

Specification

NUTRITIONAL COMPOSITION

[Technical Field]

[0001]

The present invention relates to a nutritional composition enabling easy adjustment of amounts of water, in particular, a nutritional composition suitable for patients requiring strict control of water balance, such as patients with chronic renal failure.

[Background Art]

[0002]

In patients with chronic renal failure, since salt and water are not properly excreted, fluid is easily retained in the body and symptoms such as hypertension and heart failure often occur. Therefore, in order to suppress water retention, a particularly strict control of water balance is required compared to patients with other conditions. Diet of such patients may be given by liquid food, and commercially-available packed nutritional compositions (liquid food) are often used.

[0003]

Conventional packed nutritional compositions are primarily designed on the basis of calorie (amount of energy) per unit volume such as 1 kcal/ml, to which required fortifying components are added (blended). In addition, conventional packed nutritional compositions with fairly concentrated types that are designed to provide a large amount of calorie (energy) components, e.g. 1.5 kcal/ml, have also been commercially available, but packed nutritional compositions are generally designed such that when

the entire amount of the pack with its original concentration is consumed, required calorie (amount of energy) and required fortifying components can be taken.

[0004]

Meanwhile, with regard to the nutritional compositions to be administered in a wide variety of subjects including general patients and patients in need of nursing care, nutritional compositions that are used in a combination in order to easily adjust the calorie (amount of energy), water content, and sodium chloride equivalent (amount of sodium) have been investigated (Patent Document 1); however, they are not appropriate for patients requiring strict control of water balance, in terms of adjustment of water content.

[Prior Art Document]

[Patent Document]

[0005]

Patent Document 1: WO 2009/139167

[Summary of the Invention]

[Problems to Be Solved by the Invention]

[0006]

As described above, conventional packed nutritional compositions are designed on the assumption that they are taken as they are, or taken by a combination of some of them as they are for a variety of patients. This is no surprise because benefits of designing a liquid food with a high concentration on the assumption of dilution at the time of use are generally not probable. The present inventors have recognized a problem that, when such a conventional packed nutritional composition is to be

used for patients requiring strict control of water balance, the adjustment of water content is very difficult; and they have found that conventional packed nutritional compositions are not prepared with consideration given to the following fact, i.e., when they are used for patients requiring strict control of water balance, an excess amount of water may possibly be administered to the patients, because such compositions are designed to have appropriate amounts of required calorie components and fortifying components (nutritional components) relative to the amount of water generally required for general patients. More specifically, when the conventional nutritional compositions are to be used with their original composition ratios, and when they are administered to satisfy the required amounts of calorie components and fortifying components, then the amount of water administered becomes excessive; conversely, when they are administered with reduced amounts to satisfy the appropriate amount of water, then the required amounts of calorie components and fortifying components cannot be achieved, and therefore additional calorie components and fortifying components should be separately provided; thus, such conventional compositions lack practicality, which is a whole new problem.

Accordingly, an object of the present invention is to solve the conventional problems and to provide a nutritional composition that enables easy adjustment of water content when used to administer calorie components and fortifying components.

[Means for Solving the Problems]

[0007]

During extensive studies to solve the above problems, the present inventors have found that, for patients requiring strict

control of water balance, a nutritional composition having a composition ratio that does not comprise an excess amount of water relative to the required amounts of calorie components and fortifying components can solve the above problems; as a result of further studies, the present inventors have accomplished the present invention.

[0008]

Namely, the present invention relates to the following nutritional composition, nutritional composition product, and the method for producing the nutritional composition.

[1] A nutritional composition used for a subject requiring control of water balance, wherein the composition of the calorie components, fortifying components and water in the nutritional composition is a composition ratio with which an excess amount of water is not contained relative to the required amounts of the calorie components and fortifying components for said subject.

[2] The nutritional composition according to [1], wherein the subject requiring control of water balance is a dialysis patient.

[3] The nutritional composition according to [2], wherein the dialysis patient is a patient with chronic renal failure.

[4] The nutritional composition according to any one of [1] to [3], wherein the calorie component is one or more types selected from the group consisting of fat, protein, carbohydrate, and a hydrolysate thereof.

[5] The nutritional composition according to any one of [1] to [4], wherein the fortifying component is one or more types selected from the group consisting of n-3 fatty acid, palatinose, fructooligosaccharide, dietary fiber, carnitine and selenium.

[0009]

[6] A packed product of nutritional composition comprising the

nutritional composition according to any one of [1] to [5], wherein the nutritional composition has an amount of water of 10-50 ml per 100 kcal of calories, and has a composition ratio with which one or more of said packed products are required at the time of use without the need for removal of water.

[7] The nutritional composition product according to [6], comprising carnitine as a fortifying component, with the carnitine content of 15-100 mg per 100 kcal of calories.

[8] The nutritional composition product according to [6] or [7], comprising selenium as a fortifying component, with the selenium content of 5-15 µg per 100 kcal of calories.

[9] The nutritional composition product according to any one of [6] to [8], wherein the amount of water contained in one pack is an integer multiple of 5 ml, 10 ml, 50 ml, or 100 ml.

[10] A method for preparing a nutritional composition used for a subject requiring control of water balance, comprising a step of calculating the amount of water, when necessary amounts of calorie components and fortifying components are administered to the subject using one or more packs of the nutritional composition product according to any one of [6] to [9], and a step of adding the shortage amount of water when the calculated amount of water is insufficient relative to the required amount of the subject.

[Advantageous Effects of the Invention]

[0010]

Simply by adding (blending, adding) of a shortage amount of water in the nutritional composition, the amount of water required for the patient can be strictly and easily adjusted since the nutritional composition claimed in the present invention is

prepared such that concentrations of the required amounts of calorie components (energy components) and fortifying components relative to the required amount of water are higher than those in conventional nutritional compositions, and therefore, there is no chance that an excess amount of water is supplied.

[0011]

With regard to packed nutritional compositions, when the amount of water is excessive, it is almost impossible to use the composition after removal of water alone; conversely, when a reduced amount of the composition is administered in order to adjust the appropriate amount of water, then the amounts of calorie components and/or fortifying components become insufficient, and it becomes necessary to administer those components as, for example, supplements, and because supplements are usually administered together with water, strict control of water balance cannot be achieved, which is problematic. In contrast, the nutritional composition claimed in the present invention can be used with its original composition with no excess amount of water, or it can be used with simple addition of a necessary amount of water; thus, with the present nutritional composition, a required amount of fortifying components as well as a required amount of water can be always easily and precisely administered.

[0012]

Moreover, it is possible to simplify the calculation and measurement of an amount of water added to the nutritional composition and to further rationalize strict control of water balance, by setting the amount of water contained in the nutritional composition to a value such as a unit of 10 ml, that is easy for calculation and measurement.

[Modes for Carrying out the Invention]

[0013]

The nutritional composition of the present invention is used for patients requiring strict control of water balance in various medical sites and nursing sites, etc. Typically, it is used in enteral nutrition. Here, enteral nutrition includes oral ingestion method wherein nutritional components, etc. are orally replenished, and tube feeding method wherein nutritional components, etc. are administered via a tube. In addition, tube feeding includes oral method, nasal method and method via fistula.

The form of the nutritional composition of the present invention includes a liquid, a fluent material, a paste-like or jelly-like material, and it is typically a liquid or a fluent material.

In addition, nutritional compositions are classified as elemental diet, digested-state liquid food or digested-state elemental diet, semi-digested-state liquid food or semi-digested-state elemental diet, or natural concentrated liquid food and others; they are typically digested-state liquid food or digested-state elemental diet, or semi-digested-state liquid food or semi-digested-state elemental diet.

[0014]

The water content per 100 kcal of the nutritional composition of the present invention is 10-55 ml, preferably 20-50 ml, and particularly preferably 30-50 ml; compared to conventional nutritional compositions, concentrations of nutritional components (nutrients) in terms of calorie relative to the unit of water content are high.

Water used in the nutritional composition of the present

invention includes pure water, purified water, and ion-exchanged water, etc.

[0015]

The nutritional composition of the present is used for administration to a subject requiring strict control of water balance; examples of such subject include, for example, dialysis patients, patients with heart disease, or patients with syndrome of inappropriate secretion of antidiuretic hormone (SIADH). The nutritional composition of the present invention is particularly useful for dialysis patients who chronically require dialysis. Examples of patients who chronically require dialysis include patients with chronic renal failure, etc.

[0016]

In one embodiment, the nutritional composition of the present invention is used in patients with chronic renal failure.

In such cases, fluid in the patient is not sufficiently secreted due to deterioration or loss of renal functions, resulting in swelling and edema caused by excessive intake of fluid; therefore, it is preferable to limit the amount of water intake per day to around 750-1500 ml/day. In addition, many dialysis patients suffer from malnutrition, so that they need to take a higher amount of calorie; therefore, it is preferable to adjust the amount of calorie intake per day to 1000-1600 kcal/day (35 kcal/kg/day or more).

Therefore, preferably the composition ratio of the nutritional composition is designed such that the amount of water per one pack of nutritional composition is set to a low value to avoid administration of excess water, and when the amount of water is insufficient upon sole administration of the nutritional composition, then the amount of shortage may be supplemented. In

the nutritional composition of the present invention, the amount of water per 100 kcal is smaller than that of conventional nutritional compositions (which is approximately 80-90 ml).

[0017]

In the nutritional composition of the present invention, calorie components are one or more types selected from fat, protein, carbohydrate, and a hydrolysate thereof.

Examples of fat blended in the nutritional composition of the present invention include vegetable oils such as soybean oil, palm oil, fractionated palm oil, and olive oil, animal oils such as milk fat, lard and fish oil, and free fatty acids such as oleic acid, linolenic acid, and γ -linolenic acid. Preferable examples include soy bean oil and palm oil. In addition, one or more of these fats may be used. The amount of blending of a fat is preferably in the range of 0-4%, more preferably 2.2-3.3%; from the view point of average intake amounts of healthy Japanese, it is preferably in the range of 0-30% relative to the total calorie (energy) content of the nutritional composition, and more preferably in the range of 20-25%.

[0018]

Examples of protein blended in the nutritional composition of the present invention include plant proteins such as soy bean protein, animal proteins such as casein and whey protein. Preferably, they include soy bean protein, casein, and whey protein, etc. In addition, hydrolysates of these proteins may be used, and one or more of these proteins and hydrolysates thereof may be used. The amount of blending of a protein is preferably in the range of 2-10%, and more preferably 3-6.5%. From the viewpoint of average intake amounts of healthy Japanese, it is preferably in the range of 12-40% relative to the total calorie

(energy) content of the nutritional composition, and more preferably in the range of 16-25%.

[0019]

Examples of carbohydrate blended in the nutritional composition of the present invention include dextrin, sucrose, lactose, and oligosaccharide; preferably, they include dextrin, sucrose and palatinose. In addition, hydrolysates of these carbohydrates may be used, and one or more of these carbohydrates and hydrolysates thereof may be used. The amount of blending of a carbohydrate is preferably in the range of 5-20%, and more preferably 10-15%. From the viewpoint of average intake amounts of healthy Japanese, it is preferably in the range of 20-80% relative to the total calorie (energy) content of the nutritional composition, and more preferably in the range of 40-60%.

[0020]

The nutritional composition of the present invention may comprise useful components for patients with chronic renal failure, and such useful components may be fortified in the composition, that is, such components may be contained in an amount larger than that contained in general nutritional compositions. In the present specification, such components may also be referred to as "fortifying components." Here, the fortifying components are blended in the present nutritional compositions at a concentration, for example, 1.5 to 5 times, preferably 2 to 3 times higher than that in the general nutritional compositions.

In one embodiment, in the nutritional composition of the present invention, one or more components selected from the group consisting of n-3 fatty acids, palatinose, fructooligosaccharide, dietary fiber, carnitine and selenium is/are fortified.

Particularly preferably, the fortifying component is carnitine and/or selenium.

[0021]

By fortifying n-3 fatty acids such as DHA (docosahexaenoic acid) and EPA (eicosapentaenoic acid), it is possible to reduce the risk of cardiac infarction and atherosclerotic renal artery stenosis. When DHA is contained in the nutritional composition of the present invention, its content may be 10-40 mg/100 kcal, preferably 10-30 mg/100 kcal, and particularly preferably 20-30 mg/100 kcal. In addition, when EPA is contained, its content may be 5-50 mg/100 kcal, preferably 10-40 mg/100 kcal, and particularly preferably 20-40 mg/100 kcal.

[0022]

By fortifying palatinose, it is possible to improve diabetic nephropathy often found in chronic dialysis patients. The rate of energy of palatinose in the sugar contained in the nutritional compositions of the present invention is preferably 40-60 kcal/100 kcal, more preferably 45-55 kcal/100 kcal, and particularly preferably 45-50 kcal/100 kcal.

[0023]

By fortifying fructooligosaccharide and/or dietary fiber, it is possible to improve infrequent bowel movement due to fluid restriction and disturbance of intestinal flora. In the nutritional composition of the present invention, when a fructooligosaccharide is added, its content is preferably 0.1-0.5 g/100 kcal, more preferably 0.2-0.4 g/100 kcal. In addition, because daily intake of dietary fiber should be preferably 20-25 g/day, the content of dietary fiber is preferably 1.0-3.0 g/100 kcal, and particularly preferably 1.0-2.0 g/100 kcal.

[0024]

By fortifying carnitine, it is possible to supplement carnitine that is prone to be deficient in dialysis patients, and to improve dyslipidemia that tends to develop in dialysis patients. In the nutritional composition of the present invention, the carnitine content may be 5-100 mg/100 kcal, preferably 15-100 mg/100 kcal, more preferably 20-50 mg/100 kcal, and furthermore preferably 20-30 mg/100 kcal.

[0025]

By fortifying selenium, it is possible to reduce oxidative stress accompanying with dialysis. In the nutritional composition of the present invention, the selenium content may be 2-15 µg/100 kcal, preferably 5-15 µg/100 kcal, more preferably 5-10 µg/100 kcal, and furthermore preferably 7-10 µg/100 kcal.

[0026]

In one embodiment, in the nutritional composition of the present invention, various minerals are not blended, or they are blended with reduced amounts compared to conventional ones. That is, various minerals are blended at small quantities in the nutritional composition of the present invention, compared to general nutritional compositions. Typically, the amount of one or more mineral components selected from the group consisting of potassium, phosphorus and calcium is reduced.

The content of potassium may be, because its preferable daily intake is 40-70 mEq/day, 30-100 mg/100 kcal, preferably 30-80 mg/100 kcal, and particularly preferably 30-60 mg/100 kcal.

[0027]

The content of phosphorus may be, because its preferable daily intake is 8-17 mEq/day, 30-80 mg/100 kcal, and preferably 30-60 mg/100 kcal.

The content of calcium may be, because its preferable daily

intake is 1400-1600 mEq/day, 30-80 mg/100 kcal, and preferably 30-60 mg/100 kcal.

[0028]

The amount of protein in the nutritional composition of the present invention may be typically 3.0-5.0 g/100 kcal, preferably 3.0-4.0 g/100 kcal, and particularly preferably 3.5-4.0 g/100 kcal. In cases of dialysis patients, they need to take a sufficient amount of protein because protein and amino acid are lost by dialysis, but meanwhile, they also need to prevent increases in the concentrations of serum urea nitrogen and phosphorus due to excessive intake of protein and amino acid.

In addition, the rate of energy of protein is 12-20 kcal/100 kcal, preferably 12-16 kcal/100 kcal, and particularly preferably 14-16 kcal/100 kcal; the rate of energy of fat is 20-40 kcal/100 kcal, preferably 25-40 kcal/100 kcal, and particularly preferably 30-40 kcal/100 kcal. Remaining necessary energy is supplemented mainly by sugar.

[0029]

Typically, the nutritional composition of the present invention can be packed in an airtight container and used as a nutritional composition product. The airtight container means a container (closed pack) that is sealed to prevent the content, i.e., the nutritional composition, from contacting the outer air, and the form of the container includes, typically, a pack, retort pouch, soft bag, fixed-form container and can, etc., and preferably, it is a pack, retort pouch, and soft bag. The material of the container includes, typically, paper, plastic, glass and metal, etc., and preferably, it is paper, plastic, and metal, etc.

In addition, the container may be equipped with one or more narrow opening portions for outflow and/or mixing, and said narrow

opening portions may be equipped with a mechanism that is sealed prior to use, and at the time of use, that can be directly connected to a tube for administering the nutritional composition, or to the narrow opening portion of a container for another nutritional composition.

[0030]

By adopting the above airtight container as a container to be filled with the nutritional composition of the present invention, administration of the nutritional composition to a patient and addition of water to the container can be carried out without widely opening the container, or with opening only minimally the narrow opening portion, thus preventing contamination by minimizing the contact with outer air.

[0031]

In one embodiment, the present invention relates to one pack of nutritional composition product containing the nutritional composition of the present invention, wherein in the nutritional composition, the carnitine content is 5-100 mg, selenium content is 2-15 μ g, and water content is 10-55 ml per 100 kcal of calorie, and wherein at the time of use, one or more said packs are required without the need for removal of water. The above carnitine content and/or selenium content may be appropriately changed; but the composition ratio is set such that when it is administered with the aim of fortifying these components, water is not excessive, that is, the water content is either appropriate or insufficient.

[0032]

In one embodiment, the present invention relates to a method for preparing a nutritional composition used for a subject requiring control of water balance, comprising a step of

calculating the amount of water, when necessary amounts of calorie components and fortifying components are administered to the subject using one or more packs of the nutritional composition of the present invention, and a step of adding the shortage amount of water when the calculated amount of water is insufficient relative to the required amount of the subject.

The nutritional composition of the present invention has a composition ratio with which water does not become excessive when calorie components and fortifying components are administered using a plurality of the packs to subjects and others who require control of water balance; therefore, upon preparation of the nutritional composition of the present invention, the amount of water is either in an appropriate amount, or an insufficient amount.

[0033]

The water to be added at the time of use of the nutritional composition of the present invention includes pure water, purified water and ion-exchanged water, etc. Here, "at the time of use" means, at the time of administering a nutritional composition, that is, immediately before, during, and immediately after the administration. Therefore, it includes the following: the water content of the nutritional composition is increased by the water added at the time of use, as well as the nutritional composition attached to the inner wall of the container is flushed with water (flushing) and this flushing water is administered to the patient together with the nutritional composition.

[0034]

The water added at the time of use may be measured prior to use and placed in a container different from that of the nutritional composition, or the water may be used by measuring

at the time of addition. When the nutritional composition of the present invention has a water content of an integer multiple of unit water content, then the amount of water to be added at the time of use is preferably an integer multiple of the same unit water content. Furthermore, by setting such unit water content to be, for example, numerical values easily measured by a general measuring cup such as 10 ml, 50 ml and 100 ml, it is possible to measure and calculate the amount of water more easily.

[0035]

Furthermore, in control of water balance of dialysis patients, the amount of administration of water to be aimed at by a physician is usually set such that, daily administration of water per 1 kg of body weight becomes 30 ml or 50 ml; when daily amount of fluid is very strictly controlled, it may be 15 ml/kd·DW*/day (*: standard body weight under an appropriate state of amount of body fluid, etc.).

The amount of water contained in one pack of the nutritional composition product of the present invention is not particularly limited; for example, by setting the amount at an integer multiple of 5 ml, an integer multiple of 10 ml, an integer multiple of 50 ml, or an integer multiple of 100 ml, then the calculation of the amount of water to be added becomes simple; typically, it is preferred that one pack contains an amount of water of 50 ml, 100 ml, 150 ml or 200 ml.

[0036]

Sodium, fat, protein, carbohydrate, vitamins and minerals blended in the nutritional composition of the present invention are not particularly limited as long as they are generally used in the fields of foods, drinks and pharmaceuticals. However, the use of those which are approved by the Ministry of Health, Labor

and Welfare as raw materials and additives for foods and pharmaceuticals are preferred.

Examples of fat blended in the nutritional composition of the present invention include vegetable oils such as soybean oil, palm oil, fractionated palm oil, and olive oil, animal oils such as milk fat, lard and fish oil, and free fatty acids such as oleic acid, linolenic acid, and γ -linolenic acid. Preferable examples include soy bean oil and palm oil. In addition, one or more of these fats may be used.

[0037]

Examples of protein blended in the nutritional composition of the present invention include plant proteins such as soy bean protein, animal proteins such as casein and whey protein. Preferably, they include soy bean protein, casein, and whey protein, etc. In addition, hydrolysates of these proteins may be used, and one or more of these proteins and hydrolysates thereof may be used.

Examples of carbohydrate blended in the nutritional composition of the present invention include dextrin, sucrose, lactose, and oligosaccharide; preferably, they include dextrin, sucrose and palatinose. In addition, hydrolysates of these carbohydrates may be used, and one or more of these carbohydrates and hydrolysates thereof may be used.

[0038]

Examples of vitamins blended in the nutritional composition of the present invention include vitamin A, vitamin D, vitamin E, vitamin B1, vitamin B2, niacin, vitamin B6, folic acid, vitamin B12, pantothenic acid, and vitamin C; preferably they include vitamin B1, vitamin B2, niacin, vitamin B6, folic acid, vitamin B12, pantothenic acid, and vitamin C. In addition, one or more

of these vitamins may be used.

[0039]

Examples of sodium source of the present nutritional composition include sodium acetate, sodium chloride, sodium citrate, sodium hydrate, sodium carbonate, sodium bicarbonate, monosodium hydrogen phosphate, disodium hydrogen phosphate, sodium metaphosphate, sodium pyrophosphate, and sodium tripolyphosphate, etc. Preferably they include sodium chloride and sodium citrate. In addition, one or more kinds of these sodium sources may be used.

Examples of minerals other than sodium blended in the nutritional composition of the present invention include calcium, iron, phosphorus, magnesium, potassium, copper, and zinc; preferably they include calcium, phosphorus, magnesium and potassium. In addition, one or more of these minerals may be used.

[0040]

Furthermore, the nutritional composition of the present invention may comprise dietary fibers, and examples of water-soluble dietary fibers include indigestible dextrin and reduced indigestible dextrin, etc.; examples of water-insoluble dietary fibers include cellulose. Moreover, the nutritional composition of the present invention may comprise various flavors, sweeteners, and other additives.

The value of pH of the nutritional composition of the present invention is, from the viewpoints of flavors and physical properties, preferably in the range of pH 3-11, and more preferably 4-10, and furthermore preferably 5-9, and it may practically be 7. In addition, a pH adjuster such as citric acid may be comprised to adjust the pH value.

[0041]

Osmotic pressure of the nutritional composition of the present invention is, from the viewpoint of prevention of symptoms in the digestive system such as diarrhea and abdominal pain due to high osmotic pressure, preferably in the range of 200-800 mOsm/L, and more preferably 300-750 mOsm/L.

The nutritional composition of the present invention can be prepared in accordance with routine methods publicly-known in the field. Examples include a method wherein each component is measured, mixed well with water, then emulsified, and this nutritional composition is previously heat-sterilized, then aseptically packed in a container (for example, a method wherein UHT sterilization and aseptic packaging are combined), or a method wherein such nutritional composition is packed in a container, then the container together with the composition is heat-sterilized (for example, autoclaving method).

[0042]

The nutritional composition packed in a container of the present invention can be made as a commercial product in the form of a kit, together with another container comprising a pre-measured amount of water to be used for adding.

Hereinafter, the present invention will be described in detail with reference to examples and usage examples; however, the invention is not limited to these examples, and various modifications are possible within the scope of the technical idea of the present invention.

[Examples]

[0043]

[Example 1]

Each of the raw materials listed in Table 1 below was poured and mixed into pure water of approximately 60°C, and the mixture was put in a homo-mixer for crude emulsification at approximately 5000 rpm for 10 min. Then, the mixture was heated to 90°C, allowed to stand for 5 min, and subjected to fine emulsification using a high-pressure emulsifier (20 kgf/cm²). The obtained emulsion was cooled to approximately 20°C, to which vitamins, minerals, and flavors were added, then diluted in a measuring cylinder to obtain nutritional compositions of the present invention (types A to D). Table 2 shows the amount of each component in the obtained nutritional compositions.

[0044]

[Table 1]

Name (Unit)	Type A (g/100ml)	Type B (g/100ml)	Type C (g/100ml)	Type D (g/100ml)
Milk protein concentrate	4.6	3.3	4.5	4.6
Casein sodium	4	2.9	3.9	4.0
Dextrin	17.6	14.6	9.9	20
Palatinose	10.5	11.5	13.6	11.7
Soluble dietary fiber	7.9	2.3	1.5	7.9
Vegetable fat and oil	9.7	3.6	2.7	9.7
Purified fish oil	0.6	0.2	0.1	0.6
Emulsifier	1	0.6	0.6	1
Minerals	Moderate amount	Moderate amount	Moderate amount	Moderate amount
Vitamins	Moderate amount	Moderate amount	Moderate amount	Moderate amount
Flavor	Moderate amount	Moderate amount	Moderate amount	Moderate amount
Water for dissolution	56	70.6	72.9	54.4

[0045]

[Table 2]

Classifi cation	Per 100 kcal		Type A	Type B	Type C	Type D
General composit ion	Concentration		2.48 kcal/ml	1.53 kcal/ml	1.45 kcal/ml	2.5 kcal/ml
	Water content		75 ml/ 300kcal	200 ml/ 400kcal	165 ml/ 300kcal	100 ml/ 400kcal
		ml	25.0	50.0	55.0	25.0
	Protein	% kcal	12.0	14.0	20.0	12.0
		g	3.0	3.5	5	3.0
	Fat	% kcal	40	25	20	40
		g	4.44	2.78	2.22	4.44

	DHA	mg	40	20	10	40
	EPA	mg	50	29	5	50
	Carbohydrate	% kcal	48	61	60	48
		g	14.3	16.4	15.8	14.3
	Sugar	g	11.3	14.9	14.8	11.3
	Palatinose		40% kcal in sugar	50% kcal in sugar	60% kcal in sugar	40% kcal in sugar
		g	4.5	7.4	8.9	4.5
	Fructo- oligosaccharide	g	0.3	0.3	0.3	0.0
	Dietary fiber	g	3.0	1.5	1.0	3.0
	Carnitine	mg	5	25	100	5
	Total calorie	kcal	100.0	100.0	100.0	100.0
Minerals	Na	mg	100	100	100	100
	Salt equivalent	g	0.25	0.25	0.25	0.25
	K	mg	100	60	30	100
	P	mg	80	50	30	80
	Ca	mg	80	50	30	80
	Cl	mg	50	50	50	50
	Mg	mg	15	15	15	15
	Fe	mg	1.5	1.5	1.5	1.5
Trace element	Zn	mg	1.5	1.5	1.5	1.5
	Cu	mg	0.075	0.075	0.075	0.075
	Se	µg	15	9	2	15
	Mn	mg	0.23	0.23	0.23	0.23
	Mo	µg	2.5	2.5	2.5	2.5
	Cr	µg	3	3	3	3
	I	µg	15	15	15	15
Vitamins	VA	µgRE	60	60	60	60
	Retinol		15	15	15	15
	β-carotene		45	45	45	45
	VD	µg	0.13	0.13	0.13	0.13
	Folic acid	mg	63	63	63	63
	VC	mg	9	9	9	9
	VB6	mg	1.00	1.00	1.00	1.00
	VE	mg	1.0	1.0	1.0	1.0
	VB1	mg	0.12	0.12	0.12	0.12
	VB2	mg	0.13	0.13	0.13	0.13
	Niacin	mg	1.6	1.6	1.6	1.6
	VB12	µg	0.24	0.24	0.24	0.24
	Pantothenic acid	mg	0.50	0.50	0.50	0.50
	Biotin	µg	3.0	3.0	3.0	3.0
	Vitamin K	µg	Derived from raw material ls	Derived from raw material ls	Derived from raw material ls	Derived from raw material ls

[0046]

[Example 2]

Each of the nutritional compositions types A to D obtained in the above Example 1 was poured in an airtight plastic container equipped with a connection port for enteral feeding, subjected to retort sterilization (pre-heating at 80°C, sterilization at

121°C, 9 min 30 s) to prepare nutritional compositions A to D packed in a container. Property values of the nutritional compositions packed in a container satisfy product specification standards, and changes such as significant thickening, precipitation and fat separation were not observed during long term storage.

[0047]

[Usage Example 1]

The nutritional composition A packed in a container obtained in the above Example 2 is administered via a tube to a dialysis patient to supply 300 kcal of calories and 100 ml of water per serving.

- (1) Relative to the objective of administration of 300 kcal of calories and 100 ml of water, one pack of the nutritional composition A packed in a container contains 300 kcal of calories and 75 ml of water, thus the shortage amount of water is calculated as $(100\text{ ml} - 75\text{ ml} = 25\text{ ml})$.
- (2) 25 ml of water is prepared.
- (3) The nutritional composition A packed in a container is connected to a tube, and administered via the tube.
- (4) The nutritional composition A remained on the inner wall of the container after administration is flushed with the 25 ml of water prepared in the above (2) into the tube.

[0048]

[Usage Example 2]

The nutritional composition B packed in a container obtained in the above Example 2 is administered via a tube to a dialysis patient to supply 400 kcal of calories and 300 ml of water per serving.

- (1) Relative to the objective of administration of 400 kcal of calories and 300 ml of water, one pack of the nutritional

composition B packed in a container contains 400 kcal of calories and 200 ml of water, thus the shortage amount of water when one pack is used is calculated as (300 ml - 200 ml = 100 ml).

- (2) 100 ml of water is prepared in a container in advance.
- (3) The nutritional composition B packed in a container is connected to a tube, and administered via the tube.
- (4) The nutritional composition B remained on the inner wall of the container after administration is flushed with the 100 ml of water prepared in the above (2) into the tube.

[0049]

As described in the above usage examples 1 and 2, the nutritional composition of the present invention enables administration of a relatively small amount of water compared to calories, such as "300 kcal of calories and 100 ml of water" and "400 kcal of calories and 300 ml of water." It is impossible to use a conventional nutritional composition prepared to have, for example 1 kcal/ml, for the administration of a small amount of water per serving such as "300 kcal of calories and 100 ml of water" and "400 kcal of calories and 300 ml of water." Moreover, since conventional nutritional compositions comprise a fraction of water content, even when a larger amount of water compared to the calories (such as "300 kcal of calories and 350 ml of water) is to be administered, calculation of the shortage amount of water is complex and strict control of water balance is difficult. With the nutritional composition of the present invention, calculation of such an amount of water is easy, eliminating the mistake in dosage due to miscalculation.

[Industrial Applicability]

[0050]

According to the present invention, nutritional composition suitable for administration to patients requiring strict control of water balance can be provided; control of water balance becomes easier particularly for chronic dialysis patients such as patients with renal failure, reducing and avoiding the mistakes such as administration of an excess amount of water.

[Claims]

1. A nutritional composition used for a subject requiring control of water balance, wherein the composition of the calorie components, fortifying components and water in the nutritional composition is a composition ratio with which an excess amount of water is not contained relative to the required amounts of the calorie components and fortifying components for said subject.
2. The nutritional composition according to Claim 1, wherein the subject requiring control of water balance is a dialysis patient.
3. The nutritional composition according to Claim 2, wherein the dialysis patient is a patient with chronic renal failure.
4. The nutritional composition according to any one of Claims 1 to 3, wherein the calorie component is one or more types selected from the group consisting of fat, protein, carbohydrate, and a hydrolysate thereof.
5. The nutritional composition according to any one of Claims 1 to 4, wherein the fortifying component is one or more types selected from the group consisting of n-3 fatty acid, palatinose, fructooligosaccharide, dietary fiber, carnitine and selenium.
6. A packed product of nutritional composition comprising the nutritional composition according to any one of Claims 1 to 5, wherein the nutritional composition has an amount of water of 10-50 ml per 100 kcal of calories, and has a composition ratio

with which one or more of said packed products are required at the time of use without the need for removal of water.

7. The nutritional composition product according to Claim 6, comprising carnitine as a fortifying component, with the carnitine content of 15-100 mg per 100 kcal of calories.

8. The nutritional composition product according to Claim 6 or 7, comprising selenium as a fortifying component, with the selenium content of 5-15 μ g per 100 kcal of calories.

9. The nutritional composition product according to any one of Claims 6 to 8, wherein the amount of water contained in one pack is an integer multiple of 5 ml, 10 ml, 50 ml, or 100 ml.

10. A method for preparing a nutritional composition used for a subject requiring control of water balance, comprising a step of calculating the amount of water, when necessary amounts of calorie components and fortifying components are administered to the subject using one or more packs of the nutritional composition product according to any one of Claims 6 to 9, and a step of adding the shortage amount of water when the calculated amount of water is insufficient relative to the required amount of the subject.