

Description

Title of Invention: GEL-LIKE NUTRITIONAL COMPOSITION

Technical Field

[0001]

The present invention relates to a gel-like nutritional composition, and particularly relates to a gel-like nutritional composition suitable for intake of essential vitamins and minerals.

Background Art

[0002]

Patients before and after surgeries and elders and people in need of nursing care who are difficult to take normal diet should take sufficient nutrients to live healthy lives. Nutritional care is performed through administration of a nutritional composition, which is adjusted to contain nutritional ingredients such as proteins, lipids, carbohydrates, vitamins, and minerals in a good balance (Patent Literature 1 to 4).

[0003]

Subjects suffer from administration of an enteral nutritional composition which takes a long time. Elders and people in need of nursing care often have stomachs with small capacity. If a nutritional composition having a high energy value and sufficiently containing adequate

intakes and recommended amounts of minerals and vitamins needed daily shown in Non Patent Literature 1 is used, the amount of the nutritional composition to be administered can be reduced to reduce load of subjects, thus enabling efficient nutritional support. The energy value (calorie) of the nutritional composition can be usually adjusted by adjusting the contents of lipids, proteins, and carbohydrates.

[0004]

Moreover, the gel-like enteral nutritional composition is expected to demonstrate physiological functions such as retention and discharge, which are intrinsic to the stomach. As a result, the gel-like enteral nutritional composition can be administered in a shorter time than liquid nutritional compositions, which can reduce restrictions on movement and activities and can ensure time for rehabilitation and the like. Thus, the gel-like enteral nutritional composition can contribute to early mobilization and an improvement in activities of daily living (ADL). In addition, an effect of preventing aspiration pneumonia and diarrhea, which are observed in the liquid nutritional composition, is observed.

Citation List

Patent Literature

[0005]

Patent Literature 1: WO2006/033349

Patent Literature 2: Japanese Patent No. 4047363

Patent Literature 3: WO2013/085059

Patent Literature 4: WO2014/115768

Non Patent Literature

[0006]

Non Patent Literature 1: Nihonjinno Shokujisesshukijun (2020 edition), "Nihonjinno Shokujisesshukijun" Planning and Examination Committee, December, Reiwa 1

Summary of Invention

Technical Problem

[0007]

For example, shortage of daily intakes of vitamins and minerals need be avoided also in a patient under energy management with a low dose such as about 900 kcal per day. As described above, when the patient takes about 900 kcal from a nutritional composition, a gel-like nutritional composition enabling intake of adequate intakes and recommended amounts of vitamins, minerals, and the like needed daily described in Non Patent Literature 1 has a variety of advantages. Unfortunately, such a nutritional composition has not been provided yet.

[0008]

For example, the total enteral nutritious composition disclosed in Patent Literature 1 is a composition containing large amounts of vitamin B1 and

vitamin B2, and the nutritional composition disclosed in Patent Literature 3 contains two or more minerals selected from sodium, potassium, iron, calcium, and magnesium. However, these are not in a gel form, and are not a composition from which daily intakes of vitamins, minerals, and the like can be taken.

[0009]

The gel type enteric nutrient disclosed in Patent Literature 2 is not a nutrient from which adequate intakes and recommended amounts of vitamins, minerals, and the like needed daily can be taken. The liquid nutritional composition disclosed in Patent Literature 4 is not in a gel form.

[0010]

Under such circumstances, an object of the present invention is to provide a nutritional composition which enables a daily energy intake therefrom, can contain adequate intakes and recommended amounts of vitamins, minerals, and the like needed daily, is easy to take, and is stable.

Solution to Problem

[0011]

To solve the above problems, first, the present inventors have found that an increase in vitamin and mineral concentrations of a semi-solid enteral nutritional composition disclosed in Patent Literature 2

causes local gelation, resulting in an uneven gel. On the other hand, the present inventors also have found that when a liquid nutritional composition having high concentrations of vitamins and minerals as in Patent Literature 4 is gelled, stable gelation is obstructed, resulting in an uneven gel.

[0012]

The present inventors further have conducted extensive research, and first, have used specific raw materials such as whole milk protein and casein as protein raw materials. Furthermore, because a nutritional composition containing large contents of vitamins and minerals have large concentrations of ions including calcium ion, the amount of the chelating agent has been increased. Unexpectedly, the present inventors have found that an increase in amount of the chelating agent reduces stability of the nutritional composition, have found an appropriate blending amount of the chelating agent, and have completed the present invention.

[0013]

Specifically, the present invention relates to the followings.

[1]

A gel-like nutritional composition comprising lipid, proteins, carbohydrate, a vitamin, and a mineral, and having the following compositions:

1) the composition has an energy value of 0.8 kcal/g or more and 1.2 kcal/g or less;

2) the composition contains 1.7 g or more of whole milk protein and 0.25 g or more of casein as the proteins per 100 g of the composition;

3) the total amount of magnesium derived from the whole milk protein and the casein is 1.3 mg or more per 900 kcal of the composition, and the total amount of calcium derived from the whole milk protein and the casein is 34.9 mg or more per 900 kcal of the composition;

4) the composition contains 220 mg or more of magnesium and 500 mg or more of calcium per 900 kcal of the composition;

5) the composition contains one or more minerals selected from 30 µg or more of selenium, 10 µg or more of chromium, 30 µg or more of molybdenum, and 130 µg or more of iodine per 900 kcal of the composition;

6) the composition contains 0.15% by weight or more and 0.40% by weight or less of agar and 0.125% by weight or more and 0.40% by weight or less of alginic acid or a salt thereof, and has a viscosity of 3,000 mPa·s or more and 17,000 mPa·s or less; and

7) the composition contains a chelating agent selected from citric acid or a salt thereof, phosphoric acid or a salt thereof, and EDTA or a salt thereof in a total amount of 2.0 g or more and 5.7 g or less per 900

kcal of the composition, and contains 1.1 g or more and less than 3.7 g of the phosphoric acid or a salt thereof per 900 kcal of the composition.

[2]

The gel-like nutritional composition according to [1], wherein the weight ratio of the casein to the whole milk protein is 1:1.1 to 1:13 in terms of protein contained.

[3]

The gel-like nutritional composition according to [1] or [2], wherein the whole milk protein is a milk protein concentrate.

[4]

The gel-like nutritional composition according to any one of [1] to [3], wherein the composition does not contain an animal-derived protein decomposed product and a plant-derived protein decomposed product.

[5]

The gel-like nutritional composition according to any one of [1] to [4], wherein the lipid content in the composition is 20% or more and 30% or less in an energy ratio,

the protein content in the composition is 13% or more and 30% or less in an energy ratio, and

the carbohydrate content in the composition is 50% or more and 65% or less in an energy ratio.

[6]

The gel-like nutritional composition according to any one of [1] to [5], wherein the composition contains 310 mg or more of magnesium and 650 mg or more of calcium per 900 kcal of the composition.

[7]

The gel-like nutritional composition according to any one of [1] to [6], wherein the composition contains at least vitamins and minerals below per 900 kcal of the composition:

[Table 1]

Calcium	800 mg	Cholecalciferol	8.5 µg
Magnesium	370 mg	Tocopherol acetic acid ester	7.0 mg of α-tocopherol
Phosphorus	1000 mg	Thiamine	1101 µg
Iron	11.0 mg	Riboflavin	1.6 mg
Zinc	11.0 mg	Pyridoxine	1.4 mg
Manganese	4.0 mg	Cyanocobalamin	2.4 µg
Copper	0.9 mg	Ascorbic acid	100 mg
Iodine	130 µg	Nicotinic acid amide	15 mg
Selenium	30 µg	Pantothenic acid	6 mg
Chromium	10 µg	Folic acid	240 µg
Molybdenum	30 µg	Biotin	50 µg
Retinol palmitic acid ester	900 µgRE		

[8]

The gel-like nutritional composition according to any one of [1] to [7], wherein the composition has a pH of more than 5.5 and 7.0 or less, and the ratio of the total amount of magnesium and calcium to the amount of the chelating agent per 900 kcal of the composition is 1:4.5 or less.

Advantageous Effects of Invention

[0014]

The present invention can provide a stable nutritional composition which enables intake of a daily energy intake therefrom, can contain adequate intakes and recommended amounts of vitamins, minerals, and the like needed daily, is in the form of a gel which is easy to take, and can prevent gastroesophageal reflux which may cause aspiration pneumonia.

Description of Embodiments

[0015]

Hereinafter, an embodiment implementing the present invention (hereinafter, referred to as "the present embodiment") will be specifically described. To be noted, the present invention is not limited to the present embodiment below, and can be subjected to a variety of modifications and be implemented without departing from the gist of the present invention.

[0016]

The gel-like nutritional composition according to the present embodiment comprises lipid, proteins, carbohydrate, a vitamin, and a mineral, wherein

1) the composition has an energy value of 0.8 kcal/g or more and 1.2 kcal/g or less;

2) the composition contains 1.7 g or more of whole milk protein and 0.25 g or more of casein as the proteins per 100 g of the composition;

3) the total amount of magnesium derived from the whole milk protein and the casein is 1.3 mg or more per 900 kcal of the composition, and the total amount of calcium derived from the whole milk protein and the casein is 34.9 mg or more per 900 kcal of the composition;

4) the composition contains 220 mg or more of magnesium and 500 mg or more of calcium per 900 kcal of the composition;

5) the composition contains one or more minerals selected from 30 µg or more of selenium, 10 µg or more of chromium, 30 µg or more of molybdenum, and 130 µg or more of iodine per 900 kcal of the compositions;

6) the composition contains 0.15% by weight or more and 0.40% by weight or less of agar and 0.125% by weight or more and 0.40% by weight or less of alginic acid or a salt thereof, and has a viscosity of 3,000 mPa·s or more and 17,000 mPa·s or less; and

7) the composition contains a chelating agent selected from citric acid or a salt thereof, phosphoric acid or a salt thereof, and EDTA or a salt thereof in a total amount of 2.0 g or more and 5.7 g or less per 900 kcal of the composition, and contains 1.1 g or more and

less than 3.7 g of the phosphoric acid or a salt thereof per 900 kcal of the composition.

[0017]

Examples of the whole milk protein include whole milk itself, whole milk concentrates, proteins prepared from whole milk, skim milk, skim milk concentrates, milk protein concentrates (referred to as MPCs in some cases), products of skim milk powder prepared by removing lactose therefrom, and total milk protein. Among these, preferred is use of a milk protein concentrate (containing about 80 to 82% of protein, for example).

Examples of casein (containing about 90 to 92% of protein, for example) include lactic acid casein separated from cow milk by a normal method; acid caseins, such as hydrochloric acid casein and sulfuric acid casein, and mixtures thereof; and caseinates made of casein salts such as casein sodium and casein calcium.

[0018]

The gel-like nutritional composition according to the present embodiment contains 1.7 g or more, preferably 2.0 g or more and 7.5 g or less, more preferably 2.5 g or more and 6.5 g or less, still more preferably 3.0 g or more and 5.5 g or less of whole milk protein as the protein per 100 g of the composition. The gel-like nutritional composition according to the present embodiment contains 0.25 g or more, preferably 0.25 g or more and 3.6 g or less, more preferably 0.54g or more and

2.0 g or less, still more preferably 0.88 g or more and 1.9 g or less of casein as the protein per 100 g of the composition.

In one aspect, in the gel-like nutritional composition according to the present embodiment, the total proportion (in terms of protein amount) of whole milk protein and casein in the protein is 75% by weight or more, preferably 82% by weight or more, more preferably 92% by weight or more, still more preferably 95% by weight or more, particularly preferably 98% by weight or more, most preferably 100% by weight.

[0019]

In one aspect, the gel-like nutritional composition according to the present embodiment does not contain one of an animal-derived protein decomposed product and a plant-derived protein decomposed product. In one aspect, the gel-like nutritional composition according to the present embodiment does not contain any of an animal-derived protein decomposed product and a plant-derived protein decomposed product. The animal-derived protein decomposed product and the plant-derived protein decomposed product are products prepared by decomposing a protein with an acid or an enzyme, and are used in nutritional compositions due to their high dispersibility. If these are excessively added, the flavor is worsened, and a bad smell may be sensed due to belching (so-called burping).

[0020]

The gel-like nutritional composition according to the present embodiment contains a larger amount of whole milk protein than that of casein in the protein. Although not bound to any theory, in this configuration, calcium bonded to protein can be blended, and high concentrations of magnesium and calcium can be contained by bonding free magnesium and calcium in casein.

[0021]

The weight ratio of the casein to the whole milk protein in terms of protein contained is preferably 1:1.1 to 1:13, more preferably 1:1.1 to 1:4.3, still more preferably 1:1.1 to 1:2.9, particularly preferably 1:2.5 to 1:2.8. When a larger amount of whole milk protein is contained than that of casein, the whole milk protein can contain magnesium and calcium. When a larger amount of whole milk protein is contained than that of casein, the whole milk protein can contain magnesium and calcium. Thus, the nutritional composition can be stabilized even if a large amount of minerals is contained, and is preferred. When the weight of the whole milk protein is not more than 13 times the weight of casein, it is easier to stabilize the gel state of the nutritional composition. From this viewpoint, such an amount of whole milk protein is also preferred. In the calculation of the ratio above, the casein does not include casein contained in the whole milk protein.

In one aspect, the gel-like nutritional composition according to the present embodiment contains less than 2 g/100 g, preferably 1 g/100 g or less, more preferably 0.7 g/100 g or less of whey in the protein (excluding whey contained in whole milk protein), and still more preferably contains no whey.

[0022]

The content of the protein in the gel-like nutritional composition according to the present embodiment is preferably 13 to 30%, more preferably 13 to 19% in an energy ratio. If the content of the protein is more than 30% in the energy ratio, the nutritional balance expressed by the PFC ratio specified in Dietary Reference Intakes of Ministry of Health, Labour and Welfare may be worsened in some cases. If the content is less than 13%, protein intake may be short in some cases. The energy ratio is calculated with 4 kcal/g.

[0023]

Usually, the lipid contained in the gel-like nutritional composition according to the present embodiment is not particularly limited as long as it can be administered orally or through a tube. Examples thereof include vegetable oils and fats such as soybean oil, perilla oil, shiso oil, sunflower oil, safflower oil, algae oil, canola oil, palm oil, corn oil, maize oil, coconut oil, olive oil, and rice oil; animal-derived oils and fats such as fish oil and beef tallow; MCTs

(neutral fats, fatty acids having a middle chain length); and highly unsaturated fatty acids such as eicosapentaenoic acid, docosahexaenoic acid, linolenic acid, and linoleic acid. These lipids may be used alone or in a mixture of two or more thereof. From the viewpoint of sufficiency of essential fatty acids, preferred is use of several lipids in combination.

[0024]

The content of the lipid in the gel-like nutritional composition according to the present embodiment is preferably 30% or less, more preferably 20% to 30% in the energy ratio. When the content of the lipid is 30% or less in the energy ratio, the nutritional balance expressed by the PFC ratio is good and preferred. The energy ratio is calculated with 9 kcal/g. When the content of the lipid is 20% or more in the energy ratio, essential fatty acids can be supplied as lipid. Thus, such a content is preferred.

[0025]

Usually, the carbohydrate contained in the gel-like nutritional composition according to the present embodiment is not particularly limited as long as it can be administrated orally or through a tube. Examples thereof include glucose syrup, starch, dextrin, maltodextrin, lactose, sucrose, glucose, fructose, and maltose. These carbohydrates may be used alone or in a mixture of two or more thereof. In particular, from the

viewpoint of lower sweetness and economy, preferred are glucose syrup and/or maltodextrin.

[0026]

The content of the carbohydrate in the gel-like nutritional composition according to the present embodiment is determined from the blending amounts of the protein and the lipid, which are appropriately changed. The content thereof is preferably 50% to 65% in the energy ratio. When the content of the carbohydrate is 50% to 65% in the energy ratio, the nutritional balance expressed by the PFC ratio is good and preferred. The energy ratio is calculated with the carbohydrate energy of 4 kcal/g.

[0027]

The gel-like nutritional composition according to the present embodiment contains vitamins and minerals. Examples of the vitamins and minerals include those listed in Dietary Reference Intakes for Japanese (Non Patent Literature 1). Examples of the vitamins include vitamin A, vitamin D, vitamin E, vitamin K, vitamin B1, vitamin B2, niacin, vitamin B6, vitamin B12, folic acid, pantothenic acid, biotin, and vitamin C. It is sufficient that one or more of these vitamins are contained, and it is preferred that all of them be contained. Examples of the minerals include calcium, magnesium, phosphorus, iron, zinc, copper, manganese, iodine, selenium, chromium, and molybdenum. The gel-like

nutritional composition according to the present embodiment contains at least magnesium, calcium, selenium, chromium, molybdenum, and iodine. Furthermore, the gel-like composition contains preferably one or more of these, more preferably all of them. In one aspect, because the gel-like nutritional composition according to the present embodiment contains a variety of vitamins and minerals, the vitamins and minerals needed daily can be taken only from the nutritional composition.

[0028]

The gel-like nutritional composition according to the present embodiment can contain magnesium in an amount of 220 mg or more which is the minimum value satisfying the estimated average necessary amount by age for people aged 18 and older (for females aged 75 and older), preferably 290 mg or more which is a recommended amount for females, more preferably 310 mg or more, still more preferably 370 mg or more per 900 kcal of the composition. Magnesium may be contained in another ingredient, such as whole milk protein and casein, for example. A content of magnesium of 310 mg/900 kcal or more is preferred because it satisfies the estimated average necessary amount for people aged 18 and older specified in the Dietary Reference Intakes. A content of 370 mg/900 kcal or more is more preferred because it satisfies the recommended amount for people of all ages in the Dietary Reference Intakes. Although not

particularly limited, the upper limit of the content of magnesium can be equal to the upper limit of the blending amount of calcium described below. In one aspect, for example, the upper limit of the content of magnesium can be about a half of the content of calcium.

[0029]

The gel-like nutritional composition according to the present embodiment can contain calcium in an amount of 500 mg or more which is the minimum value satisfying the estimated average necessary amount by age for people aged 18 and older (for females aged 75 and older), preferably 650 mg or more, more preferably 800 mg or more per 900 kcal of the composition. For example, calcium can be contained in an amount ranging from 650 to 2500 mg, preferably 700 to 2500 mg, more preferably 750 to 1333 mg, still more preferably 800 to 1250 mg, for example, 815 to 1250 mg per 900 kcal of the composition. Calcium may be contained in another ingredient, such as whole milk protein and casein, for example. A blending amount of calcium of 650 mg/900 kcal or more is preferred because it satisfies the estimated average necessary amount for people aged 18 and older specified in the Dietary Reference Intakes. A blending amount of 800 mg/900 kcal or more is more preferred because it satisfies the recommended amount for people of all ages specified in the Dietary Reference Intakes. In particular, when calcium is blended in the range of 1250

mg/900 kcal or less and even when 1500 kcal of energy is taken daily, for example, calcium does not exceed the tolerable upper limit of 2500 mg. Thus, the blending amount is preferred. When calcium is blended in an amount of 800 mg/900 kcal, a recommended amount of calcium can be taken when 900 kcal is taken. Even when 1500 kcal is taken, the blending amount of calcium is much lower than the tolerable upper limit, allowing intake thereof from other food products. In one aspect, in particular, when calcium is blended in the range of 1250 mg/900 kcal or less and even when 1800 kcal of energy is taken daily, for example, calcium does not exceed the tolerable upper limit of 2500 mg. Thus, the blending amount is preferred. When calcium is blended in an amount of 800 mg/900 kcal, a recommended amount of calcium can be taken when 900 kcal is taken. Even when 1800 kcal is taken, the blending amount of calcium is much lower than the tolerable upper limit, allowing intake thereof from other food products.

[0030]

From the viewpoint of stability, in the gel-like nutritional composition according to the present embodiment, preferably, the total amount of magnesium derived from the whole milk protein and the casein is 1.3 mg or more and the upper limit thereof is 370 mg or less per 900 kcal of the composition. Furthermore, the total amount thereof is preferably 13 mg or more, more

preferably 20 mg or more, still more preferably 30 mg or more per 900 kcal of the composition. Similarly, preferably, the total amount of calcium derived from the whole milk protein and the casein is 34.9 mg or more and the upper limit is 880 mg or less per 900 kcal of the composition. Furthermore, the total amount thereof is preferably 88 mg or more, more preferably 200 mg or more, still more preferably 400 mg or more, further still more preferably 640 mg or more, particularly preferably 700 mg or more.

[0031]

The gel-like nutritional composition according to the present embodiment contains a mineral, preferably contains one or more minerals selected from selenium, chromium, molybdenum and iodine, and more preferably contains all of them. In particular, the gel-like nutritional composition according to the present embodiment contains preferably one or more minerals selected from 30 μg or more of selenium, 10 μg or more of chromium, 30 μg or more of molybdenum, and 130 μg or more of iodine per 900 kcal of the composition, and more preferably contains all of these.

[0032]

The contents of vitamins and minerals other than those listed above can be preferably set to satisfy the recommended amounts or adequate intakes thereof specified in the Dietary Reference Intakes. Daily dietary

reference intakes of vitamins and minerals calculated from Non Patent Literature 1 will be shown below. In one aspect, preferably, the gel-like nutritional composition according to the present embodiment contains any one or more, preferably 5 or more, more preferably 10 or more, still more preferably 15 or more, particularly preferably all of the vitamins and minerals in (an) amount(s) per 900 kcal of the composition satisfying the contents below. Furthermore, the gel-like nutritional composition according to the present embodiment may contain vitamins and minerals other than those listed below.

[0033]

[Table 2]

Calcium	800 mg	Cholecalciferol	8.5 µg
Magnesium	370 mg	Tocopherol acetic acid ester	7.0 mg of α-tocopherol
Phosphorus	1000 mg	Thiamine	1101 µg
Iron	11.0 mg	Riboflavin	1.6 mg
Zinc	11.0 mg	Pyridoxine	1.4 mg
Manganese	4.0 mg	Cyanocobalamin	2.4 µg
Copper	0.9 mg	Ascorbic acid	100 mg
Iodine	130 µg	Nicotinic acid amide	15 mg
Selenium	30 µg	Pantothenic acid	6 mg
Chromium	10 µg	Folic acid	240 µg
Molybdenum	30 µg	Biotin	50 µg
Retinol palmitic acid ester	900 µgRE		

[0034]

For example, for an adult aged 18 and older, the recommended amounts and adequate intakes of the

ingredients taken per day are set as follows (see Non Patent Literature 1).

vitamin A (retinol palmitic acid ester): 900 to 2700 μ g RE (retinol equivalent), vitamin D (cholecalciferol): 8.5 to 100 μ g, vitamin E (tocopherol acetic acid ester): 7.0 to 650 mg (in terms of α -tocopherol), vitamin K: 150 μ g or more, vitamin B₁ (thiamine chloride hydrochloride): 1.4 mg or more (1101 μ g or more in terms of thiamine), vitamin B₂ (riboflavin): 1.6 mg or more, niacin (nicotinic acid amide): 15 to 250 mg, vitamin B₆ (pyridoxine): 1.4 to 40 mg, vitamin B₁₂ (cyanocobalamin): 2.4 μ g or more, folic acid: 240 to 900 μ g, pantothenic acid: 6 mg or more, biotin: 50 μ g or more, vitamin C (ascorbic acid): 100 mg or more, phosphorus: 1000 to 3000 mg, iron: 11 to 40 mg, zinc: 11 to 30 mg, manganese: 4.0 to 11 mg, copper: 0.9 to 7 mg, iodine: 130 to 3000 μ g, selenium: 30 to 350 μ g, chromium: 10 to 500 μ g, molybdenum: 30 to 500 μ g.

Considering this, when the vitamins and minerals are blended with the gel-like nutritional composition according to the present embodiment, it is preferred that while that 1500 kcal can be taken per day is kept in mind, the followings are satisfied per 900 kcal of the composition.

vitamin A (retinol palmitic acid ester): 900 to 1350 μ g RE, vitamin D (cholecalciferol): 8.5 to 50 μ g, vitamin E (tocopherol acetic acid ester): 7.0 to 325 mg, vitamin

K: 75 µg or more, vitamin B₁ (thiamine chlorides hydrochloride): 1.4 mg or more, vitamin B₂ (riboflavin): 1.6 mg or more, niacin(nicotinic acid amide): 15 to 125 mg, vitamin B₆ (pyridoxine): 1.4 to 20 mg, vitamin B₁₂ (cyanocobalamin): 2.4 µg or more, folic acid: 240 to 450 µg, pantothenic acid: 6 mg or more, biotin: 50 µg or more, vitamin C (ascorbic acid): 100 mg or more, phosphorus: 1000 to 1500 mg, iron: 11 to 20 mg, zinc: 11 to 15 mg, manganese: 4.0 to 5.5 mg, copper: 0.9 to 3.5 mg, iodine: 130 to 1500 µg, selenium: 30 to 175 µg, chromium: 10 to 250 µg, molybdenum: 30 to 250 µg.

In one aspect, the gel-like nutritional composition according to the present embodiment contains less than 2.7 mg of vitamin B₁ per 900 kcal of the composition.
[0035]

Because a tendency of an increase in blood concentration of potassium may be observed, the intake thereof is preferably set lower than that specified in the Dietary Reference Intakes (JJPEN. Vol. 19 No. 6, 1997, p.567-633).

With respect to the sodium concentration, the minimum necessary amount of sodium is 1.5 g in terms of table salt, and is less than 6 g when intake of table salt is restricted due to high blood pressure. Thus, preferably, the sodium concentration is set to 5 g or less in maximum (table salt equivalent) even when the assumed maximum intake of 1500 kcal is taken (2009

edition of Guidelines for the Management of Hypertension).

To prevent medical malpractice due to interaction with warfarin, the intake of phytonadione is preferably set smaller than that specified in the Dietary Reference Intakes also from the viewpoint of safety. For the same reason, the intake of vitamin K is preferably set smaller than the intake of 150 µg specified in Dietary Reference Intakes.

[0036]

In the gel-like nutritional composition according to the present embodiment, the mass ratio (Ca/P) of calcium to phosphorus is preferably 0.74 or more. A mass ratio of Ca/P of 0.74 or more is preferred because the bone density significantly increases compared to the case where blending is performed with a mass ratio of less than 0.74 (Dietary Reference Intakes for Japanese [2010 edition], p. 202).

[0037]

The gel-like nutritional composition according to the present embodiment has an energy value of preferably 0.8 to 1.2 kcal/g, more preferably 0.9 to 1.2 kcal/g, still more preferably 0.95 to 1.1 kcal/g. The energy value can be adjusted within the range of the energy ratio of the ingredients above. Adjustment of the energy value to 0.9 kcal/g or more can reduce the intake of the gel-like nutritional composition, and can shorten the

time taken in administration, thereby reducing the load to the subject.

[0038]

The gel-like nutritional composition according to the present embodiment contains agar and alginic acid or a salt thereof as thickeners. More specifically, to provide a composition having a viscosity in the range described later, agar can be contained in an amount of 0.15% by weight or more and 0.40% by weight or less, preferably 0.20% by weight or more and 0.40% by weight or less, more preferably 0.35% by weight or less, still more preferably 0.30% by weight or less, and alginic acid or a salt thereof can be contained in an amount (total amount of alginic acid and a salt thereof when both thereof are contained, and an amount in terms of alginic acid when a salt of alginic acid is contained) of 0.125% by weight or more and 0.40% by weight or less, preferably 0.15% by weight or more and 0.40% by weight or less, more preferably 0.15% by weight or more and 0.35% by weight or less, still more preferably 0.20% by weight or more and 0.30% by weight or less. A homogenous and good gel without clumping cannot be obtained with a small amount thereof to be added, and a hard gel is obtained with a large amount thereof, causing a problem in tube passability. Because the composition is in a gel-like (semi-solid) form, the time for taking energy can be reduced, and the spare time resulting from the reduction

can be used for rehabilitation or the like to accelerate recovery. The gel-like nutritional composition according to the present embodiment contains agar and alginic acid or a salt thereof in these ranges above, and can contain another thickener as long as a predetermined viscosity described later can be provided. In one aspect, the gel-like nutritional composition according to the present embodiment contains only agar and alginic acid or a salt thereof as thickeners from the viewpoint described later.

[0039]

The type of agar is not particularly limited, and agar specified in The Japanese Pharmacopoeia, agar powder, agar powder as a food material, rod agar, quick soluble agar, or the like can be used. Types of alginic acid and a salt thereof are not particularly limited, and those of pharmaceutical additive grades and those of food additive grades can be used. The type of alginic acid salt is not particularly limited, and sodium salt, calcium salt, and the like can be used.

[0040]

The gel-like nutritional composition according to the present embodiment has a viscosity of 3000 to 17000 mPa·s, preferably 4000 to 16000 mPa·s, more preferably 4500 to 15000 mPa·s, still more preferably 5000 to 14000 mPa·s, for example, about 5000 to 13000 mPa·s. The viscosity indicates a value measured by the method specified in <2.53> Viscosity Determination in Physical

Methods of The Japanese Pharmacopoeia 17th Edition. A significantly low viscosity is more likely to cause syneresis, and results in a gel-like nutritional composition having weak shape retention in the stomach, which is more likely to cause reflux esophagitis or the like. A significantly high viscosity results in a hard gel, which is more likely to cause a problem in tube passability.

[0041]

In one aspect, the gel-like nutritional composition according to the present embodiment has an extrusion force of preferably 45 N or less, more preferably 40 N or less, which is measured (measurement temperature: 20°C) by the method in Examples described later when about 30 g of a gel-like nutritional composition sample is filled into a 50-ml catheter chip syringe, a PEG tube of 20 Fr. is attached to the syringe, and the sample is discharged from the syringe using a compression tester (SV-55C-20H: Imada-SS Corporation) at a rate of 65%.

[0042]

Although a combination of agar with alginic acid or a salt thereof resists decomposition of the gel under an acidic condition such as the inside of the stomach and reduces reflux to the esophagus, it has been revealed that when a gel-like nutritional composition has a high concentration and contains a large amount of ions derived from minerals or the like, a gel-like composition stable

for a long time cannot be obtained only by using this combination. Although the present inventors have thought that such a deficit can be solved by adding a chelating agent or increasing the amount thereof, they have examined and found that the gel-like composition conversely becomes unstable. The chelating agent to be used can be one selected from citric acid and salts thereof, phosphoric acid and salts thereof, and EDTA and salts thereof, and examples thereof include citric acid salts such as sodium citrates (such as sodium dihydrogen citrate, disodium citrate, and trisodium citrate) and potassium citrates (such as potassium dihydrogen citrate, dipotassium citrate, and tripotassium citrate); citric acid; phosphoric acid salts such as potassium phosphates (such as potassium dihydrogen phosphate, dipotassium phosphate, and tripotassium phosphate), sodium phosphates (such as sodium dihydrogen phosphate, disodium phosphate, and trisodium phosphate); and EDTA. In one aspect, preferably, sodium citrates (such as sodium dihydrogen citrate, disodium citrate, and trisodium citrate), potassium citrates (such as potassium dihydrogen citrate, dipotassium citrate, and tripotassium citrate), citric acid, potassium phosphates (potassium dihydrogen phosphate, dipotassium phosphate, and tripotassium phosphate), and EDTA can be used as the chelating agent, and more preferably, a chelating agent selected from

trisodium citrate, tripotassium citrate, and dipotassium phosphate can be used.

[0043]

These chelating agents can be used alone or two, three, or more thereof can be used. In one aspect, a combination of a citric acid salt with a phosphoric acid salt can be used. For example, sodium citrate (trisodium citrate) and/or potassium citrate can be used in combination with dipotassium phosphate.

[0044]

The amount of the chelating agent to be added is 2.0 g or more and 5.7 g or less, preferably 3.0 g or more and 5.7 g or less, more preferably 3.2 g or more and 5.5 g or less, still more preferably 3.4 g or more and 5.3 g or less, particularly preferably 3.6 g or more and 5.1 g or less, for example, 5.0 g or less in terms of anhydrate per 900 kcal of the composition. When the amount of the chelating agent is short, the protein may be insufficiently dissolved. An excessively large amount of the chelating agent may result in an uneven composition (gel).

[0045]

In the nutritional composition according to the present embodiment, the productivity thereof is significantly influenced by the content of phosphoric acid or a salt thereof (e.g., dipotassium phosphate) in the chelating agent. For example, when 2.3 g of

phosphoric acid or a salt thereof is used per 900 kcal of the composition, the nutritional composition can be favorably prepared with no productivity problem even if another chelating agent (e.g., sodium citrate (trisodium citrate) and/or potassium citrate) is not contained. Thus, when phosphoric acid or a salt thereof is used alone as the chelating agent, the content thereof is preferably 2.3 g or more per 900 kcal of the composition from the viewpoint of productivity. On the other hand, when a phosphoric acid or a salt thereof is used in combination with another chelating agent (e.g., sodium citrate and/or potassium citrate), the content is preferably 1.1 g or more, more preferably 2.3 g or more per 900 kcal of the composition from the viewpoint of productivity. To this, the upper limit of the content of phosphoric acid or a salt thereof is preferably less than 3.7 g per 900 kcal of the composition from the viewpoint of the stability of the gel. As above, from the viewpoint of the stability and productivity of the composition, the content of phosphoric acid or a salt thereof is preferably 1.1 g or more and less than 3.7 g per 900 kcal of the composition.

[0046]

Although the present inventors have thought that because the gel-like nutritional composition according to the present embodiment contains a large amount of minerals and the like, a corresponding amount of the

chelating agent is needed, unexpectedly, a gel-like composition stable for a long time can be obtained by controlling the amount of the chelating agent within a predetermined range. From the above viewpoint, the weight ratio of the total amount of magnesium and calcium (in terms of magnesium and calcium) to the amount of the chelating agent (in terms of anhydrate) per 900 kcal of the gel-like nutritional composition according to the present embodiment can be, for example, 1:4.5 or less, preferably 1:4.4 or less, more preferably 1:4.3 or less, particularly preferably 1:4.2 or less. The lower limit value thereof is preferably 1:1 or more, more preferably 1:2.4 or more. In one aspect, the weight ratio of the amount of calcium to the amount of the chelating agent (in terms of anhydrate) per 900 kcal or 100 g of the gel-like nutritional composition according to the present embodiment can be 1:7.0 or less, preferably 1:6.5 or less, more preferably 1:6.0 or less. The lower limit value thereof is 1:1 or more, preferably 1:3.4 or more.

[0047]

In one aspect, the gel-like nutritional composition according to the present embodiment preferably has a pH of more than 5.5 and 7.0 or less. When the pH is out of this range, the gel is likely to be uneven, and a reduction in a variety of vitamins during storage can be accelerated.

[0048]

The gel-like nutritional composition according to the present embodiment may contain an emulsifier, salts different from the chelating agent, fruit juice, a fragrance, a suspending agent, a stabilizer, and the like as needed. For example, lecithin, a glycerol fatty acid ester, enzymatically decomposed lecithin, a sorbitan fatty acid ester, a propylene glycol fatty acid ester, and a sucrose fatty acid ester alone or in combination can be used as the emulsifier.

[0049]

The gel-like nutritional composition according to the present embodiment contains water in addition to the ingredients such as protein, lipid, carbohydrate, vitamins, and minerals as described above. The method of preparing the gel-like nutritional composition according to the present invention is not particularly limited as long as a desired gel-like nutritional composition is obtained. For example, the gel-like nutritional composition can be prepared as follows.

(1) A liquid nutritional composition is prepared by a method of adding the above-mentioned protein, carbohydrate, vitamins, minerals, oils and fats, and an emulsifier as needed to water or hot water, and emulsifying these with a homogenizer or the like.

(2) A solution of agar preliminarily dissolved by heating and alginic acid or a salt thereof is added and mixed. When added during dissolution of alginic acid or

a salt thereof, the chelating agent also functions as a solubilizing aid; however, the chelating agent can be added in any order as long as a homogenous composition is obtained.

(3) The gel-like nutritional composition is optionally filled into a pouch such as an aluminum pouch or a container such as a soft bag, and is sterilized by heating with a retort or the like. Thus, the gel-like nutritional composition is prepared. The gel-like nutritional composition may be sterilized by heating by a normal method, and a container made of a known soft synthetic resin, a laminate of paper and a metal foil, or the like can be appropriately used.

The ingredients can be added in any order as long as a desired even gel-like nutritional composition is obtained, and a high pressure homogenizer may be appropriately used in each stage of addition as needed.
[0050]

The gel-like nutritional composition according to the present embodiment thus prepared has no aggregation nor precipitation, and is stable and does not become uneven even if stored at room temperature for a long time, such as 2 or 4 weeks. In the present embodiment, the expression that the gel-like nutritional composition is stable indicates that it has no aggregation nor precipitation and does not become uneven after stored at room temperature for 2 or 4 weeks from the sterilization

by heating. In one aspect, the gel-like nutritional composition according to the present embodiment is stable and does not become uneven even if stored at 25°C and 65%RH for 13 months.

[0051]

Because the gel-like nutritional composition according to the present embodiment is a gel, it can suppress gastroesophageal reflux, and is suitable for the enteral nutritional composition.

Examples

[0052]

Hereinafter, the present invention will be further described by way of Examples and Comparative Examples, but the present invention will not be limited to the examples below. To be noted, hereinafter, that the nutritional composition (formulation) is "uneven" indicates that layered gelation and local gel of agar are visually observed and/or uneven hardness is found in the nutritional composition. The nutritional composition in which such "unevenness" was not observed was evaluated as "stable" (having high stability).

[0053]

(Comparative Example 1: addition of vitamins and minerals to gel-like nutritional composition)

When a RACOL NF-blended semi-solid formulation for enteral use (RACOL-NF SemiSolid for Enteral Use;

manufactured and sold by EN Otsuka Pharmaceutical Co., Ltd.) which was a gel-like nutritional composition containing soybean protein as the protein was prepared, daily adequate intakes of vitamins and minerals including selenium, chromium, molybdenum, choline, and carnitine were added to and mixed with 900 kcal equivalent of the formulation based on the Dietary Reference Intakes for Japanese (Non Patent Literature 1). Local gelation was caused, and the formulation became uneven. In particular, it was thought that the calcium concentration and the magnesium concentration were increased to cause local gelation.

[0054]

(Comparative Example 2: gelation of liquid nutritional composition)

An ENORAS-blended enteral solution (ENORAS Liquid for Enteral Use, manufactured and sold by EN Otsuka Pharmaceutical Co., Ltd.) as a liquid nutritional composition was 1.6 kcal/mL (the amount of whole milk protein of 5.73 g per 100 mL and the amount of casein of 1.91 g per 100 mL). In preparation of this, the solution was diluted to 1.0 kcal/g, and daily vitamins and minerals were added to prepare a nutritional composition, which was emulsified with a high pressure homogenizer. Subsequently, an agar solution dissolved by heating and an alginic acid solution containing potassium carbonate as a solubilizing aid dissolved in water were added, and

then a mixture of agar and alginic acid contained in an amount of 0.25 g each per 100 g was dissolved and then added. The resulting composition was filled into an aluminum pouch container, and was sterilized through a heat treatment. After the preparation, a homogenous gel was obtained compared to that in Comparative Example 1, although partially uneven portions were observed. The amount of whole milk protein per 100 g was 3.58 g, and the amount of casein per 100 g was 1.19 g. The amount of sodium citrate (trisodium citrate dihydrate) was 2662 mg per 900 kcal. When gelation was attempted without dilution, the properties were further worsened.

[0055]

The results of Comparative Examples 1 and 2 have revealed that a stable gel-like nutritional composition suitable for administration through a tube and sufficiently containing vitamins and minerals is not obtained by a method of simply adding vitamins and minerals to a traditional gel-like nutritional composition or by a method of gelating a traditional liquid nutritional composition with a gelation agent.

[0056]

(Comparative Example 3: increase 1 in amount of sodium citrate)

The gel-like nutritional composition in Comparative Example 2 had high concentrations of ions including calcium ions. For this reason, in order to further

stabilize the gel-like nutritional composition, a composition containing sodium citrate as a chelating agent was prepared by the same method as in Comparative Example 2 except that the amount of sodium citrate was 1.25 times that in Comparative Example 2. However, a reduction in properties and stability was observed, which was equal to or slightly worse than that in Comparative Example 2.

[0057]

(Comparative Example 4: increase 2 of sodium citrate)

A gel-like nutritional composition was prepared by the same method as in Comparative Example 3 except that the amount of sodium citrate based on the dietary reference intake was further increased (1.56 times that in Comparative Example 2). The properties and stability were further reduced compared to those of Comparative Example 3. In addition, slight burning was observed during a heat treatment.

[0058]

(Examples)

Using 7.5 L of 40 to 60°C hot water, 800 g of a milk protein concentrate (protein content: about 80%) as whole milk protein, 260 g of casein sodium (protein content: about 90%) as casein, 540 g of emulsifier-containing oils and fats as lipid, 2800 g of dextrin as carbohydrate, and a vitamin and mineral mixture having the following composition as vitamins and minerals, these were mixed to

provide a final concentration such that the PFC ratio, the ratio of casein to whole milk protein, the ratio Ca/P, the Mg concentration, the Ca concentration, and the energy amount were as shown in Table 3. 100 g of the final nutritional composition contained 4 g of the milk protein concentrate and 1.3 g of the casein.

[0059]

The vitamin and mineral mixture used was a mixture containing vitamins and minerals per 900 kcal as follows: vitamin A (retinol palmitic acid ester): 900 µgRE, vitamin B₁ (thiamine chloride hydrochloride): 1.4 mg, vitamin B₂ (riboflavin): 1.6 mg, vitamin B₆ (pyridoxine): 1.4 mg, vitamin B₁₂ (cyanocobalamin): 4.5 µg, vitamin D (cholecalciferol): 15 µg, vitamin E (tocopherol acetic acid ester): 22.5 mg, vitamin C (ascorbic acid): 200 mg, niacin (nicotinamide): 15.0 mg, pantothenic acid: 6.0 mg, folic acid: 240 µg, vitamin K: 75 µg, biotin: 50.0 µg, phosphorus: 1000 mg, iron: 11.0 mg, zinc: 11.0 mg, copper: 0.9 mg, manganese: 4.0 mg, iodine: 130 µg, selenium: 50.0 µg, chromium: 40.0 µg, molybdenum: 30.0 µg.

Calcium and magnesium were added in the forms of calcium lactate hydrate and magnesium chloride such that each content corresponded to the amount shown in Table 1 which was the total of the amount thereof added and the amount thereof contained in other ingredients such as whole milk protein. As one example, in the case of

Example 2, 998 mg of calcium lactate hydrate and 2828.9 mg of magnesium chloride were added.

[0060]

The mixture was emulsified with a high pressure homogenizer, and then, an agar solution dissolved by heating and an alginic acid solution containing potassium carbonate as a solubilizing aid dissolved in water were added. Thereafter, the mixture was sterilized by a heat treatment to prepare a gel-like nutritional composition. The agar and alginic acid were added such that their final concentrations corresponded to the concentrations shown in Table 3. The chelating agents contained per 900 kcal of the final nutritional composition are as shown in Table 3.

[0061]

The resulting compositions were evaluated for viscosity and extrusion force using the following methods. Part of the compositions were also measured for viscosity after they were stored at room temperature for 2 weeks and 4 weeks.

[Measurement of viscosity]

Each nutritional composition was stored at 20°C for 10 minutes, and 20 mL thereof was extracted and measured using a single cylindrical rotary viscometer (the method specified in <2.53> Viscosity Determination in Physical Methods of The Japanese Pharmacopoeia 17th Edition). The viscosities shown in Tables 3 and 4 were measured with a

B-type viscometer with a number of rotations of 12 rpm at 20°C.

[Measurement of extrusion force]

About 30 g of a gel-like nutritional composition sample was filled into a 50-ml catheter chip syringe (Terumo Corporation), and a PEG tube of 20 Fr. (Bard Ponsky N. B. R. catheter: Medicon Inc.) was attached to the syringe. Thereafter, using a compression tester (SV-55C-20H: Imada-SS Corporation), the extrusion force when the sample was discharged from the syringe at a rate of 65% was measured (measurement temperature: 20°C).

[Measurement of pH]

Using a pH meter, the pH was measured according to <2.54> pH Measurement Method of The Japanese Pharmacopoeia 17th Edition.

[0062]

The resulting gel-like nutritional compositions in Examples each contained daily adequate intakes of vitamins and minerals in 900 kcal equivalent, had a viscosity which was not reduced after storage for 4 weeks to 13 months, and were stable compositions in which extreme syneresis or uneven properties were also not observed.

[0063]

A variety of compositions having different PFC ratios and different amounts of agar and alginic acid are also shown in Table 3. In Table 3, the measured results

of the viscosity, the extrusion force, and the pH are shown. Examples 10-1 to 10-3 are examples of the compositions prepared in different production lots. In Example 2, the amount of whole milk protein per 100 g was 3.58 g and the amount of casein was 1.19 g per 100 g. In Table 3, the amounts of the chelating agents are each a value in terms of hydrate expressed in mg/100 g. The sodium citrate used was trisodium citrate dihydrate (represented as sodium citrate hydrate in The Japanese Pharmacopoeia), and the potassium citrate used was tripotassium citrate monohydrate. The dipotassium phosphate used was an anhydride thereof.

[0064]

Although the examples in which magnesium was blended in an amount of 370 mg per 900 kcal are shown in Table 3, a larger amount thereof can be easily blended. For the viscosity, the maximum value and the minimum value among the measured values are shown because the raw materials are those naturally derived and the viscosity of the final composition varied depending on different lots. The stability was less influenced by different lots.

[0065]

[Table 3]

	P	F	C	Whole milk protein/casein	CaP	Mg mg/900 kcal	Ca mg/900 kcal	Sodium citrate mg/100 g	Potassium citrate mg/100 g	Dipotassium phosphate mg/100 g	Agar % by weight	Alginate acid % by weight	Energy kcal/g	Viscosity mPa·s	Extrusion force N	Viscosity Two weeks	Four weeks	pH
Example 1	16	29	55	2.7	0.88	369.9	880.2	294.8	0	296.5	0.250	0.300	1.00	10315				6.36
Example 2	15	27	58	2.7	0.86	351.9	843.3	294.8	0	296.5	0.250	0.300	1.06	9448				6.53
Example 3	18	25	57	2.7	0.88	369.9	880.2	294.8	0	296.5	0.250	0.250	1.00	8715	39			6.36
Example 4	17	24	59	2.7	0.85	353.7	847.8	294.8	0	257.7	0.250	0.250	1.06	8298				6.35
Example 5	17	22	61	2.7	0.84	343.8	828.0	176.9	27.3	266.1	0.250	0.250	1.01	7282		8298	8815	6.37
Example 6	18	24	58	2.7	0.85	344.7	819.0	176.9	27.3	266.1	0.250	0.250	0.96	7998		7648	8565	6.33
Comp. Ex. 5	16	29	55	2.7	0.88	369.9	880.2	295.8	92.3	306.0	0.000	0.000	1.00	7				6.44
Example 8	16	29	55	2.7	0.88	369.9	880.2	302.9	0	296.5	0.275	0.250	1.00	9348				
Example 9	16	29	55	2.7	0.88	369.9	880.2	302.9	0	296.5	0.250	0.250	1.00	9723				
Example 10-1	16	29	55	2.7	0.88	369.9	880.2	302.9	0	296.5	0.250	0.250	1.00	6566				6.5
Example 10-2								302.9	0	296.5				6716				6.42
Example 10-3								302.9	0	296.5				6449				6.38
Example 11	16	29	55	2.7	0.88	369.9	880.2	302.9	0	296.5	0.275	0.275	1.00	8273				6.41
Example 12	16	29	55	2.7	0.88	369.9	880.2	302.9	0	296.5	0.300	0.275	1.00	9948				6.40
Example 13	16	29	55	2.7	0.88	369.9	880.2	302.9	0	296.5	0.300	0.300	1.00	8298				6.40
Example 14	16	29	55	2.7	0.88	369.9	880.2	302.9	0	296.5	0.275	0.300	1.00	9848				6.40
Example 15	16	29	55	2.7	0.88	369.9	880.2	302.9	0	296.5	0.300	0.300	1.00	11623				6.38
Example 16	18	25	57	2.7	0.88	369.9	880.2	283.4	22.4	257.7	0.200	0.200	1.00	6499				
Example 17	18	25	57	2.7	0.88	369.9	880.2	283.4	22.4	257.7	0.225	0.225	1.00	None				
Example 18	18	25	57	2.7	0.88	369.9	880.2	176.9	27.3	266.1	0.250	0.200	1.00	7215				6.52
Comp. Ex. 6	18	25	57	2.7	0.88	369.9	880.2	176.9	27.3	266.1	0.000	0.000	1.00	12				Not Applicable
Example 19	18	25	57	2.7	0.88	369.9	880.2	176.9	27.3	266.1	0.250	0.150	1.00	8565				Not Applicable
Example 20	18	25	57	2.7	0.88	369.9	880.2	176.9	27.3	266.1	0.250	0.200	1.00	9048				Not Applicable
Example 21	18	25	57	2.7	0.88	369.9	880.2	176.9	27.3	266.1	0.250	0.250	1.00	9581				Not Applicable
Example 22	18	25	57	2.7	0.88	369.9	880.2	176.9	27.3	266.1	0.250	0.250	1.00	8715				Not Applicable
Example 23	18	25	57	2.7	0.88	369.9	880.2	176.9	27.3	266.1	0.300	0.300	1.00	10081				Not Applicable
Example 24	18	25	57	2.7	0.88	369.9	880.2	176.9	27.3	266.1	0.250	0.350	1.00	10665				Not Applicable
Example 25	17	24	59	2.7	0.86	352.8	856.8	176.9	27.3	266.1	0.250	0.200	1.02	6999		7981	8498	6.28
Example 26	18	25	57	2.7	0.88	369.9	880.2	176.9	37.5	257.4	0.250	0.200	1.00	8415	36.7			6.44
Example 27	18	25	57	2.7	0.88	369.9	880.2	176.9	37.5	257.4	0.250	0.200	1.00	6965	31			6.46
Example 28	17	23	60	2.7	0.84	348.3	837.0	176.9	27.3	266.1	0.250	0.200	1.05	7215				6.52
Example 29	17	24	59	2.7	0.85	365.4	875.7	176.9	27.3	266.1	0.250	0.200	1.06	None				6.32
Example 30	18	25	57	2.7	0.88	369.9	880.2	176.9	27.3	266.1	0.250	0.210	1.08	12964				6.36
Example 31	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	257.8	0.250	0.200	1.00	7850	33.2			6.39
Example 32	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	257.8	0.250	0.200	0.99	6767	32.8			6.44
Example 33	18	24	58	2.7	0.88	370.8	880.2	176.9	37.1	257.8	0.250	0.200	0.99	5867	30.4			6.52
Example 34	18	24	58	2.7	0.88	370.8	880.2	176.9	37.1	257.8	0.250	0.200	0.99	5133	29.1			6.58
Example 35	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	257.8	0.250	0.200	1.00	6167	33.1			6.54

In Examples 19 to 24, alginate Na, rather than alginate acid, was used.

[0066]

In the gel-like nutritional composition in Example 16 shown in Table 3, the amounts of agar and alginic acid were varied and the viscosity was measured. The results are shown in Table 4. The viscosity is the average of three results of measurement.

[Table 4]

Alginic acid % by weight	Agar % by weight	Viscosity (mPa·s)
0.15	0.2	5204
0.15	0.3	8903
0.2	0.2	6499 (Example 16)
0.2	0.3	9642
0.25	0.2	7593
0.25	0.3	10665

[0067]

The gel-like nutritional composition in Comparative Example 1 contained soybean protein as the main protein. An even composition was not obtained even by adding vitamins and minerals to this composition. In contrast, in Examples, it was thought that stable gel-like nutritional compositions containing large amounts of minerals such as calcium were obtained by adding a milk protein concentrate and casein as main proteins and adjusting the amounts of the chelating agents.

[0068]

Although the liquid nutritional composition in Comparative Example 2 originally contained large amounts of vitamins and minerals, gelation of this composition

did not result in a stable gel-like nutritional composition. Because large amounts of minerals were contained, the amount of the chelating agent was increased as in Comparative Examples 3 and 4. However, the stability was not improved but reduced compared to Comparative Example 2. In contrast, in Examples, it was thought that stable gel-like nutritional compositions irrespective of large amounts of minerals and the like contained were obtained by adjusting the amounts of minerals added as well as the amount of protein added and the type thereof and finding the amounts of gelation agent and the chelating agent optimal to gelation.

[0069]

The amount of magnesium, the amount of calcium, and the amounts of the chelating agents in representative Examples and Comparative Examples are shown below. The total amount of the chelating agents is shown as the amount not containing hydrate thereof. In Examples and Comparative Examples shown in Table 5, the content of an anhydrate of dipotassium phosphate was 2749.5 mg/900 kcal (ENORAS-blended enteral solution (ENORAS Liquid for Enteral Use)), 2753.4 mg/900 kcal (Comparative Example 2), 2320.2 mg/900 kcal (Example 26), and 2663.4 mg/900 kcal (Example 2), respectively.

[Table 5]

	Mg amount (per 900 kcal) (Amount derived from MPC and casein)	Ca amount (per 900 kcal) (Amount derived from MPC and casein)	Total amount of chelating agents (per 900 kcal) Upper: total amount of hydrates Lower: total amount in terms of anhydrates	1) (Mg+Ca): chelating agent (anhydrate) 2) Ca: chelating agent (anhydrate)	Stability
ENORAS- blended enteral solution (1.6 kcal/1 mL) Not gelled	370.1 mg (MPC: 31.8 mg) (Casein: 0.2 mg)	799.9 mg (MPC: 680.1 mg) (Casein: 3.2 mg)	6114 mg 5749 mg	1)1:4.91 2)1:7.16	○ (Not gelled) Product
Comparative Example 2 (1.0 kcal/g) Gelled	370.1 mg (MPC: 31.8 mg) (Casein: 0.4 mg)	799.9 mg (MPC: 744.5 mg) (Casein: 6.5 mg)	6247 mg 5874 mg	1)1:5.02 2)1:7.34	Unstable
Example 26 (1.0 kcal/g) Gelled	370.8 mg (MPC: 35.1 mg) (Casein: 0.4 mg)	880.2 mg (MPC: 831.6 mg) (Casein: 7.3 mg)	4246 mg 4032 mg	1)1:3.22 2)1:4.58	○
Example 2 (1.06 kcal/g) Gelled	370.1 mg (MPC: 31.4 mg) (Casein: 0.4 mg)	879.9 mg (MPC: 743.6 mg) (Casein: 6.5 mg)	5322 mg 4996 mg	1)1:4.00 2)1:5.68	○

[0070]

Furthermore, nutritional compositions in Examples and Comparative Examples were prepared in the same manner as in Example 1. Specifically, using 7.5 L of 40 to 60°C hot water, 800 g of a milk protein concentrate (protein content: about 80%) as whole milk protein, 260 g of casein sodium (protein content: about 90%) as casein, 540 g of emulsifier-containing oils and fats as lipid, 2800 g of dextrin as carbohydrate, and a vitamin and mineral mixture having the following composition as vitamins and minerals, these were mixed to provide a final

concentration such that the PFC ratio, the ratio of casein to whole milk protein, the ratio Ca/P, the Mg concentration, the Ca concentration, and the energy amount were as shown in Table 6. 100 g of the final nutritional composition contained 4 g of the milk protein concentrate and 1.3 g of the casein.

[0071]

The vitamin and mineral mixture used was a mixture containing vitamins and minerals per 900 kcal as follows: vitamin A (retinol palmitic acid ester): 900 µgRE, vitamin B₁ (thiamine chloride hydrochloride): 1.4 mg, vitamin B₂ (riboflavin): 1.6 mg, vitamin B₆ (pyridoxine): 1.4 mg, vitamin B₁₂ (cyanocobalamin): 4.5 µg, vitamin D (cholecalciferol): 15 µg, vitamin E (tocopherol acetic acid ester): 22.5 mg, vitamin C (ascorbic acid): 200 mg, niacin (nicotinamide): 15.0 mg, pantothenic acid: 6.0 mg, folic acid: 240 µg, vitamin K: 75 µg, biotin: 50.0 µg, phosphorus: 1000 mg, iron: 11.0 mg, zinc: 11.0 mg, copper: 0.9 mg, manganese: 4.0 mg, iodine: 130 µg, selenium: 50.0 µg, chromium: 40.0 µg, molybdenum: 30.0 µg.

Calcium and magnesium were added in the forms of calcium lactate hydrate and magnesium chloride such that each content corresponded to the amount shown in Table 6 which was the total of the amount thereof added and the amount thereof contained in other ingredients such as whole milk protein.

[0072]

The mixture was emulsified with a high pressure homogenizer, and then, an agar solution dissolved by heating and an alginic acid solution containing potassium carbonate as a solubilizing aid dissolved in water were added. Thereafter, the mixture was sterilized by a heat treatment to prepare a gel-like nutritional composition. The agar and alginic acid were added such that their final concentrations corresponded to the concentrations shown in Table 6. The chelating agents contained per 900 kcal of the final nutritional composition are as shown in Table 6.

[0073]

[Table 6]

	P	F	C	Whole milk protein/ casein	Ca/P	Mg mg/900 kcal	Ca mg/900 kcal	Sodium citrate mg/100 g	Potassium citrate mg/100 g	Dipotassium phosphate mg/100 g	Agar % by weight	Alginate acid % by weight	Energy kcal/g	Viscosity mPas	Extrusion force N
Example 36	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	257.8	0.250	0.200	1.00	7850	33.2
Example 37	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	257.8	0.250	0.200	0.99	6767	32.8
Example 38	18	24	58	2.7	0.88	370.8	880.2	176.9	37.1	257.8	0.250	0.200	0.99	5867	30.4
Example 39	18	24	58	2.7	0.88	370.8	880.2	176.9	37.1	257.8	0.250	0.200	0.99	5133	29.1
Example 40	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	257.8	0.250	0.200	1.00	6167	33.1
Comp. Ex. 7	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	0	0.250	0.200	1.00	9000	43.2
Comp. Ex. 8	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	12.9	0.250	0.200	1.00	9933	43.8
Comp. Ex. 9	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	25.8	0.250	0.200	1.00	9817	42.5
Comp. Ex. 10	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	38.7	0.250	0.200	1.00	9883	44.4
Example 41	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	257.8	0.250	0.200	1.00	7900	35.2
Comp. Ex. 11	18	25	57	2.7	0.88	370.8	880.2	353.8	74.2	515.6	0.250	0.200	1.00	3183	19.2
Comp. Ex. 12	18	25	57	2.7	0.88	370.8	880.2	530.7	111.3	773.4	0.250	0.200	1.00	1683	12.0
Comp. Ex. 13	18	25	57	2.7	0.88	370.8	880.2	707.6	148.4	1031.2	0.250	0.200	1.00	2333	13.7
Example 42	18	25	57	2.7	0.88	370.8	880.2	88.5	18.6	128.9	0.250	0.200	1.00	9333	43.5
Comp. Ex. 14	18	25	57	2.7	0.88	370.8	880.2	44.2	9.3	64.5	0.250	0.200	1.00	9050	40.5
Example 43	18	25	57	2.7	0.88	370.8	880.2	0	0	257.8	0.250	0.200	1.00	8733	41.4
Comp. Ex. 15	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	0	0.250	0.200	1.00	8367	38.1
Example 44	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	128.9	0.250	0.200	1.00	8917	40.4
Comp. Ex. 16	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	90.2	0.250	0.200	1.00	9867	44.0
Comp. Ex. 17	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	64.5	0.250	0.200	1.00	10467	43.6
Example 45	18	25	57	2.7	0.88	370.8	880.2	0	0	257.8	0.250	0.200	1.00	8183	39.3
Example 46	18	25	57	2.7	0.88	370.8	880.2	176.9	37.1	257.8	0.250	0.200	1.00	8133	35.8
Comp. Ex. 18	18	25	57	2.7	0.88	370.8	880.2	0	0	193.4	0.250	0.200	1.00	8100	41.5
Comp. Ex. 19	18	25	57	2.7	0.88	370.8	880.2	0	0	128.9	0.250	0.200	1.00	8500	41.4
Comp. Ex. 20	18	25	57	2.7	0.88	370.8	880.2	283.04	59.36	412.48	0.250	0.200	1.00	3850	20.7

[0074]

The amount of magnesium and that of calcium derived from MPC/casein, the amount of the chelating agent, and the amount of dipotassium phosphate in Examples and Comparative Examples shown in Table 6 are shown. The total amount of the chelating agents and the amount of dipotassium phosphate are shown as amounts not containing hydrate.

[0075]

[Table 7]

	Amount of Mg derived from MPC and casein		Amount of Ca derived from MPC and casein		Dipotassium phosphate (in terms of anhydrate) g/900 kcal	Chelating agent (in terms of anhydrate) g/900 kcal		(Mg+Ca): chelating agent (anhydrate)	Ca: chelating agent (anhydrate)
	MPC mg/900 kcal	casein mg/900 kcal	MPC mg/900 kcal	casein mg/900 kcal					
Example 36	35.1	0.4	831.6	7.3	2.3	4.0	1:3.22	1:4.58	
Example 37	35.1	0.4	831.6	7.3	2.3	4.0	1:3.22	1:4.58	
Example 38	35.1	0.4	831.6	7.3	2.3	4.0	1:3.22	1:4.58	
Example 39	35.1	0.4	831.6	7.3	2.3	4.0	1:3.22	1:4.58	
Example 40	35.1	0.4	831.6	7.3	2.3	4.0	1:3.22	1:4.58	
Comp. Ex. 7	35.1	0.4	831.6	7.3	0.0	1.7	1:1.37	1:1.95	
Comp. Ex. 8	35.1	0.4	831.6	7.3	0.1	1.8	1:1.46	1:2.08	
Comp. Ex. 9	35.1	0.4	831.6	7.3	0.2	1.9	1:1.55	1:2.21	
Comp. Ex. 10	35.1	0.4	831.6	7.3	0.3	2.1	1:1.65	1:2.34	
Example 41	35.1	0.4	831.6	7.3	2.3	4.0	1:3.22	1:4.58	
Comp. Ex. 11	35.1	0.4	831.6	7.3	4.6	8.1	1:6.44	1:9.16	
Comp. Ex. 12	35.1	0.4	831.6	7.3	7.0	12.1	1:9.67	1:13.74	
Comp. Ex. 13	35.1	0.4	831.6	7.3	9.3	16.1	1:12.89	1:18.33	
Example 42	35.1	0.4	831.6	7.3	1.2	2.0	1:1.61	1:2.29	
Comp. Ex. 14	35.1	0.4	831.6	7.3	0.6	1.0	1:0.81	1:1.15	
Example 43	35.1	0.4	831.6	7.3	2.3	2.3	1:1.85	1:2.64	
Comp. Ex. 15	35.1	0.4	831.6	7.3	0.0	1.7	1:1.37	1:1.95	
Example 44	35.1	0.4	831.6	7.3	1.2	2.9	1:2.30	1:3.26	
Comp. Ex. 16	35.1	0.4	831.6	7.3	0.8	2.5	1:2.02	1:2.87	
Comp. Ex. 17	35.1	0.4	831.6	7.3	0.6	2.3	1:1.83	1:2.61	
Example 45	35.1	0.4	831.6	7.3	2.3	2.3	1:1.85	1:2.64	
Example 46	35.1	0.4	831.6	7.3	2.3	4.0	1:3.22	1:4.58	
Comp. Ex. 18	35.1	0.4	831.6	7.3	1.7	1.7	1:1.39	1:1.98	
Comp. Ex. 19	35.1	0.4	831.6	7.3	1.2	1.2	1:0.93	1:1.32	
Comp. Ex. 20	37.1	0.2	832.6	3.8	3.7	6.5	1:5.16	1:7.33	

[0076]

In Tables 6 and 7, in Examples, gel-like nutritional compositions obtained are those which enable intake of a daily energy intake therefrom, enable blending of adequate intakes and recommended amounts of vitamins and

minerals per day, and have excellent gel stability and evenness.

In contrast, in Comparative Examples 16 and 17, the gel was partially uneven, closure of the flow path by precipitates when the composition was passed through the homogenizer during production was observed, and thus productivity was slightly inferior.

In Comparative Examples 7 to 15 and 20, the properties and stability were lower than those in Examples. In Comparative Example 18, closure of the flow path by precipitates when the composition was passed through the homogenizer during production was observed, and thus productivity was slightly inferior. Furthermore, in the nutritional composition in Comparative Example 19, closure of the flow path by precipitates when the composition was passed through the homogenizer during production was often observed, and thus productivity was inferior.

Industrial Applicability

[0077]

The gel-like nutritional compositions according to the present invention are stable nutritional compositions which enable easy intake of a daily energy intake therefrom, contain daily adequate intakes and recommended amounts of vitamins and minerals, are easy to take and store because they are in a gel form, can suppress

gastroesophageal reflux, and are also suitable for enteral administration. The gel-like nutritional compositions according to the present invention have industrial applicability in the fields of medical care, rehabilitation, nursing care, and the like.

Claims

[Claim 1]

A gel-like nutritional composition comprising lipid, proteins, carbohydrate, a vitamin, and a mineral, and having the following compositions:

1) the composition has an energy value of 0.8 kcal/g or more and 1.2 kcal/g or less;

2) the composition contains 1.7 g or more of whole milk protein and 0.25 g or more of casein as the proteins per 100 g of the composition;

3) the total amount of magnesium derived from the whole milk protein and the casein is 1.3 mg or more per 900 kcal of the composition, and the total amount of calcium derived from the whole milk protein and the casein is 34.9 mg or more per 900 kcal of the composition;

4) the composition contains 220 mg or more of magnesium and 500 mg or more of calcium per 900 kcal of the composition;

5) the composition contains one or more minerals selected from 30 µg or more of selenium, 10 µg or more of chromium, 30 µg or more of molybdenum, and 130 µg or more of iodine per 900 kcal of the composition;

6) the composition contains 0.15% by weight or more and 0.40% by weight or less of agar and 0.125% by weight or more and 0.40% by weight or less of alginic acid or a

salt thereof, and has a viscosity of 3,000 mPa·s or more and 17,000 mPa·s or less; and

7) the composition contains a chelating agent selected from citric acid or a salt thereof, phosphoric acid or a salt thereof, and EDTA or a salt thereof in a total amount of 2.0 g or more and 5.7 g or less per 900 kcal of the composition, and contains 1.1 g or more and less than 3.7 g of the phosphoric acid or a salt thereof per 900 kcal of the composition.

[Claim 2]

The gel-like nutritional composition according to claim 1, wherein the weight ratio of the casein to the whole milk protein is 1:1.1 to 1:13 in terms of protein contained.

[Claim 3]

The gel-like nutritional composition according to claim 1 or 2, wherein the whole milk protein is a milk protein concentrate.

[Claim 4]

The gel-like nutritional composition according to any one of claims 1 to 3, wherein the composition does not contain an animal-derived protein decomposed product and a plant-derived protein decomposed product.

[Claim 5]

The gel-like nutritional composition according to any one of claims 1 to 4, wherein the lipid content in

the composition is 20% or more and 30% or less in an energy ratio,

the protein content in the composition is 13% or more and 30% or less in an energy ratio, and

the carbohydrate content in the composition is 50% or more and 65% or less in an energy ratio.

[Claim 6]

The gel-like nutritional composition according to any one of claims 1 to 5, wherein the composition contains 310 mg or more of magnesium and 650 mg or more of calcium per 900 kcal of the composition.

[Claim 7]

The gel-like nutritional composition according to any one of claims 1 to 6, wherein the composition contains at least vitamins and minerals below per 900 kcal of the composition:

[Table 1]

Calcium	800 mg	Cholecalciferol	8.5 µg
Magnesium	370 mg	Tocopherol acetic acid ester	7.0 mg of α-tocopherol
Phosphorus	1000 mg	Thiamine	1101 µg
Iron	11.0 mg	Riboflavin	1.6 mg
Zinc	11.0 mg	Pyridoxine	1.4 mg
Manganese	4.0 mg	Cyanocobalamin	2.4 µg
Copper	0.9 mg	Ascorbic acid	100 mg
Iodine	130 µg	Nicotinic acid amide	15 mg
Selenium	30 µg	Pantothenic acid	6 mg
Chromium	10 µg	Folic acid	240 µg
Molybdenum	30 µg	Biotin	50 µg
Retinol palmitic acid ester	900 µgRE		

[Claim 8]

The gel-like nutritional composition according to any one of claims 1 to 7, wherein the composition has a pH of more than 5.5 and 7.0 or less, and the ratio of the total amount of magnesium and calcium to the amount of the chelating agent per 900 kcal of the composition is 1:4.5 or less.