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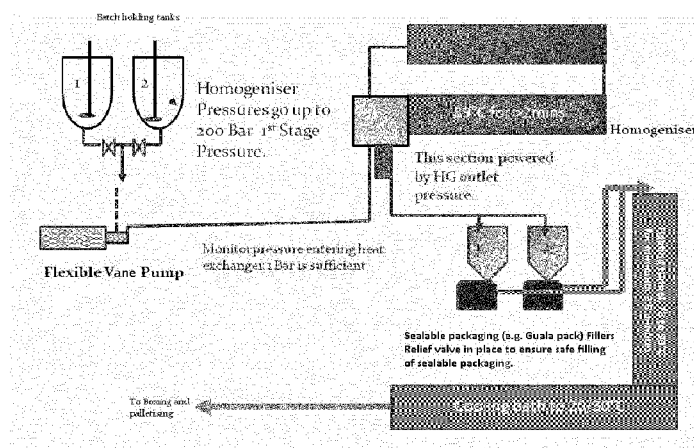


Figure 1

(57) Abstract: The present invention is directed to a mild, low pH process for the preparation of pasteurized compositions which utilizes specific heat treatment packaging. Said process is for the preparation of a composition, wherein said compositions comprise high levels of fat, protein and carbohydrate and micronutrients. The inventive process is particularly suitable for the preparation of pasteurized compositions, preferably dietetic compositions for the treatment of malnutrition, malabsorption states and other conditions requiring fortification with energy, protein and micronutrients for nutritional support. Further compositions obtainable by the inventive process are also suitable for use in any dietary modification or manipulation involving the intake of fat, protein and carbohydrate, in isolation or combination, for therapeutic effect and benefit. The present invention also describes the use of such compositions.

**Low pH Process for the Preparation of Pasteurized Compositions
Comprising Fat, Protein and Carbohydrate**

Field of the Invention

The present invention is directed to a mild, low pH process for the preparation of pasteurized compositions which utilizes specific heat treatment packaging. Said process is for the preparation of a composition, wherein said compositions comprise high levels of fat, protein and carbohydrate and micronutrients.

The inventive process is particularly suitable for the preparation of pasteurized compositions, preferably dietetic compositions for the treatment of malnutrition, malabsorption states and other conditions requiring fortification with energy, protein and micronutrients for nutritional support. Further compositions obtainable by the inventive process are also suitable for use in dietary modification or manipulation involving the intake of fat, protein and carbohydrate, in isolation or combination, for therapeutic effect and benefit. The present invention also describes the use of such compositions.

Background

Pasteurization is a process of heating food, nutritional products and the like (usually liquids) to a specific temperature for a definite length of time, followed by cooling immediately. Pasteurization has the effect of inhibiting microbial growth in said products and hence has found wide spread application within industry. Notably, unlike sterilization, pasteurization does not kill all micro-organisms in the product, but instead reduces the number of viable pathogens and hence greatly reducing the likelihood of any pathogens present causing disease.

Products containing high levels of protein, fat, carbohydrate and micronutrients can often present numerous processing difficulties in heat treatment processes such as retort and UHT pasteurization due to factors such as poor homogeneity

and high viscosity during mixing phase. Furthermore, such products are also prone to aeration during mixing due to for instance the high protein level and are furthermore often difficult to pump from the mixing tank, homogenise and heat process (pasteurize).

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In addition, a further problem often encountered is product fouling at the heating stage. In this regard, high protein in combination with high fat and micronutrients is prone to burning during heating. Additionally, for products containing high levels of protein, fat, carbohydrate and micronutrients there is often undesirable thickening of the product along with some products being unstable. Finally, all the above both alone and in combination often lead to an unsatisfactory product which has a poor taste.

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Accordingly, the present invention is directed towards an improved, mild process which allows for the preparation of products containing high levels of protein, fat, carbohydrate and micronutrients which does not suffer from the abovementioned drawbacks of existing methods of the prior art.

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Description of the Invention

As described herein, the object underlying the present invention is preferably to be accomplished by means of the independent claims as attached. The dependent claims advantageously illustrate further preferred aspects of the inventive em-
5 bodiments.

According to a first embodiment, the object underlying the present invention is preferably solved by a process for preparing a composition, preferably a composi-
10 tion as defined herein. The present invention hence describes a composition, preferably a composition obtained or obtainable according to a process for preparing such a composition as defined herein.

Hence, according to a particularly preferred aspect the object underlying the present invention is solved by a process for the preparation of a composition contain-
15 ing a high level of fat, more preferably a composition as described herein, comprising the following steps:

(a) Mixing about 4 to about 12 % by weight protein, about 5 to about 15
20 % by weight carbohydrate and preferably about 25 to about 38 % by weight fat with water;

(b) Optionally preheating the mixture;

(c) Homogenizing the mixture obtained according to step (a) or (b) at a
temperature of about 86 to about 100°C, preferably about 86 to
25 about 92°C, preferably at a pressure of about 30 to about 220 bar;

(d) Packaging the mixture into a package, which is, preferably a seal-
able package, which is preferably a pouch, bottle, stickpack with tear
top / tear top tube, or pot, which is preferably a unit or dose suitable
for administration;

- (e) Pasteurizing the packaged mixture at a temperature of about 76 to about 93°C;
- (f) Preferably cooling the pasteurized packaged mixture.

5 In this regard, any of the steps, in particular, steps (a) to (c) can be repeated as necessary – either independently or in combination.

According to a first step (a) of the inventive process about 4 to about 12 % by weight protein, about 5 to about 15 % by weight carbohydrate and preferably
10 about 25 to about 38 % by weight fat are mixed with water. Such a mixture preferably comprises proteins, fats and/or carbohydrates as defined below, more preferably in the preferred ranges as defined herein. Most preferably, ingredients including those as defined herein are added at step (a).

15 In other words, it is most preferred that no further ingredients are added in steps (b) to (f). In case further ingredients are to be added at a later stage, preferably steps (a), (b) and/or (c), and optionally further steps as defined herein may be repeated at least once, allowing further addition of ingredients as defined herein, preferably in the preferred ranges as defined herein, preferably during such a re-
20 peated step (a).

Preferably, after step (c) the homogenized product is sent to a filler head prior to packing step (d).

25 Step (c) can also be viewed as a first stage pasteurization, since said step also involves heat treatment of the mixture from step (a) or (b) using pasteurization conditions. Accordingly, step (e) which is carried out on the packaged mixture can also be seen as a second stage pasteurization step.

30 As used herein, pasteurization is a heat treatment step carried out at a temperature between about 73 to about 100°C. Preferably the pasteurization is carried out

at a temperature between about 73 to about 93°C, preferably about 76 to about 93°C, at a time of about 2 to about 10 minutes, or about 93°C to about 100°C, preferably about 94°C to about 100°C at a time of less than about 2 minutes, preferably less than about 1 minute. The heat treatment step is preferably followed by cooling immediately.

Most preferably pasteurization is carried out as described herein. As used herein, pasteurization has the effect of inhibiting microbial growth in the inventive compositions and process thereof. Notably, unlike sterilization, pasteurization does not kill all micro-organisms in the composition, but instead reduces the number of viable pathogens and hence greatly reducing the likelihood of any pathogens present causing disease.

However, for some compositions it may alternatively be preferable to carry out a sterilization step instead of the most preferred pasteurization step. For such purposes, high temperatures are used, preferably at least above about 93°C, more preferably above about 94°C. Sterilization may preferably also be carried out at high temperatures of about 94 to about 140°C, more preferably at about 95 to about 105°C, or about 98 to about 110°C, or about 105 to about 120°C, or about 110 to about 130°C, or about 120 to about 135°C.

For the purposes of the present invention, sterilization can only potentially be achieved by heat sterilization, wherein high temperatures are employed as described herein above. Likewise preferably, the time and pressures used for sterilization are as defined herein for pasteurization.

Furthermore, other methods known in the art for achieving sterilization such as using chemical or radiation for instance do not form part of the present invention.

According to step (d), it is particularly preferable that said packaging step also involves sealing said packaged mixture prior to pasteurization step (e), wherein

preferably sealing is achieved by heat sealing or capping the packaging containing the mixture.

Furthermore, it is particularly preferable that the package or sealable package is a bottle, stickpack with tear top/ tear top tube, pot or a pouch, wherein said pouch is most preferably a Guala pack and the like. According to a preferred embodiment the sealable package is a foil stickpack with a tear top. According to certain embodiments it is also preferable that the package or the sealable package is a tetra pack.

The product of the present invention is preferably further treated to avoid browning by methods known in the art by the skilled person, including purging with an inert gas such as nitrogen and/or CO₂ either alone or in combination and/or the process being vacuum sealed. Said treatment can be performed at the end of the inventive process or directly before, during or after any step or steps (a) to (f) throughout said inventive process. Preferably, such treatment is carried out in step (d).

It is particularly preferable that if degassing/vacuuming is undertaken that this occurs at step (a), and/or before step (b) of the inventive process. Furthermore, it is also preferable that any purging with inert gas occurs at step (d) of the inventive process.

Even more preferably, the mixture is a composition as defined herein for the inventive process. In a desirable aspect of the process of the present invention, the protein, the fat and/or the carbohydrate is/are derived from at least two different sources. It may be also desirable that the carbohydrate source as used herein also functions as a sweetener.

For example, the proteins are derived at least partly from animal, such as whey protein, but optionally also partly from plant source, the fat at least partly from vegetal or plant source, and the carbohydrates at least partly from vegetal source,

or from a combination of animal and vegetal. Likewise, if at least two preferably different types of fat, at least two preferably different types of protein and/or at least two preferably different types of carbohydrate is/are contained in the inventive process, such proteins, fats and/or carbohydrates of the inventive process
5 may be derived from at least two different sources, namely animal and vegetal. For instance, without being limited thereto, a fat derived from a vegetal source may be a high oleic sunflower oil; furthermore, a vegetal carbohydrate employed may be sucrose, preferably castor sugar, etc.

- 10 Unless otherwise indicated, the term "at least" in the context of the process and compositions thereof of the present invention typically preceding a series of elements is to be understood to refer to every element in the series. Those skilled in the art will recognize, or be able to ascertain using no more than routine experimentation, many equivalents to the specific embodiments of the invention de-
15 scribed herein. Such equivalents are intended to be encompassed by the process and compositions thereof of the present invention.

The mixture formed or obtained according to step (a) of the process of the present invention may contain or comprise any of the ingredients as defined below, pref-
20 erably in the defined amounts and ratios as defined herein.

Furthermore, it may also be preferred that the mixture and the composition obtained by the inventive process does not contain or comprise DHA, DPA and/or ARA.

25 According to some preferred embodiments the inventive process utilizes no artificial additives and/or utilizes whole protein. Having said this, in a preferred embodiment the process does not utilize whole milk protein in a ratio of 80:20 casein protein to whey protein.

30 It is also preferable that intact proteins are used in the inventive process and further preferred that casein is not used in said process.

Furthermore, the inventive process may also utilize linoleic acid or α -linoleic acid either alone or in combination. When used in combination, linoleic acid or α -linoleic acid preferably may be contained in the mixture or compositions of the
5 inventive process in amounts of about 1079 mg and about 48.2 mg respectively or about 2743 mg and about 61.8 mg respectively per 100g.

Preferably, the process and compositions thereof of the present invention contain linoleic acid in about 1000 mg to about 3000 mg per 100 g, preferably about 1020
10 to about 1060 mg, or about 1040 to about 1080 mg, or about 1065 to about 1100 mg, or about 1090 to about 2000 mg, or about 2500 to about 2600 mg, or about 2550 to about 2700 mg, or about 2560 to about 2750 mg, or about 2710 to about 2800 mg.

15 Preferably, the process and compositions thereof of the present invention contain α -linoleic acid in about 40 to about 70 mg per 100 g, preferably about 42 to about 45 mg, or about 43 to about 48 mg, or about 47 to about 55 mg, or about 50 to about 62 mg, or about 55 to about 65 mg.

20 According to a first step (a) of the inventive process about 4 to about 12 % by weight protein, about 5 to about 15 % by weight carbohydrate and preferably about 25 to about 38 % by weight fat are mixed with water.

It is particularly preferable that in the process of the present invention, said mixture formed or obtained according to step (a) does not comprise soy protein
25 and/or does not comprise olive oil or canula oil.

Preferably, in the process of the present invention the mixture of step (a) is adjusted to a pH of less than about 4.3, preferably about 3.5 to about 4.5, preferably
30 about 3.5 to about 4.2, more preferably to a pH of about 3.7 to about 4.1 or about pH 3.8 to about 4.3. In the process of the present invention it is preferred that the pH adjustment as described herein is achieved using citric acid and/or malic acid

and/or lactic acid and/or succinic acid and/or acetic acid or the like, and/or mixtures thereof. Acids can be added in liquid or dry form such as in hydrated or anhydrous form and the like. Compositions obtained by the present invention may consequently also exhibit a pH as defined before.

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According to a further preferred aspect the product obtained or the mixture prepared according to step (a) of the process of the present invention additionally contains about 0.5 to about 23 % by weight medium chain triglycerides and/or about 6 to about 30 % by weight long chain triglycerides.

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Medium Chain Triglycerides (MCTs) as used herein are typically composed of 6 to 10, or 6 to 11, or 6 to 12 carbon links. Because of their shorter chain length MCTs have a number of unique properties which give them advantages over the more common LCTs. The MCT's employed in the process and compositions thereof of the present invention are preferably sourced from fractionated coconut oil, macadamia oil, palm oil, palm kernel oil, etc. and combinations thereof.

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The medium chain triglycerides which may be present in product obtained or the mixture prepared by the inventive process typically range from about 0.5 to about 23 % by weight, preferably about 1 to about 1.5 % or about 1.2 to about 2 %, or about 1.7 to about 5 %, or about 4 to about 15 %, or about 12 to about 20 %, or about 18 to about 22 % by weight. Most preferably, the process and compositions thereof of the present invention has medium chain triglycerides present at about 1.49 % or about 20.03 % by weight.

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Long Chain Fatty acids (LCTs) as used herein ranging from 12 to 18 carbons long are the predominant form of fat in the human diet. Fatty acids resulting from the breakdown of LCT are a major fuel source for most body tissues. Their oxidation plays an important role in maintaining energy homoeostasis, particularly for the brain, during periods of fasting. LCT's employed in the process and compositions thereof of the present invention are preferably sourced from sunflower oil, most preferably high oleic sunflower oil, corn oil, soy oil, canola oil, sesame seed oil,

safflower oil, walnut oil, evening primrose oil, peanut oil, cottonseed oil, rapeseed oil, olive oil, fish oil (e.g., menhaden oil, sardine oil), palm olein etc. and combinations thereof.

- 5 The long chain triglycerides which may be present in the product obtained or the mixture prepared by the inventive process typically range from about 6 to about 30 % by weight, preferably about 7 to about 8 %, or about 7.5 to about 8.7 %, or about 8 to about 10 %, or about 9 to about 15 %, or about 13 to about 20 %, or about 18 to about 22 %, or about 21 to about 23 %, or about 22 to about 24.5 %, or about 24 to about 25.5 %, or about 25 to about 26.5 %, or about 26 to about 28 % by weight. Most preferably, the process and compositions thereof of the present invention has Long chain triglycerides present at about 25.5 % or at about 8.73 % by weight.
- 10
- 15 Additionally, according to one other preferred aspect, the carbohydrate source as contained in the product obtained or the mixture prepared by the inventive process typically may be selected from any suitable carbohydrate source, which preferably also functions as a sweetener. Preferably, the carbohydrate source employed in the inventive process may preferably be selected from the group consisting of sucrose, preferably castor sugar, fructose, maltodextrin, fibers, corn syrup, high fructose corn syrup, corn starch, lactose, glucose, dextrose, maltose and combinations thereof, etc. and the like either alone or in combination.
- 20

- For the purposes of the inventive process about 5 to about 15 % by weight carbohydrate is employed in the product obtained or the mixture prepared by the process, more preferably about 5.5 to about 8.5%, or about 7 to about 9%, or about 7.5 to about 10 %, or about 8 to about 11.5%, or about 11 to about 13.5%, or about 12.5 to about 14 %. The process and compositions thereof of the present invention most preferably employ or have a carbohydrate content of about 13.4 % or 10 % by weight.
- 25
- 30

For the purposes of the inventive process and compositions thereof, sweetener may also be present, which may be a combination of a high dextrose equivalent sweetener, an artificial sweetener and a highly concentrated sweetener. For instance, the sweetener or combination of sweeteners may be crystalline fructose, aspartame, corn syrup, sucrose, glucose, sucralose, maltodextrin, and/or stevia.

Sweeteners include, but are not limited to, dextrose, crystalline fructose, high fructose corn syrup 90%, high fructose corn syrup 55%, and high fructose corn syrup 42%. Other complementary sweeteners that may also be used in the optional sweetener blend include, but are not limited to fructose, sucrose, glucose, lactose, maltose, dextrose, honey, invert sugar, corn syrup, rice syrup, grain syrup, maltodextrin, polydextrose, oligodextrin, cane based sweeteners, beet based sweeteners etc. Optionally, artificial sweeteners, sugar substitutes and non-nutritive sweeteners may also be used and include, but are not limited to, edible saccharin salts, aspartame, saccharine, alitame, acesulfame K, tagatose, L-sugars, neophesperidin, thaumatin, dihydrochalcones, cyclamates, steviosides, glycyrrhizins, synthetic alkoxy aromatics, such as dulcin, sucralose, suosan, miraculin, monellin, sorbitol, xylitol, talin, cyclohexylsulfamates, synthetic sulfamic acids, oximes, aspartyl malonates, succinilic acids, amino acid based sweeteners, and carboxylates such as 3-hydroxy-4-alkyloxyphenyl aliphatic carboxylates.

Said optional sweetener blend is preferably selected according to the desired sweetness. For instance, it is well known that fructose in its pure crystalline form has a perceived sweetness of about 160 to 180, typically reported as 173, compared to sucrose at a value of 100. Hence, if the optional sweetener blend comprises fructose, other sweeteners may not be required or may only be utilized in relatively small amounts. The optional sweetener blend is also selected in order to compliment the energy requirements of the inventive composition. To this end, in some compositions the artificial sweetener saccharin may be particularly preferred since saccharin has no calories and no nutritional value. Sucralose is a further preferred non-caloric sweetener, since this is about 600 times sweeter than the sugar sucrose.

Accordingly, digestible and/or non-digestible sweeteners may be employed in the present invention either alone or in combination. Most preferably, sweeteners are present in the inventive process and compositions thereof in the ranges as indicated herein for carbohydrates.

For the purposes of the inventive process and compositions thereof, emulsifiers may also be present, which include, but are not limited to, mono- and diglycerides, distilled mono-glycerides, egg yolk and soy lecithin, which may be present either alone or in combination. Said optional emulsifiers may be present in an amount between about 0.05 to about 1%, preferably about 0.1 to about 0.2 %, or about 0.15 to about 0.3 %, or about 0.18 to about 0.4 %, or about 0.35 to about 0.5 %, or about 0.45 to about 0.65 %, or about 0.55 to about 0.8 %, or about 0.7 to about 0.9 % by weight of the inventive composition.

The term "starch" as used herein refers to a complex carbohydrate (polysaccharide) composed of chains of glucose molecules, which plants use to store food energy.

The fibre source, if employed in the inventive process may be either soluble or insoluble fibre which can be present alone or in combination which may be selected from the group consisting of inulin, oat fibre, gum acacia (i.e., Gum Arabic), corn fibre, wheat bran, oat bran, corn bran, whole corn flour, whole oat flour, fructooligosaccharides (from Inulin), pea fibre, partially hydrolyzed guar gum and mixtures thereof, etc. and the like either alone or in combination.

Fibre can be utilized in about 1 % by weight, preferably about 0.7 to about 1 %, or about 0.8 to about 2 %, or about 0.9 to about 1.5 %, or about 1 to about 1.2 %. Alternatively, in some embodiments it is preferable that no fibre is present in the process and compositions thereof of the present invention.

It is likewise highly desirable that the mixture formed or obtained according to step (a) of the process of the present invention or a composition obtained by the process contains or comprises fat at about 2 to about 30 % by weight saturates, about 1 to about 25 % by weight mono-unsaturates and about 0.1 to about 5 % by weight poly-unsaturates. These percentages are preferably defined with regard to the entire amount of the mixture.

Furthermore, according to one preferred aspect, the fat as employed in the inventive process typically may be selected from any suitable fat source, selected from the group comprising or consisting of coconut oil, preferably fractionated coconut oil (MCT), lemon oil, dietary fats, vegetable oil, such as sunflower oil, preferably high oleic sunflower oil, canola oil, corn oil, soybean oil, sesame seed oil, safflower oil, walnut oil, evening primrose oil, peanut oil, cottonseed oil, rapeseed oil, olive oil, fish oil (e.g., menhaden oil, sardine oil) macadamia oil, palm oil, palm kernel oil, or mixtures thereof, etc., either alone or in combination. According to the process and compositions thereof of the present invention, dietary fats are preferably selected from (fat) molecules composed of individual carbon atoms linked into chains ranging from 2 to 24 carbon atoms in length. Preferably, the inventive process does not comprise soy protein and/or olive oil and/or canula oil.

For the purposes of the present invention as defined herein the composition obtained or the mixture prepared by the process preferably comprises a high level of fat which is preferably about 25 to about 38 % by weight fat, or preferably about 25 to about 35% by weigh fat, more preferably about 26 to about 28 %, or about 27 to about 28.5 %, or about 27.5 to about 30 %, or about 29 to about 31 %, or about 30.5 to about 32 %, or about 31.5 to about 33.5 %, or about 33 to about 34.5%, or about 34 to about 36%, or about 35 to about 37% by weight fat.

The process and compositions thereof of the present invention most preferably employ or have a fat content of about 28.2 % or about 29.2 % by weight.

Within the context of the process and compositions thereof of the present invention may also comprise or contain fat comprising saturates, mono-unsaturates, and/or poly-unsaturates. Preferably, the inventive process and compositions thereof preferably comprise in a range of about 2 to about 30 % by weight saturates, about 1 to about 25 % by weight mono-unsaturates and about 0.1 to about 5 % by weight poly-unsaturates.

Particularly preferable, the saturated fat is present in the inventive process and compositions thereof in a range of about 2 to about 30 % by weight, preferably about 3 to about 4 %, or about 3.5 to about 4.5 %, or about 4.1 to about 6 %, or about 5 to about 10 %, or about 8 to about 15 %, or about 13 to about 18 %, or about 17 to about 19.5 %, or about 19 to about 21 %, or about 20 to about 22 %, or about 21 to about 25 %, or about 24 to about 29 % by weight.

Most preferably, the process of the present invention and compositions thereof has saturated fat present at about 4.08 % or about 20.97 % by weight. The term “%” is preferably defined as “% by weight” and in this context reflects the total amount of the saturated fat component used in the inventive process and compositions prepared thereof.

Likewise preferable, the mono-unsaturated fat is present in the inventive process and compositions thereof in a range of in the range of about 1 to about 25 % by weight, preferably about 2 to about 4 %, or about 3 to about 5 %, or about 4.5 to about 6 %, or about 5.5 to about 6.7 %, or about 6.5 to about 7 %, or about 6.8 to about 10 %, or about 9 to about 15 %, or about 14 to about 18 %, or about 19 to about 21 %, or about 20 to about 21.5 %, or about 21.3 to about 24 % by weight.

Most preferably, the process and compositions thereof of the present invention has monounsaturated fat present at about 21.15 % or at about 6.68 % by weight. The term “%” is preferably defined as “% by weight” and in this context reflects the total amount of the mono-saturated fat component used in the inventive process and compositions prepared thereof.

Similarly, it is preferred that the poly-unsaturated fat is present in the inventive process and compositions thereof in the range of about 0.1 to about 5 % by weight, preferably about 0.3 to about 0.8 % or about 0.6 to about 1 %, or about 0.9 to about 1.2 %, or about 1 to about 1.3 %, or about 1.1 to about 2 %, or about 1.8 to about 2.5 %, or about 2.3 to about 2.8 %, or about 2.6 to about 2.9 %, or about 2.8 to about 3 %, or about 2.9 to about 4 %, or about 3 to about 4.5 % by weight. Most preferably, the process of the present invention and compositions thereof has polyunsaturated fat present at about 3.04 % or about 1.2 % by weight. The term “%” is preferably defined as “% by weight” and in this context reflects the total amount of the poly-saturated fat component used in the inventive process and compositions prepared thereof.

It is further preferred that 0.4 to 2.0% by weight of the fat in the inventive process and compositions thereof is eicosapentaenoic acid (EPA). Most preferably EPA is present in the inventive process and compositions thereof at about 0.6 to about 1 % by weight fat, or about 0.8 to about 1.3 %, or about 1.1 to about 1.6%, or about 1.4 to about 1.8 % by weight fat. The term “%” is preferably defined as “% by weight” and in this context reflects the total amount of the preferred EPA component used in the inventive process and compositions prepared thereof. According to an alternative, such inventive compositions may contain no eicosapentaenoic acid (EPA).

According to a particularly preferred aspect the protein employed in step (a) of the inventive process is preferably a whey protein, more preferably a whey protein isolate and even more preferably an acidified whey protein isolate.

According to one preferred aspect, the protein as contained in the inventive process and compositions thereof typically may be selected from any suitable protein selected from the group comprising or consisting of e.g. whey protein, whey protein isolate, preferably acidified whey protein isolate, whey protein concentrate, whey powder, egg protein, pea protein, potato protein, soy protein, soy protein isolate, and combinations thereof and the like either alone or in combination. The

proteins may be intact or hydrolysed proteins. In a preferred embodiment the inventive process and compositions thereof do not contain whole milk protein in a ratio of 80:20 casein protein to whey protein.

- 5 In a preferred embodiment intact proteins are used in the inventive process. It is further preferred that casein is not used in said process.

According to a particularly preferred aspect the protein employed in step (a) of the inventive process as defined herein and compositions thereof comprises about 4
10 to about 12% by weight protein, preferably about 4 to about 11 % by weight protein, likewise preferably about 4 to about 10%, or about 5 to about 10%, or about 5 to about 7 % or about 6 to about 8 %, or about 7.5 to about 9 %, or about 8.5 to about 10 %. The process and compositions thereof of the present invention most preferably has a protein content of about 6.7 % or about 8 % by weight, which is
15 most preferably acidified whey protein isolate.

It is particularly preferable that in step (a) of the inventive process the mixture contains an antifoaming agent as defined below, or is subjected to a vacuum-
ing/degassing processing step. Preferably the anti-foaming agent is selected from
20 lecithin and/or MCT oil and/or silicone antifoamers, more preferably in an amount of about 0.5 to about 23 % by weight, most preferably in amounts of about 1 to about 5 % by weight. For the mixture used in the present inventive process MCT oil not only acts as an anti-foaming agent, but is also nutritionally required.

25 It is more preferable that the lecithin is present in the process of the present invention and compositions thereof at about 0.3 to about 0.7 %, or about 0.5 to about 0.9 %, or about 0.8 to about 1 %, or about 0.95 to about 1.3 %, or about 1.1 to about 1.5 %, or about 1.4 to about 1.8 %. The process of the present invention and compositions thereof most preferably has lecithin present at about 0.89 % or
30 at about 1.0 % by weight.

Even more preferably lecithin and/or MCT oil either separately or in combination are present in the process of the present invention and compositions thereof at about 0.5 to 5 % by weight, preferably at about 0.6 to about 0.89 %, or about 0.7 to about 1.1 %, or about 1.0 to about 1.3 %, or about 1.2 to about 1.6 %, or about 1.4 to about 2.0 %, or about 1.8 to about 2.38 %, or about 2.2 to about 2.6 %, or about 2.5 to about 3 %.

Particularly preferable is that the MCT oil is present in about 14 to about 17 %, or about 16 to about 18 %, or about 16.5 to about 19.5 %, or about 19 to about 21 %, or about 20.10 to about 21.5 %, or about 21.2 to about 22 % by weight.

Most preferably MCT oil, preferably sourced from fractionated coconut oil is present at about 1.49% by weight and Lecithin is present at about 0.89 % by weight.

Particularly preferable is that MCT oil, preferably sourced from fractionated coconut oil is present at about 20.10 % by weight and Lecithin is present at about 1 % by weight.

The fat source used in the inventive process and compositions thereof can be a 100% LCT or 100% MCT fat source, which can be employed either alone or in combination. Accordingly, the inventive process preferably may provide compositions containing a mixture of MCT and LCT as defined herein. Alternatively, if for instance solely a MCT fat source is utilized, this provides compositions which may lack an LCT component. If for instance solely a LCT fat source is utilized, this provides compositions which may lack an MCT component.

In this regard, the inventors found that in the absence of said antifoaming agents, whey protein or the like present may be prone to being aerated and during the mixing phase this may result in excessive foaming which can lead to processing difficulties in terms of pumping and homogenising the product.

Said mixture in step (a) and compositions prepared by the present process also preferably comprise micronutrients selected from vitamins, minerals and trace

elements, which may be present either alone or in combination. Alternatively, for some embodiments step (a) and compositions prepared by the present process may also not contain any micronutrients.

- 5 The term “vitamin” as used herein, refers to any of various organic substances essential in minute quantities to the nutrition of most animals act especially as coenzymes and precursors of coenzymes in the regulation of metabolic processes. Vitamins have diverse biochemical functions, including function as hormones (for example, vitamin D), antioxidants (for example, vitamin C and vitamin E), and
- 10 mediators of cell signalling, regulation of cell growth, tissue growth and differentiation (for example, vitamin A). The B complex vitamins, which is the largest in number, function as precursors for enzyme cofactor biomolecules (co-enzymes) that help act as catalysts and substrates in metabolism. For instance Vitamin B₆ and Vitamin B₁₂. Other Vitamins which may be present include Vitamin K, Thia-
- 15 min, Riboflavin, Niacin, Folic Acid, Biotin and Pantothenic Acid.

Said mixture in step (a) also preferably comprises the following vitamins per 100 kcal:

- 20 Vitamin A in about 20 to about 180 µg per 100 kcal, preferably about 35 to about 180 µg per 100 kcal, preferably at about 25 to about 70 µg per 100 kcal, or at about 40 to about 80 µg, or about 70 to about 110 µg, or about 85 to about 140 µg, or about 100 to about 150 µg, or about 135 to about 170 µg per 100 kcal.
- 25 Vitamin D in about 0.5 to about 3 µg per 100 kcal, preferably at about 0.5 µg to about 1.1 µg per 100 kcal, or about 0.9 µg to about 1.5 µg, or about 1.3 µg to about 1.9 µg, or about 1.7 µg to about 2.2 µg, or about 2 µg to about 2.6 µg, or about 2.3 µg to about 2.8 µg per 100 kcal.
- 30 Vitamin K in about 3.5 to about 20 µg per 100 kcal, preferably at about 3.5 to about 7 µg per 100 kcal, or about 5 to about 9 µg, or about 7 to about 12 µg, or about 10.5 to about 15 µg, or about 13 to about 18 µg per 100 kcal.

Vitamin C in about 2.25 to about 22 mg per 100 kcal, preferably at about 3 to about 8 µg per 100 kcal, or 5 to about 10 mg, or about 8 to about 14 mg, or about 11 to about 15 mg, or about 13 to about 18 mg per 100 kcal.

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Thiamin in about 0.05 to about 0.5 mg per 100 kcal, preferably about 0.06 to about 0.5 mg per 100 kcal, or preferably at about 0.05 to about 20 mg per 100 kcal, or about 0.1 to about 0.15 mg, or about 0.13 to about 0.19 mg, or about 0.16 to about 0.23 mg, or about 0.19 to about 0.26 mg, or about 0.22 to about 0.3 mg, or about 0.28 to about 0.35 mg, or about 0.32 to about 0.4 mg, or about 0.37 to about 0.45 mg per 100 kcal.

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Riboflavin in about 0.07 to about 0.5 mg per 100 kcal, preferably in about 0.08 to about 0.5 mg per 100 kcal, preferably at about 0.07 to about 0.15 mg, or at about 0.13 to about 0.19 mg, or about 0.17 to about 0.23 mg, or about 0.20 to about 0.29 mg, or about 0.27 to about 0.36 mg, or about 0.33 to about 0.40 mg, or about 0.37 to about 0.45 mg per 100 kcal.

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Vitamin B₆ in about 0.07 to about 0.5 mg per 100 kcal, preferably in about 0.08 to about 0.5 mg per 100 kcal, preferably at about 0.07 to about 0.15 mg, or at about 0.13 to about 0.19 mg, or about 0.17 to about 0.24 mg, or about 0.21 to about 0.30 mg, or about 0.27 to about 0.34 mg, or about 0.30 mg to about 0.38 mg, or about 0.36 to about 0.42 mg, or about 0.39 to about 0.46 mg per 100 kcal.

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Niacin in about 0.7 to about 3 mg per 100 kcal, preferably about 0.9 to 3 mg per 100 kcal, preferably at about 0.7 to about 1.5 mg, or at about 1.3 to about 1.9 mg, or about 1.7 to about 2.2 mg, or about 2.0 to about 2.5 mg, or about 2.2 to about 2.8 mg per 100 kcal.

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Folic acid in about 10 to about 50 µg per 100 kcal, preferably at about 14 to about 20 µg, or about 18 to about 24 µg, or about 21 to about 28 µg, or about 25 to

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about 32 µg, or about 29 to about 34 µg, or about 31 to about 38 µg, or about 35 to about 41 µg, or about 38 to about 45 µg per 100 kcal.

Vitamin B₁₂ in about 0.07 to about 0.7 µg per 100 kcal, preferably at about 0.1 to about 0.18 µg, or about 0.14 to about 0.22 µg, or about 0.19 to about 0.25 µg, or about 0.23 to about 0.30 µg, or about 0.28 to about 0.38 µg, or about 0.35 to about 0.43 µg, or about 0.40 to about 0.48 µg, or about 0.43 to about 0.52 µg, or about 0.49 to about 0.58 µg, or about 0.54 to about 0.62 µg, or about 0.59 to about 0.65 µg, or about 0.62 to about 0.67 µg per 100 kcal.

Pantothenic acid in about 0.15 to about 1.5 mg per 100 kcal, preferably at about 0.4 to about 0.9 mg, or about 0.7 to about 1.1 mg, or about 0.9 to about 1.3 mg, or about 1.1 to about 1.4 mg per 100 kcal.

Biotin in about 0.75 to about 7.5 µg per 100 kcal, preferably at about 1.0 to about 1.9 µg, or about 1.7 to about 2.5 µg, or about 2.3 to about 3.1 µg, or about 2.8 to about 3.6 µg, or about 3.4 to about 4.2 µg, or about 3.9 to about 4.7 µg, or about 4.4 to about 5.2 µg, or about 4.9 to about 5.6 µg, or about 5.2 to about 6.3 µg, or about 5.9 to about 6.5 µg, or about 6.2 to about 7.0 µg per 100 kcal.

Vitamin E in about 0.5 to about 3 mg per 100 kcal, preferably at about 0.8 to about 1.4, or about 1.1 to about 1.8, or about 1.5 to about 2.1, or about 1.7 to about 2.5, or about 1.9 to about 2.8 mg per 100 kcal. Wherein preferably vitamin E is present in 0.5mg/g of polyunsaturated fatty acids, preferably expressed as linoleic acid but most preferably in no case less than 0.5 mg per 100 available kcal.

The term “micronutrient” as used herein refers to vitamins and minerals that are required in the human diet in very small amounts.

Dietary minerals are chemical elements other than carbon, hydrogen, nitrogen, and oxygen that are required to sustain the health of living organisms. In humans,

dietary minerals can include calcium, magnesium, phosphorus, potassium, sodium, and sulphur.

Said mixture in step (a) also preferably comprises the following minerals per 100 kcal:

Sodium in about 30 to about 175 mg per 100 kcal, preferably at about 70 to about 110 mg, or about 90 to about 130 mg, or about 110 to about 150 mg, or about 135 to about 155mg, or about 140 to about 165 mg per 100 kcal.

Potassium in about 70 to about 295 mg per 100 kcal, preferably about 80 to about 295 mg per 100 kcal, preferably at about 70 to about 120mg, or about 110 to about 150 mg, or about 125 to about 180 mg, or about 160 to about 210 mg, or about 190 to about 240 mg, or about 220 to about 270 mg per 100 kcal.

Phosphorus in about 30 to about 80 mg per 100 kcal, preferably at about 39 to about 55 mg, or about 44 to about 60 mg, or about 57 to about 65 mg, or about 61 to about 69 mg, or about 66 to about 72 mg, or about 71 to about 76 mg per 100 kcal.

Magnesium in about 7.5 to about 25 mg per 100 kcal, preferably at about 10 to about 14 mg, or about 12 to about 18 mg, or about 16 to about 20 mg, or about 19 to about 23 mg per 100 kcal.

Calcium in about 50 to about 250 mg per 100 kcal, preferably at about 90 to about 130 mg, or about 110 to about 150 mg, or about 130 to about 170 mg, or about 160 to about 190 mg, or about 180 to about 210 mg, or about 200 to about 230 mg per 100 kcal.

Said mixture in step (a) and compositions prepared by the inventive process also most preferably comprise calcium in an amount of about 100 to about 245 mg per 100 g.

Likewise preferably, the mixture used in step (a) of the inventive process and compositions thereof may comprise or contain calcium, more preferably in an amount of about 100 to about 245 mg per 100 g and/or lecithin, even more preferably in an amount of about 0.1 to about 2%.

It is more preferable that calcium is at about 120 to about 150 mg, or about 135 to about 190 mg, or about 185 to about 200 mg, or about 195 to about 210 mg, or about 205 to about 215 mg, or about 213 to about 220 mg, or about 217 to about 230 mg, or about 220 to about 234 mg, or about 232 to about 240 mg per 100g. Most preferably calcium is present in the process and compositions thereof of the present invention at about 217 mg, or at about 234 mg, or at about 209 mg per 100g.

Furthermore, the inventors also found that by preferably using magnesium and calcium lactate in the mixture formed or obtained according to step (a) of the process of the present invention, the protein stability of the product may be significantly improved.

Preferably, calcium lactate is present in the range of about 0.5 to about 3 % by weight. More preferably, in about 0.6 % to about 1.7 %, or about 1.5 % to about 1.8 %, or about 1.6 % to about 2 %, or about 1.9 % to about 2.5 %. Most preferably, the inventive process and/or the compositions produced thereof have calcium lactate in about 1.83% or about 1.76% by weight.

Preferably, magnesium lactate is present in the range of about 0.2 to about 2 % by weight. More preferably, in about 0.3 to about 0.5 %, or about 0.4 to about 0.6 %, or about 0.55 to about 0.8 %, or about 0.7 to about 1.2 %, or about 1 to about 1.5 %. Most preferably, the inventive process and/or the compositions produced thereof have magnesium lactate in about 0.59 % or about 0.61 % by weight.

The amounts of specific vitamins and minerals in the inventive process and composition thereof may be determined by one of skill in the art.

Furthermore, minerals that are needed in relatively small quantities and may be referred to as trace elements, for example, chromium, cobalt, copper, chloride, 5 fluorine, iodine, iron, manganese, molybdenum, selenium, and zinc.

Said mixture in step (a) also preferably comprises the following trace elements per 100 kcal:

10 Iron in about 0.5 to about 2.0 mg per 100 kcal, preferably at about 0.75 to about 1.3 mg, or about 1.1 to about 1.45 mg, or about 1.30 to about 1.65 mg, or about 1.55 to about 1.85 mg, or about 1.75 to about 1.9 mg per 100 kcal.

Zinc in about 0.5 to about 1.5 mg per 100 kcal, preferably at about 0.75 to about 15 1.1 mg, or about 0.90 to about 1.3 mg, or about 1.2 to about 1.4 mg per 100 kcal.

Copper in about 60 to about 500 µg per 100 kcal, preferably at about 90 to about 130 µg, or about 115 to about 150 µg, or about 135 to about 170 µg, or about 155 to about 200 µg, or about 180 to about 230 µg, or about 210 to about 280 µg, or 20 about 250 to about 330 µg, or about 310 to about 390 µg, or about 375 to about 450 µg per 100 kcal.

Chloride in about 30 to about 175 mg per 100 kcal, preferably at about 70 to about 110 mg, or about 90 to about 130 mg, or about 110 to about 150 mg, or about 135 25 to about 165 mg, or about 155 to about 170 mg per 100 kcal.

Iodine in about 6.5 to about 35 µg per 100 kcal, preferably at about 10 to about 16 µg, or about 13 to about 18 µg, or about 16 to about 20 µg, or about 19 to about 25 µg, or about 22 to about 29 µg, or about 27 to about 33 µg per 100 kcal.

Selenium in about 2.5 to about 10 µg per 100 kcal, preferably at about 3.5 to about 5 µg, or about 4 to about 6 µg, or about 5.5 to about 8 µg, or about 7 to about 9 µg per 100 kcal.

- 5 Manganese in about 0.05 to about 0.5 mg per 100 kcal, preferably at about 0.1 to about 0.15 mg, or about 0.13 to about 0.19 mg, or about 0.16 to about 0.23 mg, or about 0.21 to about 0.26 mg, or about 0.22 to about 0.3 mg, or about 0.28 to about 0.35 mg, or about 0.32 to about 0.4 mg, or about 0.37 to about 0.45 mg per 100 kcal.

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Chromium in about 1.25 to about 15 µg per 100 kcal, preferably at about 2.0 to about 4.3 µg, or about 4 to about 6 µg, or about 5.5 to about 7.5 µg, or about 7 to about 9 µg, or about 8.5 to about 12 µg, or about 10 to about 13 µg, or about 12 to about 14 µg per 100 kcal.

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Molybdenum in about 3.5 to 18 µg per 100 kcal, preferably at about 4 to about 6 µg, or about 5 to about 8 µg, or about 7 to about 9 µg, or about 8 to about 12 µg, or about 10 to about 13, or about 12 to about 16 µg per 100 kcal.

- 20 Fluoride in about 0 to about 0.2 mg per 100 kcal, preferably at about 0.05 to about 0.09 mg, or about 0.07 to about 0.12 mg, or about 0.10 to about 0.14 mg, or about 0.12 to about 0.18 mg per 100 kcal.

The mixture utilized in the inventive process and compositions described herein can include any combination of vitamins, minerals and trace elements that is use-
25 ful in providing appropriate nutrition to the patient. The vitamins, minerals and trace elements may be used in the form of a mixture or formulation.

Further to the above, mixing is carried out in step (a) of the inventive process. For the inventive process it is specifically preferred that during step (a) mixing speeds
30 are employed, which typically range from about 320 rpm to about 800 rpm, preferably about 377 to about 725 rpm, or about 360 to about 700 rpm, or about 370 to about 750 rpm, or about 374 to about 740 rpm, or about 380 to about 730 rpm.

For some of the ingredients it is preferable to employ slow mixing speeds which are preferably of about 320 to about 400 rpm, preferably about 360 to about 380 rpm, or about 370 to about 390 rpm.

- 5 Furthermore, for some ingredients it may be preferable to employ medium mixing speeds of preferably about 401 to about 550 rpm, or about 410 to about 430 rpm, or about 420 to about 450 rpm, or about 440 to about 490 rpm, or about 460 to about 500 rpm.
- 10 Furthermore, for some ingredients it may be preferable to employ medium-fast mixing speeds, preferably of about 551 to about 800 rpm, or about 510 to about 550 rpm, or about 530 to about 580 rpm, or about 560 to about 640 rpm, or about 600 to about 700 rpm, or about 660 to about 750 rpm.
- 15 Even more preferably, stepwise mixing speeds of about 725 rpm followed by about 377 rpm or about 435 rpm, followed by about 435 rpm, followed by about 580 rpm, followed by about 435 rpm, followed by about 580 rpm, followed by about 725 rpm or the like are employed. Furthermore, combinations around stepwise mixing speeds using the aforesaid slow, medium and medium-high ranges
- 20 may also be employed.

Following the above mentioned mixing steps the pH is then checked to ensure that this is less than 4.3, and if necessary said mixture is adjusted with citric acid to obtain a pH of less than 4.3.

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In this regard, the inventors found that for some of the ingredients, if slow mixing was not employed during step (a) of the process of the present invention this may result in excessive aeration, which in turn may lead to problems in the homogenization step, namely a highly aerated product may not run through the homogenizer.

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It is highly preferable that for the process of the present invention that mixing employed during step (a) of the process of the present invention is conducted with a twin impeller agitator and/or using a Jex mixing tank. Alternatively, any low sheer/low agitation mixing tank (with variable speed agitation) would be suitable.

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It is most preferred that if a Jex mixing tank is used in the process as described herein that this preferably has the following dimensions:

Internal diameter of about 1500 mm, top of top cone to bottom of bottom cone of about 1800 mm, height of cylindrical section of about 1250 mm, bottom mixer from sloping base of about 230 mm, bottom mixer diameter of about 180 mm with 4 blades, top mixer to bottom mixer of about 300 mm, top mixer diameter of about 300 mm with 3 blades.

It is particularly preferable in the process of the present invention that the mixing step as described for step (a) of the process of the present invention is carried out at about 10 to about 15°C, or about 13 to about 19°C, or about 18 to about 26°C, or about 25 to about 32°C, or about 30 to about 36°C, or about 34 to about 43°C, or more preferably at about 17 to about 23°C.

The aforementioned temperature ranges can also be used for any preheating if carried out.

It is further preferred in the inventive process as described herein that during step (a) the order of reagent addition is preferably water, lecithin and starch, protein – which is preferably acidified whey protein, coconut oil, most preferably fractionated coconut oil, sunflower oil, most preferably high oleic sunflower oil, fibre (if added), vitamins, minerals, and trace elements, sugar, antioxidants vitamin E and C and finally lemon oil. Further components may be added as defined for the inventive process or the inventive compositions as described herein. It is preferable that the pH is then checked to ensure that this is less than about 4.3.

Wherein during the course of the reagent addition the temperature is preferably kept in one of the temperature ranges as listed above for mixing step (a), although it is more preferred that several of the abovementioned temperature ranges are employed for mixing step (a) during reagent addition. For instance, 34 to about 5 40°C, or 35 to about 43°C for the mixing in of water, lecithin and starch, followed by about 37 to about 43°C, most preferably at about 35 to about 40°C for instance for the mixing in of acidified whey protein.

10 The inventors have also surprisingly found that if the protein employed in the mixture according to step (a) of the inventive process is acidified whey protein this leads to an improved viscosity and taste compared to when standard whey protein isolates are employed.

15 As described herein, the inventive process is most preferably carried out as a continuous process although said inventive process can also preferably be carried out as a batch process.

Following a particularly preferable protocol for step (a) of the inventive process as described herein, water may be added to a mixing tank, which is preferably a Jex 20 mixing tank or the like, preferably at 20°C +/- 3°C , wherein mixing is typically conducted with a twin impeller agitator. Preferably lecithin and starch are then added to the tank, and the mixer speed is preferably set at about 725 rpm, most preferably mixing for about 5 minutes. Preferably a protein, most preferably acidified whey protein is then added, and the mixer speed preferably reduced to about 25 435 rpm, followed preferably by further mixing for about 30 minutes. Preferably fractionated coconut oil and high oleic sunflower oil is then added, followed by preferably increasing the mixer speed to about 580rpm for about 5 minutes. After said mixing it is also preferable that the mixer speed is reduced to about 435 rpm, and most preferably mixed for a further 30 minutes. Optionally, fibre is then added 30 and mixed for 15minutes at 580rpm. Preferably then any further ingredients such as vitamins, minerals and trace elements are then added, wherein preferably the

mixer speed increases to about 580 rpm, preferably mixing for about 10 minutes. It is most preferable that sugar, preferably castor sugar is then added, wherein the mixer speed preferably increased to about 725 rpm, preferably mixing for about 20 minutes. It is preferable that the lemon oil and antioxidants such as vitamin C and vitamin E are then added, followed by mixing for about 10 minutes at about 725rpm The pH is then checked to ensure that this is less than about 4.3, preferably in the range of about 3.5 to about 4.5, and then preferably adjust as is necessary with citric acid to fall within said limits. Preferably the product is left to degas at a mixing speed of about 725 rpm or higher for about 12 minutes, wherein optionally the product is processed to a Specific Gravity of about 1.01 at 20°C +/- 3°C or of about 1.05 at 20°C +/- 3°C.

According to step (b) of the inventive process, the mixture obtained according to step (a) is optionally preheated. Preheating may be carried out at a temperature range of about 10 to about 35°C, or about 15 to about 25°C, or about 12 to about 20°C, or of about 18 to about 30°C or more preferably at a temperature range of about 17 to about 23°C.

As furthermore described herein for step (c) of the inventive process, preferably the mixture obtained according to step (a) or (b) is homogenized at a temperature range of about 86 to about 92°C, preferably at a temperature range of about 80 to about 88°C, or about 77 to about 91°C, or about 84 to about 92°C or about 86 to 89°C or about 87 to about 91°C or about 90 to about 94°C, or about 94°C to about 100°C.

Homogenizing is preferably is carried out at pressures of about 15 to about 220 bar, such as about 15 to about 195 bar, preferably at about 20 to about 185 bar, or about 30 to about 170 bar, or about 40 to about 150 bar, or about 50 to about 135 bar, or about 80 to about 120 bar, or about 100 and about 140 bar, or about 130 to about 170 bar, or about 150 to about 190 bar, or about 180 to about 220 bar, or about 18 to 22 bar, or about 25 to about 45 bar, or about 40 to about 65

bar, or about 50 to about 70 bar, or about 60 to about 75 bar, or about 90 to about 115 bar, or about 110 to about 120 bar.

Said preferable homogenization step employs homogenizers known in the art,
5 particularly preferable homogenizers include Tetra Alex S15, APV or Nitro Homogenizers.

For the purpose of step (c) of the inventive process, the mixture is optionally passed through an inline sieve. This (sub-)step is preferably followed by heating
10 the mixture to about 86 to about 100°C, preferably about 86 to about 92°C, preferably for a minimum of about 2 minutes. The heated mixture is then typically homogenized using a homogenizer as known to a skilled person applying the defined temperatures and pressures.

15 The inventors have also surprisingly found that by adjusting the homogenization pressure that the viscosity of the product can be controlled.

The term “viscosity” as used herein refers to the measure of the thickness or resistance of a fluid to flow. Liquids with a high viscosity such as semi-liquids or
20 semi-solids are usually very thick and flow very slowly, while low viscosity liquids generally are thin and flow quickly.

For instance, if a viscous product is desired, a homogenization pressure of about 86 to about 220bar, such as about 86 to about 195 bar, preferably about 90 to
25 about 100 bar, or about 95 to about 120 bar, or about 110 to about 140 bar, or about 130 to about 160 bar, or about 150 to about 180 bar, or about 170 to about 190 bar, or about 190 to about 210 bar, or about 200 to about 220 bar, can be used to give a semi-liquid or semi-solid viscosity.

30 On the other hand, if a less viscous product is desired, lower homogenization pressures such as about 1 to about 85 bar, preferably about 10 to about 30 bar, or

about 20 to about 45 bar, or about 40 to about 65 bar, or about 55 to about 80 bar can be used in order to give a more liquid viscosity.

5 In order to obtain a liquid viscosity, most preferably a homogenization pressure of about 70 bar is used.

The present inventive process and composition thereof preferably encompass products as described herein having liquid, semi-liquid or semi-solid viscosities defined in centipose (cP) of about 1 to about 40,000 cP, preferably about 1000 to
10 about 40,000 cP.

Viscosities described herein were measured at 25°C using a Brookfield DV-E Viscometer (LV model). Alternatively, viscosities can also be measured by other methods known in the art. As used herein, the viscosity terms semi-solid and
15 semi-liquid can be used interchangeably. Having said this, generally speaking, a product with a semi-solid viscosity as described herein is generally more viscous than a product with a semi-liquid viscosity.

In some aspects, for a liquid product, the inventors have found that this is typically
20 from about 1000 to about 4700 cP, preferably about 1100 to about 1400 cP, or about 1350 to about 1600 cP, or about 1500 to about 1750 cP, or about 1650 to about 2000 cP, or about 1900 to about 2300 cP, or about 2100 to about 2600 cP, or about 2500 to about 2900 cP, or about 2800 to about 3100 cP, or about 3000 to about 3200 cP, or about 3150 to about 3500 cP, or about 3400 to about 3900
25 cP, or about 3800 to about 4200 cP, or about 4100 to about 4600 cP.

In a further aspect of the inventive process and product thereof, without being limited thereto, a liquid can also be further described as being honey-like which is about 351 to about 1750 cP.

As used herein, with regard to viscosity the term "honey-like" refers to liquids that have been thickened to honey consistency. The liquid flows off a spoon in a ribbon, just like actual honey.

- 5 The inventors have also surprising found that for the inventive process and product thereof a semi-liquid is typically from about 4500 cP to about 25,000 cP, preferably about 4600 to about 5000 cP, or about 4800 to about 5400 cP, or about 5200 to about 5800 cP, or about 5700 to about 6500 cP, or about 6200 to about 7000 cP, or about 6900 to about 10,000 cP, or about 9,000 to about 14,000 cP, or
10 about 12,000 to about 16,000 cP, or about 14,000 to about 20,000 cP, or about 19,000 to about 22,000 cP.

- The inventors have also surprising found that for the inventive process and product thereof a semi-solid is typically from about 18,000 to about 40,000 cP, preferably
15 about 19,000 to about 22,000 cP, or about 21,000 to about 25,000 cP, or about 24,000 to about 30,000 cP, or about 26,000 to about 32,000 cP, or about 31,000 to about 35,000 cP, or about 34, 000 to about 37,000 cP, or about 36,000 to about 39,000 cP.

- 20 The viscosities as described herein can apply for the product after step (c) of the inventive process and/or the product after step (f) of the inventive process. Depending on the processing conditions selected as described herein, such as homogenization pressure, pasteurization temperature and the type of sealable packaging used etc., the viscosity at step (c) may differ from that of step (f).

- 25 As used herein, the abovementioned descriptive or measured viscosities correspond to the viscosities as determined at the start of the shelf-life, which preferably commences after either the final process step, more preferably final process step (e). The final step of the process of course preferably depending on whether
30 all aforementioned preceding steps are performed. Preferably, the viscosity is determined within about one minute to about eight hours of said final process step, preferably one minute to about four hours, more preferably one hour to

about four hours, most preferably after about two to about four hours, or about three to about six hours, or about five to about seven hours of the final process step. The viscosity may likewise be determined subsequent to the optional cooling step (f), preferably in the aforementioned time ranges.

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More specifically, the inventive process as described herein can be used to produce compositions which are preferably either liquids or semi liquids/semi solids. The viscosity can be tailored as desired, preferably by controlling homogenisation pressure, temperature and holding time, which may be supplemented e.g. by adding starch as defined herein.

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In this regard, the inventors have also surprisingly found that when step (c) of the inventive process is repeated this can yield a product having an increased viscosity than if step (c) were only conducted once. In some cases, further repetitions of said step may also be desirable. For instance, step (c) could first be carried out with the homogenizer set at 70 bar pressure, denoted herein as first stage homogenization. This may then be followed by repeating step (c), denoted herein as second stage homogenization, wherein for instance the homogenizer is set at about 18 bar pressure or at a pressure as defined herein. In some cases, even a third or fourth stage homogenization may also be desirable. Preferably during second stage homogenization lower pressures are used than in the first stage homogenization. Furthermore, if a third stage homogenization is employed this is preferably at lower pressures than in the second stage homogenization.

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Surprisingly, in some cases, even if the second stage homogenization employs a lower pressure compared to after the first stage homogenization step, this can lead to a two-fold, preferably a threefold increase in viscosity. Accordingly, when highly viscous products are desired, preferably the inventive process as described herein includes at least a first and second stage homogenization step.

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Having said, this, when starch is employed in the inventive process as described herein, conducting a second stage homogenization step rather tends to result in

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either effectively no change in the viscosity, or even a reduction in viscosity compared to after the first stage homogenization step. Accordingly, if a highly viscous product is desired, if starch is employed, preferably the second stage homogenization step is omitted. In other words, when a highly viscous product is desired, when for instance a first and second stage homogenization step is conducted preferably starch is not used therein.

Alternatively, for a product with a viscosity in the lower range as disclosed herein, the inventive process preferably also includes starch along with a second stage homogenization step. Furthermore, preferably by employing protein at the higher range as described herein also tends to lead to products with a higher viscosity.

Most preferably, the inventive process herein and/or the product thereof of said process has a water content of about 40 % to about 65 % by weight, more preferably about 41 to about 43 %, or about 42 to about 45 %, or about 43 to about 46 %, or about 45.5 to about 47.5 %, or about 46.5 to about 49 %, or about 48 to about 52 %, or about 50 to about 55 %, or about 53 to about 59 %, or about 57 to about 61 %, or about 60 to about 63.5 % by weight. It is most preferred that the inventive product herein and/or the product of said process has a water content of 46 % by weight.

According to a further optional step the product prior to the homogenization step and obtained according to step (a) or (b) is processed at Specific Gravity 1.01 at 20°C +/- 3°C or of about 1.05 at 20°C +/- 3°C prior to carrying out homogenization in step (c).

According to step (d) of the inventive process, the mixture, typically the homogenized mixture obtained according to step (c), is preferably packed into a package, which is preferably a sealable package which is preferably a unit or dose for administration as described herein, more preferably into a pot, bottle, tear top tube /stickpack sachet with tear top, or into a pouch such as a Guala pack.

A pouch or stickpack sachet with tear top is particularly preferred since this advantageously allows to pasteurize the mixture in the unit or dose for administration without the risk of damaging the package. Pouches are preferably a cheerpack, pillow bag or stand-up pouch, which is preferably a Guala pack.

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Indeed, the inventors have also found that for the present inventive process, the pouch is particularly preferable since this is complementary to the viscosity of the inventive compositions. In this regard, if any other type of pack is used the product may thicken too much to be consumed directly from the pack. More specifically, since thickening of the composition typically occurs inside said packaging this allows for higher protein addition and hence if desired a more viscous semi-solid composition can be produced.

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As furthermore described herein for step (d) of the inventive process, the homogenized product is then preferably packed directly into a package, which is preferably a sealable package, preferably the unit or dose for administration as described herein, particularly a pouch, pot, tear top tube or bottle. Most preferably the pouch is a Guala pack or the like.

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In step (e) of the inventive process as described herein pasteurizing the packaged mixture is carried out preferably at a temperature of about 60 to about 100°C, preferably at a time of less than 1 minute to about 10 minutes, such as about 2 to about 10 minutes.

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It is particularly preferable that in the inventive process the pasteurization temperature is about 60 to about 96°C, preferably about 73 to about 93°C, or about 65 to about 80°C, or about 70 to about 85°C, or about 76 to about 90°C, or about 82 to about 94°C, or about 76 to about 93°C.

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It is particularly preferable that in the inventive process the pasteurization time is of about 2.5 to about 3.5 minutes, or about 3 to about 4.5 minutes, or about 4 to about 6 minutes, or about 5 to about 8 minutes.

- 5 In other preferred embodiments of the inventive process the pasteurization temperature is about 94 to about 100°C, preferably about 96 to about 100°C, and the pasteurization time is less than about 2 minutes, preferably less than about 1 minute, preferably about 0.5 to about 1.5 minutes, more preferably about 0.5 to about 1 minute, or about 30 to about 55 seconds.

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Furthermore, it is particularly preferable to utilise pasteurization incorporating a scrape surface heat exchanger to ensure a build up of product is avoided, hence reducing the atherosclerotic effect created during in particular UHT processing. In an alternative method a spiral heat exchanger may be used.

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Most preferably, pasteurization as described in the process herein is conducted at about 80°C to about 93°C, preferably at about 80°C to about 90°C, or at about 85°C to about 92°C, or at about 87°C to about 91°C, preferably 89°C for about 2 minutes, in the scrape surface heat exchanger and then held at about 73°C to about 93°C, or at about 73°C to about 79°C, or at about 76°C to about 80°C, or at about 77 to about 93°C, or at about 78°C to about 82°C, preferably 80°C for about 3 minutes, preferably less than 5 minutes.

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- For step (e) of the inventive process as described herein, pasteurizing is preferably followed by carrying out pasteurization into a package, preferably a sealable package, preferably as a unit or dose for administration as described herein, particularly preferable is a pot, bottle, stickpack with tear top / tear top tube, or a pouch, wherein said pouch is most preferably a Guala pack or the like, typically at conditions as described above, e.g. at about 76 to about 93°C for 3 minutes +/- 30 seconds.

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It is also particularly preferable for step (e) of the inventive process as described herein if the mixture prepared or obtained according to step (a) or (b) contains starch, preferably tapioca starch, as defined below.

- 5 The term “starch” as used herein refers to a complex carbohydrate (polysaccharide) composed of chains of glucose molecules, which plants use to store food energy.

Preferably, the inventive process as described above may also comprise starch,
10 preferably tapioca starch in amounts of about 1.5 % by weight, more preferably about 1.3 % by weight, most preferably about 0.5 to about 2.5 %, or about 1 to about 1.5 %, or about 1.3 to about 2 % by weight. If present, the process and compositions thereof of the present invention most preferably has starch present
15 is not present in the process and compositions thereof of the present invention.

Starch can however be particularly advantageous since the resulting mixture is thin at the mixing stage although the viscosity later may increase on setting in for instance the bottle, tear top tube, pot or pouch, wherein said pouch is most pref-
20 erably a Guala pack or the like, e.g. during pasteurization step. Accordingly, starch as defined herein is a further ingredient which may be employed in order to help tailor the viscosity of the composition produced by the inventive process.

The inventors have also surprisingly found that in the process and compositions
25 thereof of the present invention if the protein employed is acidified whey protein this leads to an improved viscosity and taste compared to when standard whey protein isolates are employed.

Finally, as described herein for step (f) of the inventive process, this is then pref-
30 erably followed by cooling in a cooling bath in order to obtain a product which is preferably less than 30°C at the end of cooling. Most preferably, said cooling step is conducted at between about 0 and about 10°C, preferably about 5 to about

15°C, or about 12 to about 20°C, or about 18 to about 25°C, or about 22 to about 29°C. Preferably the product is then packed into boxes.

5 Preferably, said cooling step (f) is conducted over less than about 10 minutes, or over less than about 5 minutes or over less than about 2 minutes. Most preferably said cooling step is carried out over about 1 to about 5 minutes, or about 3 to about 8 minutes or about 6 to about 10 minutes.

10 The inventive process as described herein has a flow rate which depends on the sealable package size along with the filling rate. For instance, when a 100g sealable package, preferably a pouch is employed as described herein, it is preferable that when using one filler about 85 pouches per minute are filled, which amounts to a flow rate of about 510 litres per hour (lph). Wherein said filler or fillers is/are placed directly before said sealable package.

15 Accordingly, if the inventive process employs for instance two fillers the flow rate doubles and hence increases to about 1020 lph.

20 Furthermore, the inventive process may also have a flow rate of about 250 to about 3500 lph, preferably about 350 to about 600 lph, or about 450 to about 700 lph, or about 650 to about 850 lph, or about 750 to about 950 lph, or about 800 to about 1300 lph, or about 1200 to about 1600 lph, or about 1400 to about 1800 lph, or about 1700 to about 2100 lph, or about 1900 to about 2500 lph, or about 2300 to about 3000 lph, or about 2800 to about 3250 lph.

25 It is most preferred that in the process and compositions thereof of the present invention that the pasteurized packaged mixture is a liquid or a semi liquid/semi solid.

30 In a preferred embodiment the compositions produced have a ratio of fat: protein: carbohydrate of about 4.2: 1: 2, wherein preferably each of the values for the ratio of fat: protein: carbohydrate may vary by +/- 0.3.

In some aspects ratios of 3.9: 0.7: 1.7 to 4.5: 1.3: 2.3 may be utilized. For instance, one such ratio comprised in the process and compositions thereof of the present invention is 4.1: 0.9: 2.2.

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In an embodiment of the inventive process and/or the product thereof of said process it is additionally or alternatively preferable that the weight ratio of fat to the sum of proteins and carbohydrates in the inventive process, preferably digestible carbohydrates, is 4.2: 3, which may vary by +/- 0.3. For instance, preferably the weight ratio of fat to the sum of proteins and carbohydrates, preferably digestible carbohydrates is 3.9: 2.7 to 4.5: 3.3. For example, said ratio could be 4.1: 3.2; which could consist of 4.1 fat and 1 protein and 2.2 carbohydrate.

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Further preferred is that the process of the present invention, particularly the compositions produced thereof have a ratio of fat: protein: carbohydrate of about 3.65: 1: 1.25, or about 3.1: 1: 1.7, wherein preferably each of the values for the ratio of fat: protein: carbohydrate may vary by +/- 0.3.

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Accordingly, in some aspects ratios of 3.35: 0.7: 0.95 to 3.95: 1.3: 1.55 may be utilized. For instance, one such ratio comprised in the process and compositions thereof of the present invention is 3.45: 0.9: 1.0. In some other aspects ratios of 2.8: 0.7: 1.4 to 3.4: 1.3: 2.0 may be utilized.

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In the inventive process and/or the product thereof of said process it is additionally or alternatively preferable that the weight ratio of fat to the sum of proteins and carbohydrates in the inventive process, preferably digestible carbohydrates, is 3.65: 2.25, which may vary by +/- 0.3. For instance, preferably the weight ratio of fat to the sum of proteins and carbohydrates, preferably digestible carbohydrates is 3.35: 1.95 to 3.95: 2.55. For example, said ratio could be 3.45: 2.1; which could consist of 3.45 fat and 1 protein and 1.1 carbohydrate. In an alternative embodiment the ratio of fat to the sum of proteins and carbohydrates may be about 3.1: 2.7

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In the inventive process and/or the product thereof the energy content of the pasteurized packaged mixture is preferably about 150 to about 440 kcal per 100g, or about 160 to about 190 kcal, or about 185 to about 225 kcal, or about 215 to about 240 kcal, or about 230 to about 270 kcal, or about 265 to about 285 kcal, or about 280 to about 300 kcal, or about 290 to about 320 kcal, or about 310 to about 330 kcal, or about 325 to about 340 kcal, or about 335 to about 360 kcal, or about 300 to about 380 kcal, or about 350 to about 385 kcal, or about 370 to about 400 kcal, or about 390 to about 420 kcal per 100g. Said pasteurized packaged mixture may then be administered once daily, preferably twice daily, more preferably three times daily, wherein each dose preferably comprises a 30g, 50g, 90g pouch or a 100g pouch.

It is also highly preferable that in the process of the present invention and compositions thereof for said pasteurized packaged mixture the total amount of energy contained and suitable to be administered per day is about 300 to about 635 kcal, most preferably about 300 to about 600 kcal.

The process as defined herein is intended to cover a specific heat treatment process which can be utilized for a wide range of products containing high levels of protein, fat, carbohydrate and micronutrients.

In this regard, the inventors have found that the processing of high protein, high fat compositions, especially wherein they contain added calcium and micronutrients can present difficulties during heat treatment using the methods as described in the prior art.

Products containing high levels of protein, fat, carbohydrate and micronutrients can often present processing difficulty in retort and pasteurization and/or sterilization due to:

- 1) High viscosity during mixing phases: poor homogeneity, difficult to pump, homogenize and heat process (pasteurize) particularly in steam injection plate heat exchangers.
- 2) Aeration during mixing due to high protein level: difficult to pump from mixing tank, homogenise and heat process (pasteurize).
- 3) Product fouling in the heating stage. Furthermore, high protein in combination with high fat and micronutrients is prone to burning during heating.
- 4) Undesirable thickening of the product
- 5) Overcooked taste or flavour deterioration: due to high temperatures (UHT) or long heating times (retort)

This problem has been solved herein by employing low pH (<4.3) pasteurization process which allows a lower temperature (than UHT) and shorter time (than retort) so the process is more gentle on protein containing products, giving optimum product characteristics, taste and viscosity range from liquid to semi solid.

Preferably, a scrape surface heat exchanger in tubular system are also employed since this keeps the product moving and therefore reduces risk of protein fouling so higher protein addition possible.

Furthermore, it has also been found that by preferably choosing a protein such as an acidified whey protein as a protein source, employing antifoaming agents such as lecithin and/or MCT oil and/or silicone antifoamers - which result in the reduction of foaming and increased processability. Furthermore, it has also been found that preferably slow mixing, especially during protein addition, is also beneficial for the inventive process.

In addition, preferably the inclusion of calcium lactate and/or calcium acetate and/or Magnesium lactate is also beneficial since these improve the protein stability of the product.

The inventors have also found that for the process of the present invention, the package or sealable package as used herein is a bottle, tear top tube, pot, pouch and the like. A Guala pack and the like is particularly preferable since this is complementary to the viscosity of the composition. In this regard, if any other type of pack is used the product may thicken too much to be consumed directly from the pack. More specifically, since thickening of the composition occurs inside said packaging this allows for higher protein addition and hence if desired a more viscous, semi solid/semi liquid composition can be produced.

- 10 The following are some non-limiting examples of compositions which preferably obtained/obtainable by the process as described above.

According to another embodiment, the object underlying the present invention is preferably solved by an inventive composition, which typically comprises about 4 to about 12 % by weight protein, about 5 to about 15 % by weight carbohydrate and a high level of fat which is preferably about 25 to about 38 % by weight fat. The inventive composition may be used for treatment of diseases and disorders as defined herein.

- 20 The inventive compositions and methods as described herein are most preferably obtained/obtainable by the inventive process as described herein. In this regard, said compositions may contain or comprise any of the amounts and ingredients as defined for the inventive process, preferably the mixture as employed in step (a) of the inventive process.

25 Said inventive composition, which is preferably a liquid or semi liquid/semi solid composition, may be adjusted to a pH of less than about 4.3, preferably to a range of about 3.5 to about 4.5. Most preferably the pH of the inventive composition is in such a range, more preferably about 4.2, or about 4.

- 30 According to a preferred aspect the composition of the present invention is a nutritional composition, preferably a pasteurized composition, more preferably a pas-

teurized nutritional composition. Additionally or alternatively the composition of the present invention may be a ketogenic composition. Furthermore, the composition of the present invention may be for use as a supplement or may be used as a sole source of nutrition, e.g. as a full meal. The inventive composition may be further-
5 more suitable for use in the treatment of a disease as defined herein.

The term "supplement" as used herein refers to a nutrient that may be added to the diet or a meal thereof.

- 10 As defined above, the inventive composition typically comprises about 4 to about 12 % by weight protein, about 5 to about 15 % by weight carbohydrate and a high level of fat which is preferably about 25 to about 38 % by weight fat.

- Within the context of the present invention, the inventive composition may also
15 comprise or contain fat comprising saturates, mono-unsaturates, and/or poly-unsaturates. Preferably, the inventive composition preferably comprises in a range of about 2 to about 30 % by weight saturates, about 1 to about 25 % by weight mono-unsaturates and about 0.1 to about 5 % by weight poly-unsaturates.

- 20 It is preferred that 0.4 to 2.0% by weight of the fat in the inventive composition is eicosapentaenoic acid (EPA). According to an alternative, such inventive compositions may contain no eicosapentaenoic acid (EPA).

- Within the context of the composition of the present invention, the protein, the fat
25 and/or the carbohydrate, particularly of the inventive composition is/are preferably derived from at least two different sources, namely animal and vegetal as described above for the inventive process.

- According to a particularly preferred aspect the protein present in the inventive
30 composition is preferably a whey protein, more preferably a whey protein isolate and even more preferably an acidified whey protein isolate as defined for the inventive process.

According to one further preferred aspect, the inventive composition comprises or contains an amount about 0.5 to about 23 % by weight medium chain triglycerides and/or an amount of about 6 to about 30 % by weight long chain triglycerides as defined in the inventive process above.

Additionally, according to one other preferred aspect, the carbohydrate source as contained in the inventive composition typically may be selected from any suitable carbohydrate source as defined for the inventive process above.

Furthermore, according to one other preferred aspect, the optional sweetener and/or emulsifier source as contained in the inventive composition typically may be selected from any suitable sweetener and/or emulsifier source as defined for the inventive process above.

The fibre source, if employed in the inventive composition may be either soluble or insoluble fibre which can be present alone or in combination as defined for the inventive process above. For instance, fibre can be utilized in about 1% by weight, preferably about 0.7 to about 1 %, or about 0.8 to about 2 %, or about 0.9 to about 1.5 %, or about 1 to about 1.2 %.

Likewise preferably, the composition of the present invention may comprise or contain calcium, more preferably in an amount of about 100 to about 245 mg per 100 g and/or lecithin, even more preferably in an amount of about 0.1 to about 2 %.

Furthermore, it is also particularly preferred that the inventive composition does not contain or comprise DHA, DPA and/or ARA.

According to one specific embodiment, the ratio of fat: protein: carbohydrate in the inventive composition is about 4.2: 1: 2, wherein preferably each of the values for

said ratio for fat: protein: carbohydrate may vary by +/- 0.3 as defined above for the inventive process.

According to another specific embodiment, the ratio of fat: protein: carbohydrate in the inventive composition is about 3.1: 1: 1.7 wherein preferably each of the values for said ratio for fat: protein: carbohydrate may vary by +/- 0.3 as defined above for the inventive process.

It is also particularly preferable that the inventive composition contains no artificial additives and/or contains whole protein. Having said this, in a preferred embodiment the composition does not contain whole milk protein in a ratio of 80:20 casein protein to whey protein.

It is also preferable that the inventive composition contains intact proteins and particularly preferred that casein is not present in the inventive composition.

Acids may also be employed in the inventive composition, preferably citric acid, malic acid, ascorbic acid lactic acid, succinic acid, acetic acid, either alone or in combination. Wherein the acid can be added in liquid or dry form, such as in hydrated or anhydrous form and the like.

Particularly favourable inventive compositions may comprise or contain an anti-foaming agent, preferably selected from lecithin and/or MCT oil and/or silicone antifoamers, more preferably in an amount of about 0.5 to 23 % by weight as defined for the inventive process. The MCT oil then preferably not only acts an anti-foaming agent, its presence is furthermore nutritionally required.

The inventive composition typically comprises about 4 to about 12 % by weight protein, about 5 to about 15 % by weight carbohydrate and a high level of fat, preferably about 25 to about 38 % by weight fat and optionally about 0.5 to about 2.5 % by weight fibre. Most preferably, the composition or ketogenic composition

contains about 0.5 to about 23 % by weight medium chain triglycerides and/or about 6 to about 30 % by weight long chain triglycerides.

According to a particularly preferred aspect, the inventive process leads to a composition as defined before, preferably comprising as ingredients water, vegetable oil (fractionated coconut oil and high oleic sunflower oil), sucrose; which is preferably caster sugar, whey protein isolate; which is preferably acidified whey protein isolate, calcium lactate, emulsifier (soya lecithin, e.g. E322), dietary fibre which is preferably a mixture of inulin and oat fibre (e.g. White Star AOF 200), magnesium lactate, tri potassium citrate, sodium chloride, choline bitartrate, vitamin premix, trace element mix, dipotassium phosphate, tri sodium citrate, lemon oil (e.g. lemon oil 12116), taurine (e.g. JP8), L-carnitine L-tartrate and citric acid anhydrous.

Most preferably, the composition which is preferably obtained/obtainable by the inventive process as described herein has an energy content as defined before, e.g. of about 150 to about 440 kcal per 100g, preferably per 100g of about 1348 KJ (about 322 Kcal) and preferably contains or comprises the following ingredients per 100g:

protein at about 8 g, carbohydrate at about 10 g, Fat at about 29.2 g.

Vitamin premix which preferably contains or comprises Vitamin A, Vitamin D, Vitamin E, Vitamin C, Vitamin K, thiamin, riboflavin, niacin, Vitamin B₆, folic acid, Vitamin B₁₂, biotin, pantothenic acid and choline, preferably in a combined amount of about 109.7 mg per 100g. Other vitamins may also be present as defined herein above.

Minerals which preferably contains or comprises sodium, potassium, calcium, phosphorus and magnesium, preferably in a combined amount of 907 mg per 100g. Other minerals may also be present as defined herein above.

Trace element mix which preferably contains or comprises chloride, iron, copper, zinc, manganese, iodine, molybdenum, selenium and chromium, preferably in a

combined amount of 244.9 mg per 100g. Other trace elements may also be present as defined herein above.

5 Medium chain triglycerides at about 20.03 g, long chain triglycerides at about 8.73 g, fibre at about 1 g, linoleic acid at about 1079 mg, α -linoleic acid at about 48.2 mg per 100g.

According to a particularly preferred aspect, the inventive process leads to a composition as defined before, preferably comprising as ingredients: water, vegetable
10 oil (high oleic sunflower oil and fractionated coconut oil), sucrose, whey protein isolate; preferably acidified whey protein isolate, calcium lactate, emulsifier (soya lecithin, e.g. E322), magnesium lactate, sodium chloride, dipotassium phosphate, citric acid, tri sodium citrate, vitamin premix, trace element mix, tri potassium citrate, lemon oil (e.g. lemon oil 12116), potassium chloride (with 0.5% Magnesium
15 carbonate), L-ascorbic acid and vitamin E.

Particularly preferable is that said obtained inventive composition has an energy content as defined before, e.g. of about 150 to about 440 kcal per 100g, preferably per 100g of about 1397 KJ (about 334 Kcal) and preferably contains or comprises
20 the following ingredients per 100g:

Protein at about 8 g, carbohydrate at about 13.4 g, fat at about 23.9 g.

Vitamin premix which preferably contains or comprises Vitamin A, Vitamin D, Vitamin E, Vitamin C, Vitamin K, thiamin, riboflavin, niacin, Vitamin B₆, folic acid, Vitamin B₁₂, biotin and pantothenic acid, preferably in a combined amount of about
25 22.5 mg per 100g. Other vitamins may also be present as defined herein above.

Minerals which preferably contains or comprises sodium, potassium, calcium, phosphorus and magnesium, preferably in a combined amount of about 943 mg
30 per 100g. Other minerals may also be present as defined herein above.

Trace element mix which preferably contains or comprises chloride, iron, copper, zinc, manganese, iodine, molybdenum, selenium and chromium, preferably in a combined amount of about 255.1 mg per 100g. Other trace elements may also be present as defined herein above.

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Medium Chain Triglycerides at about 1.49 g, Long Chain Triglycerides at about 25.5 g, linoleic acid at about 2742 mg and α -linoleic acid at about 61.8 mg per 100g.

- 10 According to a further embodiment, uses of the inventive compositions as described herein, or as obtained or obtainable according to the inventive process, are contemplated. The inventive composition is particularly suitable for the use in the dietary management of diseases or disorders as defined herein, such as malnutrition, malabsorption states and other conditions requiring fortification with energy, protein and micronutrients.
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The term "fortification" as used herein means to supplement or add nutrients to the inventive composition during the inventive process that may be lacking in the overall diet. Such nutrients include, but are not limited to folate, vitamins A and D, and calcium.

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The composition is also advantageously suitable for the treatment of various states of oncology, cystic fibrosis, elderly (dementia), neuro-disabilities, improvement of brain function or of cognitive skills, neurological diseases, neurodegenerative diseases, dysphasia, pre- and post operative surgery, ADHD (Attention Deficit Hyperactivity Disorder), GLUT-1 deficiency, Pyruvate Dehydrogenase (PDH) deficiency, phosphofructokinase (PFK) deficiency, stroke, liver disease, Cancer (renal, head and neck) or may be suitable for use in treatment of neurological diseases, such as for treating epilepsy, preferably refractory epilepsy in children.

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The composition is also suitable for the treatment of Dravet Syndrome (severe myoclonic epilepsy), Doose Syndrome (myoclonic astatic epilepsy), epileptic syndromes and seizures, myoclonic jerk, tumor, obesity, Diabetes, gut motility disorders including constipation, Gastro Intestinal, allergy, anti-aging and psychiatric disorders.

Furthermore, the inventive composition can also be used for treating a disorder or a disease treatable with the ketogenic diet selected from neurodegenerative diseases, improvement of brain function or of cognitive skills, Alzheimer disease/cognitive impairment, Parkinson's disease, neurological diseases, Amyotrophic lateral sclerosis, Traumatic brain injury, Hypoxic/ischemic brain injury, Autism, ADHD (Attention Deficit Hyperactivity Disorder), Depression, Headaches, Migraine Headaches, Narcolepsy, GLUT-1 deficiency, Pyruvate Dehydrogenase (PDH) deficiency, phosphofructokinase (PFK) deficiency, Glycogenosis type V (McArdle disease), Cardiac ischemia, Rett syndrome, Tuberous Sclerosis, Diabetes and Cancer (astrocytomas, prostate, gastric, renal, head and neck). As used herein, the term "a disorder" or "a disease" refers to any derangement or abnormality of function; a morbid physical or mental state. See Dorland's Illustrated Medical Dictionary, (W.B. Saunders Co. 27th ed. 1988).

Treatment of such diseases or disorders is preferably accomplished by administering a therapeutically effective amount of a composition according to the present invention to a subject in need thereof. Preferably, such a composition is to be administered once daily, preferably twice daily, more preferably three times daily, wherein during administration preferably at least one unit or dose for administration is provided, as defined herein. Upon administration, preferably the total amount of energy to be administered per day is as defined before. As used herein, the term "subject" refers to an animal. Preferably, the animal is a mammal. A subject also refers to for example, primates (e.g., humans), cows, sheep, goats, horses, dogs, cats, rabbits, rats, mice, fish, birds and the like. In a preferred embodiment, the subject is a human. The term "therapeutically effective amount" of a composition of the present invention refers to an amount of the compound of the

present invention that will elicit the biological or medical response of a subject, or ameliorate symptoms, slow or delay disease progression, or prevent a disease, etc. Preferably, such a "therapeutically effective amount" is a packaged dose or unit as obtained as described herein.

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It is particularly preferable that said inventive composition, which is preferably obtained/obtainable by the inventive process as described herein provides an energy content as defined before, e.g. of about 150 to about 440 kcal per 100g, most preferably at about 334 kcal or at about 321 kcal per 100g, preferably per unit or

10 dose for administration. Such a unit or dose for administration may be a bottle, tear top tube, pot, or a pouch, which is preferably a Guala pack etc.

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Preferably, such a unit or dose for administration exhibits a weight of about 30 to 200 g of the inventive composition, more preferably a weight of about 30 to 150 g, even more preferably a weight of about 70 to 110 g. Most preferably such a unit or dose for administration comprises e.g. a 30g pouch, 50g pouch, a 70g pouch, a 80g pouch, a 90g pouch, a 100g pouch, a 150g pouch, a 200g pouch, etc., or any further unit or dose for administration or as defined herein. The unit or dose for administration as described herein can also be expressed in terms of mL rather

20 than g. Hence, if desired 30 to 200 mL of the inventive composition can be employed. The total amount of energy to be administered by the inventive composition per day is preferably in range of about 300 to about 635 kcal, most preferably about 300 to about 600 kcal.

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According to a particularly preferable aspect, the inventive composition may be in form of a supplement (and may be packaged accordingly), preferably providing a unit or dose for administration as defined before, e.g. an amount as described above, e.g. an amount of about 1 to about 2 x 50g pouches a day, or for instance an amount of about 1 to about 2 x 90g pouches a day, or for instance an amount

30 of about 1 to about 2 x 100g pouches a day. Preferably the total amount of energy to be administered per day is between about 300 to about 635 Kcal, most preferably about 300 to about 600 Kcal a day, preferably if used as a supplement.

Alternatively, the inventive composition may preferably be used and packaged as a sole source of nutrition (e.g. as a whole meal), preferably providing a unit or dose for administration as defined before, e.g. an amount as described above, e.g. an amount of about 4 to about 8 x 50g pouches a day, or for instance an amount of about 4 to about 8 x 90g pouches a day, or for instance an amount of about 4 to about 8 x 100g pouches a day. Preferably the total amount of energy administered using the inventive composition per day is typically in the range of about 1200 to about 2500 Kcals a day, preferably if used as a sole source of nutrition (e.g. as a whole meal).

Further inventive compositions as detailed herein are also suitable for use in dietary modification or manipulation involving the intake of fat, protein and carbohydrate, in isolation or combination, for therapeutic effect and benefit.

Preferably, the composition of the present invention, could be obtained by any process suitable for a skilled person, most preferably the inventive process as described herein. More preferably, the inventive composition may be obtained or is obtainable by a method for preparing a composition as defined herein. Such a composition and any composition obtained or obtainable by such a method for preparing a composition may be used for treatment of a disease or disorder as defined herein, particularly preferably for use in treating epilepsy, preferably refractory epilepsy in children.

Particularly preferably, the inventive compositions as described herein, either as described initially or as obtained or obtainable according to the inventive process, are preferably suitable for use in children from the age of 1, in other words the inventive compositions typically may be not deemed suitable for use in infants. The composition of the present invention is however also suitable for use by adults.

In addition, in a further embodiment the present invention is directed towards a method of treating a disease or disorder as defined herein, e.g. epilepsy, preferably refractory epilepsy in children, comprising administering a patient in need thereof a composition as defined herein, typically comprising about 4 to about 12
5 % by weight protein, about 5 to about 15 % by weight carbohydrate and a high level of fat, which is preferably about 25 to about 38 % by weight fat.

The inventive compositions used in the method as described herein are most preferably obtained/obtainable by the inventive process as described herein. In
10 this regard, these compositions may contain or comprise any of the ingredients as defined for the inventive process.

The present invention also includes a method of treatment for dietary management of malnutrition, malabsorption states and other conditions requiring fortifica-
15 tion with energy, protein and micronutrients by administering a patient in need thereof a composition as defined herein, said composition preferably obtained/obtainable by the inventive process as described herein. Said method typically comprising about 4 to about 12 % by weight protein, about 5 to about 15 % by weight carbohydrate and a high level of fat, which is preferably about 25 to
20 about 38 % by weight fat. Said other conditions including areas such as various states of oncology, cystic fibrosis, elderly (dementia), neuro-disabilities, improvement of brain function or of cognitive skills, neurological diseases, neurodegenerative diseases, dysphasia, pre- and post operative surgery, ADHD (Attention Deficit Hyperactivity Disorder), Pyruvate Dehydrogenase (PDH) deficiency, phos-
25 phofructokinase (PFK) deficiency, stroke, liver disease, Cancer (renal, head and neck) or may be suitable for use in treatment of neurological diseases, such as for treating epilepsy, preferably refractory epilepsy in children. Furthermore, the present invention also includes a method of treatment for the treatment of Dravet Syndrome (severe myoclonic epilepsy) and Doose Syndrome (myoclonic astatic
30 epilepsy), epileptic syndromes and seizures, myoclonic jerk, tumor, obesity, Diabetes, gut motility disorders including constipation, Gastro Intestinal, allergy, anti-aging and psychiatric disorders

The present invention also includes a method of treating disorders treatable with the ketogenic diet and selected from neurodegenerative diseases, and improvement of brain function or of cognitive skills, Alzheimer disease/cognitive impairment, Parkinson's disease, neurological diseases, Amyotrophic lateral sclerosis, Traumatic brain injury, Hypoxic/ischemic brain injury, Autism, ADHD (Attention Deficit Hyperactivity Disorder), Depression, Headaches, Migraine Headaches, Narcolepsy, GLUT-1 deficiency, Pyruvate Dehydrogenase (PDH) deficiency, phosphofructokinase (PFK) deficiency, Glycogenosis type V (McArdle disease), Cardiac ischemia, Rett syndrome, Tuberous Sclerosis, Diabetes and Cancer (astrocytomas, prostate, gastric, renal, head and neck). Said method typically comprising about 4 to about 12 % by weight protein, about 5 to about 15 % by weight carbohydrate and a high level of fat, which is preferably about 25 to about 38 % by weight fat.

Preferably, the method of treatment of the present invention contains or comprises about 0.5 to about 23 % by weight medium chain triglycerides and/or about 6 to about 30 % by weight long chain triglycerides.

Most preferably, the method of treatment of the present invention furthermore comprises micronutrients selected from vitamins, minerals and trace elements as defined herein.

More preferably, the inventive method of treatment contains or comprises calcium, preferably in an amount of about 100 to about 245 mg per 100 g. Most preferably calcium is present in about 209 mg or about 217 mg or about 234 mg.

It is further preferred that compositions utilized in the method of treatment as described herein contain or comprise fibre, preferably in an amount of about 0.5 to about 2.5 % by weight. Having said this, in some embodiments said method does not contain or comprise fibre.

It is further preferred that compositions utilized in the method of treatment as described herein contain or comprise lecithin, preferably in an amount of about 0.1 to about 2 %.

5 It is also desirable that in the method of treatment herein, that the fat in the utilized composition contains or comprises about 2 to about 30 % by weight saturates, about 1 to about 25 % by weight mono-unsaturates and about 0.1 to about 5 % by weight polyunsaturates.

10 It is also desirable that in compositions utilized in the method of treatment herein, 0.4 to 2.0% by weight of the fat is eicosapentaenoic acid (EPA). According to an alternative, such compositions may contain no eicosapentaenoic acid (EPA).

15 It is furthermore particularly beneficial if in compositions utilized in the inventive method of treatment the protein employed is a whey protein, most preferably acidified whey protein isolate. It is also preferable if the protein, the fat and/or the carbohydrate is/are derived from at least two different sources.

20 Most preferably in the compositions utilized in the method of treatment of the present invention the composition is a liquid or a semi liquid/semi solid.

Most preferably in the compositions utilized in the inventive method of treatment of the present invention the composition has a viscosity of about 1 to about 40,000 cP as defined herein.

25 Even more preferable is that in said compositions utilized in method of treatment the ratio of fat: protein: carbohydrate is about 4.2: 1: 2 or about 3.65: 1: 1.25 and/or that preferably the energy content of the composition is about 150 to about 440 kcal per 100g.

30 It is further preferred that in the inventive method of treatment the composition is administered once daily, preferably twice daily, more preferably three times daily,

wherein preferably each dose comprises a 30g pouch, 50g pouch, a 90g pouch or preferably a 100g pouch and/or that the total amount of energy administered per day is about 300 to about 635 Kcal, most preferably about 300 to about 600 kcal.

- 5 Said inventive method of treatment is preferably used as a supplement.

It is further preferable that said method of treatment is preferably used as a sole source of nutrition as defined herein, most preferably wherein the total amount of energy administered per day is between about 1200 to about 2500 Kcals a day.

10

It is also desirable that the composition utilized in the method of treatment herein does not comprise soy protein and/or comprise olive oil or canula oil and/or does not contain whole milk protein in a ratio of 80:20 casein protein to whey protein.

- 15 It is also preferred that the composition utilized in the method of treatment herein employs intact proteins and particularly preferred that casein is not present in said method.

- 20 It is particularly preferable in the method of treatment of the present invention that the (liquid) composition is adjusted to a pH of less than about 4.3, preferably about 3.5 to about 4.5.

- 25 It is most preferable in the method of treatment of the present invention that the composition furthermore comprises an antifoaming agent, preferably selected from lecithin and/or MCT oil, and/or silicone antifoamers more preferably in an amount of about 0.5 to about 23 % by weight.

- 30 Various embodiments of the invention have been described above. The descriptions are intended to be illustrative, not limitative. Thus, it will be apparent to one skilled in the art that certain modifications maybe made to the invention as described without departing from the scope of the claims set out below.

For example, as described herein, “preferred embodiment” means “preferred embodiment of the process and compositions thereof of the present invention”. Likewise, as described herein, “various embodiments” and “another embodiment” means “various embodiments of the process and compositions thereof of the present invention” and “another embodiment of the process and compositions thereof of the present invention”, respectively.

Throughout this specification and the claims which follow, unless the context requires otherwise, the word “comprise”, and variations such as “comprises” and “comprising”, will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integer or step. When used herein the term “comprising” can be substituted with the term “containing” or sometimes when used herein with the term “having”. When used herein “consisting of” excludes any element, step, or ingredient not specified in the claim element. When used herein, “consisting essentially of” does not exclude materials or steps that do not materially affect the basic and novel characteristics of the claim. In each instance herein any of the terms “comprising”, “consisting essentially of” and “consisting of” may be replaced with either of the other two terms.

Furthermore, percentages as described in the process and compositions thereof of the present invention can be interchangeably either % weight-by-weight (w/w) or % weight-by-volume (w/v).

Finally, all publications and patents cited in this disclosure are incorporated by reference in their entirety. To the extent the material incorporated by reference contradicts or is inconsistent with this specification, the specification will supersede any such material.

Figures:

The following Figures are intended to illustrate the invention further. They are not intended to limit the subject matter of the invention thereto.

5

Figure 1: shows a schematic for the process as described herein

Examples:

The following examples are intended to illustrate the invention further. They are not intended to limit the subject matter of the invention thereto.

Example 1: Exemplary way of carrying out the process as described herein.

(Step (a))

1. Water is added to a Jex Mixing Tank at about 20°C +/- 3°C. Mixing is preferably conducted with a twin impeller agitator.
2. Lecithin and optionally starch are added to the tank, mixer speed set at about 725 rpm, mixed for about 5 minutes
3. Acidified Whey Protein is added, mixer speed is reduced to about 435 rpm, mixed for about 30 minutes.
4. Fractionated Coconut Oil and High Oleic Sunflower Oil is added then increase mixer speed to about 580 rpm, mixed for about 5 minutes.
5. Mixer speed is then reduced to about 435 rpm, mixed for about 30 minutes.
6. Optionally, fibre is then added at about 580 rpm and mixed for about 15 minutes.
7. Any further ingredients such as minerals, vitamins and trace elements are added, mixer speed remains at about 580 rpm, mixed for about 10 minutes.
8. Sugar is then added, mixer speed increased to about 725 rpm, mixed for about 20 minutes.
9. Lemon oil, Vitamin C and Vitamin E are then added, followed by mixing at about 725rpm for about 10 minutes.
10. pH checked to ensure is less than about 4.3, preferably about 3.5 to about 4.2, preferably about pH4.0, then adjust as is necessary with citric acid.
11. Product is left to degas on mixing speed of about 435 rpm for about 12 minutes. Optionally the product is processed at Specific Gravity of about 1.01 at 20°C +/- 3°C or of about 1.05 at 20°C +/- 3°C .

(Step (b))

12. Optionally preheating the mixture, preferably at a temperature as defined generally above in the description of the invention.

5 (Step (c))

13. Product goes through inline sieve.

14. Heated to about 86 to about 100°C for about 2 minutes.

10 15. Homogenised at about 30 to about 220 bar, such as about 30 to about 150 bar, preferably about 80 bar to about 120 bar or about 100 and about 140 bar; more preferably about 40 to about 65 bar.

(Step (d))

15 16. Nitrogen flushed and packed into Guala pack.

(Step (e))

17. Pasteurised in pouch at about 76 to about 93°C for 3 minutes +/- 30 seconds

20

(Step (f))

18. Cooling bath, product must be less than 30°C at the end of cooling.

19. Packed into boxes.

25

Example 2: Exemplary composition of the present invention – which can be prepared by the process as described herein

Nutritional component	per 100g	Units
energy (kJ)	1348	kJ
energy (kcal)	322	kcal
Protein	8	g
Carbohydrate	10	g
Fat	29.2	g
Vitamin premix	109.7	mg
Minerals	907	mg
Trace element mix	244.9	mg
Medium Chain Triglycerides	20,00	g
Long Chain Triglycerides	8,73	g
Fibre	1	g
Linoleic acid	1079	mg
α -Linoleic acid	48.2	mg

Notes:

Vitamin premix preferably consists of Vitamin A, Vitamin D, Vitamin E, Vitamin C, Vitamin K, thiamin, riboflavin, niacin, Vitamin B₆, folic acid, Vitamin B₁₂, biotin, pantothenic acid and choline. Other vitamins may also be present as defined herein above.

Minerals preferably consist of sodium, potassium, calcium, phosphorus and magnesium. Other minerals may also be present as defined herein above.

Trace element mix preferably consists of chloride, iron, copper, zinc, manganese, iodine molybdenum, selenium and chromium. Other trace elements may also be present as defined herein above.

The ingredients which can be used to make said composition are by example water, fractionated coconut oil, high oleic sunflower oil, caster sugar, acidified whey protein isolate obtained from Volac International Ltd (Volactive Hydrapro), calcium lactate, soya lecithin E322 (Emulpur IP), inulin (Orafti HP) and oat fibre (Whitestar AOF 200), magnesium lactate, tri potassium citrate, sodium chloride, choline bitartrate, vitamin premix - , trace element mix, dipotassium phosphate, tri sodium citrate,

rate, lemon oil 12116, taurine JP8, L-carnitine L-tartrate and citric acid anhydrous.

Example 3: Exemplary composition of the present invention – which can be prepared by the process as described herein

Nutritional component	per 100g	Units
energy (kJ)	1397	kJ
energy (kcal)	334	kcal
Protein	6,7	g
Carbohydrate	13,4	g
Fat	28,2	g
Vitamin premix	22.5	mg
Minerals	943	mg
Trace element mix	255.1	mg
Medium Chain Triglycerides	1,49	g
Long Chain Triglycerides	25.5	g
Linoleic Acid	2742	mg
α - Linoleic Acid	61.8	mg

Notes:

Vitamin premix preferably consists of Vitamin A, Vitamin D, Vitamin E, Vitamin C, Vitamin K, thiamin, riboflavin, niacin, Vitamin B₆, folic acid, Vitamin B₁₂, biotin and pantothenic acid. Other vitamins may also be present as defined herein above.

Minerals preferably consist of sodium, potassium, calcium, phosphorus and magnesium. Other minerals may also be present as defined herein above.

Trace element mix preferably consists of chloride, iron, copper, zinc, manganese, iodine, molybdenum, selenium and chromium. Other trace elements may also be present as defined herein above.

The ingredients which can be used to make said composition are by example water, high oleic sunflower oil, fractionated coconut oil, caster sugar, whey protein isolate; preferably acidified whey protein isolate obtained from Volac International Ltd (Volactive Hydrapro), calcium lactate, soya lecithin E322 (Emulpur IP), magnesium lactate, sodium chloride, dipotassium phosphate, citric acid, tri sodium

citrate, vitamin premix , trace element mix, tri potassium citrate, lemon oil 12116, potassium chloride (with 0.5% magnesium carbonate), L-ascorbic acid, Vitamin E (from Nutrabiol).

- 5 **Example 4:** Exemplary composition of the present invention – which can be prepared by the process as described herein

Nutritional component	per 100g	Units
energy (kJ)	1255	kJ
energy (kcal)	300	kcal
Protein	8	g
Carbohydrate	13,4	g
Fat	23.9	g
Vitamin premix	180	mg
Minerals	1082	mg
Trace element mix	180	mg
Medium Chain Triglycerides	1.5	g
Long Chain Triglycerides	22	g
Linoleic Acid	2318	mg
α - Linoleic Acid	57.3	mg

Notes:

- Vitamin premix preferably consists of Vitamin A, Vitamin D, Vitamin E, Vitamin C, Vitamin K, thiamin, riboflavin, niacin, Vitamin B₆, folic acid, Vitamin B₁₂, biotin and
 10 pantothenic acid. Other vitamins may also be present as defined herein above.

Minerals preferably consist of sodium, potassium, calcium, phosphorus and magnesium. Other minerals may also be present as defined herein above.

- 15 Trace element mix preferably consists of chloride, iron, copper, zinc, manganese, iodine, molybdenum, selenium and chromium. Other trace elements may also be present as defined herein above.

- 20 The ingredients which can be used to make said composition are by example water, high oleic sunflower oil, fractionated coconut oil, caster sugar, whey protein isolate; preferably acidified whey protein isolate obtained from Volac International Ltd (Volactive Hydrapro), calcium lactate, soya lecithin E322 (Emulpur IP), magnesium lactate, sodium chloride, dipotassium phosphate, citric acid, tri sodium

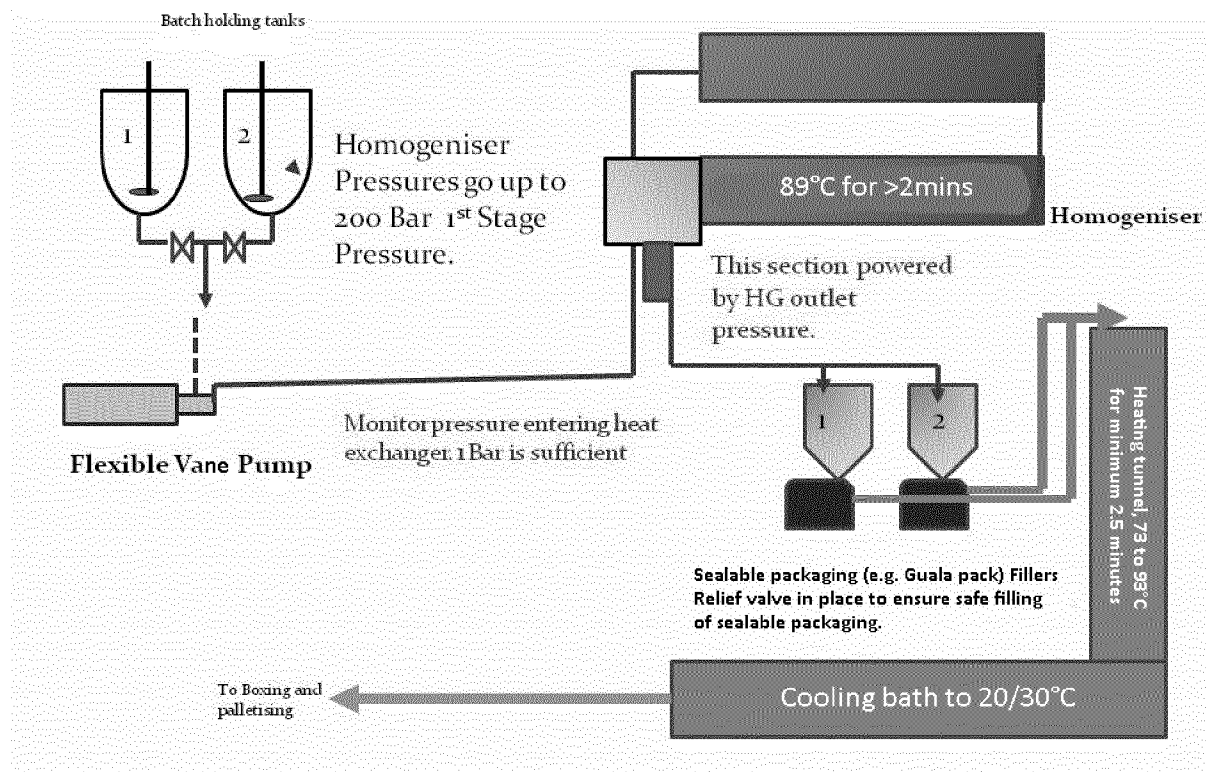
citrate, vitamin premix , trace element mix, tri potassium citrate, lemon oil 12116, potassium chloride (with 0.5% magnesium carbonate), L-ascorbic acid, Vitamin E (from Nutrabiol).

Claims

1. A process for the preparation of a composition containing a high level of fat comprising the following steps:
 - (a) Mixing about 4 to about 12 % by weight protein, and about 5 to about 15 % by weight carbohydrate and fat with water;
 - (b) Optionally preheating the mixture;
 - (c) Homogenizing the mixture obtained according to step (a) or (b) at about 86 to about 100°C, preferably about 86 to about 92°C, preferably at a pressure of about 30 to about 220 bar;
 - (d) Packaging the mixture into a package, which is preferably a sealable package;
 - (e) Pasteurizing the packaged mixture at about 76 to about 93°C;
 - (f) Preferably cooling the pasteurized packaged mixture.
2. The process of claim 1 wherein the mixture of step (a) comprises about 25 to about 38 % by weight fat.
3. The process of claim 1 or 2 wherein the mixture of step (a) is adjusted to a pH of less than about 4.3, preferably about 3.5 to about 4.2, preferably about 4.0.
4. The process of claims 1 to 3 wherein mixing speeds are in the range of about 320 rpm to about 800 rpm.
5. The process according to any of the preceding claims wherein the mixture according to step (a) additionally contains about 0.5 to about 23 % by weight medium chain triglycerides and/or about 6 to about 35 % by weight long chain triglycerides.

6. The process according to any of the preceding claims wherein the mixture furthermore comprises micronutrients selected from vitamins, minerals and trace elements.
- 5 7. The process according to any of the preceding claims wherein the mixture furthermore comprises calcium, preferably in an amount of about 100 to about 245 mg per 100 g.
8. The process according to any of the preceding claims which furthermore
10 includes about 0.5 to about 2.5 % by weight fibre.
9. The process according to any of the preceding claims wherein the fat contains about 2 to about 30 % by weight saturates, about 1 to about 30 % by weight mono-unsaturates and about 0.1 to about 5 % by weight polyunsaturates.
15
10. The process according to any of the preceding claims wherein said protein is acidified whey protein isolate.
- 20 11. The process according to any of the preceding claims wherein the protein, the fat and/or the carbohydrate is/are derived from at least two different sources.
12. The process according to any of the preceding claims wherein said pasteurized packaged mixture is a liquid or a semi liquid/semi solid.
25
13. The process according to any of the preceding claims wherein said pasteurized packaged mixture has a viscosity of about 1 to about 40,000 cP.
- 30 14. The process according to any of the preceding claims wherein the energy content of the pasteurized packaged mixture is about 150 to about 440 kcal per 100g.

15. The process according to any of the preceding claims wherein said composition furthermore comprises an antifoaming agent, preferably selected from lecithin and/or MCT oil, more preferably in an amount of about 0.5 to about 23 % by weight.
16. Composition obtained by a process according to any of claims 1 to 15.
17. Composition obtained by a process according to any of claims 1 to 15 for use in the dietary management of malnutrition, malabsorption states and other conditions requiring fortification with energy, protein and micronutrients..
18. Composition obtained by a process according to any of claims 1 to 15 for use in treating disorders treatable with the ketogenic diet selected from Alzheimer disease/cognitive impairment, Parkinson's disease, neurological diseases, Amyotrophic lateral sclerosis, Traumatic brain injury, Hypoxic/ischemic brain injury, Autism, ADHD (Attention Deficit Hyperactivity Disorder), Depression, Headaches, Narcolepsy, GLUT-1 deficiency, Pyruvate Dehydrogenase (PDH) deficiency, phosphofructokinase (PFK) deficiency, Glycogenosis type V (McArdle disease), Cardiac ischemia, Rett syndrome, Tuberous Sclerosis, and Cancer (astrocytomas, prostate, gastric, renal, head and neck).

**Figure 1**

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2013/066970

A. CLASSIFICATION OF SUBJECT MATTER INV. A23L1/29 A23L1/30 A23L1/305 A23L1/308 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		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data, FSTA, BIOSIS		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 11 September 2013		Date of mailing of the international search report 18/09/2013
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Tallgren, Antti

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Information on patent family members

International application No

PCT/EP2013/066970

Patent document cited in search report	Publication date	Patent family member(s)	Publication date