

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
4 August 2011 (04.08.2011)

PCT

(10) International Publication Number  
**WO 2011/094548 A1**

(51) International Patent Classification:

A23L 1/29 (2006.01) B65B 55/12 (2006.01)  
A23L 1/30 (2006.01) B65D 81/34 (2006.01)  
A23L 3/00 (2006.01) B67C 7/00 (2006.01)  
B65B 55/00 (2006.01)

(21) International Application Number:

PCT/US2011/022932

(22) International Filing Date:

28 January 2011 (28.01.2011)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/299,611 29 January 2010 (29.01.2010) US

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(81) Designated States (unless otherwise indicated, for every

kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every

kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))



WO 2011/094548 A1

(54) Title: ASEPTICALLY PACKAGED NUTRITIONAL LIQUIDS COMPRISING HMB

(57) Abstract: Disclosed are nutritional compositions comprising a peroxide-treated aseptic package and a nutritional liquid contained therein, wherein the nutritional liquid comprises beta-hydroxy-beta-methylbutyrate (HMB) and at least one of fat, carbohydrate, and protein. The HMB provides a buffering effect in the nutritional liquid to thus minimize an acidic pH shift that is prevalent in aseptically sterilized packages, and thus helps maintain product stability over time.

**ASEPTICALLY PACKAGED NUTRITIONAL  
LIQUIDS COMPRISING HMB**

**FIELD OF THE DISCLOSURE**

[0001] The present disclosure relates to aseptically packaged nutritional liquids comprising beta-hydroxy-beta-methylbutyrate (HMB).

**BACKGROUND OF THE DISCLOSURE**

[0002] There are many different types of packaged nutritional liquids suitable for oral administration to humans, which compositions typically comprise various combinations of macro and micro nutrients. Many of these packaged liquids are formulated as milk or protein-based emulsions for use as sole or supplemental sources of nutrition. These packaged emulsions are often manufactured as oil-in-water emulsions comprising fat, protein, carbohydrate, vitamins, and minerals, some examples of which include ENSURE® Nutritional Liquid and GLUCERNA® Shakes available from Abbott Laboratories, Columbus, Ohio USA.

[0003] During the manufacturing process, these packaged nutritional compositions are sterilized to reduce microbial contaminants to the extent necessary to render the compositions suitable for oral administration to humans. These processes often include thermal processes such as retort sterilization and aseptic process sterilization. A typical retort process involves introducing the nutritional composition into a suitable container, sealing the container, and then heating the sealed container and its contents for a time period and at temperature sufficient for sterilization. An aseptic sterilization process on the other hand typically involves separately sterilizing the interior of a food grade container and a nutritional composition and then combining the sterilized container and the sterilized nutritional composition in a clean room environment and sealing the container.

[0004] Aseptic sterilization processes for sterilizing nutritional compositions have grown in popularity over the years. By using such processes, nutritional products do not

have to be heated to a temperature as high as that required for retort sterilization. These lower temperatures are generally preferred as they result in a decreased amount of product oxidation as compared to higher temperatures. Additionally, aseptic sterilization of plastic containers is generally preferred over retort sterilization of plastic containers as retort sterilization requires high temperature heating of the plastic container which can result in failure of the plastic container during sterilization.

[0005] Although aseptic sterilization has grown in popularity and has several advantages over retort sterilization, aseptic sterilization does require that the interior of the container be sterilized prior to the introduction of the sterilized nutritional composition. This interior sterilization is often performed by introducing a peroxide-containing solution, such as a hydrogen peroxide solution, typically in atomized form, into at least the interior of the container and drying the solution to produce a sterilized surface. Irrespective of the drying process employed, peroxide residue remains on the interior surface of the container. This residue can be problematic in some applications as it can, over time, migrate into the nutritional composition and cause a reduction in pH of the nutritional composition subsequently introduced into the peroxide-treated container.

[0006] The reduction in pH of the nutritional liquid over time due to oxidation can have numerous detrimental effects on the nutritional liquid inside the package including: (1) increasing the release of bound minerals, which in ionic form can compromise stability of the nutritional liquid due to precipitation; (2) increasing the amount of catalytic oxidation, particularly of iron and copper species; (3) increasing the amount of protein precipitation; and (4) increasing vitamin C destabilization. Any one of these unwanted effects can significantly reduce the commercial acceptability of the nutritional liquid.

[0007] There is therefore a need for stable nutritional compositions, such as stable protein or milk-based liquids or emulsions, that can be introduced into peroxide-treated aseptically sterilized containers and that are stable and resistant to a reduction in pH over time.

### SUMMARY OF THE DISCLOSURE

[0008] The present disclosure is directed to a composition comprising a peroxide-treated aseptic package and a nutritional liquid contained or hermetically sealed therein, the nutritional liquid comprising beta-hydroxy-beta-methylbutyrate and at least one of fat, carbohydrate, and protein. The peroxide-treated package as referred to herein may be a package that has been subjected to peroxide-based aseptic treatment, or merely a package that otherwise contains a peroxide residue prior to, during, and or after combination with a nutritional liquid, regardless of the process or circumstance by which such peroxide materials were introduced to the package.

[0009] Peroxide residues when used to characterize the package component may range up to an acceptable amount or level that is suitable for use in a nutritional product in the country or region within which the product is sold. Such peroxide levels are most typically less than 0.5 ppm, including from about 0.001 to about 0.5 ppm, and also including from about 0.05 to about 0.1 ppm, by weight of nutritional liquid combined with or contained within the package.

[0010] The present disclosure is further directed to a method of preparing a pH-stable nutritional liquid in a peroxide-treated aseptic package. The method comprises combining a fat, protein, carbohydrate and beta-hydroxy-beta-methylbutyrate together to form a nutritional liquid, sterilizing the nutritional liquid, sterilizing aseptically a package by treating at least the interior of the package with a peroxide-containing solution, and introducing the sterilized nutritional liquid into the aseptically sterilized package.

[0011] It has been discovered that the addition of beta-hydroxy-beta-methylbutyrate (HMB) into nutritional liquids, such as nutritional emulsions, imparts a buffering effect to the nutritional liquid such that the nutritional liquid is more resistant to pH change upon a shift in hydrogen ion concentration. This unexpected effect is advantageous in that HMB is a desirable additive to nutritional compositions and, based on the discovery now made, can now be added to nutritional liquids so that the nutritional liquids can be packaged in containers that have been aseptically sterilized utilizing a peroxide-containing solution so that the resulting nutritional liquid is more pH-stable due to

the buffering effect of the HMB present in the solution. Because nutritional liquids introduced into containers aseptically sterilized utilizing a peroxide-containing solution are by nature more subject to a shift in pH over time as discussed above, the unexpected discovery of the buffering effect of HMB in a nutritional liquid is particularly useful for nutritional liquids that are introduced into containers that have been aseptically sterilized utilizing a peroxide-containing solution.

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

[0012] The packaged nutritional compositions of the present disclosure may comprise HMB and at least one of fat, protein, and carbohydrate, and may also include one or more optional or other components, features, or ingredients. The essential features of the nutritional liquids, as well as some of the many optional variations, are described in detail hereafter.

[0013] The term "HMB" as used herein, unless otherwise specified, refers to beta-hydroxy-beta-methylbutyrate (also referred to as beta-hydroxyl-3-methyl butyric acid, beta-hydroxy isovaleric acid) or a source thereof such as a calcium salt of HMB. When the source of HMB is calcium HMB, this particular source is most typically a monohydrate so that all weights, percentages, and concentrations as used herein and directed to calcium HMB are based on the weight of calcium HMB monohydrate, unless otherwise specified.

[0014] The term "nutritional liquid" as used herein, unless otherwise specified, means formulations comprising at least one of fat, protein, and carbohydrate, which are suitable for oral administration to a human and have a drinkable viscosity at the intended administration temperature, which is most typically from about 1°C to about 25°C. In this context, a drinkable viscosity at the target temperature would typically be less than about 300 cps, more typically from about 10 cps to about 160 cps, and even more typically from about 20 cps to about 70 cps. Viscosity values as used herein, unless otherwise specified, are obtained using a Brookfield Viscometer (Model DV-II+) with a 62 spindle at the target temperature. The viscosity is measured by operating the viscometer at a spindle speed that is the highest speed possible to obtain a reading that is on scale. The measured viscosity

values represent the ratio of shear stress to shear rate, expressed as dynes-second/cm<sup>2</sup>, or poise, or more typically as centipoise (cps) or one hundredth of a poise.

[0015] The term “shelf stable” as used herein, unless otherwise specified, refers to a nutritional liquid that can remain commercially stable after being packaged and then stored at 18-25°C for at least about 3 months, including from about 6 months to about 24 months, and also including from about 12 months to about 18 months.

[0016] The term “nutritional emulsion” as used herein, unless otherwise specified, means nutritional liquids formulated as aqueous emulsions, including water-in-oil, oil-in-water, and complex emulsions, but most typically oil-in-water emulsions.

[0017] 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.

[0018] The term “pH-stable” as used herein, unless otherwise specified, means that the pH is resistant or at least more resistant to pH reductions due to a buffering effect of beta-hydroxy-beta-methyl butyrate.

[0019] The term “plastic” as used herein, unless otherwise specified, means food grade plastics approved by the U.S. Food and Drug Administration or other suitable regulatory group, some non-limiting examples of which include polyvinyl chlorides, polyethylene terephthalate, high density polyethylene, polypropylenes, polycarbonates, and so forth.

[0020] The terms “sterile”, “sterilized” or “sterilization” as used herein, unless otherwise specified, refers to the reduction in transmissible agents such as fungi, bacteria, viruses, spore forms, and so forth, in food or on food grade surfaces to the extent necessary to render such foods suitable for human consumption. Sterilization processes may include various techniques involving the application of heat, peroxide or other chemicals, irradiation, high pressure, filtration, or combinations or variations thereof.

[0021] 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.

[0022] 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.

[0023] 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.

[0024] The various embodiments of the nutritional emulsions of the present disclosure may also be substantially free of any optional or selected essential ingredient or feature described herein, provided that the remaining nutritional emulsion 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 emulsion contains less than a functional amount of the optional ingredient, typically less than about 0.5% by weight, including less than about 0.1% by weight, and also including zero percent by weight, of such optional or selected essential ingredient.

[0025] The nutritional liquids and corresponding manufacturing methods of the present disclosure can comprise, consist of, or consist essentially of the essential elements and features of the disclosure as described herein, as well as any additional or optional ingredients, features, or elements described herein or otherwise useful in nutritional applications.

### **Product Form**

[0026] The nutritional liquids of the present disclosure comprise at least one of fat, protein, and carbohydrate, which are suitable for oral administration to a human and

have a drinkable viscosity at the intended administration temperature. These compositions are most typically formulated as emulsions such as oil-in-water, water-in-oil, or complex aqueous emulsions, and even more typically as oil-in-water emulsions having a continuous aqueous phase and a discontinuous oil phase. The nutritional liquids may be shelf-stable.

[0027] The nutritional liquids may also be characterized as ready-to-feed or ready-to-drink liquids, which means that the liquids are packaged in liquid form and are suitable for consumption as such immediately upon removal from the closed plastic container holding the liquid. In other words, the present disclosure does not contemplate nutritional powders or other compositions that are formulated or otherwise reconstituted and are required to be used within 24-72 hours following formulation or reconstitution.

[0028] Although the nutritional liquids are most typically in the form of shelf stable emulsions, these liquids may also be formulated as non-emulsions such as solutions, suspensions (suspended solids), gels and so forth. These nutritional liquid may also be formulated as non-shelf stable products requiring refrigeration to maintain an extended shelf life.

[0029] The nutritional liquids typically contain up to about 95% by weight of water, including from about 50% to about 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 liquids.

[0030] The nutritional liquids may be formulated with sufficient kinds and amounts of nutrients so as to provide a sole, primary, or supplemental source of nutrition, or to provide a specialized nutritional liquid for use in individuals afflicted with specific diseases or conditions. These nutritional compositions may have a variety of product densities, but most typically have a density greater than about 1.055 g/ml, including from 1.06 g/ml to 1.12 g/ml, and also including from about 1.085 g/ml to about 1.10 g/ml.

[0031] The nutritional liquids may have a caloric density tailored to the nutritional needs of the ultimate user, although in most instances the compositions comprise from about 100 to about 500 kcal/240 ml, including from about 150 to about 350 kcal/240 ml, and also including from about 200 to about 320 kcal/240 ml. These nutritional



compositions also comprise HMB as described herein, the amount of which most typically ranges from about 0.5 to about 3.0 g/240 ml, including from about 0.75 to about 2.0 g/240 ml, including about 1.5 g/240 ml.

[0032] The nutritional liquids 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 5.5 to about 7.3, including from about 6.2 to about 7.2.

[0033] Although the serving size for the nutritional emulsion can vary depending upon a number of variables, a typical serving size ranges from about 100 to about 300 ml, including from about 150 to about 250ml, including from about 190 ml to about 240 ml.

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

[0034] The nutritional liquids comprise HMB or any source thereof that is suitable for use in an oral nutritional product and is otherwise compatible with the essential elements or features of the nutritional liquids.

[0035] The nutritional liquids most suitably comprise a calcium salt of HMB, which calcium salt is most typically in a monohydrate form. Although calcium HMB or calcium HMB monohydrate is the preferred source of HMB for use herein, other suitable sources may include HMB as the free acid, other salt forms including an anhydrous salt, an ester, a lactone, or other product forms that otherwise provide a bioavailable form of HMB from the nutritional liquid. 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.

[0036] The concentration of calcium HMB, including the concentration of calcium HMB and or calcium HMB monohydrate when such are used as the HMB source herein, in the nutritional liquids may range up to about 10%, including from about 0.1% to about 8%, and also including from about 0.2% to about 5.0%, and also including from

about 0.3% to about 3%, also including from about 0.4% to about 1.5%, and also including about 0.45% by weight of the nutritional liquid.

**Macronutrients**

[0037] The nutritional liquids comprise, in addition to HMB, at least one of fat, protein, and carbohydrate. Generally, any source of fat, protein, and carbohydrate that is known or otherwise suitable for use in nutritional products may also be suitable for use herein, provided that such macronutrients are also compatible with the essential elements of the nutritional liquids as defined herein.

[0038] Although total concentrations or amounts of the fat, protein, and carbohydrates may vary depending upon the nutritional needs of the intended user, such concentrations or amounts most typically fall within one of the following embodied ranges, inclusive of other fat, protein, and or carbohydrate ingredients as described herein.

[0039] Carbohydrate concentrations most typically range from about 5% to about 40%, including from about 7% to about 30%, including from about 10% to about 25%, by weight of the nutritional liquid; fat concentrations most typically range from about 1% to about 30%, including from about 2% to about 15%, and also including from about 4% to about 10%, by weight of the nutritional liquid; and protein concentrations most typically range from about 0.5% to about 30%, including from about 1% to about 15%, and also including from about 2% to about 10%, by weight of the nutritional liquid.

[0040] The level or amount of carbohydrates, fats, and or proteins in the nutritional liquids may also be characterized in addition to or in the alternative as a percentage of total calories in the nutritional liquids as set forth in the following table.

Nutrient (% Calories)	Embodiment A	Embodiment B	Embodiment C
Carbohydrate	1-98	10-75	30-50
Fat	1-98	20-85	35-55
Protein	1-98	5-70	15-35

[0041] Non-limiting examples of suitable fats or sources thereof for use in the nutritional liquids 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.

[0042] Non-limiting examples of suitable carbohydrates or sources thereof for use in the nutritional liquids described herein may include maltodextrin, hydrolyzed or modified starch or cornstarch, glucose polymers, corn syrup, corn syrup solids, rice-derived carbohydrates, glucose, fructose, lactose, high fructose corn syrup, honey, sugar alcohols (e.g., maltitol, erythritol, sorbitol), and combinations thereof.

[0043] Non-limiting examples of suitable protein or sources thereof for use in the nutritional liquids include hydrolyzed, partially hydrolyzed or non-hydrolyzed 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, sodium and calcium caseinates, whole cow's milk, partially or completely defatted milk, soy protein isolates, soy protein concentrates, and so forth.

[0044] The nutritional liquids are particularly useful when formulated with a fat component as described herein since such ingredients may readily oxidize in an aqueous emulsion over time, thus generating increasing hydrogen ion concentrations over time that, absent the use of HMB or other buffering system herein, may result in a decrease in the composition pH and consequently a reduction in product stability.

### **Soluble Protein**

[0045] The nutritional liquids of the present disclosure may comprise selected amounts of soluble protein to improve product stability and minimize the development of bitter flavors and after taste over time.

[0046] The soluble protein may represent from about 35% to 100%, including from about 40% to about 85%, including from about 60% to about 80%, and also including from about 65% to about 75%, by weight of the total protein in the nutritional liquid. The concentration of soluble protein may range from at least about 0.5%, including from about 1% to about 26%, and also including from about 2% to about 15%, also including from about 3% to about 10%, and also including from about 4% to about 8%, by weight of the nutritional liquid.

[0047] The amount of soluble protein included in the nutritional liquids may also be characterized as a weight ratio of soluble protein to HMB, wherein the nutritional liquid includes a weight ratio of soluble protein to HMB, including calcium HMB and or calcium HMB monohydrate, of at least about 3.0, including from about 4.0 to about 12.0, also including from about 7.0 to about 11.0. and also including from about 8.0 to about 10.0.

[0048] The term "soluble protein" as used herein, unless otherwise specified, refers to those proteins having a solubility of at least about 90% as measured in accordance with a Protein Solubility Measurement Test that includes the following steps: (1) suspend the protein at 2.00% (w/w) in water; (2) stir vigorously for one hour at 20°C to form a suspension; (3) remove an aliquot of the suspension, and determine protein concentration as total protein; (4) centrifuge the suspension at 31,000 x g and at 20°C for one hour; (5) determine the protein concentration in the supernatant (the soluble protein); and (6) express the soluble protein as a percentage of the total protein.

[0049] Any soluble protein source is suitable for use herein provided that it meets the solubility requirement as defined herein, some non-limiting examples of which include sodium caseinate (>95% solubility as determined by the Protein Solubility Measurement Test), whey protein concentrate (>90% solubility as determined by the Protein Solubility Measurement Test), and combinations thereof. Non-soluble proteins may of course also be included in the nutritional emulsions.

[0050] Soluble protein suitable for use herein may also be characterized by the content of phosphoserine in the protein, wherein the soluble proteins in this context are defined as those proteins having at least about 100 mmols, including from about 150 to

400 mmoles, including from about 200 to about 350 mmoles, and also including from about 250 to about 350 mmoles, of phosphoserine per kilogram of protein.

[0051] When the soluble protein is defined in terms of phosphoserine content, it has been found that the weight ratio of the soluble protein (with the defined phosphoserine content) to the calcium HMB may be at least about 3:1, including at least about 5:1, and also including at least about 7:1, and also including from about 9:1 to about 30:1. In this context, the proteins having the requisite content of phosphoserine are most typically in the form of monovalent caseinate salts such as sodium caseinate, potassium caseinate, and combinations thereof.

[0052] In one embodiment, the soluble protein may also be characterized by a mole ratio of monovalent caseinate phosphoserine to calcium HMB monohydrate of least about 0.2, including from about 0.2 to about 2.0, and also including from about 0.25 to 1.7.

[0053] It should be understood, however, that any phosphoserine-containing protein may be suitable for use herein provided that it has the requisite phosphoserine content and that the phosphoserine used in calculating the ratios are not bound, complexed, or otherwise attached to a polyvalent cation such as calcium or magnesium.

[0054] It should also be noted that alternative definitions as described herein for soluble proteins may include proteins that have little or no phosphoserine content, so that the soluble protein fraction of the compositions may include soluble protein with and/or without phosphoserine. The soluble protein for use herein may therefore be defined by any one or more of the soluble protein characterizations, separately or in combination.

[0055] The phosphoserine moieties within the protein may therefore be available for binding with the calcium released from the calcium HMB so that the above ratios of soluble protein to calcium HMB are the ratio of protein with phosphoserine moieties that are unbound, unattached, or otherwise available to bind soluble calcium from the calcium HMB during formulation. It could be, for example, that a mixture of calcium caseinate and sodium caseinate are used in the composition, but the ratio of proteins defined by a phosphoserine content to calcium HMB is calculated based on the protein fraction from the

sodium caseinate and additionally any protein from the calcium caseinate fraction that is not bound to calcium.

### **Soluble Calcium Binding Capacity**

[0056] The nutritional compositions of the present disclosure may include emulsion embodiments comprising a selected weight ratio of a soluble calcium binding capacity (SCBC) to the total soluble calcium in the emulsion to improve product stability and minimize the development over time of bitter flavors and after taste.

[0057] The ratio of the soluble calcium binding capacity (defined herein) to total soluble calcium of the emulsions embodiments is a weight ratio of at least about 2.3, including from about 2.3 to about 12.0, also including from about 3.0 to about 8.0, and also including from about 4.0 to about 6.5, wherein the ratio is determined in accordance with the following formulas:

$$\text{Ratio} = \text{SCBC} / [\text{soluble calcium}]$$

$$\text{SCBC} = (0.32 \times [\text{soluble citrate}] + 0.63 [\text{soluble phosphate}] + 0.013 \times [\text{soluble protein}])$$

[0058] The weight ratio of SCBC to the concentration of total soluble calcium can be adjusted to minimize the concentration of unbound calcium in the nutritional emulsion, or to minimize the weight ratio of such unbound calcium to HMB in the emulsions, to improve product stability and reduce the development over time of bitter flavors and after tastes.

### **Calcium**

[0059] The nutritional liquids of the present disclosure may further comprise calcium as desirable for use in developing or maintaining healthy muscle in targeted individuals. Some or all of the calcium may be provided when calcium HMB or calcium HMB monohydrate is used as the HMB source. Any other calcium source, however, may be used provided that such other source is compatible with the essential elements of the nutritional liquids.

[0060] The concentration of calcium in the nutritional liquids may exceed about 10mg/L, and may also include concentrations of from about 25mg/L to about 3000 mg/L, also including from about 50mg/L to about 500 mg/L, and also including from about 100mg/L to about 300mg/L.

[0061] To minimize the taste and stability issues in the emulsion embodiments hereof, the calcium may be formulated so as to minimize the extent to which the calcium is solubilized in the emulsions. As such, solubilized calcium concentrations in the emulsion embodiments may be less than about 900 mg/L, including less than about 700mg/L, also including from about 500mg/L to about 700mg/L, and also including from about 400mg/L to about 600 mg/L. In this context, the term "solubilized calcium" refers to supernatant calcium in the nutritional liquids as measured at 20°C.

[0062] The calcium in the liquids may also be characterized by a ratio (on an equivalents basis) of solubilized citrate to solubilized calcium of not more than 5.0, including not more than 4.0, also including not more than 3.0, and also including from about 0.8 to about 3.0. In this context, the terms "solubilized citrate" and "solubilized calcium" refers to the equivalents of citrate and calcium cations, respectively, present in the supernatants of nutritional liquids as measured at 20°C.

[0063] The calcium component of the nutritional liquids may also be characterized by a solubilized calcium level that represents less than 900 mg/L, including less than 700 mg/L, and also including less than 600 mg/L, and also including from 400 mg/L to 700 mg/L of the nutritional emulsion, wherein the weight ratio of calcium HMB or its monohydrate form to the solubilized calcium ranges from about 6 to about 15, including from about 6 to about 12, also including from about 6 to about 10, and also including from about 6 to about 8.

### **Vitamin D**

[0064] The nutritional compositions of the present disclosure may further comprise vitamin D to help maintain healthy muscle in the targeted user. Vitamin D forms include Vitamin D2 (ergocalciferol) and Vitamin D3 (cholecalciferol) or other forms suitable for use in a nutritional product.

The amount of Vitamin D in the nutritional liquid most typically ranges up to about 1000 IU, more typically from about 10 to about 600 IU, and more typically from about 50 to 400 IU per serving size.

### **Optional Ingredients**

[0065] The nutritional liquids 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 products and may also be used in the nutritional liquids 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.

[0066] Non-limiting examples of such optional ingredients include preservatives, antioxidants, emulsifying agents, additional buffers, pharmaceutical actives, additional nutrients as described herein, colorants, flavors, thickening agents and stabilizers, and so forth.

[0067] The nutritional liquids may further comprise vitamins or related nutrients, non-limiting examples of which include vitamin A, 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.

[0068] The nutritional liquids may further comprise minerals, non-limiting examples of which include phosphorus, magnesium, iron, zinc, manganese, copper, sodium, potassium, molybdenum, chromium, selenium, chloride, and combinations thereof.

[0069] The nutritional liquids may also include one or more masking agents to reduce or otherwise obscure the development of residual bitter flavors and after taste in the liquids 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, gellan gum, and combinations thereof. The amount of masking agents in the nutritional liquids 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 at least about 0.1%, including from about 0.15% to about 3.0%, and also including from about 0.18% to about 2.5%, by weight of the nutritional liquid.

### **Method of Use**

[0070] The nutritional liquids described herein are useful to provide supplemental, primary, or sole sources of nutrition, and or to provide individuals one or more benefits as described herein. In accordance with such methods, the liquids may be administered orally as needed to provide the desired level of nutrition, most typically in the form of one to two servings daily, in one or two or more divided doses daily, e.g., serving sizes typically ranging from about 100 to about 300 ml, including from about 150 to about 250ml, including from about 190 ml to about 240 ml, wherein each serving contains from about 0.4 to about 3.0 g, including from about 0.75 to about 2.0 g, including about 1.5 g, of calcium HMB per serving.

[0071] Such methods are further directed to provide the individual upon administration of such products, most typically after daily use over an extended period of time of from about 1 to about 6 months, including from about 1 to about 3 months, one or more of 1) to support maintenance of lean body mass, 2) to support of strength and or muscle strength, 3) to decrease protein breakdown and damage of muscle cells, 4) to help with muscle recovery following exercise or other trauma, and 5) to reduce muscle protein breakdown following exercise.

[0072] Such methods are also helpful to achieve one or more of 1) to maintain and support lean body mass in elderly with sarcopenia, 2) to provide nutrition to support an active and independent lifestyle in individuals, especially in the elderly, 3) to support recovery of muscle strength, 4) to help rebuild muscle and regain strength, and 5) to improve strength, including muscle strength, and mobility.

### **Methods of Manufacture**

[0073] The nutritional liquids may be manufactured by any known or otherwise suitable method for making nutritional emulsions or other liquids, most typically for making nutritional aqueous emulsions or milk based emulsions.

[0074] 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 selected oils (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., 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 agents (e.g. Avicel, gellan, carrageenan), and calcium HMB or other HMB source. 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.), carbohydrates (e.g., fructooligosaccharide, sucrose, corn syrup, etc.). The PIW slurry is then formed by mixing with heat and agitation the remaining protein (e.g., sodium caseinate, soy protein concentrate, etc.) into water.

[0075] The resulting slurries are then blended together with heated agitation and the pH adjusted to the desired range, typically 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 or liquid.

[0076] In the aseptic sterilization method, for example, the nutritional liquid or emulsion is sterilized and a container is separately sterilized. The nutritional liquid may be

sterilized utilizing a heating process, for example. The container may be sterilized by spraying at least the interior wall of the container with hydrogen peroxide and then drying the interior wall. Once the container and the nutritional liquid or emulsion have both been sterilized, the liquid or emulsion is introduced into the container in a clean room environment and the container sealed. Residual peroxide levels within the composition are less than 0.5 ppm by weight of the composition.

[0077] Because aseptic sterilization generally may require the use of hydrogen peroxide as a sterilizing agent on the interior of the container, aseptically-treated nutritional liquids or emulsions packaged in aseptically sterilized containers can be subject to a change in pH over time as there is generally residual hydrogen peroxide on the interior walls of the aseptically-treated container which can enter into the liquid and emulsion and cause changes in pH. As such, it is particularly beneficial to introduce HMB into the nutritional liquids or emulsions as described herein to help buffer the liquid or emulsion and protect against unwanted shifts in pH in the product over time.

[0078] Other manufacturing processes, techniques, and variations of the described processes may be used in preparing the nutritional liquids or emulsions without departing from the spirit and scope of the present disclosure.

### **Packaging**

[0079] The nutritional liquids of the present disclosure are packaged into a container, all or a majority by weight of which may be plastic, metal, glass, paper, cardboard, a package comprising a combination of such materials such as a can with a plastic body and a metal cap, lid, rim, or other minor packaging component.

[0080] A container may be a single-dose container, or may be a multi-dose resealable, or recloseable container that may or may not have a sealing member, such as a thin foil sealing member located below the cap. The container is preferably capable of withstanding an aseptic sterilization process as described herein and known to those of ordinary skill in the art.

[0081] The plastic container, which in some embodiments may be an extruded plastic container, may be comprised of a single layer of plastic, or may be comprised of two or more (multi-layer) layers of plastic that may or may not have an intermediate layer. One suitable plastic material is high-density polyethylene. A suitable intermediate layer is ethylene vinyl alcohol. In one specific embodiment, the plastic container is an eight ounce multi-layer plastic bottle with a foil seal and a recloseable cap, wherein the multilayer bottle comprises two layers of high density polyethylene with an intermediate layer of ethylene vinyl alcohol. In another embodiment, the plastic container is a 32 ounce single or multi-layer plastic bottle with a foil seal and a recloseable cap.

[0082] The plastic container or package used with the nutritional compositions described herein are generally sized and configured to limit to the greatest extent possible the amount of headspace present therein. Because oxygen located in the air in the headspace can cause unwanted oxidation of various components of the nutritional composition, it is generally preferred to limit the headspace, and hence the amount of oxygen present in the plastic package. In one embodiment, the plastic package or container includes less than about 13 cubic centimeters of headspace. In another embodiment, the plastic package includes less than about 10 cubic centimeters of headspace.

[0083] Metal, glass, cardboard, and paper containers are also well-known in the art and can be suitably selected by one of ordinary skill in the art based on the disclosure herein. These types of containers are generally suitable for use with aseptic sterilization methods and, as such, as suitable for use in the present disclosure.

### **EXAMPLES**

[0084] The following examples illustrate specific embodiments and/or features of the nutritional liquids 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.

**Example 1**

[0085] This illustrates the buffering effect of HMB in reconstituted PediaSure® powder (a nutritional emulsion). Known quantities of dilute hydrochloric acid are added at room temperature to a control sample of reconstituted PediaSure® powder (Abbott Laboratories, Columbus Ohio) (no HMB) and to a sample of reconstituted PediaSure® powder wherein the powder is fortified with HMB at 5.17 grams per kilogram of reconstituted powder. The HMB used to fortify the HMB-containing sample is prepared via a cation exchange removal of calcium from calcium HMB monohydrate. Prior to the addition of the free HMB to the samples, its pH is adjusted to 6.7 with sodium hydroxide. An equimolar amount of sodium is added as sodium chloride to the control sample. With continuous stirring, the pH of each sample is measured one minute after the addition of the hydrochloric acid. From the pH reading, the hydrogen ion concentration (H<sup>+</sup>) is calculated. The results are shown in the table below:

HCl Added (mmol/Kg)	pH PediaSure Powder w/o HMB	[H <sup>+</sup> ] nmoles/kg PediaSure Powder w/o HMB	pH PediaSure Powder w/ HMB	[H <sup>+</sup> ] nmoles/kg PediaSure Powder w/ HMB
0	6.66	218	6.71	194
0.40	6.59	256	6.65	228
0.80	6.53	294	6.60	251
1.20	6.46	346	6.54	288
1.60	6.40	397	6.48	330
2.00	6.34	456	6.43	371
2.40	6.28	523	6.38	416
2.80	6.23	587	6.32	477
3.20	6.17	674	6.27	536
3.60	6.11	774	6.23	587
4.00	6.06	869	6.18	659
Change	-0.60	+651	-.053	+465

[0086] The data in the above table show a measurable buffering effect associated with the presence of HMB in a nutritional liquid. The overall reduction in pH for the sample including the HMB is less than the reduction in pH for the sample not including HMB. Also, the [H<sup>+</sup>] increase is less in the sample including the HMB as compared to the sample not including HMB. As such, HMB provides a buffering effect in nutritional liquids.

**Example 2**

[0087] This illustrates the buffering effect of HMB in reconstituted PediaSure® powder (a nutritional emulsion). A known quantity of hydrogen peroxide (1.32 mg/kg of reconstituted powder) is added to a control sample of reconstituted PediaSure® powder (no HMB) and to a sample of reconstituted PediaSure® powder wherein the powder is fortified with HMB at 5.17 grams per kilogram of reconstituted powder. The HMB used to fortify the sample including the HMB is prepared via a cation exchange removal of calcium from calcium HMB monohydrate. Prior to the addition of the free HMB to the samples, its pH is adjusted to 6.7 with sodium hydroxide. An equimolar amount of sodium is added as sodium chloride to the control sample. With continuous stirring, the pH of each sample is measured after one hour at room temperature and the [H<sup>+</sup>] concentrations calculated from the pH values. The results are shown in table below:

Time After H <sub>2</sub> O <sub>2</sub> Addition	pH PediaSure Powder w/o HMB	[H <sup>+</sup> ], nmoles/kg, PediaSure Powder w/o HMB	pH PediaSure Powder w/ HMB	[H <sup>+</sup> ], nmoles/kg, PediaSure Powder w/ HMB
0-Time	6.64	228	6.68	208
1 Hour	6.55	281	6.61	245
Change	-0.09	+53	-0.07	+37

[0088] The data in above table show a measurable buffering effect associated with the presence of HMB in the nutritional emulsion. The overall reduction in pH for the sample including the HMB is less than the reduction in pH for the sample not including HMB. Also, the [H<sup>+</sup>] increase is less in the sample including the HMB as compared to the sample not including HMB. As such, HMB provides a buffering effect in nutritional liquids.

**Example 3**

[0089] This illustrates the buffering effect of HMB in a ready-to-drink liquid as a nutritional emulsion. The buffering capacity of commercially available Ensure® Plus (Sample #1) (Abbott Laboratories, Columbus, Ohio) and Sample #2 (liquid nutritional emulsion based on Ensure® Plus and including 6.5 grams of calcium HMB per kilogram of

emulsion and 2.38 grams of phosphate per kg of emulsion) are compared via hydrochloric acid titration and sodium hydroxide titration. The results are shown in table below:

Acid or Base Added	Sample #1 (No HMB)	Sample #2 (With HMB)
HCl (mmoles) required to lower pH of 100 mL from 6.0 to 3.0	13.9	21.0
NaOH (mmoles) required to raise pH of 100 mL from 7.0 to 11.0	9.62	9.04

[0090] As shown in the above table, Sample #2 including the calcium HMB is significantly more resistant to pH decrease than is Sample #1. This data show that HMB imparts a selective buffering effect to the nutritional liquid by resisting pH decreases (via acid addition) more than pH increases (via NaOH addition). This characteristic is particularly useful in nutritional emulsions and other nutritional liquids that, over time, are more prone to pH reductions and the product instability that arises therefrom.

[0091] The pH data of Examples 1, 2, and 3 shows that when HMB is present in the nutritional liquids, it provides a buffering effect such that the nutritional liquid is more resistant to pH decreases upon addition of acids. This discovery is particularly useful when formulating nutritional liquids that are packaged in plastic containers. Because plastic containers, and especially plastic containers that are aseptically treated with a hydrogen peroxide solution, are prone to pH decreases over time, the addition of HMB into the nutritional liquid provides not only a nutritional benefit, but also a buffering effect that protects the nutritional liquid from the detrimental effects associated with a decrease in pH in the nutritional liquid.

### **Examples: Nutritional Liquids**

[0092] The following examples illustrate some of the shelf-stable nutritional liquids of the present disclosure, which may be prepared in accordance with the manufacturing methods described herein. These compositions include aqueous oil-in-water emulsions and other nutritional liquids that are packaged in plastic and other containers and

remain physically stable for 12-18 months after formulation/packaging at storage temperatures ranging from 1-25°C.

[0093] The formulations are shelf stable nutritional liquids that are packaged in plastic and other containers and are sterilized aseptic sterilization processes. The compositions develop little or no bitter flavor or after taste over time and remain pH stable and physically stable during a shelf life of from 12-18 months at a storage temperature ranging from 1-25°C. The package component compositions have a residual peroxide level of less than 0.5 ppm.

[0094] The exemplified compositions may be prepared by any known or otherwise suitable method for preparing nutritional liquids, including the methods described herein whereby the selected ingredients are combined into a separate carbohydrate-mineral slurry (CHO-MIN), a separate protein-in-water slurry (PIW), and a separate protein-in-oil slurry (PIF). For each individual slurry, the ingredients are mixed together under temperature and shear appropriate for the selected materials, after which the different slurries are combined in a blend tank, subjected to ultra high temperature treatment (UHT) and then homogenized at about 3000 psi. Vitamins, flavors and other heat-sensitive materials are then added to the homogenized mixture. The resulting mixture is diluted with water as needed to achieve the desired concentrations and density (generally about 1.085 to about 1.10 g/mL). The resulting nutritional liquid is then subjected to aseptic sterilization and packaging using 240 ml recloseable plastic bottles. The packaged emulsions have a pH of from 3.5-7.5.

#### **Examples 4-7**

[0095] Examples 4-7 illustrate nutritional emulsions 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.



Ingredient	Example 4	Example 5	Example 6	Example 7
Water	Q.S	Q.S.	Q.S.	Q.S.
Maltodextrin DE 9-12	120.0	120.0	120.0	120.0
Sucrose	71.38	71.38	71.38	71.38
Milk Protein Concentrate	18.65	18.65	18.65	18.65
Canola Oil	27.5	27.5	27.5	27.5
Sodium Caseinate	26.68	26.68	26.68	26.68
Soy Protein Concentrate	14.05	14.05	14.05	14.05
Corn Oil	15.70	15.70	15.70	15.70
Calcium HMB monohydrate	6.00	6.5	7.0	4
Whey Protein Concentrate	3.50	3.50	3.50	3.50
Magnesium Phosphate	1.92	1.92	1.92	1.92
Potassium Citrate	6.92	6.92	6.92	6.92
Sodium Citrate	0.903	0.903	0.903	0.903
Lecithin	1.50	1.50	1.50	1.50
Sodium Tripolyphosphate	1.06	1.06	1.06	1.06
Potassium Phosphate dibasic	0.730	0.730	0.730	0.730
Potassium Chloride	1.04	1.04	1.04	1.04
Ascorbic Acid	0.235	0.235	0.235	0.235
Carrageenan	0.150	0.150	0.150	0.150
Potassium Hydroxide	0.136	0.136	0.136	0.136
TM/UTM Premix	0.1684	0.1684	0.1684	0.1684
Gellan Gum	0.050	0.050	0.050	0.050
Vitamin A,D, E Premix	0.0758	0.0758	0.0758	0.0758
Water sol. Vitamin premix	0.0728	0.0728	0.0728	0.0728
Potassium Iodide	0.00022	0.00022	0.00022	0.00022
Chromium Chloride	0.000217	0.000217	0.000217	0.000217
Flavor	3.3	3.3	3.3	3.3
<b>Features</b>				
Soluble protein/total protein (wt/wt)	59%	58%	57%	50%
Soluble protein/calcium HMB (wt/wt)	6.2	5.6	5.1	7.5
Solubilized calcium (wt%)	0.045%	0.049%	0.053%	0.070%
SCBC / Solubilized calcium (wt/wt)	5.5	5.0	4.5	3.0
Solubilized citrate/solubilized calcium (equiv)	3.5	3.0	2.5	1.5

### **Examples 8-11**

[0090] These examples illustrate nutritional emulsions 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.

**Table 2: Nutritional Emulsions**

Ingredient	Example 8	Example 9	Example 10	Example 11
Water	Q.S	Q.S.	Q.S.	Q.S.
Maltodextrin DE 9-12	120.0	120.0	120.0	120.0
Sucrose	71.38	71.38	71.38	71.38
Milk Protein Concentrate	14.65	13.65	12.65	11.65
Canola Oil	27.5	27.5	27.5	27.5
Sodium Caseinate	30.68	31.68	32.68	33.68
Soy Protein Concentrate	14.05	14.05	14.05	14.05
Corn Oil	15.70	15.70	15.70	15.70
Calcium HMB monohydrate	6.00	6.5	7.0	7.5
Whey Protein Concentrate	3.50	3.50	3.50	3.50
Magnesium Phosphate	1.92	1.92	1.92	1.92
Potassium Citrate	6.92	6.92	6.92	6.92
Sodium Citrate	0.903	0.903	0.903	0.903
Lecithin	1.50	1.50	1.50	1.50
Sodium Tripolyphosphate	1.06	1.06	1.06	1.06
Potassium Phosphate dibasic	0.730	0.730	0.730	0.730
Potassium Chloride	1.04	1.04	1.04	1.04
Ascorbic Acid	0.235	0.235	0.235	0.235
Carrageenan	0.150	0.150	0.150	0.150
Potassium Hydroxide	0.136	0.136	0.136	0.136
TM/UTM Premix	0.1684	0.1684	0.1684	0.1684
Gellan Gum	0.050	0.050	0.050	0.050
Vitamin A,D, E Premix	0.0758	0.0758	0.0758	0.0758
Water sol. Vitamin premix	0.0728	0.0728	0.0728	0.0728
Potassium Iodide	0.00022	0.00022	0.00022	0.00022
Chromium Chloride	0.000217	0.000217	0.000217	0.000217
Flavor	3.3	3.3	3.3	3.3
<b>Features</b>				
Soluble protein/total protein (wt/wt)	63%	64%	65%	66%
Soluble protein/calcium HMB (wt/wt)	6.6	6.2	5.8	5.0
Solubilized calcium (wt%)	0.045%	0.049%	0.053%	0.070%
SCBC / Solubilized calcium (wt/wt)	5.5	5.0	4.5	3.0
Solubilized citrate/solubilized calcium (equiv)	3.5	3.0	2.5	1.5

**Examples 12-15**

[0091] These examples illustrate nutritional emulsions of the present disclosure, the ingredients of which are listed in the following table below. All ingredient amounts are listed as kilogram per 1000 kilogram batch of product, unless otherwise specified.

Ingredient	Example 12	Example 13	Example 14	Example 15
Water	Q.S	Q.S.	Q.S.	Q.S.
Maltodextrin DE 9-12	120.0	120.0	120.0	120.0
Sucrose	71.38	71.38	71.38	71.38
Milk Protein Concentrate	0.00	0.00	8.65	10.65
Canola Oil	27.5	27.5	27.5	27.5
Sodium Caseinate	45.33	45.33	36.68	34.68
Soy Protein Concentrate	0.00	0.00	12.05	9.05
Corn Oil	15.70	15.70	15.70	15.70
Calcium HMB monohydrate	6.0	6.5	7.0	8.0
Whey Protein Concentrate	17.55	17.55	5.50	8.50
Magnesium Phosphate	1.92	1.92	1.92	1.92
Potassium Citrate	6.92	6.92	6.92	6.92
Sodium Citrate	0.903	0.903	0.903	0.903
Lecithin	1.50	1.50	1.50	1.50
Sodium Tripolyphosphate	1.06	1.06	1.06	1.06
Potassium Phosphate dibasic	0.730	0.730	0.730	0.730
Potassium Chloride	1.04	1.04	1.04	1.04
Ascorbic Acid	0.235	0.235	0.235	0.235
Carrageenan	0.150	0.150	0.150	0.150
Potassium Hydroxide	0.136	0.136	0.136	0.136
TM/UTM Premix	0.1684	0.1684	0.1684	0.1684
Gellan Gum	0.050	0.050	0.050	0.050
Vitamin A,D, E Premix	0.0758	0.0758	0.0758	0.0758
Water sol. Vitamin premix	0.0728	0.0728	0.0728	0.0728
Potassium Iodide	0.00022	0.00022	0.00022	0.00022
Chromium Chloride	0.000217	0.000217	0.000217	0.000217
Flavor	3.3	3.3	3.3	3.3
<b>Features</b>				
Soluble protein/total protein (wt/wt)	94%	93%	71%	73%
Soluble protein/calcium HMB (wt/wt)	9.8	9.0	6.4	5.1
Solubilized calcium (wt%)	0.045%	0.050%	0.058%	0.070%
SCBC / Solubilized calcium (wt/wt)	10	8.8	5.9	3.8
Solubilized citrate/solubilized calcium (equiv)	3.8	3.4	2.9	1.5

### **Examples 16-19**

[0092] These examples illustrate nutritional emulsions of the present disclosure, the ingredients of which are listed in the following table below. All ingredient amounts are listed as kilogram per 1000 kilogram batch of product, unless otherwise specified.

Table 4: Nutritional Emulsions

Ingredient	Example 16	Example 17	Example 18	Example 19
Water	Q.S	Q.S.	Q.S.	Q.S.
Sucrose	96.05	96.05	96.05	96.05
Maltodextrin DE 5	16.46	16.46	16.46	16.46
Milk Protein Concentrate	18.95	0.00	8.95	25.00
Soy Oil	13.31	13.31	13.31	13.31
Fructooligosaccharides	8.69	8.69	8.69	8.69
Soy Protein Concentrate	13.80	0.00	10.80	5.92
Canola Oil	5.32	5.32	5.32	5.32
Sodium Caseinate	25.64	58.39	61.39	28.00
Corn Oil	11.70	11.70	11.70	11.70
Calcium HMB monohydrate	6.70	7.00	2.50	5.00
Dietary Fiber	4.51	4.51	4.51	4.51
Whey Protein Concentrate	3.44	3.44	13.44	2.92
Potassium Citrate	4.48	4.48	4.48	4.48
Flavor	2.00	2.00	2.00	2.00
Magnesium Phosphate	2.75	2.75	2.75	2.75
Lecithin	1.50	1.50	1.50	1.50
Di sodium Phosphate Dihyd	0.436	0.436	0.436	0.436
Potassium Phosphate Dibasic	0.556	0.556	0.556	0.556
Sodium Chloride	0.498	0.498	0.498	0.498
Choline Chloride	0.480	0.480	0.480	0.480
Ascorbic Acid	0.465	0.465	0.465	0.465
Carrageenan	0.300	0.300	0.300	0.300
Trace/Ultra Trace minerals	0.420	0.420	0.420	0.420
Potassium Chloride	0.698	0.698	0.698	0.698
Potassium Hydroxide	0.321	0.321	0.321	0.321
L-carnitine	0.180	0.180	0.180	0.180
Water soluble Vitamin Premix	0.07269	0.07269	0.07269	0.07269
Vitamin DEK premix	0.128	0.128	0.128	0.128
Gellan Gum	0.050	0.050	0.050	0.050
Vitamin A Palmitate	0.008245	0.008245	0.008245	0.008245
Vitamin D3	0.000399	0.000399	0.000399	0.000399
Potassium Iodide	0.000194	0.000194	0.000194	0.000194
Features				
Soluble protein/total protein (wt/wt)	58%	95%	80%	61%
Soluble protein/calcium HMB (wt/wt)	5.4	8.4	30	
Solubilized calcium (wt%)	0.050%	0.060%	0.080%	0.055%
SCBC / Solubilized calcium (wt/wt)	4.4	9.7	8.8	4.9
Solubilized citrate/solubilized calcium (equiv)	1.3	3.1	2.7	2.9

**Examples 20-23**

[0093] These examples illustrate nutritional emulsions of the present disclosure, the ingredients of which are listed in the following table below. All ingredient amounts are listed as kilogram per 1000 kilogram batch of product, unless otherwise specified.

Ingredient	Example 20	Example 21	Example 22	Example 23
Water	Q.S	Q.S.	Q.S.	Q.S.
Sucrose	96.05	96.05	96.05	96.05
Maltodextrin DE 5	16.46	16.46	16.46	16.46
Milk Protein Concentrate	24.98	0.00	25.00	10.00
Soy Oil	13.31	13.31	13.31	13.31
Fructooligosaccharides	8.69	8.69	8.69	8.69
Soy Protein Concentrate	13.64	0.00	5.87	10.64
Canola Oil	5.32	5.32	5.32	5.32
Sodium Caseinate	25.64	58.39	61.39	28.00
Corn Oil	11.70	11.70	11.70	11.70
Calcium HMB monohydrate	6.50	3.5	4.25	7.5
Dietary Fiber	4.51	4.51	4.51	4.51
Whey Protein Concentrate	3.40	17.04	6.87	6.40
Potassium Citrate	4.48	4.48	4.48	4.48
Flavor	2.00	2.00	2.00	2.00
Magnesium Phosphate	2.75	2.75	2.75	2.75
Lecithin	1.50	1.50	1.50	1.50
Di sodium Phosphate Dihyd	0.436	0.436	0.436	0.436
Potassium Phosphate Dibasic	0.556	0.556	0.556	0.556
Sodium Chloride	0.498	0.498	0.498	0.498
Choline Chloride	0.480	0.480	0.480	0.480
Ascorbic Acid	0.465	0.465	0.465	0.465
Carrageenan	0.300	0.300	0.300	0.300
Trace/Ultra Trace minerals	0.420	0.420	0.420	0.420
Potassium Chloride	0.698	0.698	0.698	0.698
Potassium Hydroxide	0.321	0.321	0.321	0.321
L-carnitine	0.180	0.180	0.180	0.180
Water soluble Vitamin Premix	0.07269	0.07269	0.07269	0.07269
Vitamin DEK premix	0.128	0.128	0.128	0.128
Gellan Gum	0.050	0.050	0.050	0.050
Vitamin A Palmitate	0.008245	0.008245	0.008245	0.008245
Vitamin D3	0.000399	0.000399	0.000399	0.000399
Potassium Iodide	0.000194	0.000194	0.000194	0.000194
Features				
Soluble protein/total protein (wt/wt)	56%	94%	74%	68%
Soluble protein/calcium HMB (wt/wt)	5.8	20	17	5.0
Solubilized calcium (wt%)	0.057%	0.085%	0.079%	0.060%
SCBC / Solubilized calcium (wt/wt)	2.9	7.9	6.8	4.7
Solubilized citrate/solubilized calcium (equiv)	3.0	0.9	1.5	2.2

**Examples 24-27**

[0094] These examples illustrate clear, non-emulsion, liquids of the present disclosure, the ingredients of which are listed in the following table below. All ingredient amounts are listed as kilogram per 1000 kilogram batch of product, unless otherwise specified. The liquids have an adjusted pH of between 4.5 and 7.2.

Ingredient	Example 24	Example 25	Example 26	Example 27
Ingredient Water	Q.S.	Q.S.	Q.S.	Q.S.
Sucrose	27.5	27.5	27.5	27.5
Calcium HMB monohydrate	3.00	5.00	9.69	18.00
L-Lysine Monohydrochloride	2.26	2.26	2.26	2.26
Flavor	1.80	1.80	1.80	1.80
Citric Acid	1.03	1.03	1.03	1.03
Ascorbic Acid	0.504	0.504	0.504	0.504
Malic Acid	0.342	0.342	0.342	0.342
Liquid Sucralose (25%)	0.194	0.194	0.194	0.194
Acesulfame Potassium	0.113	0.113	0.113	0.113
Vitamin D3 Water dispersible	0.0242	0.0242	0.0242	0.0242
Colorant	0.0012	0.0012	0.0012	0.0012

## WHAT IS CLAIMED IS:

1. A packaged composition comprising a peroxide-treated aseptic package and a nutritional liquid hermetically sealed therein, the nutritional liquid comprising beta-hydroxy-beta-methylbutyrate and at least one of fat, carbohydrate, and protein.
2. The packaged composition of claim 1 wherein a majority by weight of the peroxide-treated aseptic package is plastic.
3. The composition of claim 1 wherein a majority by weight of the peroxide-treated aseptic package is metal.
4. The packaged composition of claim 1 wherein the nutritional liquid comprises from about 0.2% to about 5.0% beta-hydroxy-beta-methylbutyrate by weight of the nutritional liquid.
5. The composition of claim 1 wherein the nutritional liquid comprises fat, carbohydrate, protein, and beta-hydroxy-beta-methylbutyrate, wherein the protein comprises from 50% to 100% by weight of soluble protein and includes phosphoserine-containing protein having at least about 100 mmoles of phosphoserine per kilogram of phosphoserine-containing protein.
6. The composition of claim 5 wherein the soluble protein is selected from sodium caseinate, whey protein concentrate, or combinations thereof.
7. The composition of claim 1 wherein the nutritional liquid has a weight ratio of a soluble calcium binding capacity to total soluble calcium of from about 2.3:1 to about 12:1.
8. The composition of claim 1 wherein the peroxide-treated aseptic package contains at least about 13 cubic centimeters of headspace.
9. A method of preparing a pH-stable nutritional liquid in a peroxide-treated aseptic package, the method comprising:

combining a fat, protein, carbohydrate and beta-hydroxy-beta-methylbutyrate together to form a nutritional liquid;

sterilizing the nutritional liquid;

sterilizing aseptically a package by treating the interior of the package with a peroxide-containing solution; and

introducing the sterilized nutritional liquid into the aseptically sterilized package.

10. The method of claim 9 wherein the peroxide-treated aseptic package comprises a material selected from the group consisting of glass, plastic, metal, paper, cardboard, and combinations thereof.

11. The method of claim 9 wherein the peroxide-treated aseptic package is reclosable.

12. The method of claim 9 wherein the protein includes a soluble protein selected from the group consisting of sodium caseinate, whey protein concentrate, and combinations thereof.

13. The method of claim 9 wherein the nutritional composition has a weight ratio of a soluble calcium binding capacity to total soluble calcium of from about 2.3:1 to about 12:1.

14. The method of claim 9 wherein the nutritional liquid comprises a weight ratio of a soluble calcium binding capacity to total soluble calcium of from about 5:1 to about 12:1.

15. The method of claim 9 wherein the peroxide-containing solution is hydrogen peroxide.



# INTERNATIONAL SEARCH REPORT

International application No

PCT/US2011/022932

**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A23L1/29      A23L1/30      A23L3/00      B65B55/00      B65B55/12  
       B65D81/34      B67C7/00

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 B65B B65D B67C

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 practical, search terms used)

EPO-Internal, BIOSIS, FSTA, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/215640 A1 (BAXTER JEFFREY H [US] ET AL) 29 September 2005 (2005-09-29) paragraphs [0146] - [0148]; claims -----	1-15
A	KREIDER R B ET AL: "EFFECT OF CALCIUM BETA-HYDROXY-BETA-METHYLBUTYRATE (HMB) SUPPLEMENTATION DURING RESISTANCE-TRAINING ON MARKERS OF CATABOLISM, BODY COMPOSITION AND STRENGTH", INTERNATIONAL JOURNAL OF SPORTS MEDICINE, THIEME, STUTTGART, DE, vol. 20, no. 8, 1 November 1999 (1999-11-01), pages 503-509, XP008037671, ISSN: 0172-4622, DOI: DOI:10.1055/S-1999-8835 "Procedures" on page 505table 2 ----- -/--	1-15

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
- "E" earlier document but published on or after the international filing date
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- "O" document referring to an oral disclosure, use, exhibition or other means
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- "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
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- "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.
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Date of the actual completion of the international search

12 May 2011

Date of mailing of the international search report

23/05/2011

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# INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2011/022932

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 101 45 818 C1 (ALFILL ENGINEERING GMBH & CO K [DE]) 10 October 2002 (2002-10-10) the whole document -----	1-15

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