The present invention provides methods and compositions for providing long-term tube-fed nutrition. More specifically, the present invention provides methods and compositions for providing long-term tube-fed maintenance to a patient.
BACKGROUND

[0001] The present application relates to nutrition. More specifically, the present invention relates to clinical nutrition.

[0002] Due to a variety of diseases, insults, and complications, patients may not be able to obtain the necessary nutrition by ingesting food through the mouth, e.g., eating food. Therefore, it has been known to provide clinical nutrition either enterally or parenterally. A variety of different formulations have been developed to provide such clinical nutrition.

[0003] Even with respect to typical enteral nutritional products, these products are designed for short-term use, typically 10 to 24 days. In this regard, the products usually provide the essential nutritional components to provide necessary nutrition to patients having acute pathologies during their hospital stays. Although these products are suitable for such short term use, they have not necessarily been designed for long-term feeding of patients. With advances in medicine resulting in increased life expectancy and better disease treatments, a number of individuals could benefit from products designed to provide long-term enteral nutrition.

SUMMARY

[0004] The present invention provides methods and compositions for providing long-term tube-fed nutrition. More specifically, the present invention provides methods and compositions for providing long-term tube-fed nutrition to a normo-metabolic patient who is unable to eat a normal diet.

[0005] To this end, in an embodiment, a method for providing long-term tube-fed nutrition to a patient is provided comprising the steps of providing to a patient in need of long-term tube-fed nutrition, at least once a day, an enteral nutrition product through a tube comprising per 100 kcal of product: a source of protein; a source of carbohydrates; a source of lipids; sodium 100 to 200 mg; potassium 25 to 250 mg; calcium above 50 mg; phosphorus less than 150 mg; magnesium at least 15 mg; chloride at least 100 mg; iron 0.4 to 1.5 mg; zinc 0.4 to 2.0 mg; copper 0.08 to 0.4 mg;
fluoride 0 to 0.15 mg; chromium 2.0 to 10.0 micrograms; molybdenum 2.0 to 14.0 micrograms; selenium 3.0 to 9.0 micrograms; manganese 0.1 to 0.4 mg; iodine 7.0 to 15.0 micrograms; Vit A 100 to 500 IU; Vit D 0.5 to 2.5 micrograms; Vit E 1.5 to 4.0 mg; Vit K greater than 4.0 micrograms; Vit C greater than 4.0 mg; Vit B1 greater than 0.06 mg; Vit B2 greater than 0.07 mg; Vit B3 0.7 to 3.5 mg; Vit B5 0.2 to 2.0 mg; Vit B6 0.1 to 0.7 mg; Vit B8 at least 1.0 micrograms; Vit B9 at least 12.0 micrograms; and Vit B12 0.1 to 1.0 micrograms.

[0006] The enteral nutrition product of the method can, in an embodiment, comprise further components. For example, at least 30 mg of choline per 100 kcal of product, at least 4.0 mg of taurine per 100 kcal of product, and/or at least 3.0 mg of carnitine per 100 kcal of product.

[0007] In an embodiment of the method, the source of protein provides 10 to 18% by caloric content of the product. The protein source can be selected from the group consisting of casein, whey, and soy. Moreover, the protein can be intact or partially hydrolyzed. With respect to the carbohydrate source, it can provide 40 to 65% by caloric content of the product. The source of lipids can provide 25 to 40% by caloric content of the product, with saturated fatty acids of not greater than 1.1 g/100 kcal, the composition contains between 0.3 and 1.1 g linoleic acid per 100 kcal, the composition contains at least 0.06 g linolenic acid per 100 kcal, and the n6:n3 ratio is between 2 and 7. The product can also contain a source of dietary fiber that provides at least 10 g/1. The fiber can comprise insoluble fibers and soluble fibers. For example, the insoluble fiber can comprise at least 25% of the fiber source. The fiber can comprise soy polysaccharides and pea outer fibers.

[0008] If desired, the composition can comprise a prebiotic. In an embodiment, the prebiotic can be inulin. In another embodiment, the product has a density of 0.8 to 1.4 kcal/ml.

[0009] Additionally, in an embodiment, the present invention provides a method of providing nutrition to a patient comprising the steps of providing on a long term basis, at least once a day, to a patient requiring nutrition, an enteral nutrition product comprising: a source of protein providing 10 to 18% by caloric content of the product; a source of carbohydrate providing 40 to 65% by caloric content of the product; a source of lipids providing 25 to 40% by caloric content of the product; a
source of dietary fiber in an amount of at least 10 g/l comprising soluble and insoluble fiber; sodium 100 to 200 mg; potassium 25 to 250 mg; calcium above 50 mg; phosphorus less than 150 mg; magnesium at least 15 mg; chloride at least 100 mg; iron 0.4 to 1.5 mg; zinc 0.4 to 2.0 mg; copper 0.08 to 0.4 mg; fluoride 0 to 0.15 mg; chromium 2.0 to 10.0 micrograms; molybdenum 2.0 to 14.0 micrograms; selenium 3.0 to 9.0 micrograms; manganese 0.1 to 0.4 mg; iodine 7.0 to 15.0 micrograms; lycopene at least 0.2 mg; beta-carotene at least 0.1 mg; Vit A 100 to 500 IU; Vit D 0.5 to 2.5 micrograms; Vit E 1.5 to 4.0 mg; Vit K more than 6.0 micrograms; Vit C more than 4.0 mg; Vit B1 more than 0.06 mg; Vit B2 more than 0.07 mg; Vit B3 0.7 to 3.5 mg; Vit B5 0.2 to 2.0 mg; Vit B6 0.1 to 0.7 mg; Vit B8 at least 1.0 micrograms; Vit B9 at least 12.0 micrograms; and Vit B12 0.1 to 1.0 micrograms.

[0010] Yet further, in an embodiment, the present invention provides an enteral nutrition product comprising: sodium 100 to 200 mg; potassium 25 to 250 mg; calcium above 50 mg; phosphorus less than 150 mg; magnesium at least 15 mg; chloride at least 100 mg; iron 0.4 to 1.5 mg; zinc 0.4 to 2.0 mg; copper 0.08 to 0.4 mg; fluoride 0 to 0.15 mg; chromium 2.0 to 10.0 micrograms; molybdenum 2.0 to 14.0 micrograms; selenium 3.0 to 9.0 micrograms; manganese 0.1 to 0.4 mg; iodine 7.0 to 15.0 micrograms; Vit A 100 to 500 IU; Vit D 0.5 to 2.5 micrograms; Vit E 1.5 to 4.0 mg; Vit K more than 6.0 micrograms; Vit C more than 4.0 mg; Vit B1 more than 0.06 mg; Vit B2 more than 0.07 mg; Vit B3 0.7 to 3.5 mg; Vit B5 0.2 to 2.0 mg; Vit B6 0.1 to 0.7 mg; Vit B8 at least 1.0 micrograms; Vit B9 at least 12.0 micrograms; and Vit B12 0.1 to 1.0 micrograms; lycopene at least 0.2 mg; beta-carotene at least 0.1 mg; a source of protein providing 10 to 18% by caloric content of the product; a source of carbohydrate providing 40 to 65% by caloric content of the product; a source of lipids providing 25 to 40% by caloric content of the product; and a source of dietary fiber in an amount of at least 10 g/l providing both soluble and insoluble fibers.

[0011] As noted above, the enteral nutrition product can also comprise at least 30 mg of choline, at least 5.0 mg of taurine, and at least 3.0 mg of carnitine, all per 100 kcal of product.

[0012] Still further, in an embodiment, the present invention provides a method of providing nutrition to a patient comprising the steps of administering long term via a tube to a patient requiring maintenance at least once a day a product comprising: at
least one of lycopene; lutein; β-carotene; β-cryptoxanthine; polyphenol; a source of protein; a source of carbohydrate; a source of fiber; and a source of lipids.

[0013] In an embodiment, the polyphenols are selected from the group consisting of: catechin; isoflavones; and quercetin.

[0014] An advantage of the present invention is to provide improved enteral nutrition products.

[0015] Another advantage of the present invention is to provide enteral nutrition products targeted to long-term use.

[0016] Furthermore, an advantage of the present invention is to provide compositions for providing long-term nutrition to a patient requiring same.

[0017] Additionally, an advantage of the present invention is to provide methods for providing long-term nutrition to a patient requiring same.

[0018] Additional features and advantages are described herein, and will be apparent from, the following Detailed Description.

DETAILED DESCRIPTION

[0019] The present invention relates to clinical nutrition. More specifically, the present invention relates to providing long-term tube-fed nutrition to patients requiring same. As used herein, the term "long-term" means greater than one month (30 days). As used herein, the term "tube-fed" means to provide a product to a patient through a feed tube that is received within a portion of the digestive tract of a patient, for example, a percutaneous endoscopic gastrostomy or nasogastric feed tube. Applicants have herewith filed a patent application entitled "METHODS OF PROVIDING LONG-TERM NUTRITION," which discloses various long-term enteral nutrition products and methods as well as business methods based thereon, the disclosure of which is hereby incorporated herein by reference.

[0020] The long-term tube-fed nutrition product is designed for maintenance patients. As used herein, "maintenance patient" refers to an adult patient under the age of sixty-five who cannot receive nutrition through a normal diet but who is normo-metabolic (i.e. not suffering from a metabolic disorder). Such a patient may previously have undergone surgery for a cancer of the head or neck leaving an incomplete digestive tract or an inability to swallow, may have received an injury to the neck leaving him or her unable to swallow or may be unable to swallow as a result
of neurological damage caused by a stroke for example. As used herein, the term "normal diet" means to receive at least substantially all nutrition by eating, i.e., using one's mouth, without the use of any feed tube or parenteral feed.

[0021] The present invention provides methods as well as products that are optimized and/or improved for long-term use, especially to provide complete nutrition to maintenance patients, as compared to standard enteral nutrition products. As used herein, the term "standard enteral nutrition product" refers to products that are not specifically advertised or promoted for long-term use. A variety of such products are available, for example, from Nestle Clinical Nutrition, Abbott, Novartis, Numico, and Fresenius. In an embodiment, these product are provided to the patient outside of a hospital setting. For example, the products can be provided in a nursing home, out care patient center, or even the home of the patient. Preferably, the nutrition products are housed in a plastic bag. A variety of such bags are known, for example, 500 ml, 1000 ml, and 1500 ml bags are known in the art. It should be noted, however, that any suitable container can be used to house the nutrition product. Typically, the product is administered so that the patient receives 1500 ml per day, although those skilled in the art will appreciate that variations to the amount of product administered are possible.

[0022] Because the long-term enteral nutrition formulation of the present invention is provided for maintenance, it is not directed to any specific, qualitative, or quantitative complement. Patients are typically stable, normo-metabolic, healthy patients except for the fact that they require enteral nutrition in order to receive necessary nutritional requirements. Thus, these patients can suffer from a variety of disorders including swallowing disorders of a variety of etiologies, particularly surgical consequences of ear/nose/throat cancer, and patients suffering from a cerebral vascular accident.

[0023] One of the goals of the formulation is to optimize metabolic status and stability in long-term enteral fed patients. By providing not only necessary macronutrients but also the micronutrients that contribute to, for example the antioxidant status, the formulation can maintain the metabolic status of the body in a comparable condition to a completely healthy individual of the same age eating a balanced diet. Thus, the present invention provides a method of improving the metabolic stability of long-term enteral fed patients.
[0024] Although the formula is designed to provide, in a preferred embodiment, necessary nutritional minerals, and vitamins to meet government requirements (defined below), there are some exceptions with respect to these recommendations. In this regard, preferably, excess calcium is utilized. In this regard, in an embodiment, preferably at least 33 percent more calcium is utilized. One of the reasons for this increase is that these patients have a reduced physical activity. In addition, excess vitamin D is preferably provided. In a preferred embodiment, at least 150 percent more vitamin D is provided than required by at least certain government requirements. Because of their reduced mobility, these patients are exposed to less sunlight and consequently have less endogenous synthesis of this vitamin. The maintenance of a satisfactory bone reserve is expected from this increased calcium and vitamin D intake. Also, in the formulation in an embodiment, the iron intake corresponds to the typical governmental requirements for females. These are usually considerably higher than that of a male. The idea is to avoid recurrence of an iron deficiency to which women are predisposed.

[0025] The protein source preferably provides 10 to 18 percent by caloric content of the product. Any high quality protein source or mixture thereof can be utilized. Examples include casein, whey, and soy protein. Proteins may be intact or partially hydrolyzed. Free amino acids may be added if desired. In an embodiment, a mixture is utilized of 50 percent caseinate and 50 percent soy. Preferably, the protein source is obtained through a mix of caseins and soy proteins allowing a balanced intake of amino acids.

[0026] The carbohydrate source preferably comprises 40 to 65 percent by caloric content of the product. Any carbohydrate or mixture of carbohydrates can be utilized. Examples include starches, maltodextrins, sucrose, and mixtures thereof. In an embodiment, 100 percent maltodextrins are used.

[0027] Preferably, the lipids comprise 25 to 40 percent by caloric content of the product. Any suitable mixture of dietary lipids can be provided including saturated fatty acids (SFA), monounsaturated fatty acids (MUFA), polyunsaturated fatty acids (PUFA), and medium-chain triglycerides (MCT). Preferably, saturated fatty acids are present in an amount less than 1.1 g/100 kcal. Preferably, the composition contains between 0.3 and 1.1 g linoleic acid (or higher derivative thereof) per 100 kcal. The
composition may contain at least 0.06 g/linolenic acid, or higher derivative thereof, per 100 kcal. The n6:n3 ratio is preferably 2 to 7.

[0028] Preferably, the composition has an energy density of 0.80 to 1.4 kcal/ml.

[0029] Fiber intake is preferably high in the formula of the present invention. Constipation presents itself frequently in this patient population. Preferably, the fiber composition comprises at least 10 g/l. Any suitable fiber or mix of fibers can be used. Examples of insoluble fibers are soy polysaccharides, pea outer fiber. Examples of soluble fibers are acacia gum, pectin, inulin, and guar gum. Generally, a mixture of soluble and insoluble fibers is preferred. In addition, prebiotic fibers may be included. A prebiotic is defined as a non-digestible food ingredient that beneficially affects the host by selectively stimulating the growth and/or activity of one or a limited number of bacteria in the colon and thus improves host health. Examples of prebiotic fibers include acacia gum and fructo-oligosaccharides such as inulin and hydrolysed inulin. In an embodiment, a mixture of 50 percent pea outer fiber, 37 percent pea inner fiber and 13 percent prebiotic fiber (inulin and hydrolysed inulin) at 16.7 g/l is used. This corresponds to a mixture of 66% insoluble fiber and 34% soluble fiber (including the prebiotic fiber).

[0030] The nutrition products are specifically designed, in an embodiment, so that they can provide complete long-term nutrition and attempt to provide the same macro and micro nutrients as would be ingested by a healthy person eating a balanced diet. Therefore, the formulas mimic, in an embodiment, what is referred to herein as the 5/8 a day. As used herein, the term "5/8 a day" refers to governmental guidelines to consumers to eat five to eight helpings of fruits and vegetable per day. Thus, in an embodiment, the products are designed so that, to the extent possible, they attempt to mimic a normal diet that is preferably ingested by individuals that do not require a tube-fed product by providing micronutrients and phytonutrients found in fruit and vegetables. In an embodiment, the present invention provides a method of designing long-term enteral nutrition products based on attempting to mimic the 5/8 a day. By providing such a nutrition product, the patient's antioxidant status can be maintained as well as metabolic status. A goal being to place these patients in a state comparable,
to the extent possible, to that of a completely healthy individual of the same age eating a balanced diet.

[0031] Phytonutrients have been found to provide the following characteristics: antioxidant, anti-inflammatory, detoxification, cancer protective, prevention of atherosclerosis, alleviation of metabolic syndromes, and prevention of bone loss. To achieve the necessary phytonutrients, the compositions of the present invention can include one or more of carotenoids such as lycopene (tomato), B-carotene (carrot, spinach, tomato), lutein (spinach), B-cryptoxanthin, vitamins such as mixed tocopherols (oils and nuts), and vitamin C (orange); and polyphenols such as catechins (green tea).

[0032] Preferably, the products include the necessary nutritional components to provide complete nutrition to the patient on a long-term basis. In this regard, the products include, among other possible ingredients: protein, carbohydrate, fat, vitamins, and minerals. In an embodiment, the products substantially, if not completely, comply with at least certain governmental requirements. As used herein, "governmental requirements" means any recommendations from any one of the following governments: U.S., typically the USRDA; German, typically the German RDA; and French, typically the French RDA. In an embodiment, the nutrition product meets or exceeds at least one of the governmental requirements.

[0033] By way of example and not limitation, examples of the present invention will now be given.

Example No. 1

<table>
<thead>
<tr>
<th>Component</th>
<th>Embodiment Maintenance per 1500 ml</th>
<th>Embodiment per 100 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calories</td>
<td>Kcal</td>
<td>1875</td>
</tr>
<tr>
<td>Protein</td>
<td>g</td>
<td>62</td>
</tr>
<tr>
<td>Ca Caseinate</td>
<td>g</td>
<td>31</td>
</tr>
<tr>
<td>Soya</td>
<td>g</td>
<td>31</td>
</tr>
<tr>
<td>Carbohydrates</td>
<td>g</td>
<td>252</td>
</tr>
<tr>
<td>Maltodextrins</td>
<td>g</td>
<td>237</td>
</tr>
<tr>
<td>Carbohydrates from other sources</td>
<td>g</td>
<td>15</td>
</tr>
<tr>
<td>Fiber</td>
<td>g</td>
<td>23</td>
</tr>
<tr>
<td>Insoluble</td>
<td>%</td>
<td>66</td>
</tr>
<tr>
<td>Soluble</td>
<td>%</td>
<td>34</td>
</tr>
<tr>
<td>Lipids</td>
<td>g</td>
<td>72</td>
</tr>
<tr>
<td>-------------</td>
<td>----</td>
<td>----</td>
</tr>
<tr>
<td>n-3</td>
<td>g</td>
<td>11</td>
</tr>
<tr>
<td>MUFA</td>
<td>g</td>
<td>43</td>
</tr>
<tr>
<td>PUFA</td>
<td>g</td>
<td>11</td>
</tr>
<tr>
<td>linoleic acid (n-6)</td>
<td>g</td>
<td>8.4</td>
</tr>
<tr>
<td>α-linolenic acid (n-3)</td>
<td>g</td>
<td>1.6</td>
</tr>
<tr>
<td>Ratio o6/o3</td>
<td></td>
<td>5.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Minerals and Trace Elements</th>
<th></th>
<th></th>
<th></th>
</tr>
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<tbody>
<tr>
<td>Sodium</td>
<td>mg</td>
<td>2400</td>
<td>160</td>
</tr>
<tr>
<td>Potassium</td>
<td>mg</td>
<td>2445</td>
<td>163</td>
</tr>
<tr>
<td>Calcium</td>
<td>mg</td>
<td>1290</td>
<td>86</td>
</tr>
<tr>
<td>Phosphorous</td>
<td>mg</td>
<td>855</td>
<td>57</td>
</tr>
<tr>
<td>Magnesium</td>
<td>mg</td>
<td>405</td>
<td>27</td>
</tr>
<tr>
<td>Chloride</td>
<td>mg</td>
<td>3225</td>
<td>215</td>
</tr>
<tr>
<td>Iron</td>
<td>mg</td>
<td>18</td>
<td>1.2</td>
</tr>
<tr>
<td>Zinc</td>
<td>mg</td>
<td>12</td>
<td>0.78</td>
</tr>
<tr>
<td>Copper</td>
<td>mg</td>
<td>2</td>
<td>0.13</td>
</tr>
<tr>
<td>Fluoride</td>
<td>mg</td>
<td>1.4</td>
<td>0.09</td>
</tr>
<tr>
<td>Chromium</td>
<td>µg</td>
<td>105</td>
<td>7.0</td>
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<tr>
<td>Molybdenum</td>
<td>µg</td>
<td>98</td>
<td>6.5</td>
</tr>
<tr>
<td>Selenium</td>
<td>µg</td>
<td>81</td>
<td>5.4</td>
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<tr>
<td>Manganese</td>
<td>mg</td>
<td>4.4</td>
<td>0.29</td>
</tr>
<tr>
<td>Iodine</td>
<td>µg</td>
<td>165</td>
<td>11</td>
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<table>
<thead>
<tr>
<th>Vitamins</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Vitamin A total</td>
<td>IU</td>
<td>4500</td>
<td>300</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>µg</td>
<td>20</td>
<td>1.3</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>IU</td>
<td>48</td>
<td>3.2</td>
</tr>
<tr>
<td>Vitamin K</td>
<td>µg</td>
<td>105</td>
<td>7.0</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>mg</td>
<td>180</td>
<td>12.0</td>
</tr>
<tr>
<td>Vitamin B1 (Thiamin)</td>
<td>mg</td>
<td>2.0</td>
<td>0.13</td>
</tr>
<tr>
<td>Vitamin B2 (Riboflavin)</td>
<td>mg</td>
<td>1.7</td>
<td>0.11</td>
</tr>
<tr>
<td>Vitamin B3-PP (Niacin)</td>
<td>mg</td>
<td>23</td>
<td>1.50</td>
</tr>
<tr>
<td>Vitamin B5 (Pantothenic acid)</td>
<td>mg</td>
<td>9.5</td>
<td>0.63</td>
</tr>
<tr>
<td>Vitamin B6 (Pyridoxine)</td>
<td>mg</td>
<td>2.3</td>
<td>0.15</td>
</tr>
<tr>
<td>Vitamin B8 (Biotin)</td>
<td>µg</td>
<td>57</td>
<td>3.8</td>
</tr>
<tr>
<td>Vitamin B9 (Folic Acid)</td>
<td>µg</td>
<td>450</td>
<td>30</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>µg</td>
<td>5.7</td>
<td>0.38</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Choline</td>
<td>mg</td>
<td>810</td>
<td>54</td>
</tr>
<tr>
<td>Taurine</td>
<td>mg</td>
<td>81</td>
<td>5.4</td>
</tr>
<tr>
<td>Carnitine</td>
<td>mg</td>
<td>150</td>
<td>10</td>
</tr>
<tr>
<td>Beta-carotene (carrot)</td>
<td>mg</td>
<td>3.8</td>
<td>0.25</td>
</tr>
<tr>
<td>Lycopene (tomato)</td>
<td>mg</td>
<td>5.9</td>
<td>0.39</td>
</tr>
</tbody>
</table>
Example No. 2

<table>
<thead>
<tr>
<th></th>
<th>Embodiment Maintenance per 1500 ml</th>
<th>RANGE for 100 kcal</th>
<th>Embodiment per 100 ml</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Calories</strong></td>
<td>1875</td>
<td>0.8-1.4 kcal/ml</td>
<td>125</td>
</tr>
<tr>
<td><strong>Protein</strong></td>
<td>g 62</td>
<td>10-18% of total energy content, intact or partially hydrolysed</td>
<td>4.1</td>
</tr>
<tr>
<td>Ca Caseinate</td>
<td>g 31</td>
<td></td>
<td>2.06</td>
</tr>
<tr>
<td>Soya</td>
<td>g 31</td>
<td></td>
<td>2.06</td>
</tr>
<tr>
<td>Carbohydrates</td>
<td>g 252</td>
<td>40-65% of total energy content</td>
<td>16.8</td>
</tr>
<tr>
<td>Maltodextrins</td>
<td>g 237</td>
<td></td>
<td>15.8</td>
</tr>
<tr>
<td>Carbohydrates from other sources</td>
<td>g 15</td>
<td></td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Fibers</strong></td>
<td>g 23</td>
<td>&gt;10g/litre</td>
<td>1.5</td>
</tr>
<tr>
<td>Insoluble</td>
<td>% 66</td>
<td></td>
<td>66</td>
</tr>
<tr>
<td>Soluble</td>
<td>% 34</td>
<td></td>
<td>34</td>
</tr>
<tr>
<td><strong>Lipids</strong></td>
<td>g 72</td>
<td>25-40% of total energy content</td>
<td>4.8</td>
</tr>
<tr>
<td>SFA</td>
<td>g 11</td>
<td>saturated fats (not inc. MCT) &lt;10% of total energy content; or &lt;1.11g/100kcal</td>
<td>0.73</td>
</tr>
<tr>
<td>MUFA</td>
<td>g 43</td>
<td></td>
<td>2.9</td>
</tr>
<tr>
<td>PUFA</td>
<td>g 11</td>
<td></td>
<td>0.73</td>
</tr>
<tr>
<td>Linoleic acid (n-6)</td>
<td>g 8.4</td>
<td>3-10% of total energy content linoleic acid or higher w6 derivatives or 0.33-1.11g/100kcal</td>
<td>0.56</td>
</tr>
<tr>
<td>α-linolenic acid (n-3)</td>
<td>g 1.6</td>
<td>&gt;0.5% of total energy content or &gt;0.06g/100kcal</td>
<td>0.11</td>
</tr>
<tr>
<td>Ratio α6/α3</td>
<td>5.2</td>
<td>2-7</td>
<td>5.2</td>
</tr>
</tbody>
</table>

**Minerals and Trace Elements**

<table>
<thead>
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Pursuant to the methods of the claimed invention, by way of example, either the formulas of Examples 1 and 2 can be administered to a patient requiring nutrition who cannot eat a normal diet, at least once a day on a long-term basis for as long as necessary.

It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present subject matter and without diminishing its intended advantages. It is therefore intended that such changes and modifications be covered by the appended claims.
CLAIMS

The invention is claimed as follows:

1. A method for providing long-term tube-fed nutrition to a patient comprising the steps of:

providing to a patient in need of long-term tube-fed nutrition, at least once a day, for a long term, an enteral nutrition product through a tube comprising per 100 kcal of product:

- a source of protein;
- a source of carbohydrates;
- a source of lipids;
- sodium 100 to 200 mg;
- potassium 25 to 250 mg;
- calcium above 50 mg;
- phosphorus less than 150 mg;
- magnesium at least 15 mg;
- chloride at least 100 mg;
- iron 0.4 to 1.5 mg;
- zinc 0.4 to 2.0 mg;
- copper 0.08 to 0.4 mg;
- fluoride 0 to 0.15 mg;
- chromium 2.0 to 10.0 micrograms;
- molybdenum 2.0 to 14.0 micrograms;
selenium 3.0 to 9.0 micrograms;
manganese 0.1 to 0.4 mg;
iodine 7.0 to 15.0 micrograms;
Vit A 100 to 500 IU;
Vit D 0.5 to 2.5 micrograms;
Vit E 1.5 to 4.0 mg;
Vit K greater than 4.0 micrograms;
Vit C greater than 4.0 mg;
Vit B1 greater than 0.06 mg;
Vit B2 greater than 0.07 mg;
Vit B3 0.7 to 3.5 mg;
Vit B5 0.2 to 2.0 mg;
Vit B6 0.1 to 0.7 mg;
Vit B8 at least 1.0 micrograms;
Vit B9 at least 12.0 micrograms; and
Vit B12 0.1 to 1.0 micrograms.

2. The method of claim 1 wherein the enteral nutrition product comprises at least 30 mg of choline per 100 kcal of product.

3. The method of claim 1 wherein the enteral nutrition product comprises at least 4.0 mg of taurine per 100 kcal of product.

4. The method of claim 1 wherein the enteral nutrition product comprises at least 3.0 mg of carnitine per 100 kcal of product.
5. The method of claim 1 wherein:

the source of protein provides 10 to 18% by caloric content of the product;

the source of carbohydrate provides 40 to 65% by caloric content of the product;

the source of lipids provides 25 to 40% by caloric content of the product; and

the product comprises a source of dietary fiber in an amount of at least 10 g/1.

6. The method of claim 1 wherein the enteral nutrition product comprises:

saturated fatty acids of not greater than 1.1 g/100 kcal;

the composition contains between 0.3 and 1.1 g linoleic acid per 100 kcal;

the composition contains at least 0.06 g linolenic acid per 100 kcal; and

the n6:n3 ratio is between 2 and 7.

7. The method of claim 1 wherein the fiber comprises insoluble fibers and soluble fibers.

8. The method of claim 7 wherein the insoluble fiber comprises at least 25% of the fiber source.

9. The method of claim 1 comprising a prebiotic.

10. The method of claim 9 wherein the prebiotic comprises inulin and/or acacia gum.

11. The method of claim 1 wherein the vitamin A is provided at least in part by beta-carotene.

12. The method of claim 1 wherein the fiber comprises soy polysaccharides and pea outer fibers.
13. The method of claim 1 comprising soluble fiber, insoluble fiber, and prebiotic fiber.

14. The method of claim 1 wherein the product comprises a protein source selected from the group consisting of: casein, whey, and soy.

15. The method of claim 14 wherein the protein can be intact or partially hydrolyzed.

16. The method of claim 14 wherein the product has a density of 0.8 to 1.4 kcal/ml.

17. A method of providing nutrition to a patient comprising the steps of:

- providing on a long term basis, at least once a day, to a patient requiring tube-fed nutrition, an enteral nutrition product comprising:
  - a source of protein providing 10 to 18% by caloric content of the product;
  - a source of carbohydrate providing 40 to 65% by caloric content of the product;
  - a source of lipids providing 25 to 40% by caloric content of the product;
  - a source of dietary fiber in an amount of at least 10 g/1 comprising soluble and insoluble fiber;
  - sodium 100 to 200 mg;
  - potassium 25 to 250 mg;
  - calcium above 50 mg;
  - phosphorus less than 150 mg;
  - magnesium at least 15 mg;
  - chloride at least 100 mg;
  - iron 0.4 to 1.5 mg;
zinc 0.4 to 2.0 mg;
copper 0.08 to 0.4 mg;
fluoride 0 to 0.15 mg;
chromium 2.0 to 10.0 micrograms;
molybdenum 2.0 to 14.0 micrograms;
selenium 3.0 to 9.0 micrograms;
manganese 0.1 to 0.4 mg;
iodine 7.0 to 15.0 micrograms;
lycopene at least 0.2 mg;
beta-carotene at least 0.1 mg;
Vit A 100 to 500 IU;
Vit D 0.5 to 2.5 micrograms;
Vit E 1.5 to 4.0 mg;
Vit K more than 4.0 micrograms;
Vit C more than 4.0 mg;
Vit B1 more than 0.06 mg;
Vit B2 more than 0.07 mg;
Vit B3 0.7 to 3.5 mg;
Vit B5 0.2 to 2.0 mg;
Vit B6 0.1 to 0.7 mg;
Vit B8 at least 1.0 micrograms;
Vit B9 at least 12.0 micrograms; and

Vit B1 2 0.1 to 1.0 micrograms.

18. The method of claim 17 wherein the product comprises a protein source selected from the group consisting of: casein, whey, and soy.

19. The method of claim 17 wherein the enteral nutrition product comprises at least 30 mg of choline per 100 kcal of product.

20. The method of claim 17 wherein the enteral nutrition product comprises at least 4.0 mg of taurine per 100 kcal of product.

21. The method of claim 17 wherein the enteral nutrition product comprises at least 3.0 mg of carnitine per 100 kcal of product.

22. The method of claim 17 wherein the enteral nutrition product comprises:

- saturated fatty acids of not greater than 1.1 g/100 kcal;

- the composition contains between 0.3 and 1.1 g linoleic acid per 100 kcal;

- the composition contains at least 0.06 g linolenic acid per 100 kcal; and

- the n6:n3 ratio is between 2 and 7.

23. An enteral nutrition product comprising:

- sodium 100 to 200 mg;

- potassium 25 to 250 mg;

- calcium above 50 mg;

- phosphorus less than 150 mg;

- magnesium at least 15 mg;

- chloride at least 100 mg;
iron 0.4 to 1.5 mg;  

zinc 0.4 to 2.0 mg;  

 copper 0.08 to 0.4 mg;  

fluoride 0 to 0.15 mg;  

chromium 2.0 to 10.0 micrograms;  

molybdenum 2.0 to 14.0 micrograms;  

selenium 3.0 to 9.0 micrograms;  

manganese 0.1 to 0.4 mg;  

iodine 7.0 to 15.0 micrograms;  

Vit A 100 to 500 IU;  

Vit D 0.5 to 2.5 micrograms;  

Vit E 1.5 to 4.0 mg;  

Vit K more than 4.0 micrograms;  

Vit C more than 4.0 mg;  

Vit B1 more than 0.06 mg;  

Vit B2 more than 0.07 mg;  

Vit B3 0.7 to 3.5 mg;  

Vit B5 0.2 to 2.0 mg;  

Vit B6 0.1 to 0.7 mg;  

Vit B8 at least 1.0 micrograms;  

Vit B9 at least 12.0 micrograms;
Vitamin B₁₂ 0.1 to 1.0 micrograms;
lycopene at least 0.2 mg;
beta-carotene at least 0.1 mg;
a source of protein providing 10 to 18% by caloric content of the product;
a source of carbohydrate providing 40 to 65% by caloric content of the product;
a source of lipids providing 25 to 40% by caloric content of the product; and
a source of dietary fiber in an amount of at least 10 g/1 providing both soluble and insoluble fibers.

24. The enteral nutrition product of claim 23 comprising at least 30 mg of choline per 100 kcal of product.

25. The enteral nutrition product of claim 23 comprising at least 4.0 mg of taurine per 100 kcal of product.

26. The enteral nutrition product of claim 23 comprising at least 3.0 mg of carnitine per 100 kcal of product.

27. The enteral nutrition product of claim 23 comprising:
saturated fatty acids of not greater than 1.1 g/100 kcal;
the composition contains between 0.3 and 1.1 g linoleic acid per 100 kcal;
the composition contains at least 0.06 g linolenic acid per 100 kcal; and
the n6:n3 ratio is between 2 and 7.

28. The enteral nutrition product of claim 23 wherein the insoluble fiber comprises at least 25% of the fiber source.

29. The enteral nutrition product of claim 23 comprising a prebiotic.
30. The enteral nutrition product of claim 23 comprising a protein source selected from the group consisting of: casein, whey, and soy.

31. The enteral nutrition product of claim 23 wherein the protein can be intact or partially hydrolyzed.

32. A method of providing nutrition to a patient comprising the steps of:

administering via a tube to a patient at least once a day on a long term basis a product comprising a source of protein, a source of carbohydrate, a source of fiber, a source of lipids and one or more of:

lycopene;

lutein;

B-carotene;

B-cryptoxanthine;

polyphenol;

33. The method of claim 32 wherein the polyphenols are selected from the group consisting of: catechin; isoflavons; and quercetin.

34. The method of claim 32 wherein the product comprises a prebiotic.
### A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K45/06 A23L1/29 A61P3/02

According to International Patent Classification (IPC) arts. both national classification and IPC

### B. FIELDS SEARCHED

Minimum documentation search field (classification system followed by classification symbols)

A61K A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database consulted during the international search (name of database and, where practical, search terms used)

EPO-Internal, WPI Data, BIOSIS, EMBASE

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>US 5 686 429 A (LIN PAUL M [US] ET AL) 11 November 1997 (1997-11-11) claims 1,4 column 1, line 64 - column 2, line 4 column 4, lines 26-55 column 6, line 34 - column 7, line 33</td>
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Further documents are listed in the continuation of Box C

See patent family annex

* Special categories of cited documents

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

Date of the actual completion of the international search

20 February 2008

Date of mailing of the international search report

27/02/2008

Name and mailing address of the ISA:

European Patent Office
P B 5818 Patentlaan 2
NL - 2280 HV RIVIERPLAT
Tel (+31-70) 340-2040, Tx 31 651 epc nl
Fax (+31-70) 340-3016

Authorized officer

Peris Antoli, Bert a
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