositol phosphatides). Commercial sources of soy lecithin also typically contain roughly 30-35% unrefined soy oil.

[00034] Soy lecithin can be classified into three broad types: unrefined or natural, refined, and chemically modified. Unrefined or natural lecithin comes in six basic varieties, long defined by specifications of the National Soybean Processors Association: plastic or fluid, each either unbleached, bleached, or double bleached. (Because fluid lecithins are easier to handle and dissolve more rapidly in various solvents, only small amounts of plastic grades are now produced.) Refined lecithin (which has had the oil removed using acetone) comes in three basic varieties: custom blended natural, oil free phosphatides (as is or custom blended), and alcohol-fractionated oil-free phosphatides (as is or custom blended). These latter special refined grades, which may contain 60-99.7% phosphatidyl choline, are used mostly for pharmaceutical

applications and research. Chemically modified lecithin products, altered through selective chemical treatment, improve lecithin's compatibility to certain systems.

[00035] As previously discussed, in certain embodiments according to the first and third embodiments, the liquid nutritional compositions include lecithin. When present, the lecithin may be provided by a single source or by more than one source. In certain embodiments according to the first and third embodiments, lecithin is present in an amount based on the amount of fat per 100 mL of nutritional composition, accordingly, lecithin is present in an amount of between 0.5 and 5% of the fat present in the liquid nutritional composition, including from 0.5 to 2 % based on weight of fat in the nutritional composition. In certain embodiments the amount of lecithin utilized within the liquid nutritional composition can also be based upon the relative amount of fat contained within the liquid nutritional composition, according to the foregoing amounts. Commercial sources of lecithin are available including soy lecithin and sunflower lecithin among others, non-limiting examples include: Natural unbleached lecithin supplied by Solae and acetylated lecithin from ADM Corporation.

[00036] In certain other embodiments according to the first and third embodiments, lecithin may be replaced with another emulsifying agent. Emulsifying agents useful in the disclosed embodiments include mono and diglycerides, polyglycerol esters, milk phospholipids, citric acid esters, and datem. Moreover, other emulsifiers useful with the disclosed embodiments will be those emulsifiers with a hydrophilic–lipophilic balance (HLB) of between 5 and 16, including but not limited to certain lecithins.

[00037] As previously discussed, according to the second embodiment, the liquid nutritional compositions comprise an anti-foaming agent. In certain embodiments according to the first and third embodiments disclosed herein, the liquid nutritional compositions optionally contain an anti-foaming agent. Non-limiting examples of anti-foaming agents useful for the liquid nutritional compositions disclosed herein include: simethicone, lecithin, milk phospholipid, dimethylpolysiloxane and fumed silicone dioxide. The anti-foaming agent may be present in an amount of between 0.6 and 6% by weight of the nutritional composition.

[00038] In certain embodiments according to the second embodiment, the nutritional composition further comprises a chelating agent. Examples of chelating agents useful with the nutritional compositions disclosed herein include monovalent chelating agents and divalent chelating agents. Non-limiting examples of monovalent chelating agents useful with the nutritional compositions disclosed herein include: sodium citrate, potassium citrate, potassium phosphate, sodium phosphate and combinations thereof. In other embodiments disclosed herein, the chelating agents include divalent chelating agents such as divalent citrates and divalent phosphates. More particularly, the divalent citrate may be calcium citrate, magnesium citrate, tri magnesium dicitrate or combinations thereof; and the divalent phosphate may be magnesium phosphate, calcium phosphate, mono-calcium phosphate, di-calcium phosphate, disodium hydrogen phosphate, dipotassium hydrogen phosphate and combinations thereof. When present in the nutritional compositions, the chelating agents are generally present in an amount of 0.3 weight % - 0.5 weight % based on the total weight of the nutritional composition.

[00039] The liquid nutritional compositions according to the first, second and third embodiments disclosed herein can have widely varying calorie contents. One way to express the calorie content of a liquid nutritional composition is on a kilocalorie per serving basis. Generally, the liquid nutritional compositions according to the first, second and third embodiments disclosed herein have an amount of calories of 200-1000 kilocalories per 3 to 5 ounce serving. In certain embodiments according to the first, second and third embodiments disclosed herein, the liquid nutritional compositions have a calorie content of 200-750 kilocalorie (kcal) per serving, including 200-450 kcal per serving, including 240-350 kcal per serving.

[00040] In certain embodiments according to the first, second and third embodiments disclosed herein, the liquid nutritional compositions contain other ingredients, non-limiting examples of which include preservatives, antioxidants, emulsifying agents, buffers, pharmaceutical actives, additional nutrients, colorants, flavors, thickening agents and stabilizers. In certain embodiments, stabilizers ~~present in the disclose embodiments~~ include: octenyl succinic anhydride, gellan gum, alginate, pectin, guar gum, locust bean gum, konjack, carboxymethyl cellulose and microcrystalline cellulose and combinations thereof. Those of skill in the art will

agents to reduce or otherwise obscure the development of any residual bitter flavors and after taste in the emulsions over time. Suitable masking agents include natural and artificial sweeteners, sodium sources such as sodium chloride, and hydrocolloids, such as guar gum, xanthan gum, carrageenan, and combinations thereof. The amount of masking agent in the nutritional emulsion may vary depending upon the particular masking agent selected, other ingredients in the formulation, and other formulation or product target variables. Such amounts, however, most typically range from 0.1% to 3 %, including from 0.15% to 3 %, and also including from 0.18% to 2.5%, by weight of the nutritional emulsion.

[00046] As previously mentioned, methods for the production of a stable, low viscosity, high caloric density liquid nutritional composition are provided. The steps of this method of manufacture (as described herein) can also be useful for formulating liquid nutritional compositions according to the first and second embodiments disclosed herein. The method of the third embodiment comprises the formulation of a series of mixtures which are then combined in certain amounts in order to achieve the low viscosity, high caloric density liquid nutritional compositions described herein. The method comprises combining fat and at least one emulsifier selected from the group consisting of lecithin, monoglycerides, diglycerides, polyglycerol esters, milk phospholipids, citric acid esters, datem and emulsifiers with a ~~hydrophobic~~hydrophilic-lipophilic balance between 5 and 16, to make a first mixture, where the lecithin is present in an amount of 0.5 to 4 weight %, based on the total amount of fat, and the first mixture is free of water. A portion (*i.e.,* 5 to 20% by weight of the first mixture) of this first mixture is then combined with water in a ratio of 1:20 to 1:110 to make a second mixture; including 5-10% by weight of the first mixture which is combined with water in ratio of 1:110 to 1:55. Once the second mixture is formed, the desired amounts of non-micellar milk protein and partially hydrolyzed caseinate are combined with the second mixture to make a third mixture. The non-micellar milk protein is selected from the group consisting of non-micellar milk protein isolate, non-micellar milk protein concentrate, and combinations thereof and is selected commensurate with the discussion provided above. Likewise, the partially hydrolyzed caseinate is selected according to the relevant discussion provided above. The third mixture is then combined with the remainder of the first mixture to make a fourth mixture. The fourth mixture is then mixed with any additional ingredient to produce a liquid nutritional composition having a viscosity of 45-140 cps (and in

certain embodiments, a viscosity of 90-125 cps), 8 to 27 grams of protein per 100 mL, 0 to 17 grams of fat per 100 mL and a total amount of protein and fat of 8-27 grams per 100 mL.

[00047] The viscosity values provided herein are measured at 22.5 °C ± 0.5°C, using a Brookfield Model LV Series (Model DV-II) Viscometer, with a #1 spindle installed, operated at 60 rpm (to create a shear rate of about 13 sec-1), utilizing AR&S Method 11.01. The Brookfield Viscometer is a rotational viscometer. It measures the torque required to rotate an immersed spindle (geometry) in a fluid. The spindle is driven by a motor through a calibrated spring; deflection of the spring is indicated by a pointer and dial or a digital display. The viscous drag of the fluid against the spindle is measured by the spring deflection. The measurement range is determined by the rotational speed of the spindle, the size and shape of the spindle, the container the spindle is rotating within and the full scale torque of the calibrated spring. As those skilled in the art will appreciate, while viscosities can be measured under other conditions and according to different methods, modification of one or more test conditions may result in a different viscosity number.

Examples

[00048] The following examples illustrate specific and exemplary embodiments and features of the liquid nutritional compositions disclosed herein. The examples are provided solely for the purposes of illustration and should not be construed as limitations of the present disclosure. Numerous variations over these specific examples are possible without departing from the spirit and scope of the presently disclosed liquid nutritional compositions.

[00049] **Example 1**: The table below shows compositional data for a series of liquid nutritional compositions formulated according to embodiments of liquid nutritional compositions described herein. Further, the table shows measured viscosity data for the compositions. The viscosity was measured at room temperature (*i.e.* approximately 22.5 °C) with a Brookfield LV series viscometer with agitation for 10 sec. prior to measurement at 60 rpm.

Vitamin D, mcg	3.20	4.00
Vitamin E, mg	3.36	4.20
Vitamin K, mcg	19.19	23.99
Thiamin, mg	0.32	0.40
Riboflavin, mg	0.43	0.54
Niacin, mg	4.16	5.20
Pantothenic Acid, mg	1.76	2.20
Vitamin B6, mg	0.43	0.54
Folic Acid, mcg	63.97	79.96
Vitamin B12, mcg	0.88	1.10
Biotin, mcg	9.59	11.99
Vitamin C, mg	19.19	23.99
Choline, mg	87.95	109.94
L-Carnitine,mg	---	---
Taurine, mg	---	---
Viscosity, cps	70 cP	

[00054] While the discussion above refers to the nutritional compositions in liquid form, one of skill in the art will recognize that the nutritional compositions may be prepared as reconstitutable powder and still fall within the disclosed embodiments according to the first, second and third embodiments. A nutritional solid, such as a spray dried nutritional powder or drymixed nutritional powder, may be prepared by any collection of known or otherwise effective technique, suitable for making and formulating a nutritional powder.

[00055] For example, when the nutritional powder is a spray dried nutritional powder, the spray drying step may likewise include any spray drying technique that is known for or otherwise suitable for use in the production of nutritional powders. Many different spray drying methods and techniques are known for use in the nutrition field, all of which are suitable for use in the manufacture of the spray dried nutritional powders herein.

[00056] One method of preparing the spray dried nutritional powder comprises forming and homogenizing an aqueous slurry or liquid comprising predigested fat, and optionally protein, carbohydrate, and other sources of fat, and then spray drying the slurry or liquid to produce a spray dried nutritional powder. The method may further comprise the step of spray drying, drymixing, or otherwise adding additional nutritional ingredients, including any one or more of the ingredients described herein, to the spray dried nutritional powder.

[00057] In certain embodiments according to the first, second and third embodiments disclosed herein, the liquid nutritional compositions, may potentially provide either a primary source or a supplemental source of nutrition to an individual. In this context, a sole source of nutrition is one that can be administered once or multiple times each day to potentially provide an individual with all or substantially all their fat, protein, carbohydrate, mineral, and vitamin needs per day or during the intended period of administration. A supplemental source of nutrition is defined herein as a dietary source that does not provide an individual with a potentially sole source of nutrition.

[00058] To the extent that the term "includes" or "including" is used in the specification or the claims, it is intended to be inclusive in a manner similar to the term "comprising" as that term is interpreted when employed as a transitional word in a claim. Furthermore, to the extent that the term "or" is employed (*e.g.*, A or B) it is intended to mean "A or B or both." When the applicants intend to indicate "only A or B but not both" then the term "only A or B but not both" will be employed. Thus, use of the term "or" herein is the inclusive, and not the exclusive use. *See* Bryan A. Garner, *A Dictionary of Modern Legal Usage* 624 (2d. Ed. 1995). Also, to the extent that the terms "in" or "into" are used in the specification or the claims, it is intended to additionally mean "on" or "onto." Furthermore, to the extent the term "connect" is used in the specification or claims, it is intended to mean not only "directly connected to," but also "indirectly connected to" such as connected through another component or components.

[00059] While the present application has been illustrated by the description of embodiments thereof, and while the embodiments have been described in considerable detail, it is not the intention of the applicants to restrict or in any way limit the scope of the appended

CLAIMS

What is claimed is:

Claim 1. A low viscosity, high caloric density liquid nutritional composition comprising:

a) protein in an amount of between 8 to 27 grams per 100 mL of the nutritional composition, the protein comprising (i) non-micellar milk protein isolate, non-micellar milk protein concentrate, or both, and (ii) a partially hydrolyzed caseinate;

b) fat in an amount of between 0 and 17 grams per 100 mL of the nutritional composition; and

c) at least one emulsifier selected from the group consisting of lecithin, monoglycerides, diglycerides, polyglycerol esters, milk phospholipids, citric acid esters, datem and emulsifiers with a ~~hydrophobic~~hydrophilic-lipophilic balance between 5 and 16, and combinations thereof;

wherein the nutritional composition has a viscosity of between 45 and 140 cps, a caloric density of 200 to 300 kcal per 100 mL of the nutritional composition, and wherein the total combined amount of fat and protein is 8-27 grams per 100 mL of the nutritional composition.

Claim 2. The low viscosity, high caloric density liquid nutritional composition of claim 1, wherein the composition has a caloric density of 200 to 240 kcal per 100 mL of the nutritional composition.

Claim 3. A low viscosity, high caloric density liquid nutritional composition according to claim 1, wherein the protein comprises 0-25% by weight of protein from a partially hydrolyzed caseinate; 25-50% by weight of protein selected from the group consisting of whey protein, soy protein, pea protein potato protein and combinations thereof; and 50 to 75% by weight of non-micellar milk protein isolate, non-micellar milk protein concentrate or a combination thereof.

Claim 4. A low viscosity, high caloric density liquid nutritional composition according to claim 1, wherein the non-micellar protein is denatured through one or more of hydrolysis, heat treatment, homogenization, or reaction with soluble divalent minerals.

Claim 5. A low viscosity, high caloric density liquid nutritional composition according to any one of claims 1-4, wherein the emulsifier is lecithin and the lecithin is present in an amount of between 0.5 and 5% by weight based on the total amount of fat in the nutritional composition.

Claim 6. A low viscosity, high caloric density liquid nutritional composition according to claim 5, wherein the lecithin is selected from the group consisting of soy lecithin, sunflower lecithin, milk phospholipid, or combinations thereof.

Claim 7. A low viscosity, high caloric density liquid nutritional composition according to claim 5, wherein the soy lecithin or sunflower lecithin is natural, refined or chemically modified.

Claim 8. A low viscosity, high caloric density liquid nutritional composition according to any one of claims 1-4 further comprising a stabilizer selected from the group consisting of octenyl succinic anhydride, gellan gum, alginate, pectin, guar gum, locust bean gum, konjack, carboxymethyl cellulose, microcrystalline cellulose, and combinations thereof.

Claim 9. A low viscosity, high caloric density liquid nutritional composition comprising:

a) protein in amount of between 8 to 27 grams per 100 mL of the nutritional composition;

b) fat in an amount of between 0 and 17 grams per 100 mL of the nutritional supplement;

c) an anti-foaming agent ~~selected from the group consisting of simethicone, dimethylpolysiloxane, silicone dioxide, lecithin, milk phospholipid, and combinations thereof~~; and

~~e~~d) a chelating agent ~~selected from the group consisting of monovalent chelating agents, divalent chelating agents, and combinations thereof;~~ in an amount of 0.3 weight % to 0.5 weight %;

wherein the nutritional composition has a viscosity of between 45 and 140 cps; wherein the protein comprises (i) non-micellar milk protein isolate or non-micellar milk protein concentrate and (ii) a hydrolyzed caseinate; wherein the composition has a caloric density of 200 to 300 kcal per 100

mL of the nutritional supplement; and wherein the total combined amount of fat and protein is 8-27 grams per 100 mL of the nutritional composition.

Claim 10. A low viscosity, high caloric density liquid nutritional composition according to claim 9, wherein the chelating agent is selected from the group consisting of calcium citrate, magnesium citrate, magnesium phosphate, calcium phosphate, monocalcium phosphate, and combinations thereof.

Claim 11. A low viscosity, high caloric density liquid nutritional composition according to claim 9 or 10 wherein the anti-foaming agent is selected from the group consisting of simethicone, dimethylpolysiloxane, silicone dioxide, lecithin, milk phospholipid, and combinations thereof.

Claim 12. A low viscosity, high caloric density liquid nutritional composition according to claim 9 or 10, where the protein comprises: 50-75% by weight of non-micellar milk protein isolate, non-micellar milk protein concentrate or a combination thereof; and

0 – 50% by weight of partially hydrolyzed caseinate; or

0-25% by weight of partially hydrolyzed caseinate~~;~~ and 0-25% by weight of at least one protein selected from the group consisting of: micellar milk protein, non-hydrolyzed caseinate, soy, pea, whey, rice, corn, meat, fish, egg albumen, potato, canola, algal protein, mycoprotein and combinations thereof.

Claim 13. A low viscosity, high caloric density liquid nutritional composition according to claim 12, wherein the non-micellar protein is denatured through one or more of: hydrolysis, heat treatment, homogenization, or reaction with soluble divalent minerals.

Claim 14. A low viscosity, high caloric density liquid nutritional composition according to any one of claims 9-13 , wherein the anti-foaming agent is present in an amount ~~of~~ between 0.6 and 6% by weight ~~based on the total amount of fat in~~ of the nutritional composition.

Claim 15. A low viscosity, high caloric density liquid nutritional composition according to any one of claims 9-13 where the anti-foaming agent is simethicone, dimethylpolysiloxane or

silicone dioxide and the anti-foaming agent is present in an amount ~~of~~ between 0.6 and 6 % by weight of the nutritional composition.

Claim 16. A low viscosity, high caloric density liquid nutritional composition according to claim 9, wherein the chelating agent is selected from the group consisting of divalent citrates, and divalent phosphates.

Claim 17. A low viscosity, high caloric density liquid nutritional composition according to claim 9, wherein the chelating agent is selected from the group consisting of monovalent chelating agents, divalent chelating agents, and combinations thereof.

Claim 18. A method for the manufacture of a stable, low viscosity, high caloric density liquid nutritional composition comprising:

a) combining fat and at least one emulsifier selected from the group consisting of lecithin, monoglycerides, diglycerides, polyglycerol esters, milk phospholipids, citric acid esters, datem, emulsifiers with a ~~hydrophobic~~hydrophilic-lipophilic balance between 5 and 16, and combinations thereof to make a first mixture, wherein the first mixture is free of water;

b) combining 5-20% by weight of the first mixture with water in a ratio of 1:110 to 1:20 to make a second mixture;

c) adding protein comprising non-micellar milk protein and partially hydrolyzed caseinate to the second mixture to make a third mixture, wherein the non-micellar milk protein is selected from the group consisting of non-micellar milk protein isolate, non-micellar milk protein concentrate, and combinations thereof; and

d) combining the third mixture with the remainder of the first mixture to make a fourth mixture,

wherein the fourth mixture is mixed with one or more carbohydrates, vitamins and minerals to produce a liquid nutritional composition having a viscosity of 45-140 cps, 8 to 27 grams of protein per 100 mL, 0 to 17 grams of fat per 100 mL, and a total amount of protein and fat of 8-27 grams per 100 mL.

Claim 19. A method according to claim 18 wherein the partially hydrolyzed caseinate is selected from the group consisting of sodium caseinate, potassium caseinate, magnesium caseinate, calcium caseinate, and combinations thereof.

Claim 20. A method according to claim 18, wherein the protein comprises 50-75% nonmicellar milk protein; and

0 – 50% by weight of partially hydrolyzed caseinate; or

0-25% by weight of partially hydrolyzed caseinate; and 0-25% by weight of at least one protein selected from the group consisting of: micellar milk protein, non-hydrolyzed caseinate, soy, pea, whey, rice, corn, meat, fish, egg albumen, potato, canola, algal protein, mycoprotein and combinations thereof.

Claim 21. A method according to any one of claims 18-20, wherein the emulsifier is lecithin and the lecithin is present in an amount of 0.5 to 5 weight %, based on the total ~~amount~~ weight of fat

Claim 22. A method according to any one of claims 18-20, wherein the nonmicellar protein is denatured through one or more of: hydrolysis, heat treatment, homogenization, or reaction with soluble divalent minerals, and combinations thereof.

Claim 23. A method according to any one of claims 18-20, wherein the emulsifier is lecithin and the lecithin is added to the first mixture in an amount of from 0.5 to 2% by weight based on the total weight of fat.

Claim 24. The method according to any one of claims 18-20, wherein the final mixture has a viscosity of between 45 and 125 cps.

Claim 25. The method according to any one of claims 18-20, wherein the final mixture has a protein content of between 8 and 17 g per 100mL of the final mixture.