

DESCRIPTION

DILUTE-TYPE NUTRITIONAL COMPOSITION

Technical Field

The present invention relates to a dilute-type nutritional composition, such as a dilute-type nutritional composition capable of being subjected to long-term storage, and a dilute-type nutritional composition which can be used for a patient with dysphagia and/or a tube-fed patient.

Background Art

As the elderly population increases, the number of individuals having difficulty swallowing (i.e., swallowing an orally-ingested substance)-that is, patients with dysphagia-is also increases. When a patient with dysphagia introduces a liquid food with high fluidity, such as water or tea, into his/her mouth, it reaches the throat within a very short period of time. In the case of a patient with dysphagia, specifically, a liquid food reaches the throat before the pharyngeal reflex occurs, the liquid food enters the trachea, and he/she may accidentally swallow the food. A person having difficulty with food intake and chewing (i.e., a person for whom chewing is difficult) may experience accidental swallowing by mis-swallowing food without sufficient chewing. An effective method to modify liquid food for a patient with dysphagia and a person having difficulty with chewing, in order to prevent such accidental swallowing, is to increase the viscosity of a liquid food with the use of a thickener.

For the purpose of nutritional support for patients who have difficulty with or are incapable of oral ingestion of nutrients, in general, a method of administering a nutritional composition (i.e., a nutrient preparation) by means of nutritional tubing (through the nasal cavity; i.e., transnasal administration), gastric fistula, or intestinal fistula (i.e., tubal feeding) has been employed.

In the case of tubal feeding, such as via transnasal administration, a feeding tube is inserted through the nasal cavity. In order to avoid breathing interruption, accordingly, it is necessary to maintain the diameter of the feeding tube thin (in general, the outer diameter is about 2 to 3 mm). When the diameter of the feeding tube is thin, it is necessary to maintain

the viscosity of a nutritional composition low, so that the nutritional composition can readily flow through the feeding tube. When the viscosity of the nutritional composition is maintained low, however, gastro-esophageal reflux or diarrhea may occur. Accordingly, it has been necessary to adequately increase the viscosity of the nutritional composition and administer small amounts thereof to patients or the like over long periods of time.

On the other hand, in the case of tubal feeding through means such as gastric fistula or intestinal fistula, a fistulous opening is surgically provided in the esophagus, stomach, or jejunum of a patient or the like, a button or tube is implanted therein, and a nutritional composition is administered therethrough. Thus, the diameter of the feeding tube can be increased. Through tubal feeding by means of gastric fistula, the nutritional composition is directly administered into the stomach of a patient or the like. It is known that when the viscosity of the nutritional composition is maintained low, as described above, gastro-esophageal reflux or the like may occur. In order to prevent gastro-esophageal reflux or the like, accordingly, a method of administering a semi-solid liquid food with an increased viscosity (i.e., viscosity of 4,000 to 20,000 mPa·s at 20°C) instead of a liquid food with a low viscosity to a patient or the like within a short period of time has been widely employed. However, when a semi-solid liquid food with viscosity increased to a certain extent is administered to a patient or the like, the conventional technique employing free fall (free drip) cannot be adopted. In general, accordingly, an injector such as a syringe is used to administer a nutritional composition directly into the stomach of a patient or the like. For example, JP 2007-289164 A (Patent Document 1) and JP 2007-137792 A (Patent Document 2) describe liquid foods for patients with gastric fistulae, and administration of such liquid foods or a nutritional composition involves the use of a syringe or plunger pump.

Thus, (semi-solid) liquid foods with increased viscosity are effectively used in applications such as oral administration and tubal administration (including enteral administration, such as via gastric fistula or intestinal fistula), and the concept of the use of a thickener or the like to increase the viscosity of a liquid food is already known.

From the viewpoint of ease of handling, liquid foods that can retain flavor, quality, and other properties for a long period time are known. For example, WO 2007/026474 (Patent Document 3) describes a nutritional composition with high protein content that can be

easily administered via various routes to a patient without losing its taste or flavor. It has been found that such nutritional composition has the viscosity of 400 to 7000 mPa·s at 25°C and that such composition can be stored at 25°C for as long as 6 months. In addition, WO 2012/157571 (Patent Document 4) describes a liquid food with high protein content and low water content; that is, a high concentration type liquid food, which is supplemented with carrageenan or organic acid monoglyceride as a thickener.

Related Documents

Patent Documents

Patent Document 1: JP 2007-289164 A

Patent Document 2: JP 2007-137792 A

Patent Document 3: WO 2007/026474

Patent Document 4: WO 2012/157571

Summary of the Invention

Objects to Be Attained by the Invention

With regard to conventional liquid foods with increased viscosity, highly concentrated (or enriched) forms of liquid foods, such as food with high protein content, for long-term storage, have been known. However, when highly concentrated liquid foods are administered to patients with various diseases whose energy intake is regulated on a daily basis, patients can ingest only small amounts thereof so as to receive necessary and sufficient amounts of nutrients, and they cannot ingest (intake) sufficient amounts of water. When a highly concentrated liquid food is administered and water with low viscosity is then administered orally to a patient with dysphagia whose energy intake is regulated on a daily basis so as to supply sufficient amount of water, the patient may accidentally swallow the liquid food. Alternatively, if water is solely administered via tubal feeding, the patient may suffer from gastro-esophageal reflux or the like. For such patients, accordingly, it has been necessary to separately increase the viscosity of water content using a thickener or the like before administration, and handling thereof accompanied difficulties. When a highly concentrated liquid food is to be administered in the manner described above, accordingly, it

was necessary to increase the viscosity of water separately and then administer the same, doubling the necessary amount of time and effort. Accordingly, a dilute-type nutritional composition, which was also suitable for hydration, was needed.

When a highly concentrated nutritional composition with high protein content is simply diluted in order to try to attain a dilute-type nutritional composition, the emulsion structure may be destroyed, and an emulsion state cannot be maintained stably, and the composition may clog the feeding tube. Thus, such simply diluted composition cannot be adequately used for general applications. On the other hand, when a highly concentrated nutritional composition with high protein content is continuously administered to an elderly person, he/she may develop a lifestyle-related disease such as diabetes due to overnutrition. Accordingly, a dilute-type nutritional composition for long-term storage that can maintain stable emulsion state is needed.

The liquid food described in WO 2012/157571 is a so-called "highly concentrated liquid food" with high protein content and low water content. As described in the comparative examples of the present specification below, a nutritional composition that could be sufficiently used for general applications cannot be obtained by simply diluting such highly concentrated liquid food because the cream would separate during storage. That is, if a nutritional composition is supplemented with carrageenan or organic acid monoglyceride alone, as in the case of highly concentrated liquid foods, a so-called dilute-type liquid food with high water content that maintains stable quality and properties cannot be produced.

Accordingly, it is an object of the present invention to develop a dilute-type nutritional composition (e.g., liquid foods and enteral nutrient preparations) with high viscosity with sufficient storage stability, low protein content, and high water content.

Means for Attaining the Objects

The present inventor carried out extensive studies in order to attain the above object. As a result, the present inventor discovered that a nutritional composition having desirable properties could be obtained by incorporating, as a thickener, 0.1% to 0.5% by weight of carrageenan and a dextrin exhibiting a dextrose equivalent (DE) value between 11 and 29 in which the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition is at least a value determined by multiplying said DE by 1.5 into a

nutritional composition. This has led to the completion of the present invention. In addition, the present inventor examined milk protein materials to be used and found that a nutritional composition having desirable emulsion stability and suitability for tubal administration could be obtained with the use of a casein digest having a particular degradation rate for a nutritional composition. This has led to the completion of the present invention. Further, the present inventor examined processed starch to be used and discovered that a nutritional composition having desirable emulsion stability and being suitable for tubal administration could be obtained with the use of a particular type of processed starch for a nutritional composition. This has led to the completion of the present invention.

According to the present invention, it is possible to provide a nutritional composition (e.g., liquid foods and enteral nutrient preparations) with sufficient storage stability, low protein content, and high water content, which could not be produced by conventional techniques. The nutritional composition according to the present invention is effectively administered orally to patients with dysphagia whose energy intake is regulated on a daily basis. Among the nutritional compositions of the present invention, those certain types of nutritional composition which form curds when mixed with artificial (simulated) gastric juice, for example, those certain types of such composition which form curds without syneresis upon protein solidification will solidify in the stomach and solidify without syneresis and are not likely to cause diarrhea when such compositions are used for tubal feeding, such as via gastric fistula or intestinal fistula. Accordingly, the use of such compositions is effective for patients who intend to avoid diarrhea while receiving hydration.

Among the nutritional compositions according to the present invention, those nutritional compositions having a non-Newtonian viscosity index of 0.3 to less than 1.0 are not only suitable for tubal administration, such as via transnasal administration but also such nutritional compositions have properties (i.e., physical properties) suitable for direct administration into the stomach by free fall at the time of tubal feeding, such as via gastric fistula or intestinal fistula, wherein the protein content thereof is 1% to 10% by weight, and water content thereof is 70% to 95% by weight and can be used as a dilute-type nutritional composition for patients in need of tubal feeding, such as via transnasal administration. In such a case, the characteristics of the nutritional composition are similar to those of a

Newtonian fluid, and such composition can be administered by free fall without interruption (without halt of drip). If the nutritional composition can be administered slowly by free fall, problems such as gastro-esophageal reflux are less likely to occur. Further, among the nutritional compositions according to the present invention having a non-Newtonian viscosity index of 0.3 to less than 1.0, those which form curds when mixed with simulated gastric juice, for example, those which form curds without syneresis upon protein solidification are believed to be less likely to cause diarrhea since the composition solidifies in the stomach and, for example, solidifies in the stomach without syneresis when used for tubal feeding, such as via gastric fistula or intestinal fistula.

In addition, among the nutritional compositions according to the present invention, those nutritional compositions having a non-Newtonian viscosity index of (0.1 to) less than 0.3 has properties (i.e., physical properties) suitable for direct administration into the stomach at the time of tubal feeding, such as via gastric fistula or intestinal fistula, with the use of a syringe or plunger pump, wherein the protein content thereof is 1% to 10% by weight, and the water content thereof is 70% to 95% by weight. Thus, the same can be used as a dilute-type nutritional composition for patients in need of tubal feeding, such as via gastric fistula or intestinal fistula. Among the nutritional compositions according to the present invention that have a non-Newtonian viscosity index of (0.1 to) less than 0.3, those which form curds when mixed with simulated gastric juice, for example, those which form curds without syneresis upon protein solidification are believed to be less likely to cause diarrhea when such compositions are used for tubal feeding, such as via gastric fistula or intestinal fistula.

Among the nutritional compositions according to the present invention having a non-Newtonian viscosity index of (0.1 to) less than 0.3 those which do not form curds when mixed with simulated gastric juice are believed to be easily digested and absorbed immediately into the intestinal tract since such composition does not solidify, or is not likely to solidify, in the stomach.

Further, the nutritional composition according to the present invention has the property that when the same is heated (sterilized by heating), the viscosity thereof increases (i.e., the nutritional composition is thickened). Since the viscosity of such starting solution is low before it is heated (sterilized by heating) following homogenization, it can readily be

introduced into a container, such as a soft bag (e.g., a pouch), a brick-shaped container (e.g., a paper container), or a can container. If the nutritional composition according to the present invention is introduced into a container in a state of a low-viscosity liquid and then heated (sterilized by heating) via retort treatment, a high-viscosity semi-solid is obtained. Thus, a nutritional composition for oral administration and tubal administration (e.g., a nutritional composition used for direct administration into the stomach by free fall) that is hygienically produced can be obtained.

Specifically, the present invention includes the following.

[1] A nutritional composition comprising:

(i) dextrin exhibiting a dextrose equivalent (DE) value between 11 and 29 in which the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition is at least (equal to or more than) a value determined by multiplying said DE by 1.5;

(ii) 0.1% to 0.5% by weight of carrageenan as a thickener; and

(iii) 1% to 10% by weight of a protein.

[2] A nutritional composition comprising:

(i) dextrin exhibiting a dextrose equivalent (DE) value between 11 and 29 in which the percentage accounted for by monosaccharides to heptasaccharides within the total sugar composition is 45% to 90% by weight;

(ii) 0.1% to 0.5% by weight of carrageenan as a thickener; and

(iii) 1% to 10% by weight of a protein.

[3] The nutritional composition according to [1] or [2], wherein the protein contains a casein digest in which the amount of amino nitrogen (AN) relative to the total amount of nitrogen (TN), i.e., the AN/TN, is 4.5% to 10% by weight.

[4] The nutritional composition according to [1] or [2], wherein the protein contains a collagen peptide or a casein digest in which the AN/TN is 10% to 50% by weight.

[5] The nutritional composition according to any of [1] to [4], which further comprises (ii) processed starch as a thickener.

[6] The nutritional composition according to [5], wherein the average particle diameter of the processed starch is 1 μm to 10 μm .

[7] The nutritional composition according to any of [1] to [6], which further comprises (ii) tamarind gum as a thickener.

[8] The nutritional composition according to any of [1] to [7], wherein the viscosity measured at 20°C after heat sterilization is 20 to 3000 mPa·s (measured with a B type (rotary) viscometer in which the rotor is operated at 12 rpm).

[9] The nutritional composition according to any of [1] to [8], wherein when the shear stress and the shear rate measured at 2 or more arbitrary points in the shear rate range of 0.1/s to 1000/s are represented by the equation shown below, the value "n" is from 0.3 to less than 1.0, and wherein the viscosity measured at 25°C after heat sterilization is 20 to 3000 mPa·s (measured with a B type (rotary) viscometer in which the rotor is operated at 12 rpm):

$$P = \mu D^n$$

[wherein P represents shear stress (Pa), D represents shear rate (1/s), μ represents the non-Newtonian viscosity coefficient, and n represents the non-Newtonian viscosity index].

[10] The nutritional composition according to any of [1] to [8], wherein when the shear stress and the shear rate measured at 2 or more arbitrary points in the shear rate range of 0.1/s to 1000/s are represented by the equation shown below, the value "n" is 0.1 to less than 0.3, and wherein the viscosity measured at 25°C after heat sterilization is 20 to 3000 mPa·s (measured with a B type (rotary) viscometer in which the rotor is operated at 12 rpm):

$$P = \mu D^n$$

[wherein P represents shear stress (Pa), D represents shear rate (1/s), μ represents the non-Newtonian viscosity coefficient, and n represents the non-Newtonian viscosity index].

[11] The nutritional composition according to [9] or [10], which forms curds when mixed with simulated gastric juice (pH 1.2).

[12] The nutritional composition according to [9] or [10], which does not form curds when mixed with simulated gastric juice (pH 1.2).

[13] The nutritional composition according to any of [1] to [12], wherein the caloric content is 0.5 to 1.5 kcal/ml.

[14] The nutritional composition according to any of [1] to [13], which is for tubal feeding.

[15] The nutritional composition according to any of [1] to [14], which can maintain a stable emulsion state after being stored at 40°C for 1 month.

[16] A method for producing a nutritional composition comprising the following steps:

(a) a step of mixing a composition comprising:

(i) dextrin exhibiting a dextrose equivalent (DE) value between 11 and 29 in which the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition is at least a value determined by multiplying said DE by 1.5;

(ii) 0.1% to 0.5% by weight of carrageenan as a thickener; and

(iii) 1% to 10% by weight of a protein;

(b) a step of homogenizing the composition; and

(c) a step of heat sterilizing the composition.

[17] A method for producing a nutritional composition comprising the following steps:

(a) a step of mixing a composition comprising:

(i) dextrin exhibiting a dextrose equivalent (DE) value between 11 and 29 in which the percentage accounted for by monosaccharides to heptasaccharides within the total sugar composition is 45% to 90% by weight;

(ii) 0.1% to 0.5% by weight of carrageenan as a thickener; and

(iii) 1% to 10% by weight of a protein;

(b) a step of homogenizing the composition; and

(c) a step of heat sterilizing the composition.

[18] The method for production according to [16] or [17], wherein the protein contains a casein digest in which the amount of amino nitrogen (AN) relative to the total amount of nitrogen (TN), i.e., the AN/TN, is 4.5% to 10% by weight.

[19] The method for production according to [16] or [17], wherein the protein contains a collagen peptide or a casein digest in which the AN/TN is 10% to 50% by weight.

[20] The method for production according to any of [16] to [19], which further comprises (ii) use of processed starch as a thickener.

[21] The method for production according to [20], wherein the average particle diameter of the processed starch is 1 μm to 10 μm .

[22] The method for production according to any of [16] to [21], wherein the nutritional composition forms curds when mixed with simulated gastric juice (pH 1.2).

[23] The method for production according to any of [16] to [21], wherein the nutritional composition does not form curds when is mixed with simulated gastric juice (pH 1.2).

[24] The method for producing the nutritional composition according to any of [16] to [23], which further comprises the following step:

(d) a step of filling a container with the composition.

[25] The method for producing the nutritional composition according to any of [16] to [24], which further comprises (ii) tamarind gum as a thickener.

[26] The method for producing the nutritional composition according to any of [16] to [25], wherein the viscosity of the composition measured at 20°C after (b) the step of homogenizing the composition and/or (c) the step of heat sterilizing the composition is 20 to 3000 mPa·s (measured with a B type (rotary) viscometer in which the rotor is operated at 12 rpm).

[27] The method for producing the nutritional composition according to any of [16] to [26], wherein the caloric content of the nutritional composition is 0.5 to 1.5 kcal/ml.

[28] The method for producing the nutritional composition according to any of [16] to [27], wherein the nutritional composition is for tubal feeding.

[29] The method for producing the nutritional composition according to any of [16] to [28], wherein the nutritional composition can maintain a stable emulsion state after it has been stored at 40°C for 1 month.

This description includes the content as disclosed in the descriptions of Japanese Patent Application Nos. 2014-139017 and 2015-012770, which are priority documents of the present application.

Effects of the Invention

According to the present invention, it is possible to provide a nutritional composition (e.g., liquid foods and enteral nutrient preparations) with sufficient storage stability, low protein content, and high water content, which previously could not be produced with

conventional techniques. The nutritional composition according to the present invention is effective for oral administration to patients with dysphagia whose energy intake is regulated on a daily basis. That is, the nutritional composition according to the present invention is effective for oral administration to healthy elderly persons who are at risk of accidental swallowing.

Among the nutritional compositions according to the present invention, those having a non-Newtonian viscosity index of 0.3 to less than 1.0 are suitable for tubal administration, such as via transnasal administration and, in addition, such nutritional compositions have properties (i.e., physical properties) suitable for direct administration into the stomach by free fall at the time of tubal feeding, such as via gastric fistula or intestinal fistula, wherein the protein content thereof is 1% to 10% by weight, and water content thereof is 70% to 95% by weight. Thus, such composition can be used as a dilute-type nutritional composition for patients in need of tubal feeding via transnasal administration or other means. That is, by administering the nutritional composition according to the present invention via tubal feeding or other means, physical burdens imposed on doctors, nurses, caregivers, persons involved in caregiving, and the like who actually carry out administration and the like in clinical and caregiving settings can be effectively reduced. In such a case, the characteristics of the nutritional composition are similar to those of a Newtonian fluid, and such composition can be administered by free fall without interruption. If the nutritional composition can be administered slowly by free fall, problems such as diarrhea or gastro-esophageal reflux are less likely to occur. Among the nutritional compositions according to the present invention having a non-Newtonian viscosity index of 0.3 to less than 1.0, those which form curds when mixed with simulated gastric juice, for example, those compositions which form curds without syneresis upon protein solidification are less likely to cause diarrhea when used for tubal feeding, such as via gastric fistula or intestinal fistula, and therefore preferable.

In addition, among the nutritional compositions according to the present invention, those having a non-Newtonian viscosity index of (0.1 to) less than 0.3, have properties (i.e., physical properties) suitable for direct administration into the stomach with the use of a syringe or plunger pump at the time of tubal feeding, such as via gastric fistula or intestinal fistula, wherein the protein content thereof is 1% to 10% by weight, and water content thereof

is 70% to 95% by weight. Thus, the same can be used as a dilute-type nutritional composition for patients in need of tubal feeding, such as via transnasal administration. Further, among the nutritional compositions according to the present invention having a non-Newtonian viscosity index of (0.1 to) less than 0.3, those which form curds when mixed with simulated gastric juice, for example, those which form curds without syneresis upon, for example, protein solidification are less likely to cause diarrhea when used for tubal feeding, such as via gastric fistula or intestinal fistula, and therefore preferable.

Furthermore, among the nutritional compositions according to the present invention having a non-Newtonian viscosity index of (0.1 to) less than 0.3, those which do not form curds when mixed with simulated gastric juice are readily digested and absorbed immediately by the intestinal tract, and therefore preferable.

Further, when the nutritional composition according to the present invention is heated (sterilized by heating), the viscosity thereof is increased (i.e., the nutritional composition is thickened). Since the viscosity of such starting solution is low prior to being heated (sterilized by heating) following homogenization, it can be readily introduced into a container, such as a soft bag (e.g., a pouch), a brick-shaped container (e.g., a paper container), or a can container. After the nutritional composition according to the present invention is introduced into a container in the state of a low-viscosity liquid and then heated (sterilized by heating) via retort treatment, a high-viscosity liquid or semi-solid can be obtained. In spite of the small amount of thickener contained in the nutritional composition according to the present invention, by carrying out heat (sterilization) by means of retort treatment or other means, the viscosity thereof can effectively be increased at the time of actual administration to a patient by a person involved in caregiving.

With regard to conventional nutritional compositions, for dilute-type compositions with high water content and high viscosity, cream could separate therefrom or other problems could occur during storage (e.g., at room temperature or in a refrigerator) and the storage stability thereof was not sufficient. Thus, regarding conventional nutritional compositions of dilute-type with high water content and low viscosity, a person involved in caregiving has been required to add a powder, such as a thickener, immediately before the composition was actually administered to a patient so as to prepare a

dilute-type composition with high water content and high viscosity (extemporaneous preparation). However, this method (procedure) is laborious, and physical burdens were imposed on persons involved in caregiving.

While the nutritional composition according to the present invention is of a dilute-type with low protein content and high water content, it nevertheless can maintain a stable emulsion state, and the storage stability thereof is sufficient and, therefore, can be stored for a long period of time (e.g., at room temperature or in a refrigerator). Thus, the nutritional composition according to the present invention has various advantages due to this longevity of preservation. For example, the nutritional composition according to the present invention can be collectively produced in advance at a commercial-scale factory or the like. Accordingly, a person involved in caregiving is not required to add a powdered thickener to the composition immediately before administration thereof to a patient, so as to prepare a composition with high viscosity (before use). Thus, physical burdens imposed on persons involved in caregiving can be effectively reduced. Since large quantities of the nutritional composition according to the present invention can be collectively produced at a commercial-scale factory or the like, the formulation (composition), physical properties, quality, and other conditions thereof can be controlled at constant levels. When a person involved in caregiving or the like administers such composition to a patient or the like, accordingly, variations in the nutrition or absorption conditions when the patient actually ingests such composition can be suppressed or prevented.

Embodiments for Carrying out the Invention

The nutritional composition according to an embodiment of the present invention comprises carrageenan as a thickener and dextrin with a given quality. The carrageenan content is preferably 0.1% to 0.5% by weight. According to an embodiment, the protein content of the nutritional composition according to the present invention is 1% to 10% by weight, and the water content thereof is 70% to 95% by weight. According to an embodiment, the nutritional composition according to the present invention can further comprise processed starch and/or tamarind gum. According to an embodiment, the nutritional composition

according to the present invention can comprise a casein digest having a particular degradation rate as a protein.

In the description of the present invention, the concentration of a particular ingredient represented in terms of "% by weight" indicates the final concentration thereof relative to the entire composition represented in terms of "% by weight."

According to an embodiment of the present invention, a nutritional composition having a non-Newtonian viscosity index of 0.3 to less than 1.0 is suitable for tubal administration, such as via transnasal administration. In addition, such nutritional composition has properties (i.e., physical properties) suitable for direct administration into the stomach by free fall at the time of tubal feeding, such as via gastric fistula or intestinal fistula, wherein the protein content thereof is 1% to 10% by weight, and water content thereof is 70% to 95% by weight. Thus, it can be used as a dilute-type nutritional composition for patients in need of tubal feeding, such as via transnasal administration. That is, by administering the nutritional composition according to the present invention to a patient or the like via tubal feeding or other means, physical burdens imposed on doctors, nurses, caregivers, persons involved in caregiving, and the like who actually carry out administration to a patient or the like in clinical and caregiving settings can be effectively reduced. In such a case, the characteristics of the nutritional composition are similar to those of a Newtonian fluid, and such composition can be administered by free fall without interruption. If the nutritional composition can be administered slowly by free fall, problems such as diarrhea or gastro-esophageal reflux are less likely to occur. Among the nutritional compositions according to the present invention having a non-Newtonian viscosity index of 0.3 to less than 1.0, those which form curds when mixed with simulated gastric juice (e.g., a type of such nutritional composition that forms curds without syneresis upon protein solidification) are believed to be less likely to cause diarrhea when used for tubal feeding, such as via gastric fistula or intestinal fistula.

In addition, among the nutritional compositions according to the present invention, those having a non-Newtonian viscosity index of (0.1 to) less than 0.3 have properties (i.e., physical properties) suitable for direct administration into the stomach with the use of a syringe or plunger pump at the time of tubal feeding, such as via gastric fistula or intestinal

fistula, wherein the protein content thereof is 1% to 10% by weight, and water content thereof is 70% to 95% by weight. Such composition can be used as a dilute-type nutritional composition for patients in need of tubal feeding, such as via transnasal administration. Among the nutritional compositions according to the present invention having a non-Newtonian viscosity index of (0.1 to) less than 0.3, those which form curds when mixed with simulated gastric juice (e.g., a type of such nutritional composition that forms curds without syneresis upon protein solidification) are believed to be less likely to cause diarrhea when used for tubal feeding, such as via gastric fistula or intestinal fistula.

Among the nutritional compositions according to the present invention having a non-Newtonian viscosity index of (0.1 to) less than 0.3, those which do not form curds when mixed with simulated gastric juice are readily digested and absorbed immediately by the intestinal tract.

While a nutritional composition of semi-solid form with increased viscosity that is gelatinized with the addition of a gelling agent may be suitable for oral administration, such composition cannot be administered with the conventional technique of tubal administration performed by free fall (free dripping). Accordingly, the nutritional composition according to the present invention is in a liquid state, unless otherwise specified, and the present composition is not in a semi-solid or solid state.

Dextrin is also referred to as British gum, starch gum, or Dextrine. Dextrin is classified on the basis of the dextrose equivalent (DE) value. The dextrose equivalent (DE) value is an indicator of the degree of saccharification. The amount of reducing sugar contained in a certain type of dextrin is converted into dextrose-equivalent terms, and the percentage accounted for by dextrose within the total solid content of the dextrin is represented in terms of "% by weight." For example, the DE value of dextrose is 100, and the degree of saccharification of maltodextrin exhibiting a DE value of 10 is 10% by weight. The DE value can be determined via a conventional technique, such as the Lane method (e.g., Dziedzic, S. Z. et al., 1995, Handbook of starch hydrolysis products and their derivatives, London: Blackie Academic & Professional, page 230, the Lane-Eynon titration method). Dextrin used for the nutritional composition according to the present invention has a DE value of 11 or greater, 12 or greater, 13 or greater, 14 or greater, 15 or greater, 16 or greater, or 16.5

or greater. Dextrin used for the nutritional composition according to the present invention has a DE value of 29 or less, 28 or less, or 27 or less. When the lower limit and the upper limit of the DE value are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, dextrin used for the nutritional composition according to the present invention has a DE value between 11 and 29, 11 and 28, 11 and 27, 12 and 29, 12 and 28, 12 and 27, 13 and 29, 13 and 28, 13 and 27, 14 and 29, 14 and 28, 14 and 27, 15 and 29, 15 and 28, 15 and 27, 16 and 29, 16 and 28, 16 and 27, 16.5 and 29, 16.5 and 28, or 16.5 and 27. A single type of dextrin or a mixture of a plurality of types of dextrin is used for the nutritional composition according to the present invention. In the latter case, the weight average of the DE values of various dextrans is determined on the basis of the mixing ratio. If the determined value is within the range described above, such mixture of dextrans may be used. It should be noted that the term "dextrose" used herein is synonymous with the term "glucose."

In the description of the present invention, a component (ingredient) comprising a single α -glucose molecule within a dextrin is referred to as a "monosaccharide (G1)," a component comprising two α -glucose molecules polymerized with each other is referred to as a "disaccharide (G2)," and a component comprising "n" number of α -glucose molecules polymerized with each other is referred to as an "n-saccharide (Gn)" (with "n" being an integer such as 1, 2, 3, 4, 5, 6, 7, 8...). In such case, the amount of monosaccharides, disaccharides, or n-saccharides in the total sugar composition of dextrin is represented in terms of "% by weight." Ingredients comprising 8 or more α -glucose molecules polymerized with each other can be collectively referred to as "octasaccharides and greater (G8+)." In such case, the percentage accounted for by monosaccharides to heptasaccharides within the total sugar composition of dextrin and that accounted for by octasaccharides and greater within the total sugar composition of dextrin can be represented separately as the sugar contents.

In the description of the present invention, dextrin with a given quality is a dextrin which has a DE value between 11 and 29 in which the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition of dextrin is at least

(equal to or larger than) a value determined by multiplying DE by 1.5. Preferably, such dextrin has a DE value of 11 or greater, 12 or greater, 13 or greater, 14 or greater, 15 or greater, 16 or greater, or 16.5 or greater to 29 or less, 28 or less, 27 or less, such as 11 to 29, 11 to 28, 11 to 27, 12 to 29, 12 to 28, 12 to 27, 13 to 29, 13 to 28, 13 to 27, 14 to 29, 14 to 28, 14 to 27, 15 to 29, 15 to 28, 15 to 27, 16 to 29, 16 to 28, 16 to 27, 16.5 to 29, 16.5 to 28, or 16.5 to 27 and in such dextrin, the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition is at least a value determined by multiplying DE by 1.5, 1.6, or 1.7. In the description of the present invention, the term "pentasaccharides to heptasaccharides of dextrin" refers to pentasaccharides, hexasaccharides, and heptasaccharides combined. For example, Dextrin L-SPD (Showa Sangyo Co., Ltd.) is comprised of 14% pentasaccharides, 17% hexasaccharides, and 13% heptasaccharides, the percentage of pentasaccharides to heptasaccharides (44%) is greater than the value (24.75) determined by multiplying a DE value of Dextrin L-SPD (16.5) by 1.5. That is, Dextrin L-SPD falls under a dextrin with a given quality. If the DE value is represented by A and the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition of such dextrin is represented by B, in theory, the indicator (B/A) does not have a theoretical upper limit, since the value B can be very large. The putative upper limit of B/A, if need be, can be 30, 25, 20, 15, 10, 5, 4, or 3. Accordingly, the percentage of the total sugar composition of such dextrin used in the present invention accounted for by pentasaccharides to heptasaccharides is, for example, at most the value determined by multiplying DE by 30, 25, 20, 15, 10, 5, 4, or 3. When the lower limit and the upper limit of the percentage of the total sugar composition of dextrin accounted for by pentasaccharides to heptasaccharides are provided herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, the percentage of the total sugar composition of dextrin accounted for by pentasaccharides to heptasaccharides used for the nutritional composition according to the present invention is, for example, between $(DE \times 1.5)$ and $(DE \times 30)$, between $(DE \times 1.5)$ and $(DE \times 25)$, between $(DE \times 1.5)$ and $(DE \times 20)$, between $(DE \times 1.5)$ and $(DE \times 15)$, between $(DE \times 1.5)$ and $(DE \times 10)$, between $(DE \times 1.5)$ and $(DE \times 5)$, between $(DE \times 1.6)$ and $(DE \times 30)$, between $(DE \times 1.6)$ and $(DE \times 25)$, between $(DE \times 1.6)$ and $(DE \times 20)$, between $(DE \times 1.6)$ and $(DE \times 15)$,

between (DE $\times$ 1.6) and (DE $\times$ 10), between (DE $\times$ 1.6) and (DE $\times$ 5), between (DE $\times$ 1.7) and (DE $\times$ 30), between (DE $\times$ 1.7) and (DE $\times$ 25), between (DE $\times$ 1.7) and (DE $\times$ 20), between (DE $\times$ 1.7) and (DE $\times$ 15), between (DE $\times$ 1.7) and (DE $\times$ 10) , or between (DE $\times$ 1.7) and (DE $\times$ 5).

According to an embodiment, a dextrin with a given quality exhibits a dextrose equivalent (DE) value between 11 and 29, and the percentage accounted for by monosaccharides to heptasaccharides of such dextrin within the total sugar composition is 45% to 90% by weight. When the lower limit and the upper limit of the DE value of the dextrin with a given quality are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. Such dextrin preferably exhibits a DE value of 11 or greater, 12 or greater, 13 or greater, 14 or greater, 15 or greater, 16 or greater, or 16.5 or greater to 29 or less, 28 or less, or 27 or less, such as 11 to 29, 11 to 28, 11 to 27, 12 to 29, 12 to 28, 12 to 27, 13 to 29, 13 to 28, 13 to 27, 14 to 29, 14 to 28, 14 to 27, 15 to 29, 15 to 28, 15 to 27, 16 to 29, 16 to 28, 16 to 27, 16.5 to 29, 16.5 to 28, or 16.5 to 27 and, in addition, the percentage accounted for by monosaccharides to heptasaccharides of such dextrin within the total sugar composition is preferably 45% or more, 50% or more, 60% or more, 70% or more, 80% or more, or 84% or more to 90% or less, such as 45% to 90%, 50% to 90%, 60% to 90%, 70% to 90%, 80% to 90%, or 84% to 90%. For example, Dextrin L-SPD (Showa Sangyo Co., Ltd.) exhibits a DE value of 16.5, and the percentage of the total sugar composition accounted for by monosaccharides to heptasaccharides thereof is 84%. Thus, Dextrin L-SPD falls under dextrin with a given quality.

Any dextrin with a given quality can be used for the nutritional composition according to the present invention without limitation in terms of origin or type. A commercially available dextrin can be used for the nutritional composition according to the present invention as well. The sugar composition of dextrin can be analyzed by a conventional technique, such as thin-layer chromatography or gel filtration chromatography using a cation-exchange column. Examples of dextrin exhibiting a DE value between 11 and 29 in which the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition is at least a value determined by multiplying said DE by 1.5 (the

percentage within the total sugar composition accounted for by pentasaccharides to heptasaccharides is at least a value determined by multiplying said DE by 1.5) and dextrin exhibiting a DE value between 11 and 29 in which the percentage accounted for by monosaccharides to heptasaccharides within the total sugar composition is 45% to 90% by weight include, but are not limited to, L-SPD (Showa Sangyo Co., Ltd.), M-SPD (Showa Sangyo Co., Ltd.), and K-SPD (Showa Sangyo Co., Ltd.). The nutritional composition according to the present invention can comprise dextrin with a given quality in an amount of 3% by weight or more, 3.5% by weight or more, 4% by weight or more, 4.5% by weight or more, 5% by weight or more, 5.5% by weight or more, or 6% by weight or more. The nutritional composition according to the present invention can comprise dextrin with a given quality in an amount of 15% by weight or less, 14.5% by weight or less, 14% by weight or less, 13.5% by weight or less, 13% by weight or less, 12.5% by weight or less, 12.3% by weight or less, 12% by weight or less, 11.5% by weight or less, 11% by weight or less, 10.5% by weight or less, or 10% by weight or less. When the lower limit and the upper limit of dextrin (% by weight) are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, the nutritional composition according to the present invention can comprise dextrin with a given quality in an amount of 3% to 15% by weight, 3.5% to 15% by weight, 3% to 14% by weight, 3.5% to 14% by weight, 3% to 13% by weight, 3.5% to 13% by weight, 3% to 12.3% by weight, 3.5% to 12.3% by weight, 4% to 15% by weight, 4.5% to 15% by weight, 4% to 14% by weight, 4.5% to 14% by weight, 4% to 13% by weight, 4.5% to 13% by weight, 4% to 12.3% by weight, 4.5% to 12.3% by weight, 5% to 15% by weight, 5.5% to 15% by weight, 5% to 14% by weight, 5.5% to 14% by weight, 5% to 13% by weight, 5.5% to 13% by weight, 5% to 12.3% by weight, 5.5% to 12.3% by weight, 6% to 15% by weight, 6% to 14.5% by weight, 6% to 14% by weight, 6% to 13.5% by weight, 6% to 13% by weight, 6% to 12.5% by weight, 6% to 12.3% by weight, 6% to 12% by weight, 6% to 11.5% by weight, 6% to 11% by weight, 6% to 10.5% by weight, or 6% to 10% by weight.

The nutritional composition according to the present invention can comprise a thickener. In the examples herein, production examples involving the use of carrageenan, tamarind gum, and processed starch are provided. It should be noted, however, that the

thickener that can be used for the nutritional composition according to the present invention is not limited thereto. A conventional thickener (which is also referred to as a gelling agent, stabilizer, thickening stabilizer, or starch adhesive) can be used, as long as the nutritional composition can maintain a stable emulsion state after heat sterilization. A single type of thickener or a plurality of types of thickeners can be used for the nutritional composition according to the present invention. For example, carrageenan can be used in combination with tamarind gum, or carrageenan can be used in combination with processed starch as thickeners for the nutritional composition according to the present invention. The nutritional composition according to the present invention can comprise a thickener in an amount of 0.1% by weight or more, 0.15% by weight or more, 0.2% by weight or more, or 0.25% by weight or more. The nutritional composition according to the present invention can comprise a thickener in an amount of 4.0% by weight or less, 3.5% by weight or less, 3% by weight or less, 2.5% by weight or less, 2.0% by weight or less, 1.5% by weight or less, 1.0% by weight or less, 0.5% by weight or less, 0.45% by weight or less, 0.4% by weight or less, or 0.35% by weight or less. When the lower limit and the upper limit of a thickener (% by weight) are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, the nutritional composition according to the present invention can comprise a thickener in an amount of 0.1% to 4.0% by weight, 0.1% to 3.5% by weight, 0.1% to 3.0% by weight, 0.1% to 2.5% by weight, 0.1% to 2.0% by weight, 0.1% to 1.5% by weight, 0.1% to 1.0% by weight, 0.1% to 0.8% by weight, 0.1% to 0.6% by weight, 0.1% to 0.5% by weight, 0.1% to 0.4% by weight, 0.1% to 0.35% by weight, 0.15% to 4.0% by weight, 0.15% to 3.5% by weight, 0.15% to 3.0% by weight, 0.15% to 2.5% by weight, 0.15% to 2.0% by weight, 0.15% to 1.5% by weight, 0.15% to 1.0% by weight, 0.15% to 0.8% by weight, 0.15% to 0.6% by weight, 0.15% to 0.5% by weight, 0.15% to 0.4% by weight, 0.15% to 0.35% by weight, 0.2% to 4.0% by weight, 0.2% to 3.5% by weight, 0.2% to 3% by weight, 0.2% to 2.5% by weight, 0.2% to 2.0% by weight, 0.2% to 1.5% by weight, 0.2% to 1.0% by weight, 0.2% to 0.8% by weight, 0.2% to 0.6% by weight, 0.2% to 0.5% by weight, 0.2% to 0.4% by weight, 0.2% to 0.4% by weight, 0.2% to 0.35% by weight, or 0.3% by weight.

The nutritional composition according to the present invention can comprise carrageenan as a thickener. Any carrageenan can be used for the nutritional composition according to the present invention without limitation in terms of origin or type. Examples of carrageenan types include κ -carrageenan, ι -carrageenan, and λ -carrageenan, and any other carrageenans can be used in combination therewith.

A commercially available carrageenan can be used for the nutritional composition according to the present invention. The nutritional composition according to the present invention can comprise carrageenan in an amount of 0.1% by weight or more, 0.125% by weight or more, 0.15% by weight or more, 0.175% by weight or more, 0.2% by weight or more, 0.225% by weight or more, or 0.25% by weight or more. The nutritional composition according to the present invention can comprise carrageenan in an amount of 0.5% by weight or less, 0.45% by weight or less, 0.4% by weight or less, or 0.35% by weight or less. When the lower limit and the upper limit of carrageenan (% by weight) are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, the nutritional composition according to the present invention can comprise carrageenan in an amount of 0.1% to 0.5% by weight, 0.1% to 0.45% by weight, 0.1% to 0.40% by weight, 0.1% to 0.35% by weight, 0.15% to 0.5% by weight, 0.15% to 0.45% by weight, 0.15% to 0.40% by weight, 0.15% to 0.35% by weight, 0.2% to 0.5% by weight, 0.2% to 0.45% by weight, 0.2% to 0.40% by weight, 0.2% to 0.35% by weight, 0.25% to 0.5% by weight, 0.25% to 0.45% by weight, 0.25% to 0.40% by weight, 0.25% to 0.35% by weight, or 0.3% by weight. If the carrageenan content of the nutritional composition according to the present invention exceeds 0.5% by weight, the emulsion state of the composition becomes unstable, and such excessive content is thus not preferable. If the carrageenan content is lower than 0.1% by weight in the nutritional composition according to the present invention, the viscosity of such composition cannot be increased, and such low content is thus not preferable.

The nutritional composition according to the present invention can further comprise processed starch as a thickener. Any processed starch can be used for the nutritional composition according to the present invention without limitation in terms of origin or type. Examples of processed starch include soluble starch, British starch, oxidized starch, starch

ester, starch ether, and fine-grained starch, and any other processed starch products can be used in combination. Examples of fine-grained starch include processed starch with an average particle diameter of 1 μm to 10 μm , 2 μm to 8 μm , 3 μm to 6 μm , and 4 μm to 5 μm . The average starch particle diameter can be determined by observing a starch sample in a solution under a scanning electron microscope or optical microscope, measuring particle diameters of a given number of starch particles in the solution that are randomly selected, and calculating the resulting average. In such case, the particle diameter is a sphere equivalent diameter of the size of a spherical particle equivalent to the projected area of the particle. Commercially available processed starch can be used for the nutritional composition according to the present invention, and an example thereof is, but is not limited to, Fine Snow (Joetsu Starch Co., Ltd.). The nutritional composition according to the present invention can comprise processed starch in an amount of 0.01% by weight or more, 0.05% by weight or more, 0.1% by weight or more, 0.2% by weight or more, or 0.23% by weight or more. The nutritional composition according to the present invention can comprise processed starch in an amount of 5% by weight or less, 4% by weight or less, 3% by weight or less, 2% by weight or less, or 1.9% by weight or less. When the lower limit and the upper limit of the processed starch (% by weight) are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, the nutritional composition according to the present invention can comprise processed starch in an amount of 0.01% to 5.0% by weight, 0.01% to 4.0% by weight, 0.01% to 3.0% by weight, 0.01% to 2.0% by weight, 0.01% to 1.9% by weight, 0.05% to 5.0% by weight, 0.05% to 4.0% by weight, 0.05% to 3.0% by weight, 0.05% to 2.0% by weight, 0.05% to 1.9% by weight, 0.1% to 5.0% by weight, 0.1% to 4.0% by weight, 0.1% to 3.0% by weight, 0.1% to 2.0% by weight, 0.1% to 1.9% by weight, 0.2% to 5.0% by weight, 0.2% to 4.0% by weight, 0.2% to 3.0% by weight, 0.2% to 2.0% by weight, 0.2% to 1.9% by weight, 0.23% to 5.0% by weight, 0.23% to 4.0% by weight, 0.23% to 3.0% by weight, 0.23% to 2.0% by weight, 0.23% to 1.9% by weight, or 0.5% to 1.0% by weight.

The nutritional composition according to the present invention can further comprise tamarind gum as a thickener. Any tamarind gum can be used for the nutritional composition according to the present invention without limitation in terms of origin or type.

Commercially available tamarind gum can also be used for the nutritional composition according to the present invention. The nutritional composition according to the present invention can comprise tamarind gum in an amount of 0.1% by weight or more, 0.15% by weight or more, 0.2% by weight or more, or 0.25% by weight or more. The nutritional composition according to the present invention can comprise tamarind gum in an amount of 0.5% by weight or less, 0.45% by weight or less, 0.4% by weight or less, or 0.35% by weight or less. When the lower limit and the upper limit of tamarind gum (% by weight) are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, the nutritional composition according to the present invention can comprise tamarind gum in an amount of 0.1% to 0.5% by weight, 0.1% to 0.45% by weight, 0.1% to 0.40% by weight, 0.1% to 0.35% by weight, 0.15% to 0.5% by weight, 0.15% to 0.45% by weight, 0.15% to 0.40% by weight, 0.15% to 0.35% by weight, 0.2% to 0.5% by weight, 0.2% to 0.45% by weight, 0.2% to 0.40% by weight, 0.2% to 0.35% by weight, 0.25% to 0.5% by weight, 0.25% to 0.45% by weight, 0.25% to 0.40% by weight, 0.25% to 0.35% by weight, or 0.3% by weight.

The nutritional composition according to the present invention can further comprise an emulsifier, so as to stabilize the emulsion state. A known emulsifier, such as a commercially available emulsifier, can be used. Any emulsifier can be used for the nutritional composition according to the present invention without limitation in terms of origin or type. Examples of emulsifiers include glycerin fatty acid ester, organic acid monoglyceride (e.g., a monoglyceride of acetic acid, lactic acid, citric acid, succinic acid, or diacetyltartaric acid), polyglycerin fatty acid ester, propylene glycol fatty acid ester, polyglycerin condensed ricinoleic acid ester, sorbitan fatty acid ester, sucrose fatty acid ester, lecithin, and soybean lysolecithin. A commercially available emulsifier can be used for the nutritional composition according to the present invention. According to an embodiment, an emulsifier used for the nutritional composition according to the present invention can comprise diacetyltartaric acid monoglyceride. The nutritional composition according to the present invention can comprise a conventional emulsifier in an amount of 0.02% to 2.0% by weight, 0.05% to 1.5% by weight, 0.05% to 1.0% by weight, 0.05% to 0.6% by weight,

0.06% to 0.6% by weight, 0.07% to 0.6% by weight, 0.07% to 0.5% by weight, or 0.05% to 0.5% by weight. When the lower limit and the upper limit of an emulsifier (% by weight) are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above.

The nutritional composition according to the present invention can comprise any known food materials or food additives, provided that the effects of the present invention are not impaired.

The nutritional composition according to the present invention can comprise a protein. Any protein-containing food material can be used for the nutritional composition according to the present invention without limitation in terms of origin or type. Examples of proteins include milk-derived protein (e.g., casein), soybean-derived protein, wheat-derived protein, livestock-meat-derived protein, fish-derived protein, chicken-egg-derived protein, and pork-skin-derived protein. Commercially available protein-containing food materials (e.g., a milk protein concentrate (MPC), a whey protein concentrate, sodium caseinate, skim milk powder, whole milk powder, whey powder, a milk protein digest (e.g., a casein digest having a particular degradation rate), and a whey protein digest) and a collagen peptide can also be used for the nutritional composition according to the present invention. Examples of such collagen peptide include, but are not limited to, collagen peptide derived from a pig, a cow, a chicken, and a fish. A single type of protein or a mixture of a plurality of proteins is used for the nutritional composition according to the present invention.

A protein used for the nutritional composition according to an embodiment of the present invention can be a casein protein hydrolysate having a particular degradation rate. The degree of protein hydrolysis can be represented in terms of the amount of amino nitrogen (AN) as the percentage of the total amount of nitrogen (TN) in the sample (i.e., AN/TN). In the description of the present invention, AN/TN is represented in terms of a percentage by weight (0% to 100%). Since a protein that is not hydrolyzed has an exposed amino group, in general, the AN/TN value of a protein is greater than 0. The AN/TN value of a hydrolyzed protein is greater than that of a protein that is not hydrolyzed. A casein protein hydrolysate that can be used for the nutritional composition according to an embodiment of the present invention has an AN/TN value of 4.5% to 10%, such as 4.5% to 9%, 4.5% to 8%, 4.5% to 7%,

4.5% to 6%, 4.5% to 5.4%, 4.6% to 5.4%, 4.7% to 5.4%, 4.8% to 5.4%, 4.9% to 5.4%, or 5.0% to 5.4%. A casein protein hydrolysate that can be used for the nutritional composition according to another embodiment of the present invention has an AN/TN value of 10% to 50%, such as 10% to 40% or 10% to 30%. When the lower limit and the upper limit of AN/TN (%) are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. AN/TN (%) can be determined by measuring the amount of amino nitrogen and that of the total nitrogen in a sample. The amount of amino nitrogen can be determined by, for example, the Van Slyke method, the Sorensen method (formol titration), or the ninhydrin colorimetric method. The total amount of nitrogen can be determined by, for example, the Kjeldahl method, a modified Kjeldahl method, the LECO method, the Dumas method, or combustion analysis. In this description, AN/TN is represented based on the AN value determined by formol titration and the TN value determined by the Kjeldahl method. A casein protein hydrolysate can be obtained by any conventional technique, such as acid hydrolysis and/or enzymolysis of casein, followed by separation such as ultrafiltration, according to need. A commercially available casein hydrolysate may be used, and a mixture of a plurality of types of caseins may be used.

The nutritional composition according to the present invention can comprise a protein in an amount of 1% by weight or more, 2% by weight or more, 3% by weight or more, or 3.5% by weight or more. The nutritional composition according to the present invention can comprise a protein in an amount of 10% by weight or less, 8% by weight or less, 6% by weight or less, 5.5% by weight or less, or 5.4% by weight or less. When the lower limit and the upper limit of the protein content (% by weight) are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, the nutritional composition according to the present invention can comprise a protein in an amount of 1% to 10% by weight, 1% to 8% by weight, 1% to 6% by weight, 1% to 5.5% by weight, 1% to 5.4% by weight, 2% to 10% by weight, 2% to 8% by weight, 2% to 6% by weight, 2% to 5.5% by weight, 2% to 5.4% by weight, 3% to 10% by weight, 3% to 8% by weight, 3% to 6% by weight, 3% to 5.5% by weight, 3% to 5.4% by weight, 3.5% to 10% by weight, 3.5% to 8% by weight, 3.5% to 6% by weight, 3.5% to 5.5% by weight, or 3.5% to 5.4% by weight.

The nutritional composition according to the present invention can comprise a carbohydrate. Any carbohydrate-containing food material can be used for the nutritional composition according to the present invention without limitation in terms of origin or type. Examples of carbohydrates include polysaccharides, such as cellulose, glucomannan, and glucan, chitins, fructooligosaccharides, galactooligosaccharides, mannan oligosaccharides, sucrose, low-molecular-weight polysaccharides, low-molecular-weight cellulose, and low-molecular-weight glucomannan. The nutritional composition according to the present invention can comprise a carbohydrate in an amount of 1.0% to 6.0% by weight or 2.0% to 5.0% by weight.

The nutritional composition according to the present invention can comprise water (moisture). The nutritional composition according to the present invention is a dilute-type composition with low protein content and water content of 70% by weight or more, it can maintain a stable emulsion state, and it has sufficient storage stability. Thus, such nutritional composition (e.g., a liquid food or an enteral nutrient preparation) has a high degree of viscosity, so that it can be stored for a long period of time (e.g., at room temperature or in a refrigerator). The nutritional composition according to the present invention can comprise water in an amount of 70% by weight or more, 73% by weight or more, or 75% by weight or more. The nutritional composition according to the present invention can comprise water in an amount of 95% by weight or less, 90% by weight or less, or 85% by weight or less. When the lower limit and the upper limit of water content (% by weight) are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, the water content of the nutritional composition according to the present invention can be, for example, 70% to 95% by weight, 70% to 90% by weight, 70% to 85% by weight, 73% to 95% by weight, 73% to 90% by weight, 73% to 85% by weight, 75% to 95% by weight, 75% to 90% by weight, or 75% to 85% by weight. If the water content of the nutritional composition according to the present invention exceeds 95% by weight, the viscosity of such composition cannot be increased, and such excessive content is thus not preferable.

The nutritional composition according to the present invention can adequately comprise a protein, a lipid, and a carbohydrate, so that its caloric content (i.e., energy level)

can be adjusted. The nutritional composition according to the present invention can comprise a protein in an amount equivalent to, for example, 1 to 10 g/100 g, and preferably 2 to 6 g/100 g. The nutritional composition according to the present invention can comprise a lipid in an amount equivalent to, for example, 1 to 10 g/100 g, and preferably 2 to 6 g/100 g. The nutritional composition according to the present invention can comprise a carbohydrate in an amount equivalent to, for example, 1 to 10 g/100 g, and preferably 2 to 6 g/100 g.

The nutritional composition according to the present invention can adequately comprise a protein, a lipid, and a carbohydrate, so that the caloric content (i.e., energy level) of the nutritional composition according to the present invention can be adjusted to, for example, 0.5 kcal/ml or more, 0.55 kcal/ml or more, 0.6 kcal/ml or more, 0.65 kcal/ml or more, or 0.70 kcal/ml or more. The caloric content of the nutritional composition according to the present invention can be adjusted to, for example, 1.5 kcal/ml or less, 1.3 kcal/ml or less, 1.1 kcal/ml or less, 0.99 kcal/ml or less, or 0.97 kcal/ml or less. When the lower limit and the upper limit of the caloric content (i.e., energy level) are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, the caloric content of the nutritional composition according to the present invention can be adjusted to 0.5 to 1.5 kcal/ml, 0.5 to 1.3 kcal/ml, 0.5 to 1.1 kcal/ml, 0.5 to 0.99 kcal/ml, 0.5 to 0.95 kcal/ml, 0.6 to 1.5 kcal/ml, 0.6 to 1.3 kcal/ml, 0.6 to 1.1 kcal/ml, 0.6 to 0.99 kcal/ml, 0.6 to 0.97 kcal/ml, 0.65 to 1.5 kcal/ml, 0.65 to 1.3 kcal/ml, 0.65 to 1.1 kcal/ml, 0.65 to 0.99 kcal/ml, 0.65 to 0.95 kcal/ml, or 0.67 to 0.99 kcal/ml.

As the caloric content and the concentration of a nutritional composition (that is, a liquid food) are reduced (with the latter indicating decreased solid content), such as to less than 1 kcal/ml (e.g., 0.99 kcal/ml or less), it is necessary to incorporate a larger amount of a thickener and a stabilizer into the composition, so as to achieve an adequate degree of viscosity. If a large amount of a stabilizer or a thickener is incorporated into a nutritional composition, however, solid-liquid separation (e.g., aggregation or sedimentation) is likely to occur when the composition is heat sterilized (e.g., via retort sterilization) in a neutral pH range, and the emulsion state is likely to be destroyed (disrupted). Thus, it was previously difficult or impossible to achieve an adequate degree of viscosity when the caloric content or

the concentration of the nutritional composition was low (with the latter indicating decreased solid content). The present invention has effectively dissolved the problems described above.

The nutritional composition according to the present invention can adequately comprise a protein, a lipid, and a carbohydrate, so that its specific gravity can be adjusted. The specific gravity of the nutritional composition according to the present invention can be adjusted to 1.04 or more or 1.05 or more. The specific gravity of the nutritional composition according to the present invention can be adjusted to 1.1 or less, 1.09 or less, or 1.08 or less. When the lower limit and the upper limit of the specific gravity are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, the specific gravity of the nutritional composition according to the present invention can be adjusted to 1.04 to 1.1, 1.04 to 1.09, 1.04 to 1.08, 1.05 to 1.1, 1.05 to 1.09, or 1.05 to 1.08. In general, the specific gravity varies depending on temperature. The term "specific gravity" used herein refers to specific gravity measured at 20°C.

Among the nutritional compositions according to the present invention, those which have a non-Newtonian viscosity index of 0.3 to less than 1.0 have properties similar to those of a Newtonian fluid, such that the shear flow properties are suppressed to a low level relative to its viscosity, in comparison with a typical type of non-Newtonian fluid. Among the nutritional compositions according to the present invention, those which have a non-Newtonian viscosity index of 0.3 to less than 1.0 do not experience termination of dropping and, therefore are suitable for tubal administration, such as via transnasal administration and, in addition, can be administered directly into the stomach by free fall at the time of tubal feeding, such as via gastric fistula or intestinal fistula.

The pH level of the nutritional composition according to the present invention can be adjusted. The pH level of the nutritional composition according to the present invention can be adjusted to 4.5 or more, 5.0 or more, 5.5 or more, 5.7 or more, 5.8 or more, 5.9 or more, or 6.0 or more. The pH level of the nutritional composition according to the present invention can be adjusted to 7.5 or less, 7.3 or less, 7.0 or less, 6.8 or less, 6.7 or less, 6.6 or less, or 6.5 or less. When the lower limit and the upper limit of the pH level are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper

limit)" provided above. According to an embodiment, specifically, the pH level of the nutritional composition according to the present invention can be adjusted to 4.5 to 7.5, 4.5 to 7.3, 4.5 to 7.0, 4.5 to 6.8, 4.5 to 6.7, 4.5 to 6.6, 4.5 to 6.5, 5.0 to 7.5, 5.0 to 7.3, 5.0 to 7.0, 5.0 to 6.8, 5.0 to 6.7, 5.0 to 6.6, 5.0 to 6.5, 5.5 to 7.5, 5.5 to 7.3, 5.5 to 7.0, 5.5 to 6.8, 5.5 to 6.7, 5.5 to 6.6, 5.5 to 6.5, 5.7 to 7.5, 5.7 to 7.3, 5.7 to 7.0, 5.7 to 6.8, 5.7 to 6.7, 5.7 to 6.6, 5.7 to 6.5, 5.8 to 7.5, 5.8 to 7.3, 5.8 to 7.0, 5.8 to 6.8, 5.8 to 6.7, 5.8 to 6.6, 5.8 to 6.5, 5.9 to 7.5, 5.9 to 7.3, 5.9 to 7.0, 5.9 to 6.8, 5.9 to 6.7, 5.9 to 6.6, 5.9 to 6.5, 6.0 to 7.5, 6.0 to 7.3, 6.0 to 7.0, 6.0 to 6.8, 6.0 to 6.7, 6.0 to 6.6, or 6.0 to 6.5. The nutritional composition according to the present invention may also be referred to as, for example, a neutral nutritional composition or a weakly acidic nutritional composition.

The nutritional composition according to the present invention can be produced in accordance with, for example, a conventional technique for producing a liquid food. For example, necessary starting materials may be mixed, the mixture may be homogenized to stabilize the emulsion state, the mixture may be introduced into a container, and the resultant may then be heat-sterilized with the use of a retort sterilizer. Some or all starting materials may be mixed, and the mixture may be homogenized before heat sterilization, according to need.

The nutritional composition according to the present invention can be produced in accordance with, for example, a conventional technique for producing a liquid food. For example, necessary starting materials may be mixed, and the mixture may be homogenized and then subjected to heat sterilization. Alternatively, the mixture may be heat sterilized and then subjected to homogenization. Thereafter, the resultant may be introduced into a container, such as a soft bag (e.g., a pouch), a brick-shaped container (e.g., a paper container), or a can container that has been sterilized.

When producing the nutritional composition according to the present invention, heat sterilization can be performed under conventional heat sterilization conditions for general food products. Heat sterilization can be performed with the use of a common apparatus. For example, sterilization at 62°C to 140°C for 15 seconds to 20 minutes or longer, preferably 62°C to 65°C for 30 minutes, 72°C or higher for 15 seconds or longer, 72°C or higher for 15 minutes or longer, or 120°C to 150°C for 1 to 5 seconds, disinfection at 121°C to 124°C for 5

to 20 minutes or 105°C to 140°C for 15 seconds to 20 minutes, retort (pressure heating) sterilization, autoclave sterilization, or other techniques can be employed, although techniques are not limited thereto. Preferably, heat sterilization can be performed under pressure. The nutritional composition according to the present invention can be sterilized and the viscosity thereof can be increased via heat treatment. In the description of the present invention, the term "disinfection" is synonymous with the term "sterilization." Retort sterilization is employed as an embodiment of heat sterilization.

The viscosity of the nutritional composition according to the present invention can be measured in accordance with a conventional technique. According to an embodiment, the viscosity of the nutritional composition according to the present invention can be measured with the use of a B-type viscometer while maintaining the shear rate at a constant level (e.g., measured with a B-type viscometer at 20°C to 85°C and 12 rpm). A B-type viscometer is a type of a rotational viscometer that is operated in the following manner. That is, an inner cylinder is allowed to rotate at a constant speed in a sample, and the force that the inner cylinder receives is measured. A B-type viscometer is also referred to as a "Brookfield viscometer," and these terms can be used interchangeably. When measurement is performed while varying the shear rate, according to an embodiment, a viscoelasticity measuring apparatus (Physica MCR301, Anton Paar) equipped with parallel plates (each 25 mm in diameter; 1 mm gap) can be used, and measurement can be performed at 25°C and with a shear rate of 0.1 to 100/s, for example.

The viscosity of the nutritional composition according to the present invention measured at the shear rate of 10/s or 12/s is 20 mPa·s or more, 30 mPa·s or more, 40 mPa·s or more, 50 mPa·s or more, 60 mPa·s or more, 70 mPa·s or more, 80 mPa·s or more, 90 mPa·s or more, 100 mPa·s or more, 110 mPa·s or more, 120 mPa·s or more, 130 mPa·s or more, 140 mPa·s or more, 150 mPa·s or more, 160 mPa·s or more, 170 mPa·s or more, 180 mPa·s or more, 190 mPa·s or more, or 200 mPa·s or more. The viscosity of the nutritional composition according to the present invention measured at the shear rate of 10/s or 12/s is 3800 mPa·s or less, 3000 mPa·s or less, 2800 mPa·s or less, 2600 mPa·s or less, or 2500 mPa·s or less. When the lower limit and the upper limit of the viscosity are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided

above. According to an embodiment, specifically, the viscosity of the nutritional composition according to the present invention measured at the shear rate 10/s or 12/s is 20 to 3800 mPa·s, 30 to 3800 mPa·s, 40 to 3800 mPa·s, 50 to 3800 mPa·s, 100 to 3800 mPa·s, 150 to 3800 mPa·s, 20 to 3000 mPa·s, 150 to 3000 mPa·s, 20 to 2800 mPa·s, 150 to 2800 mPa·s, 20 to 2600 mPa·s, 150 to 2600 mPa·s, 20 to 2500 mPa·s, 150 to 2500 mPa·s, 200 to 3000 mPa·s, 160 to 3800 mPa·s, 160 to 3000 mPa·s, 160 to 2800 mPa·s, 160 to 2600 mPa·s, 160 to 2500 mPa·s, 170 to 3800 mPa·s, 170 to 3000 mPa·s, 170 to 2800 mPa·s, 170 to 2600 mPa·s, 170 to 2500 mPa·s, 180 to 3800 mPa·s, 180 to 3000 mPa·s, 180 to 2800 mPa·s, 180 to 2600 mPa·s, 180 to 2500 mPa·s, 190 to 3800 mPa·s, 190 to 3000 mPa·s, 190 to 2800 mPa·s, 190 to 2600 mPa·s, 190 to 2500 mPa·s, 200 to 3800 mPa·s, 200 to 3000 mPa·s, 200 to 2800 mPa·s, 200 to 2600 mPa·s, or 200 to 2500 mPa·s.

The viscosity of the nutritional composition according to the present invention measured with the use of a B-type viscometer (with the rotor operated at 12 rpm and 20°C) is 20 mPa·s or more, 30 mPa·s or more, 40 mPa·s or more, 50 mPa·s or more, 60 mPa·s or more, 70 mPa·s or more, 80 mPa·s or more, 90 mPa·s or more, 100 mPa·s or more, 110 mPa·s or more, 120 mPa·s or more, 130 mPa·s or more, 140 mPa·s or more, 150 mPa·s or more, 160 mPa·s or more, 170 mPa·s or more, 180 mPa·s or more, 190 mPa·s or more, 200 mPa·s or more, 250 mPa·s or more, 300 mPa·s or more, 350 mPa·s or more, 400 mPa·s or more, or 450 mPa·s or more. The viscosity of the nutritional composition according to the present invention measured with the use of a B-type viscometer (with the rotor operated at 12 rpm and 20°C) is 3000 mPa·s or less, 2800 mPa·s or less, or 2600 mPa·s or less. When the lower limit and the upper limit of the viscosity are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, the viscosity of the nutritional composition according to the present invention measured with the use of a B-type viscometer (with the rotor operated at 12 rpm and 20°C) is 20 to 3000 mPa·s, 30 to 3000 mPa·s, 40 to 3000 mPa·s, 50 to 3000 mPa·s, 100 to 3000 mPa·s, 200 to 3000 mPa·s, 20 to 2800 mPa·s, 200 to 2800 mPa·s, 20 to 2600 mPa·s, 200 to 2600 mPa·s, 250 to 3000 mPa·s, 250 to 2800 mPa·s, 250 to 2600 mPa·s, 300 to 3000 mPa·s, 300 to 2800 mPa·s, 300 to 2600 mPa·s, 350 to 3000 mPa·s,

350 to 2800 mPa·s, 350 to 2600 mPa·s, 400 to 3000 mPa·s, 400 to 2800 mPa·s, 400 to 2600 mPa·s, 450 to 3000 mPa·s, 450 to 2800 mPa·s, or 450 to 2600 mPa·s.

The viscosity of the nutritional composition according to the present invention measured with the use of a B-type viscometer (with the rotor operated at 60 rpm and 20°C) is 20 mPa·s or more, 30 mPa·s or more, 40 mPa·s or more, 50 mPa·s or more, 60 mPa·s or more, 70 mPa·s or more, 80 mPa·s or more, 90 mPa·s or more, 100 mPa·s or more, 110 mPa·s or more, 120 mPa·s or more, 130 mPa·s or more, 140 mPa·s or more, 150 mPa·s or more, 160 mPa·s or more, 170 mPa·s or more, 180 mPa·s or more, 190 mPa·s or more, 200 mPa·s or more, or 250 mPa·s or more. The viscosity of the nutritional composition according to the present invention measured with the use of a B-type viscometer (with the rotor operated at 60 rpm and 20°C) is 3000 mPa·s or less, 2500 mPa·s or less, 2000 mPa·s or less, 1500 mPa·s or less, or 1100 mPa·s or less. When the lower limit and the upper limit of the viscosity are stated herein, the range therebetween adequately includes all the combinations of "(the lower limit) to (the upper limit)" provided above. According to an embodiment, specifically, the viscosity of the nutritional composition according to the present invention measured with the use of a B-type viscometer (with the rotor operated at 60 rpm and 20°C) is 20 to 3000 mPa·s, 30 to 3000 mPa·s, 40 to 3000 mPa·s, 50 to 3000 mPa·s, 100 to 3000 mPa·s, 200 to 3000 mPa·s, 20 to 2800 mPa·s, 20 to 2600 mPa·s, 20 to 2500 mPa·s, 200 to 2500 mPa·s, 20 to 2000 mPa·s, 200 to 2000 mPa·s, 20 to 1500 mPa·s, 200 to 1500 mPa·s, 20 to 1100 mPa·s, 200 to 1100 mPa·s, 250 to 3000 mPa·s, 250 to 2500 mPa·s, 250 to 2000 mPa·s, 250 to 1500 mPa·s, or 250 to 1100 mPa·s.

The viscosity of the nutritional composition according to the present invention (measured with the use of a B-type viscometer at 20°C and 12 rpm) can be determined in accordance with, for example, "Standards for Approval of Food Labeling for Special Dietary Uses: Method of Testing Food for the Elderly; 3: Viscosity (Approval of Food Labeling for the Elderly)" (Notification No. 15, issued by Director General, Office of Health Policy on Newly Developed Food, Food Sanitation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, Japan, February 23, 1996). Specifically, the viscosity is measured with the use of a B-type viscometer while operating the rotor at 12 rpm, the viscosity value is read 2 minutes later, the read value is multiplied by a

coefficient corresponding thereto, and the obtained value is represented in terms of mPa·s. Measurement is performed at $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$. The viscosity can be measured in the same manner while operating the rotor at 60 rpm.

The viscosity of the nutritional composition according to the present invention can be measured with the use of a known viscometer, such as a torsional oscillation viscometer, an ultrasonic viscometer, or a rotary viscometer.

The nutritional composition according to the present invention can be subjected to an accelerated aging test, following heating treatment, so as to determine emulsion condition or storage stability. When an accelerated aging test is performed, the aging of a product is intentionally accelerated under severe conditions, and storability or the life of the product is then examined. In the case of the nutritional composition according to the present invention, the composition is stored at a temperature higher than room temperature, so as to accelerate the aging thereof, and the emulsion conditions of the composition may be investigated under such conditions. In such a case, the nutritional composition is stored at 30°C to 50°C , such as 35°C , 37°C , or 40°C , for a given period of time, such as 1 day, 2 days, several days, 1 week to several weeks, or 1 month to several months, and whether or not the stable emulsion conditions are maintained can be determined by, for example, observing the composition's appearance. In the present specification, the phrase the emulsion conditions of the nutritional composition according to the present invention are maintained refers to the nutritional composition according to the present invention not converting into a cream state, and no or substantially no cream suspension being observed, and the emulsion structure being maintained. In the present specification, the phrase the nutritional composition according to the present invention maintains a stable emulsion state refers to the nutritional composition according to the present invention not converting into a cream state, no or substantially no cream suspension being observed, and the emulsion structure being maintained, even after the composition has been stored at 40°C for 1 month. In the case of the nutritional composition according to the present invention, storage at 40°C for 1 month is approximately equivalent to storage at room temperature for 4 months.

The nutritional composition according to the present invention can be stored at room temperature or a lower temperature for a long period of time. In general, the nutritional

composition according to the present invention can maintain its emulsion state and the storage stability thereof is better at lower temperatures. A nutritional composition that can maintain a stable emulsion state when stored at 40°C for 1 month can be stored at room temperature approximately for 4 months or at a lower temperature (e.g., 4°C) approximately for 1 year. If physical properties are not changed as a result of thawing, in addition, the nutritional composition according to the present invention can be cryopreserved. In such a case, regarding a nutritional composition that can maintain a stable emulsion state, storage at 40°C for 1 month corresponds to being cryopreserved (e.g., at -20°C) for approximately for 2 to 3 years. Accordingly, the nutritional composition according to the present invention can be stored at 40°C for 1 month or longer, at room temperature for 6 months or longer, or at a lower temperature for 1 year or longer, or it can be cryopreserved for 2 to 3 years or longer while maintaining its emulsion state. The storage period and the expiration date of the nutritional composition according to the present invention can be adequately determined on the basis of the results of the accelerated aging test.

The nutritional composition according to the present invention can be introduced into a hermetically sealed container with an oxygen absorber, or it may be introduced into a hermetically sealed container in which the air is replaced with an inert gas such as nitrogen, carbon dioxide, argon, or helium. Thus, storability can be improved. In such a case, the dissolved oxygen level in the nutritional composition according to the present invention can be 10 ppm or less or 6 ppm or less. Thus, oxidation of the nutritional composition according to the present invention can be suppressed, and the emulsion state of the composition can be stably maintained. The configuration of a hermetically sealed container is not particularly limited, provided that the content therein does not come into contact with the outside. Examples of containers that can be used include a pack, a soft bag (e.g., a pouch), a cheer pack, a tube, a paper container (e.g., a brick-shaped package), a can, a canned can, and a bottle.

The nutritional composition according to the present invention can be prepared for oral administration with an adequate degree of viscosity in accordance with different degrees of swallowing difficulty, or the age and/or other conditions of the person who ingests such nutritional composition (e.g., as a fluid diet or a liquid food). In general, it is known that

swallowing dynamics deteriorate with age. For example, it has been reported that the correlation between the amount of tested food and its passage through the throat varies in accordance with age (Eating/Swallowing difficulty, pp. 29 to 32, Jeri A Logemann, Ishiyaku Pub., Inc.). According to this report, the time necessary for food to pass through the throat significantly varies based on age. Accordingly, the nutritional composition according to the present invention can be used for healthy elderly people as well as patients with dysphagia. The viscosity of the nutritional composition according to the present invention can be adequately determined by taking into consideration factors such as the route of administration (e.g., oral or tubal administration), the subject (e.g., a patient), the mode of use (e.g., administered as a drip through a tube from a package), and the mode of storage (e.g., a hermetically sealed package or container).

The nutritional composition according to the present invention is applicable to various means of tubal feeding whereby a drug or the like is directly administered into the gastrointestinal tract through a fistulous opening, such as a gastric fistula or intestinal fistula. Also, the nutritional composition according to the present invention is applicable to tubal feeding via transnasal administration through the nasal cavity. An example of tubal feeding includes transnasal feeding through the nasal cavity. Administration can be carried out by free fall or with the use of a syringe or plunger pump. The nutritional composition according to the present invention can be administered to, for example, a person having swallowing and chewing problems, a person experiencing difficulty swallowing and/or chewing, a healthy person of any age, an elderly person having stomach contraction caused by aging, a person suffering from lowered pharyngeal responses caused by aging or a cerebral disorder, a person suffering from the decreased swallowing and/or chewing ability caused by a cerebrovascular disorder or neuromyopathy, a patient having difficulty with oral ingestion due to a consciousness disorder, and a postoperative patient. The nutritional composition according to the present invention is applicable to treatment of gastrointestinal tract functions, treatment of undernutrition, treatment of reflux esophagitis, prevention and/or treatment of aspiration pneumonitis, hydration, and nutrition support.

According to the present invention, the term "low shear flow properties" refers to properties similar to those of a Newtonian fluid where the non-Newtonian viscosity index "n" determined by the viscosity equation below is relatively close to 1:

$$P = \mu D^n$$

[wherein P represents shear stress (Pa) determined by multiplying the viscosity value by the shear rate; D represents shear rate; μ represents the non-Newtonian viscosity coefficient; and n represents the non-Newtonian viscosity index, provided that the viscosity (25°C, Pa·s) is measured with the use of a viscoelasticity measuring apparatus (Physica MCR301, Anton Paar) equipped with parallel plates (each 25 mm in diameter; 1 mm gap) at 25°C and with a shear rate of 0.1 to 1000/s, such as at 0.1 to 100/s]. The phrase the non-Newtonian viscosity index "n" being relatively close to 1 refers to the non-Newtonian viscosity index "n" of the nutritional composition according to the present invention being closer to 1 in comparison to the non-Newtonian viscosity index "n" of a conventional nutritional composition. For example, where the non-Newtonian viscosity index "n" of a conventional nutritional composition is less than 0.3, and if the non-Newtonian viscosity index "n" of the nutritional composition according to the present invention is 0.3 to less than 1.0, then the non-Newtonian viscosity index "n" thereof can be referred (determined) to be relatively close to 1. The viscosity figures for non-Newtonian fluids (that is, those that are not perfect Newtonian fluids) vary depending on the shear rate. Thus, the shear flow properties of the nutritional composition according to the present invention are represented by a range for the non-Newtonian viscosity index "n" obtained on the basis of the relationship between the shear rates measured at 2 or more points and the shear stress that can be determined based on the viscosity measured at such shear rate. The range of shear rates can be, for example, 0.1 to 1000/s or 1 to 100/s, depending on the apparatus used. The shear stress (Pa) can be determined by integrating viscosity (Pa·s) with shear rate (1/s).

The nutritional composition according to the present invention having properties (i.e., physical properties) suitable for tubal administration, such as via transnasal administration, and for direct administration into the stomach by free fall at the time of tubal feeding, such as via gastric fistula or intestinal fistula, preferably has a non-Newtonian viscosity index "n" close to 1.0, such as 0.3 to less than 1.0. In this embodiment, the non-Newtonian viscosity

index "n" of the nutritional composition according to the present invention is 0.3 or more, 0.35 or more, 0.4 or more, 0.45 or more, 0.5 or more, 0.55 or more, or 0.6 or more. The non-Newtonian viscosity index "n" of the nutritional composition according to the present invention is less than 1.0. When the lower limit and the upper limit of the non-Newtonian viscosity index "n" of the nutritional composition according to the present invention have any of the values stated herein, "n" can be described as "(the lower limit) to less than (the upper limit)," and the range therebetween adequately includes all the combinations of "(the lower limit) to less than (the upper limit)" provided above. According to an embodiment, specifically, the non-Newtonian viscosity index "n" of the nutritional composition according to the present invention is 0.3 to less than 1.0, 0.35 to less than 1.0, 0.4 to less than 1.0, 0.45 to less than 1.0, 0.5 to less than 1.0, 0.55 to less than 1.0, or 0.6 to less than 1.0. When the non-Newtonian viscosity index of the nutritional composition according to the present invention is less than 0.3, it is difficult to administer such nutritional composition directly into the stomach by free fall. When the non-Newtonian viscosity index is 1.0, in theory, the composition is a Newtonian fluid, and, theoretically, no non-Newtonian viscosity index higher than such figure exists. The nutritional composition according to the present invention having a non-Newtonian viscosity coefficient of 0.3 to less than 1.0 can be used, regardless of tube type, size, form, or type of container or package that accommodates the nutritional composition.

When a syringe or plunger pump for a patient with a gastric fistula is used, in contrast, the non-Newtonian viscosity index "n" of the nutritional composition according to the present invention may be less than 0.3. In this embodiment, the non-Newtonian viscosity index "n" of the nutritional composition according to the present invention is less than 0.3. The non-Newtonian viscosity index "n" of the nutritional composition according to the present invention is 0.1 or more, 0.15 or more, 0.2 or more, or 0.25 or more. When the lower limit and the upper limit of the non-Newtonian viscosity index "n" of the nutritional composition according to the present invention are designated as having any of the values described herein, "n" can be described as "(the lower limit) to less than (the upper limit)," and the range therebetween adequately includes all the combinations of "(the lower limit) to less than (the upper limit)" provided above. According to an embodiment, specifically, the non-

Newtonian viscosity index "n" of the nutritional composition according to the present invention is 0.1 to less than 0.3, 0.15 to less than 0.3, 0.2 to less than 0.3, or 0.25 to less than 0.3.

By determining whether or not the nutritional composition according to the present invention forms curds when mixed with simulated gastric juice, and, in particular, whether or not the nutritional composition forms curds without syneresis, the coagulation properties thereof in the stomach can be evaluated. A test can be performed by preparing simulated gastric juice in accordance with the procedure described in "First Fluid, Disintegration Test, the Japanese Pharmacopoeia, Fourteenth Edition," mixing the prepared simulated gastric juice with the nutritional composition to be tested, and detecting the development of turbidity (haze) in the mixture immediately after mixing.

Examples

The following examples are provided for the illustrative purpose and the technical scope of the present invention is not limited to these examples. Unless otherwise specified, a commercially available reagent is used or a reagent is obtained or prepared in accordance with techniques known in the art or procedures described in known literature.

[Test Example 1]

Using conventional techniques, the sugar composition and the dextrose equivalent (DE) value of commercially available dextrin products were measured. Regarding the sugar composition of commercially available dextrin products, specifically, the distribution of degree of polymerization was examined via gel filtration chromatography using a cation-exchange column. All peaks on the chromatogram were regarded as being derived from sugar, and the degrees of polymerization were deduced based on glucose and oligosaccharides of the maltose series. Under the conditions described above, however, salts are observed as peaks. Accordingly, an aqueous solution of 0.1% sodium chloride was subjected to the measurement under the same conditions, and salt-derived peaks observed on the chromatogram were excluded. The results of measurement are as shown in Table 1. Dextrin products (K-SPD, L-SPD, M-SPD, and SPD, Showa Sangyo Co., Ltd.) were exclusively subjected to the measurement. In contrast, the information regarding the sugar composition of dextrin (Sanwa

Starch Co., Ltd.) was obtained from a known product catalog. DE values of various dextrin products were measured by the LANE method.

Table 1

Product name	Manu- fac- turer	Example of sugar composition (%) analysis								DE (Lane method)	A		Emulsion condition after retort treatment	B/A
		Mono- saccharide	Di- saccharide	Tri- saccharide	Tetra- saccharide	Penta- saccharide	Hexa- saccharide	Hepta- saccharide	Octa- saccharide and greater		DE median	Total of penta- to hepta- saccharides		
L-SPD		5	8	19	8	14	17	13	16	16.5±2	16.5	44	⊙	2.7
M-SPD	Showa	1	9	21	8	16	20	14	11	20±2	20.0	50	⊙⊙	2.5
K-SPD	Sangyo	3	14	20	8	19	20	6	10	27±2	27.0	45	○	1.7
SPD		3	15	20	8	19	21	5	9	30±2	30.0	45	×	1.5
Sandec #70		0.2	1.3	2.4	1.9	2.1	2.7	2.8	86.6	10-11	10.5	7.6	×	0.72
Sandec #100	Sanwa	0.5	3.3	5.6	4	4.4	5.8	5.6	70.8	13-16	14.5	15.8	×	1.09
Sandec #150	Starch	1	5.7	8.8	5.7	6.9	8.9	7	56	17-22	19.5	22.8	×	1.17

The results of measurement shown in Table 1 demonstrate that K-SPD, L-SPD, and M-SPD (Showa Sangyo Co., Ltd.) are all dextrin products exhibiting the dextrose equivalent (DE) value between 11 and 29 in which the percentage accounted for by monosaccharides to heptasaccharides within the total sugar composition is 45% to 90% by weight or dextrin products exhibiting the dextrose equivalent (DE) value 11 to 29 in which the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition is at least a value determined by multiplying said DE by 1.5.

[Test Example 2]

Nutritional compositions were prepared at 0.86 kcal/ml in accordance with the formulation shown in Table 2-1 and Table 4. In the tables, the unit of each component is in terms of g/L. In the tables, the viscosity unit is mPa·s. The compositions were prepared in the same manner as described in WO 2012/157571. Specifically, all starting materials were dissolved, heated, and homogenized. The resultant was introduced into a container and then subjected to retort sterilization.

More specifically, raw materials were prepared in accordance with the formulation shown in the upper table, the raw materials were mixed and agitated to prepare various nutritional compositions, the compositions were heated to 50°C to 60°C to dissolve and disperse materials therein, and the resultants were homogenized at 20 MPa, followed by homogenization at 50°C to 60°C and 30 MPa. The viscosity of the nutritional compositions was measured prior to retort sterilization. Subsequently, the nutritional compositions were introduced into containers, and the containers were hermetically sealed, followed by retort sterilization at 121°C to 123.5°C for 5 to 20 minutes. The viscosity of the nutritional compositions was measured after retort sterilization (immediately after retort sterilization). The viscosity was measured using a B type (rotary) viscometer at 12 rpm or 60 rpm and 20°C (or 50°C). Milk protein used in this test example contains 26% by weight of MPC, 53% by weight of sodium caseinate, and 21% by weight of a milk protein digest (a casein digest with a degradation degree AN/TN (%) of 5.0 to 5.4). In the description of the present invention, a casein digest with the AN/TN (%) of 5.0 to 5.4 is occasionally referred to as a casein digest having a particular degradation rate. The pH level of the nutritional composition was 6.3 after retort sterilization.

The lower sections of the table show the viscosity of the prepared composition immediately after retort sterilization and the appearance after stored at 40°C. A double circle (◎) or a circle (○) indicates a good composition that maintains a stable emulsion state. A cross mark (×) indicates a separated composition with destroyed emulsion state. According to Tables 2-1 to 4, Production Examples 3, 4, and 10 to 13 were of good condition. Glyloid 3S (Sumitomo Dainippon Pharma Co., Ltd.) was used as the tamarind gum. Pine Ace #3 (Matsutani Chemical Industry Co., Ltd.) was used as the processed starch.

The test results are as demonstrated below. The emulsion state of the nutritional composition using various types of dextrin products was first examined. The results are shown in Tables 2-1 and 2-2.

Table 2-1

		0.86 kcal/ml			
		1	2	3	4
Protein	Milk protein	47.9	47.9	47.9	47.9
Saccharide	SPD	100	105	100	100
	KSPD				
	MSPD				
	LSPD				
	Dextrin Sandec #30				
	Sandec #70				
	Sandec #100				
	Sandec #150				
	Sucrose	10.3	10.3	10.3	10.3
Dietary fiber	Soybean dietary fiber	2.6	2.6	2.6	2.6
	Indigestible dextrin	3	5	8	8
Thickener	Carrageenan	3	3	3	3
	Tamarind gum (Glyloid 3S)	5	3	0	0
	Processed starch (Pine Ace #3)	15	10	15	15
Oil and fat	Liquid plant oil and fat	21.6	21.6	21.6	21.6
Nutrients	Mineral mix	6.7	6.7	6.7	6.7
	Vitamin mix	1.5	1.5	1.5	1.5
Other additives	pH modifier	1.8	1.8	1.8	1.8
	Emulsifier (monoglyceride of diacetyl tartaric acid)	2.6	2.6	4.2	4.2
	Flavoring	2	2	2	2
Starting water		848.4	848.4	848.4	848.4
Total		1071.4	1071.4	1073.0	1073.0

Immediately after retort treatment	Specific gravity	1.07	1.07	1.07	1.07
	Viscosity at 12 rpm	-	-	1550	1300
	Viscosity at 60 rpm	-	-	690	600
	Appearance	○	○	◎	◎
40°C, 2 days later	Appearance	×	×	◎	◎
		Separated	Separated	Good	Good
40°C, 1 month later	Appearance	-	-	◎	◎
				Good	Good

Table 2-2

		0.86 kcal/ml			
		5	6	7	8
Protein	Milk protein	47.9	47.9	47.9	47.9
Saccharide	SPD	100	100	100	100
	KSPD				
	MSPD				
	LSPD				
	Dextrin	100	100	100	100
	Sandec #30				
	Sandec #70				
	Sandec #100				
	Sandec #150				
Sucrose		10.3	10.3	10.3	10.3
Dietary fiber	Soybean dietary fiber	2.6	2.6	2.6	2.6
	Indigestible dextrin	8	8	8	8
Thickener	Carrageenan	3	3	3	3
	Tamarind gum (Glyloid 3S)	0	0	0	0
	Processed starch (Pine Ace #3)	15	15	15	15
Oil and fat	Liquid plant oil and fat	21.6	21.6	21.6	21.6
Nutrients	Mineral mix	6.7	6.7	6.7	6.7
	Vitamin mix	1.5	1.5	1.5	1.5
Other additives	pH modifier	1.8	1.8	1.8	1.8
	Emulsifier (monoglyceride of diacetyltartaric acid)	4.2	4.2	4.2	4.2
	Flavoring	2	2	2	2
Starting water		848.4	848.4	848.4	848.4
Total		1073.0	1073.0	1073.0	1073.0

Immediately after retort treatment	Specific gravity	1.07	1.07	1.07	1.07
	Viscosity at 12 rpm	3720	2080	2090	1620
	Viscosity at 60 rpm	1370	820	813	655
	Appearance	⊙	⊙	⊙	⊙
40°C, 2 days later	Appearance	○	×	×	×
		Sign of separation	Cream emerged	Cream emerged	Cream emerged
40°C, 1 month later		×	—	—	—
		Separated			

According to Table 2-1, the nutritional compositions using Dextrin L-SPD and Dextrin M-SPD were found to yield good results based on the viscosity measured at 20°C and the appearance (the emulsion state) of the nutritional compositions after they were stored 40°C for 1 month. Specifically, the compositions according to Production Examples 3 and 4 exhibited good appearance after they were stored at 40°C for 1 month.

Subsequently, the emulsion state of nutritional compositions using other types of dextrin products was examined. The results are shown in Table 2-2. In the case of Production Example 5, separation was observed in the nutritional composition after it was stored at 40°C for 1 month; that is, good results were not obtained. In the case of Production Examples 6, 7, and 8, cream emerged in the nutritional compositions after they were stored at 40°C for 2 days; that is, good results were not obtained.

Subsequently, the emulsion states of nutritional compositions using various polysaccharide thickeners and soybean fibers were examined. The results are shown in

Table 3

		0.86 kcal/ml			
		9	10	11	12
Protein	Milk protein	47.9	47.9	47.9	47.9
Saccharide	SPD	105	105	105	105
	KSPD				
	MSPD				
	LSPD				
	Dextrin Sandec #30				
	Sandec #70				
	Sandec #100				
	Sandec #150				
	Sucrose	10.3	10.3	10.3	10.3
Dietary fiber	Soybean dietary fiber	2.6	2.6	2.6	2.6
	Indigestible dextrin	11	8	8	11
Thickener	Carrageenan	0	3	3	3
	Tamarind gum (Glyloid 3S)	3	3	3	0
	Processed starch (Pine Ace #3)	10	10	10	10
Oil and fat	Liquid plant oil and fat	21.6	21.6	21.6	21.6
Nutrients	Mineral mix	6.7	6.7	6.7	6.7
	Vitamin mix	1.5	1.5	1.5	1.5
Other additives	pH modifier	1.79	1.79	1.79	1.79
	Emulsifier (monoglyceride of diacetyl tartaric acid)	4.2	4.2	4.2	4.2
	Flavoring	2	2	2	2
Starting water		845.3	845.3	845.3	845.3
Total		1072.9	1072.9	1072.9	1072.9

Immediately after retort treatment	Specific gravity	1.07	1.07	1.07	1.07
	Viscosity at 12 rpm	155	2140	2010	1002
	Viscosity at 60 rpm	85.7	998	933	426
	Appearance	⊙	⊙	⊙	⊙
40°C, 2 days later	Appearance	⊙	⊙	⊙	⊙
		Good	Good	Good	Good
40°C, 1 month later		×	⊙	⊙	○-⊙

According to Table 3, the nutritional compositions according to Production Examples 10 to 12 were found to be good based on the appearance (the emulsion state)

thereof after they were stored at 40°C for 1 month. Concerning the composition according to Production Example 9 that did not use carrageenan, the emulsion state thereof was not stable and cream separation was apparent after it was stored at 40°C for 1 month; that is, good results were not obtained. The emulsion state of the nutritional compositions according to Production Examples 10 to 12 was stable after they were stored at 40°C for 1 month. According to the results of Production Examples 10 to 12, when Dextrin L-SPD or Dextrin M-SPD was used for the nutritional composition, good results were obtained by incorporating carrageenan into the composition in an amount of 0.3% by weight therein.

According to Table 3, the emulsion state of the nutritional composition was stable after it was stored at 40°C for 1 month if tamarind gum was further incorporated into the composition that had been prepared using Dextrin L-SPD or Dextrin M-SPD and incorporating carrageenan in an amount of 0.3% by weight therein; that is, good results were obtained (Production Examples 10 and 11).

Table 4

		0.86 kcal/ml
		13
Protein	Milk protein	47.9
Saccharide	SPD	105
	KSPD	
	MSPD	
	LSPD	
	Sandec #30	
	Sandec #70	
	Sandec #100	
	Sandec #150	
Sucrose		10.3
Dietary fiber	Soybean dietary fiber	2.6
	Indigestible dextrin	11
Thickener	Carrageenan	3
	Tamarind gum (Glyloid 3S)	0
	Processed starch (Pine Ace #3)	10
Oil and fat	Liquid plant oil and fat	21.6
Nutrients	Mineral mix	6.7
	Vitamin mix	1.5
Other additives	pH modifier	1.8
	Emulsifier (monoglyceride of diacetyl/tartaric acid)	4.2
	Flavoring	2
Starting water		845.3
Total		1072.9

Immediately after retort treatment	Specific gravity	1.07
	Viscosity at 12 rpm	1002
	Viscosity at 60 rpm	426
	Appearance	◎
40°C, 2 days later	Appearance	◎
		Good
40°C, 1 month later		○-◎

According to Table 4, the nutritional composition according to Production Example 13, which was prepared using Dextrin M-SPD and incorporating carrageenan in an amount of

0.3% by weight therein, maintained a stable emulsion state after it was stored at 40°C for 1 month; that is, good results were obtained.

Thus, it was found that a dilute-type nutritional composition with a high degree of viscosity and sufficient storage stability, in which protein content is 1% to 10% by weight and water content is 70% to 95% by weight, could be realized by incorporating dextrin exhibiting a DE value between 11 and 29 in which the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition is at least a value determined by multiplying said DE by 1.5 and carrageenan in an amount of 0.1% to 0.5% by weight. In addition, tamarind gum may further be incorporated into the composition, so as to obtain a dilute-type nutritional composition with a high degree of viscosity and sufficient storage stability, in which protein content is 1% to 10% by weight and water content is 70% to 95% by weight.

[Test Example 3]

Nutritional compositions were prepared at 0.67 kcal/ml in accordance with the formulation shown in Table 5. In the table, the unit of each ingredient is in terms of g/L. In the table, the viscosity unit is mPa·s. The compositions were prepared in the same manner as described in WO 2012/157571. Specifically, all starting materials were dissolved, heated, and homogenized. The resultant was introduced into a container and then subjected to retort sterilization.

More specifically, raw materials were prepared in accordance with the formulation shown in the upper table, the raw materials were mixed and agitated to prepare various nutritional compositions, the compositions were heated to 50°C to 60°C to dissolve and disperse materials therein, and the resultants were homogenized at 20 MPa, followed by homogenization at 50°C to 60°C and 30 MPa. The viscosity of the nutritional compositions was measured prior to retort sterilization. Subsequently, the nutritional compositions were introduced into containers, and the containers were hermetically sealed, followed by retort sterilization at 121°C to 123.5°C for 5 to 20 minutes. The viscosity of the nutritional compositions was measured after retort sterilization (immediately after retort sterilization). The viscosity was measured using a B type (rotary) viscometer at 12 rpm or 60 rpm and 20°C (or 50°C). Milk protein used in this test example contains 26% by weight of MPC, 53% by

weight of sodium caseinate, and 21% by weight of a casein digest having a particular degradation rate (a degradation degree (AN/TN (%)) of 5.0 to 5.4). The pH level of the nutritional composition was 6.3 after retort sterilization.

The lower section in the table shows the viscosity of the prepared composition immediately after retort sterilization and the appearance after it was stored at 40°C. A double circle (⊙) or a circle (○) indicates a good composition that maintains a stable emulsion state. A cross mark (×) indicates a separated composition with destroyed emulsion state.

Table 5

		0.67 kcal/ml		
		14	15	16
Protein	Milk protein	37	37	37
Saccharide	SPD	64	64	69
	Dextrin KSPD			
	MSPD			
	LSPD			
	Sucrose	8	8	8
Dietary fiber	Soybean dietary fiber	2	2	2
	Indigestible dextrin	3.2	6.2	6.2
Thickener	Carrageenan	3	3	3
	Tamarind gum (Glyloid 3S)	3	0	0
	Processed starch (Pine Ace #3)	20	20	15
Oil and fat	Liquid plant oil and fat	16.8	16.8	16.8
Nutrients	Mineral mix	5.2	5.2	5.2
	Vitamin mix	1.6	1.6	1.6
Other additives	pH modifier	2.4	2.4	2.4
	Emulsifier (monoglyceride of diacetyl tartaric acid)	2.5	3.3	3.3
	Flavoring	2	2	2
Starting water		881.2	881.2	881.2
Total		1052.0	1052.8	1052.8

Immediately after retort treatment	Specific gravity	1.05	1.05	1.05
	Viscosity at 12 rpm	1450	545	613
	Viscosity at 60 rpm	719	271	336
	Appearance	◎	◎	◎
40°C, 2 days later	Appearance	◎	◎	◎
		Good	Good	Good
40°C, 1 month later		○	○-◎	○

According to Table 5, the emulsion state of the nutritional compositions according to Production Examples 14 to 16, which were prepared using Dextrin K-SPD or Dextrin M-SPD and incorporating carrageenan in an amount of 0.3% by weight therein, were stable after they were stored at 40°C for 1 month; that is, good results were obtained.

Thus, it was found that a dilute-type nutritional composition with a high degree of viscosity and sufficient storage stability, in which protein content is 1% to 10% by weight and water content is 70% to 95% by weight, could be realized (produced) by incorporating dextrin exhibiting a DE value between 11 and 29 in which the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition is at least a value determined by multiplying said DE by 1.5 and carrageenan in an amount of 0.1% to 0.5% by weight into the nutritional composition adjusted at 0.67 kcal/ml. In addition, tamarind gum may further be incorporated into the composition, so as to obtain a dilute-type nutritional composition with a high degree of viscosity and sufficient storage stability, in which protein content is 1% to 10% by weight and water content is 70% to 95% by weight (Production Example 14).

[Test Example 4]

Nutritional compositions were prepared at 1.05 kcal/ml in accordance with the formulation shown in Table 6. In the table, the unit of each ingredient is in terms of g/L. In the table, the viscosity unit is mPa·s. The compositions were prepared in the same manner as described in WO 2012/157571. Specifically, all starting materials were dissolved, heated, and homogenized. The resultant was introduced into a container and then subjected to retort sterilization.

More specifically, raw materials were prepared in accordance with the formulation shown in the upper table, the raw materials were mixed and agitated to prepare various nutritional compositions, the compositions were heated to 50°C to 60°C to dissolve and disperse materials therein, and the resultants were homogenized at 20 MPa, followed by homogenization at 50°C to 60°C and 30 MPa. The viscosity of the nutritional compositions was measured prior to retort sterilization. Subsequently, the nutritional compositions were introduced into containers, and the containers were hermetically sealed, followed by retort sterilization at 121°C to 123.5°C for 5 to 20 minutes. The viscosity of the nutritional compositions was measured after retort sterilization (immediately after retort sterilization). The viscosity was measured using a B type (rotary) viscometer at 12 rpm or 60 rpm and 20°C (or 50°C). Milk protein used in this test example contains 26% by weight of MPC, 53% by weight of sodium caseinate, and 21% by weight of a casein digest having a particular

degradation degree (a degradation degree (AN/TN (%)) of 5.0 to 5.4). The pH level of the nutritional composition was 6.3 after retort sterilization.

The lower portion of the table shows the viscosity of the prepared composition immediately after retort sterilization and the appearance after it was stored at 40°C. A double circle (⊙) or a circle (○) indicates a good composition that maintains a stable emulsion state. A cross mark (×) indicates a separated composition with destroyed emulsion state.

Table 6

		1.05 kcal/ml		
		17	18	19
Protein	Milk protein	57.9	57.9	57.9
Saccharide	SPD			
	Dextrin KSPD			
	MSPD	128.1	130.3	133.1
	LSPD			
	Sucrose	12.5	12.5	12.5
Dietary fiber	Soybean dietary fiber	3.1	3.1	3.1
	Indigestible dextrin	6.7	6.7	6.7
Thickener	Carrageenan	3	3	3
	Tamarind gum (Glyloid 3S)	3	3	3
	Processed starch (Pine Ace #3)	5	2.5	0
Oil and fat	Liquid plant oil and fat	26.2	26.2	26.2
Nutrients	Mineral mix	8.1	8.1	8.1
	Vitamin mix	1.8	1.8	1.8
Other additives	pH modifier	0.93	0.93	0.93
	Emulsifier (monoglyceride of diacetyltartaric acid)	5.1	5.1	5.1
	Flavoring	2	2	2
Starting water		818.7	818.7	818.7
Total		1082.1	1081.8	1082.0

Immediately after retort treatment	Specific gravity	1.08	1.08	1.08
	Viscosity at 12 rpm	2520	1140	463
	Viscosity at 60 rpm	1080	513	229
	Appearance	⊙	⊙	⊙
40°C, 2 days later	Appearance	⊙	⊙	⊙
		Good	Good	Good
40°C, 1 month later		○-⊙	○-⊙	○-⊙

According to Table 6, the emulsion state of the nutritional compositions according to Production Examples 17 to 19 prepared using Dextrin M-SPD and incorporating carrageenan in an amount of 0.3% by weight therein was found to be stable after they were stored at 40°C for 1 month; that is, good results were obtained. While the composition of Production Example 19 did not contain processed starch (Pine Ace #3), the emulsion state of the nutritional composition was stable after it was stored at 40°C for 1 month; that is, good results were obtained. This indicates that the addition of processed starch is not essential for the nutritional composition according to the present invention.

Thus, it was found that a dilute-type nutritional composition with a high degree of viscosity and sufficient storage stability, in which protein content is 1% to 10% by weight and water content is 70% to 95% by weight, could be realized by incorporating dextrin exhibiting a DE value between 11 and 29 in which the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition is at least a value determined by multiplying said DE by 1.5 and carrageenan in an amount of 0.1% to 0.5% by weight into the nutritional composition adjusted at 1.05 kcal/ml.

[Test Example 5]

In Test Examples 2 to 4, the dynamic viscoelasticity of the nutritional compositions according to the production examples exhibiting a stable emulsion state and sufficient storage stability after they were stored at 40°C for 1 month was measured, and the non-Newtonian viscosity index "n" was determined.

The compositions and the methods for producing the nutritional composition according to the present invention are as described above. A commercially available liquid food (tradename: F2 Light) is considered to have the nutritional components and physical properties shown in Table 7 below on the basis of the information concerning the nutritional components and physical properties described in the pamphlet of commercially available liquid foods.

Table 7

	Commercial liquid food (per package)
Volume (g)	400
Caloric content (kcal)	300
Protein (g)	12
Lipid (g)	6.6
Carbohydrate (g)	50.8
Saccharide (g)	45.9
Dietary fiber (g)	4.9
water (g)	330
Viscosity (mPa·s)	4,000
Specific gravity	1.06

Method for measuring shear-rate-dependent viscosity

The nutritional compositions according to the present invention (Production Examples) and commercially available liquid foods (Comparative Examples) were tested. The viscosity was measured with the use of a viscoelasticity measuring apparatus (Physica MCR301, Anton Paar) equipped with parallel plates (each 25 mm in diameter; 1 mm gap) at 25°C and with a shear rate of 1 to 100/s. Also, the non-Newtonian viscosity index "n" was determined using the viscosity equation below:

$$P = \mu D^n$$

wherein P represents the shear stress (Pa) determined by multiplying the viscosity value by the shear rate; D represents the shear rate; μ represents a non-Newtonian viscosity coefficient; and n represents a non-Newtonian viscosity index, provided that the viscosity (25°C, Pa·s) is measured with the use of a viscoelasticity measuring apparatus (Physica MCR301, Anton Paar) equipped with parallel plates (each 25 mm in diameter; 1 mm gap) at 25°C and with a shear rate of 0.1 to 1000/s, for example, at 1 to 100/s. An ideal Newtonian fluid has a non-Newtonian viscosity index "n" of 1. When the shear rate (1/s) and the shear stress (Pa) are logarithmically shown on the horizontal axis and on the vertical axis, respectively, a straight line passing through the origin is obtained. In contrast, a non-Newtonian fluid has a slope of

"n," where the value "n" is a fluidity index of the non-Newtonian fluid. The viscosity (Pa·s) is determined by dividing the shear stress (Pa) by the shear rate (1/s).

The non-Newtonian viscosity index "n" of the nutritional composition according to Production Example 4 was 0.54. The non-Newtonian viscosity index "n" of the nutritional composition according to Production Example 14 was 0.46. The non-Newtonian viscosity index "n" of the nutritional composition according to Production Example 15 was 0.55. The non-Newtonian viscosity index "n" of the nutritional composition according to Production Example 18 was 0.44.

As a comparative example, the non-Newtonian viscosity index "n" of a commercially available liquid food (tradename: F2 Light, manufactured by Terumo) was measured under the same conditions and it was found to be 0.29.

[Comparative Examples]

Nutritional compositions were prepared at 0.86 kcal/ml in accordance with the formulation shown in Table 8. In the table, the unit of each ingredient is in terms of g/L. In the table, the viscosity unit is mPa·s. The compositions were prepared in the same manner as described in WO 2012/157571. Specifically, all starting materials were dissolved, heated, and homogenized. The resultant was introduced into a container and then subjected to retort sterilization.

More specifically, raw materials were prepared in accordance with the formulation shown in the upper table, the raw materials were mixed and agitated to prepare various nutritional compositions, the compositions were heated to 50°C to 60°C to dissolve and disperse materials therein, and the resultants were homogenized at 20 MPa, followed by homogenization at 50°C to 60°C and 30 MPa. The viscosity of the nutritional compositions was measured prior to retort sterilization. Subsequently, the nutritional compositions were introduced into containers, and the containers were hermetically sealed, followed by retort sterilization at 121°C to 123.5°C for 5 to 20 minutes. The viscosity of the nutritional compositions was measured after retort sterilization (immediately after retort sterilization). The viscosity was measured using a B type (rotary) viscometer at 12 rpm or 60 rpm and 20°C (or 50°C). Milk protein used in this test example contains 26% by weight of MPC, 53% by weight of sodium caseinate, and 21% by weight of a casein digest having a particular

degradation degree (a degradation degree (AN/TN (%)) of 5.0 to 5.4). The pH level of the nutritional composition was 6.3 after retort sterilization.

The lower section of the table shows the viscosity of the prepared composition immediately after retort sterilization and the appearance after it was stored at 40°C. A double circle (⊙) or a circle (○) indicates a good composition that maintains a stable emulsion state. A cross mark (×) indicates a separated composition with destroyed emulsion state. Glyloid 3S (Sumitomo Dainippon Pharma Co., Ltd.) was used as the tamarind gum. Pine Ace #3 (Matsutani Chemical Industry Co., Ltd.) was used as the processed starch.

Table 8

		0.86 kcal/ml	
		20	21
Protein	Milk protein	47.9	47.9
Saccharide	SPD	115	105
	KSPD		
	MSPD		
	LSPD		
	Dextrin Sandec #30		
	Sandec #70		
	Sandec #100		
	Sandec #150		
	Sucrose	10.3	10.3
Dietary fiber	Soybean dietary fiber	2.6	2.6
	Indigestible dextrin	10	8
Thickener	Carrageenan	6	6
	Tamarind gum (Glyloid 3S)	0	0
	Processed starch (Pine Ace #3)	0	10
Oil and fat	Liquid plant oil and fat	21.6	21.6
Nutrients	Mineral mix	6.7	6.7
	Vitamin mix	1.5	1.5
Other additives	pH modifier	1.8	1.8
	Emulsifier (monoglyceride of diacetyl tartaric acid)	4.2	4.2
	Flavoring	2	2
Starting water		845.3	845.3
	Total	1074.9	1072.9

Immediately after retort treatment	Specific gravity	-	1.07
	Viscosity at 12 rpm	-	1540
	Viscosity at 60 rpm	-	3890
	Appearance	× Destroyed emulsion	○ Somewhat blackened
40°C, 2 days later	Appearance	—	—
40°C, 1 month later		—	× Blackened, poor appearance

According to Table 8, the nutritional compositions according to Production Examples 20 and 21, which were prepared by incorporating carrageenan in an amount of 0.6% by weight therein, were not good based on the appearance (the emulsion state) thereof after they were stored at 40°C for 1 month. In the case of Production Example 20, emulsion was destroyed after retort sterilization. In the case of Production Example 21, blackening was observed after the nutritional composition was stored at 40°C for 1 month. That is, the composition of Production Example 21 exhibited poor appearance.

According to Table 8, specifically, the emulsion state and the color hue of the nutritional compositions were not stable after they were stored at 40°C for 1 month when the nutritional compositions were prepared with the use of M-SPD and incorporating carrageenan in an amount of 0.6% by weight therein; that is, good results were not obtained (Production Examples 20 and 21).

[Test Example 6]

Nutritional compositions were prepared at 0.71 kcal/ml in accordance with the formulation shown in Table 9. In the table, the unit of each ingredient is in terms of g/L. In the table, the viscosity unit is mPa·s. The compositions were prepared in the same manner as described in WO2012/157571. Specifically, all starting materials were dissolved, heated, and homogenized. The resultant was introduced into a container and then subjected to retort sterilization.

More specifically, raw materials were prepared in accordance with the formulation shown in the upper table, the raw materials were mixed and agitated to prepare various nutritional compositions, the compositions were heated to 50°C to 60°C to dissolve and disperse materials therein, and the resultants were homogenized at 20 MPa, followed by homogenization at 50°C to 60°C and 40 MPa. The viscosity of the nutritional compositions was measured before retort sterilization. Subsequently, the nutritional compositions were introduced into containers, and the containers were hermetically sealed, followed by retort sterilization at 121°C to 123.5°C for 5 to 20 minutes. The viscosity of the nutritional compositions was measured after retort sterilization (immediately after retort sterilization). The viscosity was measured using a B type (rotary) viscometer at 12 rpm or 60 rpm and 20°C (or 50°C). Milk protein used in this test example was sodium caseinate (undegraded AN/TN

(%) of 4.5), MPC, a casein digest having a particular degradation rate (AN/TN (%) of 5.0 to 5.4), a casein peptide (AN/TN (%) of 27), or a collagen peptide. A pork-derived collagen peptide was used. Dextrin used was MSPD and the pH level of the nutritional composition was 6.3 after retort sterilization.

The lower section of the table shows the viscosity of the prepared composition on the following day of retort treatment and the appearance after it was stored at 40°C. A double circle (⊙) or a circle (○) indicates a good composition that maintains a stable emulsion state. A cross mark (×) indicates a separated composition with destroyed emulsion state.

In addition, the test results concerning coagulation properties of the nutritional compositions in the stomach are shown in the lower table. The test was performed by preparing simulated gastric juice in accordance with the procedure described in "First fluid, Disintegration Test, the Japanese Pharmacopoeia, Fourteenth Edition" in the manner described below.

[Preparation of simulated gastric juice]

Hydrochloric acid (7 mL) and water were added to 2 g of sodium chloride to dissolve the same and the amount of the solution was adjusted to 1,000 mL (pH 1.2).

[Test method]

Into a 100-ml glass triangular flask containing 50 ml of simulated gastric juice, 50 ml of the nutritional composition was rapidly introduced from the top of the flask, and the occurrence of turbidity (haze) in the mixture was detected immediately after mixing.

[Evaluation]

A double circle (⊙) indicates that no turbidity is observed. A circle (○) indicates that slight turbidity is observed. A triangle (Δ) indicates that some turbidity is observed. A cross mark (×) indicates that apparent turbidity is observed.

If no turbidity is observed, the composition is found to form curds without syneresis upon protein solidification. If slight turbidity is observed, the composition is found to form curds with slight syneresis upon protein solidification. If some turbidity is observed, the composition is found to form curds with some syneresis upon protein solidification. If apparent turbidity is observed, apparent syneresis is observed upon protein solidification; that is, the composition does not form curds. The term "syneresis" used herein refers to the

situation in which water flows away from a solidified matter upon protein solidification. Nutritional compositions that are evaluated as "◎," "○," or "△" are found to form curds when they are mixed with simulated gastric juice. Thus, such compositions can be used as nutritional compositions for tubal feeding that are less likely to cause diarrhea in the present invention. Nutritional compositions that are evaluated as "×" are found to form no curds when they are mixed with simulated gastric juice. Thus, such compositions can be used as nutritional compositions that are easily digested and absorbed immediately by the intestinal tract in the present invention.

The test results are as described below. At the outset, the emulsion state of nutritional compositions prepared with the use of milk proteins with various degradation degrees was examined.

Table 9

		0.71 kcal/ml				
		22	23	24	25	26
Protein	Sodium caseinate (AN/TN%=4.5)	35.2	-	-	-	-
	MPC	4.1	-	-	-	-
	Casein digest (AN/TN%=5.0-5.4)	-	39.3	39.3	-	-
	Casein peptide (AN/TN%=27)	-	-	-	39.3	-
	Collagen peptide	-	-	-	-	39.3
Saccharide	Dextrin	87	87	92	87	87
	Sucrose	7.6	7.6	7.6	7.6	7.6
Dietary fiber	Soybean dietary fiber	2	2	2	2	2
	Indigestible dextrin	9.1	6.6	6.6	6.6	6.6
Thickener	Carrageenan	1.5	4	4	4	4
	Processed rice starch	5	5	-	5	5
Oil and fat	Liquid plant oil and fat	14.5	14.5	14.5	14.5	14.5
Nutrients	Mineral mix	8.4	8.4	8.4	8.4	8.4
	Vitamin mix	0.78	0.78	0.78	0.78	0.78
Other additives	pH modifier	0.85	0.85	0.85	0.85	0.85
	Emulsifier (diacetyl tartaric acid monoglyceride)	3.3	3.3	3.3	3.3	3.3
	Flavoring	2	2	2	2	2
Starting water		875	875	875	875	875
Total		1056.3	1056.3	1056.3	1056.3	1056.3

Following day of retort treatment	Specific gravity	1.057	1.057	1.057	1.056	1.056
	Viscosity at 60 rpm	50	47	21	68	24
	Appearance	○	○	○	○	○
40°C, 1 week later	Appearance(4-step)	○	○	○	○	○
Mixing with simulated gastric juice at 1:1 to form curd		○	◎	◎	×	×

According to Table 9, compositions according to Production Examples 22 to 26 were good in appearance and these compositions exhibited emulsion stability. In addition, the nutritional compositions were mixed with simulated gastric juice, so as to evaluate coagulation properties of the nutritional compositions in the stomach. As a result, the compositions according to Production Examples 22, 23, and 24 were found to form curds. When such nutritional compositions are subjected to tubal administration, the compositions are solidified in the stomach, and they are less likely to cause diarrhea. Thus, such nutritional compositions are preferable. Specifically, nutritional compositions exhibiting emulsion

stability and suitable for tubal administration were obtained with the use of casein digests having a casein degradation degree (AN/NT (%)) of 4.5 to 5.4. With the use of a protein exhibiting a casein protein degradation degree (AN/NT (%)) of approximately 27 or a degradation degree equivalent to that of a collagen peptide, nutritional compositions with a stable emulsion state were obtained. When the compositions according to Production Examples 25 and 26 exhibiting emulsion stability were mixed with simulated gastric juice, curd formation was not observed. Such nutritional compositions are preferable since they can be digested and absorbed immediately by the intestinal tract. In addition, a nutritional composition exhibiting good emulsion stability and suitable for tubal administration was obtained when the viscosity of the nutritional composition (at 60 rpm) was adjusted to 21 mPa·s (Production Example 24).

[Test Example 7]

Subsequently, the amount of an emulsifier added was reduced and the results thereof were investigated. Nutritional compositions were prepared at 0.71 kcal/ml in accordance with the formulation shown in Table 10. In the table, the unit of each ingredient is in terms of g/L. In the table, the viscosity unit is mPa·s. The compositions were prepared in the same manner as described in WO 2012/157571. Specifically, all starting materials were dissolved, heated, and homogenized. The resultant was introduced into a container and then subjected to retort sterilization.

More specifically, raw materials were prepared in accordance with the formulation shown in the upper table, the raw materials were mixed and agitated to prepare various nutritional compositions, the compositions were heated to 50°C to 60°C to dissolve and disperse materials therein, and the resultants were homogenized at 20 MPa, followed by homogenization at 50°C to 60°C and 40 MPa. The viscosity of the nutritional compositions was measured prior to retort sterilization. Subsequently, the nutritional compositions were introduced into containers, and the containers were hermetically sealed, followed by retort sterilization at 121°C to 123.5°C for 5 to 20 minutes. The viscosity of the nutritional compositions was measured after retort sterilization (immediately after retort sterilization). The viscosity was measured using a B type (rotary) viscometer at 12 rpm or 60 rpm and 20°C (or 50°C). Milk protein used in this test example was a casein digest having a particular

degradation degree (AN/TN (%)) of 5.0 to 5.4). The dextrin used was MSPD, and the pH level of the nutritional composition was 6.3 after retort sterilization.

The lower section of the table shows the viscosity of the prepared composition on the following day of retort treatment and the appearance after it was stored at 40°C. The test results concerning coagulation properties of the nutritional compositions in the stomach are also shown. The tests were performed in the manner described above.

Table 10

		0.71kcal/ml	
		27	28
Protein	Casein digest (AN/TN%=5.0-5.4)	39.3	39.3
Saccharide	Dextrin	87	87
	Sucrose	7.6	7.6
Dietary fiber	Soybean dietary fiber	2	2
	Indigestible dextrin	6.6	6.6
Thickener	Carrageenan	4	4
	Processed rice starch	5	5
Oil and fat	Liquid plant oil and fat	14.5	14.5
Nutrients	Mineral mix	8.4	8.4
	Vitamin mix	0.78	0.78
Other additives	pH modifier	0.85	0.85
	Flavoring	2	2
Emulsifier	diacetyltartaric acid monoglyceride	1.65	0.83
Starting water		875	875
Total		1054.7	1053.9

Following day of retort treatment	Specific gravity	1.056	1.056
	Viscosity at 60 rpm	46	46
	Appearance	○	○
40°C, 1 week later	Appearance(4-step)	○	○
Mixing with simulated gastric juice at 1:1 to form curd		◎	◎

According to Table 10, compositions according to Production Examples 27 and 28 were good in appearance and these compositions exhibited emulsion stability. In addition, the nutritional compositions were examined in terms of coagulation properties in the stomach. As a result, the nutritional compositions according to Production Examples 27 and 28 were found to form curds when they were mixed with simulated gastric juice. Thus, nutritional

compositions maintaining emulsion stability and suitable for tubal feeding were obtained even if the amount of an emulsifier added was reduced to 1.65 g (in 1054.7 g) and further to 0.83 g (in 1053.9 g).

[Test Example 8]

Subsequently, the use of fine-grained starch in addition to carrageenan as a thickener was investigated. Nutritional compositions were prepared at 0.71 kcal/ml or 0.67 kcal/ml in accordance with the formulation shown in Table 11. In the table, the unit of each ingredient is in terms of g/L. In the table, the viscosity unit is mPa·s. The compositions were prepared in the same manner as described in WO 2012/157571. Specifically, all starting materials were dissolved, heated, and homogenized. The resultant was introduced into a container and then subjected to retort sterilization.

More specifically, raw materials were prepared in accordance with the formulation shown in the upper table, the raw materials were mixed and agitated to prepare various nutritional compositions, the compositions were heated to 50°C to 60°C to dissolve and disperse materials therein, and the resultants were homogenized at 20 MPa, followed by homogenization at 50°C to 60°C and 30 MPa. The viscosity of the nutritional compositions was measured prior to retort sterilization. Subsequently, the nutritional compositions were introduced into containers, and the containers were hermetically sealed, followed by retort sterilization at 121°C to 123.5°C for 5 to 20 minutes. The viscosity of the nutritional compositions was measured after retort sterilization (immediately after retort sterilization). The viscosity was measured using a B type (rotary) viscometer at 12 rpm or 60 rpm and 20°C (or 50°C). Milk protein used in this test example was a casein digest having a particular degradation rate (AN/TN (%)) of 5.0 to 5.4. The dextrin used was MSPD, and the pH level of the nutritional composition was 6.3 after retort sterilization.

The lower section of the table shows the viscosity of the prepared composition on the following day of retort treatment and the appearance after it was stored at 40°C. The test results concerning coagulation properties of the nutritional compositions in the stomach are also shown. The test was performed in the manner described above.

Table 11

		0.71 kcal/ml				0.67 kcal/ml			
		29	30	31	32	33	34	35	36
Protein	Casein digest (AN/TN%=5.0-5.4)	39.3	39.3	39.3	39.3	37.4	37.4	37.4	37.4
Saccharide	Dextrin	87	82	77	72	66.5	64	61.5	56.5
	Sucrose	7.6	7.6	7.6	7.6	8	8	8	8
Dietary fiber	Soybean dietary fiber	2	2	2	2	1.9	1.9	1.9	1.9
	Indigestible dextrin	5.6	6.6	6.6	6.6	5.3	5.3	5.3	5.3
Thickener	Carrageenan	5	4	4	4	4	4	4	4
	Processed rice starch	5	10	10	10	10	10	10	10
	Rice starch	-	-	5	10	10	12.5	15	20
Oil and fat	Liquid plant oil and fat	14.5	16	16	16	15	15	15	15
Nutrients	Mineral mix	8.4	8.4	8.4	8.4	6.9	6.9	6.9	6.9
	Vitamin mix	0.78	0.78	0.78	0.78	0.73	0.73	0.73	0.73
Other additives	pH modifier	0.85	0.85	0.85	0.85	0.88	0.88	0.88	0.88
	Flavoring	2	2	2	2	2	2	2	2
Emulsifier	diacetyltartaric acid monoglyceride	3.3	0.83	0.83	0.83	0.83	0.83	0.83	0.83
Starting water		875	875	875	875	883	883	883	883
Total		1056.3	1055.4	1055.4	1055.4	1052.4	1052.4	1052.4	1052.4

Following day of retort treatment	Specific gravity	1.057	1.055	1.055	1.055	1.052	1.052	1.052	1.052
	Viscosity at 60 rpm	93	63	100	190	115	210	245	373
	Appearance	○	○	○	○	○	○	○	○
40°C, 1 week later	Appearance(4-step)	○	○	○	○	○	○	○	○
Mixing with simulated gastric juice at 1:1 to form curd		◎	◎	◎	◎	◎	◎	◎	◎

According to Table 11, compositions according to Production Examples 29 to 36 were good in appearance and these compositions exhibited emulsion stability. In addition, the nutritional compositions were examined in terms of coagulation properties in the stomach. As a result, the nutritional compositions according to Production Examples 29 to 36 were found to form curds when they were mixed with simulated gastric juice. When fine-grained starch was used in addition to carrageenan as a thickener, accordingly, nutritional compositions maintaining emulsion stability and suitable for tubal feeding were obtained. In addition,

nutritional compositions exhibiting emulsion stability and suitable for tubal feeding were obtained even if the amount of an emulsifier added was reduced.

Industrial Applicability

According to the present invention, a nutritional composition with sufficient storage stability, low protein content, and high water content, which previously had been impossible to realize through conventional techniques (e.g., a liquid food or an enteral nutrient preparation), can be provided. The nutritional composition according to the present invention is effectively used for oral administration to patients with dysphagia whose energy intake is regulated on a daily basis. In addition, the nutritional composition having a non-Newtonian viscosity index of 0.3 to less than 1.0 according to the present invention is suitable for tubal administration, such as via transnasal administration, and such nutritional composition has properties (i.e., physical properties) suitable for direct administration into the stomach by free fall at the time of tubal feeding, such as via gastric fistula or intestinal fistula.

Further, a certain type of nutritional composition according to the present invention forms curds when mixed with simulated gastric juice. For example, a certain type of composition forms curds without undergoing syneresis. Such composition solidifies in the stomach, and diarrhea is not likely to occur. Thus, such composition is suitable for tubal administration, such as via transnasal administration, and has properties (i.e., physical properties) suitable for direct administration into the stomach by free fall at the time of tubal feeding, such as via gastric fistula or intestinal fistula. Furthermore, a certain type of nutritional composition according to the present invention does not form curds when mixed with simulated gastric juice, and such composition is expected to be digested and absorbed immediately by the intestinal tract.

All publications, patents, and patent applications cited herein are incorporated herein by reference in their entirety.

CLAIMS

[1] A nutritional composition comprising:

(i) dextrin exhibiting a dextrose equivalent (DE) value between 11 and 29 in which the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition is at least a value determined by multiplying said DE by 1.5;

(ii) 0.1% to 0.5% by weight of carrageenan as a thickener; and

(iii) 1% to 10% by weight of a protein.

[2] A nutritional composition comprising:

(i) dextrin exhibiting a dextrose equivalent (DE) value between 11 and 29 in which the percentage accounted for by monosaccharides to heptasaccharides within the total sugar composition is 45% to 90% by weight;

(ii) 0.1% to 0.5% by weight of carrageenan as a thickener; and

(iii) 1% to 10% by weight of a protein.

[3] The nutritional composition according to claim 1 or 2, wherein the protein contains a casein digest in which the amount of amino nitrogen (AN) relative to the total amount of nitrogen (TN), i.e., the AN/TN, is 4.5% to 10% by weight.

[4] The nutritional composition according to claim 1 or 2, wherein the protein contains a collagen peptide or a casein digest in which the AN/TN is 10% to 50% by weight.

[5] The nutritional composition according to any one of claims 1 to 4, which further comprises (ii) processed starch as a thickener.

[6] The nutritional composition according to claim 5, wherein the average particle diameter of the processed starch is 1 μm to 10 μm .

[7] The nutritional composition according to any one of claims 1 to 6, which further comprises (ii) tamarind gum as a thickener.

[8] The nutritional composition according to any one of 1 to 7, wherein the viscosity measured at 20°C after heat sterilization is 20 to 3000 mPa·s (measured with a B type (rotary) viscometer in which the rotor is operated at 12 rpm).

[9] The nutritional composition according to any one of claims 1 to 8, wherein when the shear stress and the shear rate measured at 2 or more arbitrary points in the shear rate range of 0.1/s to 1000/s are represented by the equation shown below, the value "n" is from 0.3 to less than 1.0 and wherein the viscosity measured at 25°C after heat sterilization is 20 to 3000 mPa·s (measured with a B type (rotary) viscometer in which the rotor is operated at 12 rpm):

$$P = \mu D^n$$

[wherein P represents shear stress (Pa), D represents shear rate (1/s), μ represents the non-Newtonian viscosity coefficient, and n represents the non-Newtonian viscosity index].

[10] The nutritional composition according to any one of claims 1 to 8, wherein when the shear stress and the shear rate measured at 2 or more arbitrary points in the shear rate range of 0.1/s to 1000/s are represented by the equation shown below, the value "n" is 0.1 to less than 0.3 and wherein the viscosity measured at 25°C after heat sterilization is 20 to 3000 mPa·s (measured with a B type (rotary) viscometer in which the rotor is operated at 12 rpm):

$$P = \mu D^n$$

[wherein P represents shear stress (Pa), D represents shear rate (1/s), μ represents the non-Newtonian viscosity coefficient, and n represents the non-Newtonian viscosity index].

[11] The nutritional composition according to claim 9 or 10, which forms curds when mixed with simulated gastric juice (pH 1.2).

[12] The nutritional composition according to claim 9 or 10, which does not form curds when mixed with simulated gastric juice (pH 1.2).

[13] The nutritional composition according to any one of claims 1 to 12, wherein the caloric content is 0.5 to 1.5 kcal/ml.

[14] The nutritional composition according to any one of claims 1 to 13, which is for tubal feeding.

[15] The nutritional composition according to any one of claims 1 to 14, which can maintain a stable emulsion state after being stored at 40°C for 1 month.

[16] A method for producing a nutritional composition comprising the following steps:

(a) a step of mixing a composition comprising:

(i) dextrin exhibiting a dextrose equivalent (DE) value between 11 and 29 in which the percentage accounted for by pentasaccharides to heptasaccharides within the total sugar composition is at least a value determined by multiplying said DE by 1.5;

(ii) 0.1% to 0.5% by weight of carrageenan as a thickener; and

(iii) 1% to 10% by weight of a protein;

(b) a step of homogenizing the composition; and

(c) a step of heat sterilizing the composition.

[17] A method for producing a nutritional composition comprising the following steps:

(a) a step of mixing a composition comprising:

(i) dextrin exhibiting a dextrose equivalent (DE) value between 11 and 29 in which the percentage accounted for by monosaccharides to heptasaccharides within the total sugar composition is 45% to 90% by weight;

(ii) 0.1% to 0.5% by weight of carrageenan as a thickener; and

(iii) 1% to 10% by weight of a protein;

(b) a step of homogenizing the composition; and

(c) a step of heat sterilizing the composition.

[18] The method for production according to claim 16 or 17, wherein the protein contains a casein digest in which the amount of amino nitrogen (AN) relative to the total amount of nitrogen (TN), i.e., the AN/TN is 4.5% to 10% by weight.

[19] The method for production according to claim 16 or 17, wherein the protein contains a collagen peptide or a casein digest in which the AN/TN is 10% to 50% by weight.

[20] The method for production according to any one of claims 16 to 19, which further comprises (ii) use of processed starch as a thickener.

[21] The method for production according to claim 20, wherein the average particle diameter of the processed starch is 1 μm to 10 μm .

[22] The method for production according to any one of claims 16 to 21, wherein the nutritional composition forms curds when mixed with simulated gastric juice (pH 1.2).

[23] The method for production according to any one of claims 16 to 21, wherein the nutritional composition does not form curds when mixed with simulated gastric juice (pH 1.2).

[24] The method for producing the nutritional composition according to any one of claims 16 to 23, which further comprises the following step:

(d) a step of filling a container with the composition.